



# Medical Marijuana Dispensary License Application

Department of Health, Office of Health Care Assurance

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▶ #4559

Criteria 1. Ability to operate a business, including but not limited to education, knowledge, and experience

Criteria 2. Plan for operating a medical marijuana dispensary in the county for which the applicant is seeking a license, including but not limited to a timeline for opening a retail dispensing location

Criteria 3. Proof of financial stability and access to financial resources

Criteria 4. Ability to comply with the security requirements of this chapter and section 329D-7, HRS

Criteria 5. Capacity to meet the needs of qualifying patients

Criteria 6. Ability to comply with criminal background check requirements pursuant to this chapter and sections 329D-7, 329D-12, and 846-2.7, HRS

Criteria 7. Ability to comply with the requirements in this chapter and chapters 329 and 329D, HRS, for inventory tracking, security, and dispensing limits for qualifying patients

Criteria 8. Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products

Criteria 9. Ability to conduct or contract for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 329D-7 and 329D-8, HRS

Criteria 10. Ability to comply with requirements for packaging, labeling, and chain of custody of products

Criteria 11. A plan for secure disposal of marijuana and manufactured marijuana products

Criteria 12. Ability to ensure product safety, in accordance with this chapter and sections 329D-8, 329D-10, 329D-11, HRS

Criteria 13. No history of having a business license revoked.

Total Merit Criteria Points Awarded to Applicant

### HELPFUL INFORMATION FOR FILLING OUT THIS FORM:

1. You can save your work on this form by checking the 'Save my progress and resume later' box and then clicking the 'Save form and resume later' button : **IMPORTANT: Remember to do this every time you leave your application or you will lose the information you have entered.**
2. To keep your information secure, remember to log out of your application each time you finish working on it.
3. Use a current version of Google Chrome or Firefox browser when completing this form.
4. Save the form every 20 minutes to avoid timing out. When entering information in a spreadsheet, save and exit the form first.
5. Do not include single or double quote marks (' or ") or more than one period (.) in your document names.

### INSTRUCTIONS FOR THE MEDICAL MARIJUANA DISPENSARY LICENSE APPLICATION

Before applying for a medical marijuana dispensary license, applicants must acknowledge that they have read the statute and administrative rules on medic be redirected to the statute and administrative rules.

Hawaii Revised Statute (HRS) 329D

✓ I acknowledge that I have read [Chapter 329D, HRS \(http://health.hawaii.gov/content/blogs.dir/93/files/2015/12/2015-329D-HRS.pdf\)](http://health.hawaii.gov/content/blogs.dir/93/files/2015/12/2015-329D-HRS.pdf), and I am aware of the ap

Hawaii Administrative Rules (HAR) Chapter 11-850

✓ I acknowledge that I have read [HAR, Chapter 11-850 \(http://health.hawaii.gov/content/blogs.dir/93/files/2015/12/Dispensary-Rules-Chapter-11-850-signed-by-licensing-requirements\)](http://health.hawaii.gov/content/blogs.dir/93/files/2015/12/Dispensary-Rules-Chapter-11-850-signed-by-licensing-requirements).

Disclaimer:

✓ I understand that the use and possession of marijuana is illegal under federal law, ; Chapters 329 and 329D, HRS.

**MINIMUM REQUIREMENTS**

All individual applicants and applying entities must meet the requirements listed below or the application will not be accepted. Applicants must attach proof sections.

**INDIVIDUAL APPLICANT**

- \* Individual applicant shall be at least 21 years old.
- \* Shall be a legal resident of the State of Hawaii for at least five (5) uninterrupted years immediately preceding the date of the license application.
- \* Shall not have any felony convictions or any other disqualifying background history.
- \* Shall be authorized by the applying entity to submit an application for a dispensary license, and act as the primary point of contact with the department.

**APPLYING ENTITY**

- \* The applying entity must be organized under the laws of the State of Hawaii.
- \* Have a Hawaii tax identification number.
- \* Have a Department of Commerce and Consumer Affairs Business Registration Division number and suffix.
- \* Have a federal employer identification number.
- \* Not be less than fifty-one percent held by Hawaii legal residents or entities wholly controlled by Hawaii legal residents who have been legal residents for no application was submitted.
- \* Have financial resources under its control of not less than \$1,000,000 for each license applied for, plus not less than \$100,000 for each retail dispensing location bank statements or escrow accounts, and those financial resources shall have been under the control of the applying entity for not less than ninety days immediately preceding the application.
- \* Be composed of owners, principals, or members, each of whom is not less than twenty-one years of age and has no felony convictions or any other disqualifying background history.

**APPLICATION FEE**

The license application fee of \$5,000 by certified check or cashier's check payable to the State of Hawaii, Department of Health, is part of the minimum requirements for Medical Marijuana Dispensary Licensing, Room 337, 601 Kamokila Blvd., Kapolei, HI 96707 or be postmarked by 4:30 pm Hawaii Standard Time on the last day of the application.

Please note the application number on the check. This is found in the heading of the email confirmation you receive upon submittal, and is also visible when you log into the application system.

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**NOTE: ALL QUESTIONS MUST BE ANSWERED TO SUBMIT YOUR APPLICATION UNLESS OTHERWISE INDICATED.**

**SECTION A: APPLICATION FOR COUNTY**

**NOTE:** An applicant may apply for a license for more than one county, but may only receive one license. Indicating here that you are applying for a license for one county; separate applications must be submitted. The applicant and applying entity must complete a separate application with all required refundable application fee of \$5,000 for each application. The financial resources required (\$1,000,000 plus not less than \$100,000 for each retail dispensing location) only apply toward one license, if granted.

1. For which county are you requesting a license?	City & County of Honolulu
2. Are you also applying for a dispensary license in another county?	No
2a. If YES, what other county or counties are you applying for a license? (NOTE: A separate application and check will be required for each county.)	

**SECTION B: INDIVIDUAL APPLICANT INFORMATION**

**GENERAL INFORMATION**

3. Legal Name of Applicant	Mr Henk Brouwer Rogers
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4. Upload Proof of Legal Name of Applicant

Scan and submit a certified copy of AT LEAST ONE (1) of the following:

- \* Certified copy of a birth certificate or marriage certificate filed with a state office of vital statistics or equivalent agency in the individual's state of birth or marriage;
- \* Valid, unexpired U.S. passport [inside cover and first page only] or U.S. passport card;
- \* Consular report of birth abroad Form FS-240, DS-1350 or FS-545 issued by the U.S. Department of State;
- \* Valid, unexpired permanent resident card (Form I-551) issued by the Department of Homeland Security (DHS) or the U.S. Citizenship and Immigration Services (USCIS);
- \* Unexpired employment authorization document issued by the DHS, Form I-766 or Form I-688B;
- \* Unexpired foreign passport with the following: a valid, unexpired U.S. visa affixed, and an approved I-94 form documenting the applicant's most recent admittance into the United States or a DHS admittance stamp on the passport;
- \* Certified copy of the Certificate of Naturalization issued by DHS, Form N-550 or Form N-570;
- \* Certificate of citizenship, Form N-560 or Form N-561, issued by DHS;
- \* Court-issued, certified copy of a divorce decree;
- \* Certified copy of a legal change of name order

0 [Redacted]

5. Date of Birth (must be at least 21 years old)

[Redacted]

6. Upload Proof of Date of Birth of Applicant

Scan and submit a certified copy of AT LEAST ONE (1) of the following:

- \* Certified copy of a birth certificate or marriage certificate filed with a state office of vital statistics or equivalent agency in the individual's state of birth or marriage;
- \* Valid, unexpired U.S. passport [inside cover and first page only] or U.S. passport card;
- \* Consular report of birth abroad Form FS-240, DS-1350 or FS-545 issued by the U.S. Department of State;
- \* Valid, unexpired permanent resident card (Form I-551) issued by the Department of Homeland Security (DHS) or the U.S. Citizenship and Immigration Services (USCIS);
- \* Unexpired employment authorization document issued by the DHS, Form I-766 or Form I-688B;
- \* Unexpired foreign passport with the following: a valid, unexpired U.S. visa affixed, and an approved I-94 form documenting the applicant's most recent admittance into the United States or a DHS admittance stamp on the passport;
- \* Certificate of naturalization issued by DHS, Form N-550 or Form N-570;
- \* Certificate of citizenship, Form N-560 or Form N-561, issued by DHS;
- \* Valid, unexpired driver's license or government issued photo identification card.

0 [Redacted]

7. Social Security No. or Identifier No. (last 4 digits only):

[Redacted]

8. Applicant's Address

[Redacted]  
United States

9. Daytime Phone No.

[Redacted]

10. Fax No.

[Redacted]

11. Email

[Redacted]

CRIMINAL HISTORY INFORMATION

12. Has the individual applicant ever been convicted of a felony? If YES, STOP, you are not an eligible applicant.

13. Has the individual applicant ever been convicted of a crime?

13a. If YES, please describe (e.g., conviction, date, disposition, etc.)

14. Has the individual applicant ever been arrested?

14a. If YES, please describe (e.g., date, disposition, etc.)

**Obtain a Criminal History Report**

Copy the Validation code from an eCrim report for the individual applicant generated by the Hawaii Criminal Justice Data Center no earlier than December 12, 2015 at 8:00 a.m. (Hawaii-Aleutian Standard Time).

[Redacted]

Visit [eCrim.ehawaii.gov \(https://ecrim.ehawaii.gov/ahewa/\)](https://ecrim.ehawaii.gov/ahewa/) to obtain the eCrim report.

15. Enter the eCrim Validation Code here:

16. NOTICE: Pursuant to Chapter 329D HRS and Chapter 11-850 HAR, applicants are required to provide consent to a background check, including fingerprinting, to be conducted by the Department of Health or its designee.

I consent

Further information and instructions will be provided on <http://health.hawaii.gov/medicalmarijuana/>. If the information and instructions are not yet posted, please check the website often.

RESIDENCY INFORMATION 17. Is the Applicant a legal resident of the State of Hawaii for at least five years? If NO, STOP, you are not an eligible applicant. Yes

18. Upload Proof of Hawaii Residency:

Scan and submit AT LEAST ONE (1) of the following source documents as proof of Hawaii state residency for at least five years:

- \* State of Hawaii tax return Form N-11 without schedules, worksheets, or attachments, and redacted to remove all financial information and all but the last four digits of the individual's social security number;
- \* Evidence of voter registration;
- \* Ownership, lease, or rental documents for place of primary domicile;
- \* Billing statements including utility bills; or
- \* Vehicle registration.

[Redacted]

19. Authorized to Act on Behalf of Applying Entity

Scan and submit evidence of the authority of the individual to act on behalf of the applying entity, and supporting documentation (e.g. corporate resolution, bylaws, articles of incorporation):

[Redacted]

**SECTION C: APPLYING ENTITY INFORMATION**

20. Name of Applying Entity Blue Planet Healing, LLC

21. Applying Entity's Business Address 55 Merchant St Suite 1700  
Honolulu, Hawaii 96813  
United States

22. Entity Phone # [Redacted]

23. Entity Email [Redacted]

24. Entity Fax # [Redacted]

25. Is the applying entity organized under the laws of the State of Hawaii? If the answer is 'NO', STOP, you are not an eligible applicant. Yes

26. Upload Applying Entity Incorporation or Business Status Documentation:

Upload a certified copy of applying entity's incorporation documents in the State of Hawaii.

[Redacted]

Visit [Hawaii Business Express \(https://hbe.ehawaii.gov/documents/search.html\)](https://hbe.ehawaii.gov/documents/search.html) for available documents.

27. Provide the entity's Hawaii Department of Commerce & Consumer Affairs Business Registration Division Number & Suffix (file number).

135521 C5

Visit [Hawaii Business Express - Business Name Search \(https://hbe.ehawaii.gov/documents/search.html\)](https://hbe.ehawaii.gov/documents/search.html) to locate your entity's file number.

28. Upload a copy of the entity's Certificate of Good Standing from the Department of Commerce and Consumer Affairs. 

29. Hawaii Tax Identification Number:

Provide the number along with a copy of the State of Hawaii Tax Identification Number (see question immediately below). 

Visit [Tax ID Search \(https://dotax.ehawaii.gov/tls/app\)](https://dotax.ehawaii.gov/tls/app) for this information.

30. Upload a copy of the entity's State of Hawaii Tax Identification document. 

31. Federal Employer Identification Number: Provide the Federal Employer Identification Number. 

32. Upload a copy of the entity's Federal Employer Identification Number document. 

**OWNER(S), PRINCIPAL(S), & MEMBER(S) INFORMATION**

33. Enter the total number of Owner(s), Principal(s), and Member(s) of the applying entity here: 3

34. Upload Owner, Principal, and Member Information Spreadsheet

**INSTRUCTIONS:** Download the EXCEL spreadsheet below, enter the following information in the format required, and upload it to attach it to your application.

Information to be provided:

**1) List of Owners, Principals, and Members of the Applying Entity**

For each Owner, Principal, and Member of the Applying Entity:

- A) Name, Address, Phone number, and Email Address
- B) Each individual's percent interest in the company
- C) State of primary residence
- D) Number of years each person has lived in Hawaii (the most recent, uninterrupted number of years that the person has been a resident), and
- E) A criminal background check for each Owner, Principal, and Member.



Copy the validation code from an eCrim report for the individual generated by the Hawaii Criminal Justice Data Center no earlier than December 12, 2015 at 8:00 a.m. (Hawaii-Aleutian Standard Time).

Visit [eCrim.ehawaii.gov \(https://ecrim.ehawaii.gov/ahewa/\)](https://ecrim.ehawaii.gov/ahewa/) to obtain the eCrim report.

Please include a signed statement by each Owner, Principal, or Member certifying that the information is complete and accurate. Upload the signed statements in the following question (35.)

**2) Other Businesses Holding an Interest**

If there are businesses that hold an interest in the company, list the business names and percent interest on a separate tab on the spreadsheet.

[Download Owner Principal Member Information Spreadsheet \(mmjdisp/templates/Owner\\_Principal\\_Member\\_Report.xls\)](#)

35. Upload Proof of Name, Date of Birth, and Residency for each Officer, Principal, or Member listed on the spreadsheet

1) Proof of Legal Name of Each Owner, Principal, and Member:

Scan and submit a certified copy of AT LEAST ONE (1) of the following:

- \* Certified copy of a birth certificate or marriage certificate filed with a state office of vital statistics or equivalent agency in the individual's state of birth or marriage;
- \* Valid, unexpired U.S. passport [inside cover and first page only] or U.S. passport card;
- \* Consular report of birth abroad Form FS-240, DS-1350 or FS-545 issued by the U.S. Department of State;
- \* Valid, unexpired permanent resident card (Form I-551) issued by the Department of Homeland Security (DHS) or the U.S. Citizenship and Immigration Services (USCIS);
- \* Unexpired employment authorization document issued by the DHS, Form I-766 or Form I-688B;
- \* Unexpired foreign passport with the following: a valid, unexpired U.S. visa affixed, and an approved I-94 form documenting the applicant's most recent admittance into the United States or a DHS admittance stamp on the passport;
- \* Certificate of naturalization issued by DHS, Form N-550 or Form N-570;
- \* Certificate of citizenship, Form N-560 or Form N-561, issued by DHS;
- \* Court-issued, certified copy of a divorce decree;
- \* Certified copy of a legal change of name order;

2) Proof of Date of Birth

Scan and submit a certified copy of AT LEAST ONE (1) of the following:

- \* Certified copy of a birth certificate or marriage certificate filed with a state office of vital statistics or equivalent agency in the individual's state of birth or marriage;
- \* Valid, unexpired U.S. passport [inside cover and first page only] or U.S. passport card;
- \* Consular report of birth abroad Form FS-240, DS-1350 or FS-545 issued by the U.S. Department of State;
- \* Valid, unexpired permanent resident card (Form I-551) issued by the Department of Homeland Security (DHS) or the U.S. Citizenship and Immigration Services (USCIS);
- \* Unexpired employment authorization document issued by the DHS, Form I-766 or Form I-688B;
- \* Unexpired foreign passport with the following: a valid, unexpired U.S. visa affixed, and an approved I-94 form documenting the applicant's most recent admittance into the United States or a DHS admittance stamp on the passport;
- \* Certificate of naturalization issued by DHS, Form N-550 or Form N-570;
- \* Certificate of citizenship, Form N-560 or Form N-561, issued by DHS;
- \* Valid, unexpired driver's license or government issued photo identification card.



3) Proof of Hawaii Residency:

Scan and submit AT LEAST ONE (1) of the following source documents as proof of Hawaii state residency for at least five years:

- \* State of Hawaii tax return Form N-11 without schedules, worksheets, or attachments, and redacted to remove all financial information and all but the last four digits of the individual's social security number;
- \* Evidence of voter registration;
- \* Ownership, lease, or rental documents for place of primary domicile;
- \* Billing statements including utility bills; or
- \* Vehicle registration.

Document size limit is 2 MB. Up to 10 documents may be attached.

SECTION D: FINANCIAL INFORMATION

36. FINANCIAL RESOURCES GENERAL INFORMATION

INSTRUCTIONS: Download the EXCEL spreadsheet below, enter the following information in the format required, and upload it to attach it to your application.

Information to be provided:

1) Financial Resources the applying entity has under its control. List each financial resource, amount of the resource (round to nearest dollar, no cents), and verifying information (account type, account number, account name, name of financial institution, applicant contact information) as shown on the spreadsheet



2) Date Resource/Dollar amount under the applying entity's control

[Download Financial Resources General Information Spreadsheet \(/mmjdisp/templates/Financial\\_Resources\\_General.xls\)](#)

Upload the completed Financial Resources General Information Spreadsheet

37. Upload Financial Resources General Information Supporting Source Documents

Upload supporting source documents, i.e. bank statements, escrow account information, balance sheets etc. Supporting source documents for Financial Resources General Information must be provided as proof of the financial resources.



Document size limit is 10 MB. Up to 5 documents may be attached.

38. FINANCIAL RESOURCES - RETAIL DISPENSING LOCATION INFORMATION

INSTRUCTIONS: Download the EXCEL spreadsheet below, enter the following information in the format required, and upload it to attach it to your application.

Data to be provided:

1) Financial Resources the applying entity has under its control for each retail dispensing location allowed (2 locations maximum)

2) Dollar Amount (total aggregate for each retail dispensing location shall be not less than \$100,000, or \$200,000 for 2 locations)



3) Date Resource/Dollar amount under the applying entity's control (resources have been under the Applying Entity's control for not less than 90 days)

[Download Financial Resources - Retail Dispensing Location Information Spreadsheet \(/mmjdisp/templates/Financial\\_Resources\\_Retail\\_Dispensing\\_Location.xls\)](#)

Upload the completed Financial Resources - Retail Dispensing Location Information Spreadsheet

39. Upload Retail Dispensary Location Supporting Source Documents

Upload supporting source documents, i.e. bank statements, escrow account information, balance sheets etc. Supporting source documents for retail dispensary locations must be provided as proof of the financial resources.



Document size limit is 10 MB. Up to 5 documents may be attached.

SECTION E: MERIT INFORMATION - OPTIONAL

Responses for each criteria shall be no longer than specified for each criteria, double spaced, font size no smaller than 12, and margins no less than 1 inch

- (1) Ability to operate a business, including but not limited to education, knowledge, and experience with:
- (A) Regulated industries;
  - (B) Agriculture or horticulture;
  - (C) Commercial manufacturing;
  - (D) Pharmaceutical companies;
  - (E) Operating or working in a medical marijuana dispensary business;
  - (F) Creating and implementing a business plan, including a timeline for opening a business;
  - (G) Creating and implementing a financial plan;
  - (H) Retail sales;
  - (I) Secure inventory tracking and control;
  - (J) Protecting confidential customer information;
  - (K) Owning or managing a business that required twenty four hour security monitoring; and
  - (L) Any other experience the applicant considers relevant;

0 [Redacted]

Response to (1) shall be no longer than five (5) pages.

Upload Response to (1)

- (2) Plan for operating a medical marijuana dispensary in the county for which the applicant is seeking a license, including but not limited to a timeline for opening a retail dispensing location;

0 [Redacted]

Response to (2) shall be no longer than five (5) pages.

Upload Response to (2)

- (3) Proof of financial stability and access to financial resources, including but not limited to:

- (A) Legal sources of finances immediately available to begin operating a dispensary;
- (B) A summary of financial statements in businesses previously or currently owned or operated by the applicant;
- (C) A financial plan for operating a medical marijuana dispensary in Hawaii;
- (D) Good credit history; and
- (E) History of bankruptcy by the applicant or entities owned or operated by the applicant;

0 [Redacted]

Response to (3) shall be no longer than five (5) pages.

Upload Response to (3)

- (4) Ability to comply with the security requirements of Chapter 11-850 and Section 329D-7, HRS;

0 [Redacted]

Response to (4) shall be no longer than five (5) pages.

Upload Response to (4)

- (5) Capacity to meet the needs of qualifying patients, including but not limited to:

- (A) Educating patients on how marijuana can be used to assist patients with debilitating medical conditions and about the marijuana and manufactured marijuana products that will be available in the applicant's retail dispensing locations;
- (B) Producing and maintaining a supply of marijuana that is sufficient to meet the needs of qualifying patients;
- (C) Providing safe, accessible retail dispensing locations; and
- (D) Measuring and improving customer satisfaction;

0 [Redacted]

Response to (5) shall be no longer than five (5) pages.

Upload Response to (5)

- (6) Ability to comply with criminal background check requirements pursuant to Chapter 11-850 and Sections 329D-7, 329D-12, and 846-2.7, HRS;

0 [Redacted]

Response to (6) shall be no longer than three (3) pages.

Upload Response to (6)

(7) Ability to comply with the requirements in Chapter 11-850 and Sections 329 and 329D, HRS, for inventory tracking, security, and dispensing limits for qualifying patients;

[Redacted]

Response to (7) shall be no longer than five (5) pages.

Upload Response to (7)

(8) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

[Redacted]

Response to (8) shall be no longer than three (3) pages.

Upload Response to (8)

(9) Ability to conduct or contract for certified laboratory testing on marijuana and manufactured marijuana products pursuant to Chapter 11-850 and Sections 329D-7 and 329D-8, HRS;

[Redacted]

Response to (9) shall be no longer than three (3) pages.

Upload Response to (9)

(10) Ability to comply with requirements for packaging, labeling, and chain of custody of products;

[Redacted]

Response to (10) shall be no longer than three (3) pages.

Upload Response to (10)

(11) A plan for secure disposal of marijuana and manufactured marijuana products;

[Redacted]

Response to (11) shall be no longer than five (5) pages.

Upload Response to (11)

(12) Ability to ensure product safety, in accordance with Chapter 11-850 and Sections 329D-8, 329D-10, 329D-11, HRS.

[Redacted]

Response to (12) shall be no longer than five (5) pages.

Upload Response to (12)

(13) No history of having a business license revoked.

[Redacted]

Response to (13) shall be no longer than three (3) pages.

Upload Response to (13)

**SECTION F: CERTIFICATION AND SUBMITTAL**

**Certification**  I hereby certify under penalty of law that the information submitted as part of this ap

By checking the box above and entering the individual applicant's name below, the applicant has electronically signed this application.

**Applicant Name** Mr Henk Brouwer Rogers

If you have previously submitted an application and this is a revision, enter the unique entry number(s) of your previous submission(s) here.

**User ID** [Redacted]

**User Email** [Redacted]

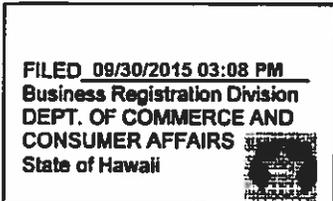
**Entry Info**

**Date Created** 29 Jan 2016 - 04:02:39 PM

**Date Updated**

**IP Address**

10/01/201520016



STATE OF HAWAII  
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS  
Business Registration Division  
335 Merchant Street  
Mailing Address: P.O. Box 40, Honolulu, Hawaii 96810  
Phone No. (808) 586-2727



10/01/201520016

**ARTICLES OF ORGANIZATION FOR LIMITED LIABILITY COMPANY**

(Section 428-203, Hawaii Revised Statutes)

PLEASE TYPE OR PRINT LEGIBLY IN BLACK INK

The undersigned, for the purpose of forming a limited liability company under the laws of the State of Hawaii, do hereby make and execute these Articles of Organization:

I

The name of the company shall be:

BLUE PLANET HEALING, LLC

(The name must contain the words Limited Liability Company or the abbreviation L.L.C. or LLC)

II

The mailing address of the initial principal office is:

55 MERCHANT STREET, 17TH FLOOR, HONOLULU, HI 96813

III

The company shall have and continuously maintain in the State of Hawaii a registered agent who shall have a business address in this State. The agent may be an individual who resides in this State, a domestic entity or a foreign entity authorized to transact business in this State.

a. The name (and state or country of incorporation, formation or organization, if applicable) of the company's registered agent in the State of Hawaii is:

KENT OTSU

HAWAII

(Name of Registered Agent)

(State or Country)

b. The street address of the place of business of the person in State of Hawaii to which service of process and other notice and documents being served on or sent to the entity represented by it may be delivered to is:

55 MERCHANT STREET, 17TH FLOOR, HONOLULU, HI 96813

IV

The name and address of each organizer is:

HENK B. ROGERS

55 MERCHANT STREET, 17TH FLOOR

HONOLULU, HI 96813

V

The period of duration is (check one):

At-will

For a specified term to expire on: DECEMBER 31 2100  
(Month) (Day) (Year)

VI

The company is (check one):

a.  Manager-managed, and the names and addresses of the initial managers are listed in paragraph "c", and the number of initial members are: \_\_\_\_\_ .

b.  Member-managed, and the names and addresses of the initial members are listed in paragraph "c",

c. List the names and addresses of the initial managers if the company is Manager-managed, or List the names and addresses of the initial members if the company is Member-managed.

HENK B. ROGERS

55 MERCHANT STREET, 17TH FLOOR

HONOLULU, HI 96813

VII

The members of the company (check one):

Shall not be liable for the debts, obligations and liabilities of the company.

Shall be liable for all debts, obligations and liabilities of the company.

Shall be liable for specified debts, obligations and liabilities of the company *as stated below*, and have consented in writing to the adoption of this provision or to be bound by this provision.

We certify, under the penalties set forth in the Hawaii Uniform Limited Liability Company Act, that we have read the above statements, I am authorized to sign this Articles of Organization, and that the above statements are true and correct to the best of our knowledge and belief.

Signed this 29TH day of SEPTEMBER, 2015

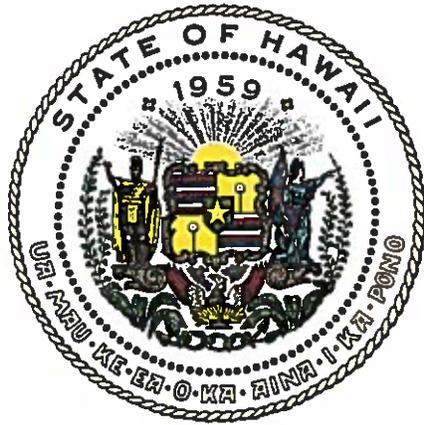
HENK B. ROGERS

(Type/Print Name of Organizer)

(Signature of Organizer)

(Signature of Organizer)

SEE INSTRUCTIONS PAGE. The articles must be signed and certified by at least one organizer of the company.



## Department of Commerce and Consumer Affairs

### CERTIFICATE OF GOOD STANDING

I, the undersigned Director of Commerce and Consumer Affairs of the State of Hawaii, do hereby certify that according to the records of this Department,

**BLUE PLANET HEALING, LLC**

was organized under the laws of the State of Hawaii on 09/30/2015 ; that it is an existing limited liability company in good standing and is duly authorized to transact business.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of the Department of Commerce and Consumer Affairs, at Honolulu, Hawaii.

Dated: January 13, 2016



Director of Commerce and Consumer Affairs



List the business name(s) and percent interest on the spreadsheet if there are businesses that hold an interest i

Other Businesses Holding an Interest

Percent Interest

Rogers Medicinals, LLC





### Application Response Question 1

Blue Planet Healing, LLC., (“BPH” or “Company”) is uniquely qualified to operate a business whose sole mission is to provide, to duly registered patients, in strict compliance with Hawai‘i law, safe and consistent pharmaceutical grade marijuana in the form of unprocessed flower buds and the marijuana infused products permitted pursuant to Hawai‘i law.

In order to accomplish this mission, BPH has assembled a team of highly qualified professionals in the local business, medical, scientific, horticultural, and legal communities. This talented group of individuals comprise the core BPH team and possess vast knowledge and business experience in: regulated industries; horticulture; pharmacology; commercial manufacturing; operating a medical marijuana business which includes experience with retail sales, protecting confidential customer information, secure inventory control and tracking and the utilization of 24-hour security monitoring. BPH has created a business plan and financial plan (financial pro-forma model) for the guidance, implementation and deployment of its organizational and operational goals and objectives which has been included as an attachment hereto. (See Attachment “1.1” and Attachment “1.2”)

BPH’s individual applicant, Henk Rogers ("Henk") (Profile attached as “1.3”) is an internationally recognized entrepreneur, philanthropist and community leader who was recognized as Hawai‘i's 2015 CEO of the Year. A longtime resident of Hawai‘i who studied computer science at the University of Hawai‘i, Henk has skillfully assembled a dynamic group of individuals with the necessary education, training, skills and real life experience necessary and advisable to start and successfully operate a business that will accomplish the statutory goals of HRS Chapter 329D.

In addition, as demonstrated hereinafter, BPH has unconditional access to all of the necessary financial resources needed to execute its startup and roll out plans.



### Application Response Question 1

In addition to Henk, the owners/principals ("Principals") of BPH include Andrew Salini a graduate of Princeton University in Economics and Finance and the Chief Compliance Officer of High Country Healing ("HCH") (See Attachment "1.4") one of the first medical marijuana ("MM") dispensaries in the State of Colorado. Andrew will act as BPH's Chief Compliance Officer ("CCO"). Over the last 6 years, HCH has successfully, cultivated, produced and distributed high quality pharmaceutical grade MM in full compliance with Colorado's laws. HCH operates three Colorado based MM retail dispensing locations ("RDL"), as that term is defined in HRS § 329D-1, and three recreational marijuana ("RM") stores. As a result of its development and implementation of a comprehensive financial and business plan, HCH has grown from one RDL and Production Center ("PC"), to three RDLs and three RM stores (consisting of 9000 sq. ft.) and three PCs and three RM production centers (consisting of 35,000 sq. ft.). HCH has obtained high profile recognition within the industry for its quality products and kudos from Colorado's law enforcement community for its exemplary behavior and legal and regulatory compliance. BPH has entered into a consulting agreement with HCH to provide advice, counsel and guidance in connection with the development and operation of BPH's cultivation, manufacturing and dispensing operations. HCH brings extensive knowledge and experience in: regulated industries; horticulture; commercial manufacturing; and operating a medical marijuana business which includes experience with retail sales and other relevant experience to BPH for the successful operation of its business.

To further strengthen BPH's operational capacity, BPH has entered into an agreement with UNDRNWMNGMNT, LLC. (UNM), an established marijuana product manufacturing-licensing company headquartered in Colorado. (See Attachment "1.5") Under this agreement, BPH will have the exclusive right, in Hawai'i, to manufacture marijuana infused products using UNM's



### Application Response Question 1

proprietary techniques and processes. UNM will also provide consultation to BPH in all aspects of manufacturing marijuana products. The other principals and officers of BPH will all bring additional relevant expertise and business acumen to the table. Maya Rogers-Kiyomura ("Maya") (Profile attached as "1.6") will be the CEO of BPH. For the last several years she has helmed Blue Planet Software, one of Hawai'i's most successful high tech companies, through the highly complex and competitive high-tech world with international sophistication and a sense of local pride and style. As the Business Development Manager of Blue Startups, Hawai'i's premier Business Accelerator Organization and a 2015 top 20 US Accelerator, Maya assists and trains promising start-up entrepreneurs to compete on a global scale using a mentor driven model that reaches networks throughout Hawai'i, Asia and Silicon Valley.

BPH's Chief Financial Officer, Kent Otsu, has significant finance experience working for some of Hawai'i's most notable companies and will be responsible for the financial affairs of BPH. (Profile attached as "1.7") Kent will oversee all financial and accounting functions including: cash control; preparing budgets and financial statements; coordinating financing; monitoring expenditures and liquidity; managing tax issues; reporting financial performance to the board; providing timely financial data to the CEO; and working with appropriate financial and other government regulators.

BPH's distinguished Board of Advisors includes: 1) **Dr. Bradley Willcox M.D.** (Profile attached as "1.8") is a UH affiliated scientist, researcher and practicing physician who will act as BPH's Chief Medical Advisor ("CMA") and, among other things, provide guidance to BPH regarding the latest credible scientific research involving MM and will act as the Company's information gatekeeper in connection with the preparation and dissemination of medical and scientific information to registered patients as permitted by the Department of Health, State of



### Application Response Question 1

Hawai'i ("DOH"). Dr. Willcox is an investigator in the area of geriatrics and gerontology at the Pacific Health Research and Education Institute and is a clinical assistant professor in the Department of Geriatric Medicine at the John A. Burns School of Medicine, University of Hawai'i. Dr. Willcox's education, training, background and experience make him particularly well-suited to provide scientific and medical guidance to a MM dispensary business; 2) **Dr. Andrew Bachman, M.D.** (Profile attached as "1.9") is a co-founder of LeafLine Labs a MM research and manufacturing company located in Minnesota. Dr. Bachman earned his medical degree from Georgetown University School of Medicine and his undergraduate degree in biology from Amherst College and will provide advice and guidance to BPH regarding early stage development of its MM dispensary operations; 3) **Greta Inofer, R.N.** (Profile attached as "1.10") is a registered nurse with over five years experience in patient case management and care coordination. Greta is a registered member of the American Cannabis Nurse Association. Under the guidance of Dr. Willcox, Greta will facilitate dissemination of patient information and provide face-to-face patient consultation regarding the safe use of MM; 4) **Dr. Marisa Kesaji, Pharm.D.** (Profile attached as "1.11") is a graduate of Roosevelt High School (Summa Cum Laude) and received her Doctor of Pharmacy from the University of Southern California. Dr. Kesaji will provide advice, counsel and guidance to BPH regarding pharmacological issues and will work in consultation with BPH's CMA and CHA; and 5) **Dr. Kenneth Leonhardt, Ph.D.** (Profile attached as "1.12") also a UH affiliated scientist, will act as the Company's Chief Horticultural Advisor ("CHA") and provide BPH with guidance regarding the best horticultural practices necessary to economically produce quality pharmaceutical grade MM for Hawai'i's patients. Dr. Leonhardt will work closely with BPH's Cultivation Manager.



### Application Response Question 1

BPH's Cultivation Manager will be Michael Rogers a graduate in Horticulture Science from the College of Tropical Agriculture at the University of Hawai‘i at Mānoa.

Finally, BPH has engaged a team of local business and regulatory attorneys and a nationally recognized cannabis lawyer – Greg Anton, Esq., (Profile attached as "1.14") to provide the legal advice, counsel and guidance necessary to assure that BPH complies with all applicable state laws and regulations and understands the complexities inherent in operating a business that is legal under state law but in violation of the federal Controlled Substances Act (21 USC § 801 et. seq.). With over 35 years’ experience in cannabis law. Mr. Anton has litigated cannabis law matters at all levels of State and Federal courts, including the US Supreme Court. In 2015 he achieved a landmark legal victory with an unprecedented ruling that his client can distribute medical cannabis without Federal interference. Mr. Anton represents the first licensed medical cannabis dispensary in the United States. BPH’s general counsel Bill Meyer has been practicing law in Hawai‘i since 1979. For more than three decades, Mr. Meyer has provided creative legal and business guidance to a broad spectrum of clients both in Hawai‘i and on the mainland. Mr. Meyer was selected for inclusion in “Hawai‘i Super Lawyers” in intellectual property (2008 through 2015) and is peer review rated “AV” (preeminent) by Martindale-Hubbell, the highest rating available for legal ability and professional ethics.

This highly credentialed and competent team possesses the required business savvy and MM expertise and will provide the necessary training, guidance and oversight to the employees, contractors, and vendors of BPH to ensure that BPH is not only successful from a business standpoint but that it sets the standard for excellence in patient care and safety for Hawai‘i’s registered MM patients. Additional information regarding BPH’s core team is contained in the attached Business Plan.



# **BUSINESS PLAN**

Medical Marijuana Cultivation, Manufactured  
Marijuana Products and Retail Dispensing Facilities



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# Executive Summary

## Mission Statement

"To provide relief that Hawai'i patients deserve through the highest quality, sustainable, and responsibly grown medical cannabis."

Hawaii is the most beautiful and pleasant place to live in the US if not the world. The weather is perfect, nature is beautiful, culture is rich, and most importantly; the people live with aloha. Residents of Hawaii know how lucky we are to live in paradise. However, the universe works in mysterious ways, and we do not always get everything we want. Many of us either know of people close to us or are themselves suffering from health issues that prevent them from enjoying their lives, or live in constant pain. Many of these ailments have no known cure or require prescription drugs with devastating side effects. For the first time in history, Hawaii has the opportunity to improve the quality of lives of these with varieties of medicinal marijuana that were researched and developed to provide direct relief to these patients. Blue Planet Healing was formed to provide relief that Hawaii patients deserve through the highest quality, sustainable, and responsibly grown medical marijuana.

Blue Planet Healing, LLC. (BPH) is a family owned local company dedicated to improving the quality of lives of the people of Hawaii. The company is comprised of highly experienced and talented individuals that gathered under the cause of improving the lives of our neighbors. It is an organization that allows them to achieve what they alone can not. These members bring together with them expertise in business, medicine, horticulture, community, sustainability, technology and the medical marijuana industry to create a team that will set the bar in the medical marijuana industry. BPH will create a patient centric medical marijuana dispensary system that brings the most benefit to the patients while being professional and innovative.

BPH along with its consultants, bring the highest quality of products and services to the patients. Colorado has the most mature medical marijuana industry in the United States. BPH's team include a member recognized to produce the highest quality medicinal marijuana and a member recognized to produce the highest quality marijuana manufactured products. Their experience navigating through the constantly evolving industry and regulations will be vital to BPH.

BPH includes in its mission a notion for a sustainable operation. As Marijuana production is such a heavy consumer of electricity, BPH has taken the concept of sustainability and stewardship into its mission. The unique experiences and background in clean energy, software, and other technologies, BPH has the capability to turn this industry from the heaviest of polluters to one of the cleanest.

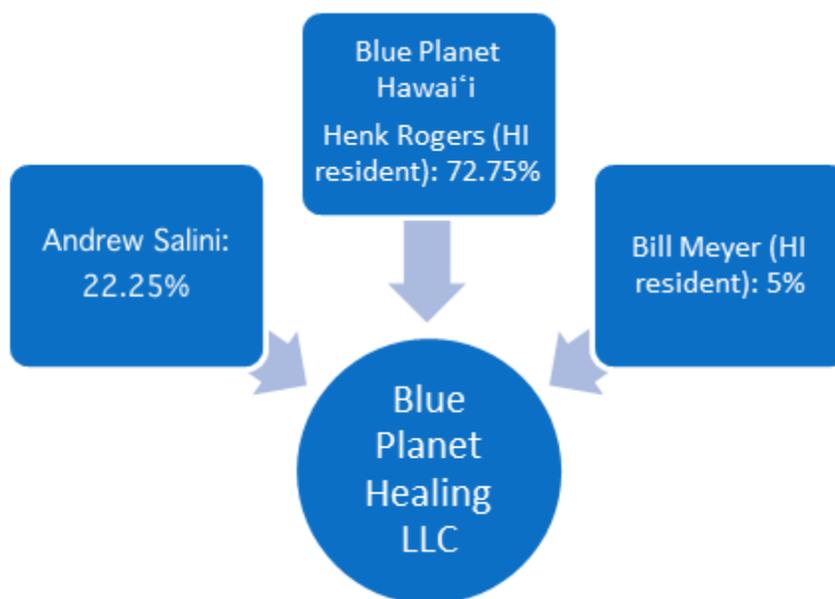


Following the mission with conviction and fortitude, BPH will be the most beneficial operator of a medical marijuana dispensary business for the people of the state of Hawaii and the medical marijuana industry globally.

## Company Profile

Blue Planet Healing, LLC., (“BPH”) a family owned company, and is uniquely qualified to operate a business whose sole mission is to provide, to duly registered patients, in strict compliance with Hawai‘i law, safe and consistent pharmaceutical grade marijuana in the form of unprocessed flower buds and the marijuana infused products permitted pursuant to Hawai‘i Revised Statutes (“HRS”) § 329D-10 and § 11-850-72 of the Hawai‘i Administrative Rules (“HAR”).

BPH is owned by Rogers Medicinals, LLC and High Country Healing Hawaii LLC, and Bill Meyer. The total ownership interest of BPH by Hawai‘i residents is 77.75% as shown below.



In order to accomplish this mission, BPH has assembled a team of highly qualified professionals with long histories and deep roots in the local business, medical, scientific, horticultural, and legal communities. This talented group of individuals comprise the core BPH team and possess vast knowledge and business experience in: regulated industries; horticulture: commercial manufacturing; operating a medical marijuana business which includes experience with retail sales, protecting confidential customer information, secure inventory control and tracking and the utilization of 24-hour security monitoring. BPH’s core team members have the ability and experience required to successfully operate a business. BPH has created this business plan and financial plan (financial pro-forma model) for the guidance, implementation and deployment of its organizational and operational goals and objectives.



BPH's individual applicant, Henk Rogers ("Henk") is an internationally recognized entrepreneur, philanthropist and community leader who was recognized as Hawai'i's 2015 CEO of the Year. A longtime resident of Hawai'i who studied computer science at the University of Hawai'i, Henk has skillfully assembled a dynamic group of individuals with the necessary education, training, skills and real life experience necessary and advisable to start and successfully operate a business that will accomplish the statutory goals of HRS Chapter 329D.

In addition, BPH has unconditional access to all of the necessary financial resources needed to execute its startup and roll out plans.

In addition to Henk, the owners/principals ("Principals") of BPH include Andrew Salini, who is a Princeton University in Economics and Finance and the Chief Operating Officer of High Country Healing ("HCH"), which is one of the first medical marijuana ("MM") dispensaries in the State of Colorado. Andrew will act as BPH's Chief Operations Officer ("COO").

Over the last 6 years, HCH has successfully, cultivated, produced and distributed high quality pharmaceutical grade MM in full compliance with Colorado's laws and regulatory scheme which, among other things, requires: maintaining strict inventory control, tracking and reporting; and protecting confidential customer information. HCH operates three Colorado based MM retail dispensing locations ("RDL"), as that term is defined in HRS § 329D-1, and three recreational marijuana ("RM") stores all under the watchful eye of a comprehensive and effective 24 hour security monitoring system. HCH employs and manages a team of over 57 skilled workers in its operations.

As a result of their development and implementation of a comprehensive financial and business plan, HCH has grown from one RDL and Production Center ("PC"), as that term is defined in HRS § 329D-1, to three (3) RDLs and three (3) RM stores (consisting of ≈9,000 sq. ft.) and three PCs and three (3) RM production centers (consisting of ≈ 35,000 sq. ft.). HCH has obtained high profile recognition within the industry for its quality products and kudos from Colorado's law enforcement community for its exemplary behavior and legal and regulatory compliance. HCH brings extensive knowledge and experience in: regulated industries; horticulture; commercial manufacturing; operating a medical marijuana business which includes experience with retail sales and other relevant experience to BPH for the successful operation of its business.

To further strengthen BPH's operational strategy, BPH has entered into a consulting agreement with UNDRNWMNGMNT, LLC. ("UNM"), an established marijuana product manufacturing-licensing company headquartered in Colorado since 2010. Under its agreement with UNM, BPH will have the exclusive right, in Hawai'i, to manufacture marijuana infused products using UNM's proprietary techniques and processes. UNM will also provide consultation and serve as an advisor to BPH in all aspects of manufacturing marijuana products. UNM licenses its proprietary manufacturing methods, industry experience and compliance services to clients in several states.



UNM specializes in pharmaceutical-grade marijuana extraction, production, formulation, packaging and branding of dosed and tested products for regulated MM markets. UNM has been consistently recognized by dispensaries, physicians and patients for the quality and consistency of the MM products created using their proprietary techniques. MM industry experts have also awarded UNM multiple honors for the quality of their products and approach toward patient education and the safe use of MM.

The other principals of BPH will all bring additional relevant expertise and business acumen to the table.

Maya Rogers Kiyomura ("Maya") will be the CEO of BPH. For the last several years she has helmed Blue Planet Software, one of Hawai'i's most successful high tech companies, through the highly complex and competitive high-tech world with international sophistication and a sense of local pride and style. As co-founder and Partner of Blue Startups, Hawai'i's premier Business Accelerator Organization and a 2015 top 20 US Accelerator, Maya assists and trains promising start-up entrepreneurs to compete on a global scale using a mentor driven model that reaches networks throughout Hawai'i, Asia and Silicon Valley.

BPH's Chief Financial Officer, Kent Otsu, has significant finance experience working for some of Hawai'i's most notable companies and will be the executive responsible for the financial control and planning of BPH. Kent will oversee all financial and accounting functions including: (1) cash control, (2) preparing budgets and financial statements, (3) coordinating financing (4) monitoring expenditures and liquidity, (5) managing tax issues, (6) reporting financial performance to the board, (7) providing timely financial data to the CEO and (8) working with appropriate financial and other government regulators.

BPH's distinguished Board of Advisors includes:

1) Dr. Bradley Willcox M.D., a UH affiliated scientist, researcher and practicing physician who will act as BPH's Chief Medical Advisor ("CMA") and, among other things, provide guidance to BPH regarding the latest credible scientific research involving MM and will act as the Company's information gatekeeper in connection with the preparation and dissemination of medical and scientific information to registered patients as permitted by the Department of Health, State of Hawai'i ("DOH"). Dr. Willcox is an investigator in the area of geriatrics and gerontology at the Pacific Health Research and Education Institute and is a clinical assistant professor in the Department of Geriatric Medicine at the John A. Burns School of Medicine, University of Hawai'i. As his attached profile attests, Dr. Willcox's education, training, background and experience make him particularly well suited to provide scientific and medical guidance to a MM dispensary business. DOH has recently compiled and published information regarding the demographics of the roughly 12,000+ MM patients in the State of Hawai'i. The DOH data indicates that an overwhelming number of these patients use MM to alleviate pain from (their physician certified) debilitating medical condition. Accordingly, it appears that a substantial number of Hawai'i's registered MM patients use MM to treat symptoms associated with many of the chronic diseases that afflict Hawai'i's kūpuna. Dr. Willcox's medical and scientific background nicely fits this



demographic. In addition, the recent expansion of the definition of "debilitating medical condition," for which physicians may prescribe MM, to include "post-traumatic stress disorder" increases the relevance of Dr. Willcox's skill set to BPH's mission.

2) Dr. Andrew Bachman, M.D. is a co-founder of LeafLine Labs, a MM research and manufacturing company located in Minnesota. Dr. Bachman earned his medical degree from Georgetown University School of Medicine and his undergraduate degree in biology from Amherst College and will provide advice and guidance to BPH regarding early stage development of its MM dispensary operations.

3) Greta Inofer, R.N. is a registered nurse with over five years experience in patient case management and care coordination. Under the guidance of Dr. Willcox, Greta will facilitate dissemination of patient information and provide face-to-face patient consultation regarding the safe use of MM.

4) Dr. Marisa Kesaji, Pharm.D. is a graduate of Roosevelt High School (Summa Cum Laude) received her Doctor of Pharmacy from the University of Southern California. Dr. Kesaji will provide advice and guidance to BPH regarding pharmacological issues and working in consultation with BPH's CMO and CHA.

5) Dr. Kenneth Leonhardt, Ph.D., also a UH affiliated scientist, will act as the Company's Chief Horticultural Advisor ("CH") and provide BPH with guidance regarding the best horticultural practices necessary to economically produce quality pharmaceutical grade MM for Hawai'i's patients. Dr. Leonhardt will work closely with BPH's Cultivation Manager.

BPH's Cultivation Manager will be Michael Rogers a graduate in Horticulture Science from the College of Tropical Agriculture at the University of Hawai'i at Mānoa.

Finally, BPH has engaged a team of local business and regulatory attorneys and a nationally recognized cannabis law attorney, Greg Anton, Esq. to provide the legal advice, counsel and guidance necessary to assure that BPH complies with all applicable state laws and regulations and understands the complexities inherent in operating a business that is legal under state law but in violation of the federal Controlled Substances Act (21 USC § 801 et. seq.). Attorney Greg Anton has been a champion of medical cannabis patients for over 35 years; working to help ensure safe access to this valuable medicine. Greg has litigated issues of cannabis law at all levels of State and Federal courts, including the US Supreme Court. (In 2015 he achieved a landmark legal victory with an unprecedented ruling that his client can distribute medical cannabis without Federal interference). Besides working with state and local government officials to develop safe, effective regulations; Greg has provided legal counsel to all aspects of the medical cannabis industry. Greg represents the first licensed medical cannabis dispensary in the United States.

This highly credentialed and competent team possesses the required business savvy and will provide the necessary training, guidance and oversight to the employees, contractors, and vendors of BPH to ensure that BPH is not only successful from a business standpoint but that it sets the standard for excellence in patient care and safety for Hawai'i's registered MM patients.



## Company mission statement

Mission Statement: To provide relief that Hawai'i patients deserve through the highest quality, sustainable, and responsibly grown medical cannabis.

We hold patient safety as number one, and are committed to providing a safe, consistent, high quality medical marijuana to the registered patients. How we will differ from others will be in the care in which the medical marijuana will be grown. Our operating partners, High Country Healing, has won several awards for its quality product. They make up our core team and will be bringing their cultivation expertise. We have also recruited on our team a Chief Horticultural Advisor, an established Ph.D at the University of Hawai'i

## Blue Planet Software

The Tetris brand is one of the leading and most distinctive video game brands and franchises in the world with over 500 million mobile downloads, and over a billion games played online per year. In the game's 31 year history, Tetris has partnered with the likes of Electronic Arts, Ubisoft, Sega and Hasbro and continues to be one of the most widely recognized video games of all time.

Some other interesting facts of Tetris:

- Tetris is played in more than 185 countries
- Tetris has been translated into more than 50 languages
- Tetris has been released on over 50 platforms
- Over 35 million units of Tetris were sold for the original Game Boy platform
- More than 23 billion games of Tetris Battle on Facebook have been played to date, making it one of the social platform's most popular games
- Hundreds of millions of Tetris products have been sold around the world.

Blue Planet Software, Inc. (BPS), the sole Agent for Tetris, was established in Hawaii 20 years ago. Currently, with a dozen employees all based in downtown Honolulu, BPS continues to develop the Tetris brand identity that millions of fans have grown to love. As its sole agent, BPS delivers brand consistency and represents Tetris in all licensing relationships including the following:

- Product ideation
- Product quality assurance and approvals
- Promotional and public relations support
- Global Intellectual property protection

For more information, visit [www.tetris.com](http://www.tetris.com)

## Blue Planet Energy Systems



Founded in 2015, Blue Planet Energy Systems is a Honolulu based energy storage company. Working in partnership with Sony, Blue Planet Energy has created the “Blue Ion” solution which combines solar, energy storage and an energy efficiency management software to help homes and businesses become energy self-sufficient. Blue Ion is used to help homes and business maximize renewable energy, shift energy from low energy periods to peak periods and provide standby power protecting against black-outs.

Henk Rogers provided the vision and inspiration behind Blue Planet Energy Systems. In his Hawai‘i homes, Henk installed solar panels and reduced his energy consumption with efficient lighting and electric vehicles but after doing so he felt there was more that could be done. So he began exploring different battery technologies by purchasing and installing different options. In Sony he found a technology that was safe, powerful and cool.

He struck a relationship with Sony’s corporate leadership and negotiated an exclusive relationship to resell Sony’s industry leading and proprietary Fortelion™ chemistry.

Today Blue Planet Energy is one of the leaders in Energy Storage with its Blue Ion systems deployed in homes, commercial facilities in Hawai‘i and California.

For more information, visit [www.blueplanetenergy.com](http://www.blueplanetenergy.com)

## **Blue Startups**

Blue Startups is a Honolulu-based venture accelerator founded by Henk Rogers and Maya Rogers Kiyomura. Blue Startups invests and provides hands-on mentorship to capital-efficient and scalable-technology companies, including Internet, software, mobile, gaming and e-commerce. Blue Startups is a nexus of entrepreneurial activity not only in Hawai‘i, but also between Asia and the Continental U.S.

Blue Startups concentrates on helping scalable-technology companies including web, software, mobile, gaming and e-commerce compete on a global scale. A member of the Global Accelerator Network, Blue Startups follows the Techstars mentor-driven accelerator model, reaching networks in Hawai‘i, Asia and the Silicon Valley.

Blue Startups has a network of more than 80 mentors reaching from Hawaii and Japan to Silicon Valley. The interaction of mentors with teams will assist in developing Hawai‘i as a node of entrepreneurship by bringing in expertise, capital and other resources from across the Pacific. Our premise is that people make innovation happen, that growth follows effective execution, and that sustained success will require access to global resources.

Blue Startups has 50 companies in its portfolio to date, has deployed over \$1 million dollars in funding, and the companies have gone on to raising over \$25 million in follow-on funding. Over 75% of the companies have received outside capital, and the average raise of each graduate company is \$500,000. Today, Blue Startups is ranked as top 20 accelerators in the U.S. as ranked by TechCrunch.



For more information, visit: [www.bluestartups.com](http://www.bluestartups.com).

## **Blue Planet Foundation**

Henk founded the Blue Planet Foundation in 2007 as a 501(c)(3) nonprofit organization. Blue Planet Foundation's mission is to clear the path for 100% clean energy, starting in Hawaii. Blue Planet Foundation's vision is a world powered by abundant renewable energy that sustains all life on Earth. The Foundation focuses on implementing transformative clean energy policy and developing innovative and scalable energy engagement programs by directing its efforts in three areas of change: (1) encouraging leaders to make policy changes that accelerate cost-effective, secure, renewable energy; (2) engaging communities through smart, replicable renewable energy and energy efficiency solutions; and (3) inspiring everyone, through creative communications, to believe in the power and possibility of a future beyond fossil fuels. By leveraging activities in these three programmatic areas of advocacy, action, and awareness, Blue Planet Foundation is making meaningful change on an issue that touches every aspect of our lives and economy.

### *Advocacy*

Blue Planet Foundation's advocacy work seeks to implement innovative legislative and regulatory policy solutions to remove barriers and accelerate the transition to 100% clean energy. The Foundation advocates at the state legislature and Public Utilities Commission and acts as a resource at conferences and in working groups like the Hawaii Clean Energy Initiative. Blue Planet Foundation also convenes world renowned experts to help decision leaders make smart policy choices. In 2015, Blue Planet Foundation led the campaign to pass the nation's first 100% renewable energy requirement, as well as a community renewables bill that could dramatically increase access to renewable power.

### *Action*

Blue Planet Foundation's action programs provide tools to the community to control their energy consumption and allow them to support renewable energy. A clear example of this is the Foundation's WEfficiency crowdfunding program. Since its launch in 2014, WEfficiency has enabled individuals to fund projects that will displace 200,000 gallons of oil, avoid 5 million pounds of carbon pollution, and save local nonprofits \$1.2 million. Nonprofits such as YWCA, Damien Memorial School, Boys & Girls Club, and others have used WEfficiency to decrease their carbon footprints while increasing their capacities to serve our community.

### *Awareness*

Blue Planet Foundation's awareness initiatives engage communities in a new conversation about energy, helping to build understanding about the damage caused by fossil fuels and the solutions available through renewable energy and smarter energy use. Blue Planet Foundation tracks Hawaii's progress toward 100% clean energy with its Energy Report Card, published annually in print and online. Developed to inform decision leaders and the public, the report evaluates the annual progress in five categories of energy transformation: transportation, efficiency,



renewables, smart grid, and economics. Blue Planet Foundation also increases awareness through its Island Pulse kiosks. The kiosks help make the invisible, visible, by providing a real-time breakdown of our energy use as well as the sources of that energy (solar, wind, coal, etc.). The Island Pulse was developed in partnership with Hawaiian Electric, who provided the energy data for the first time publicly.

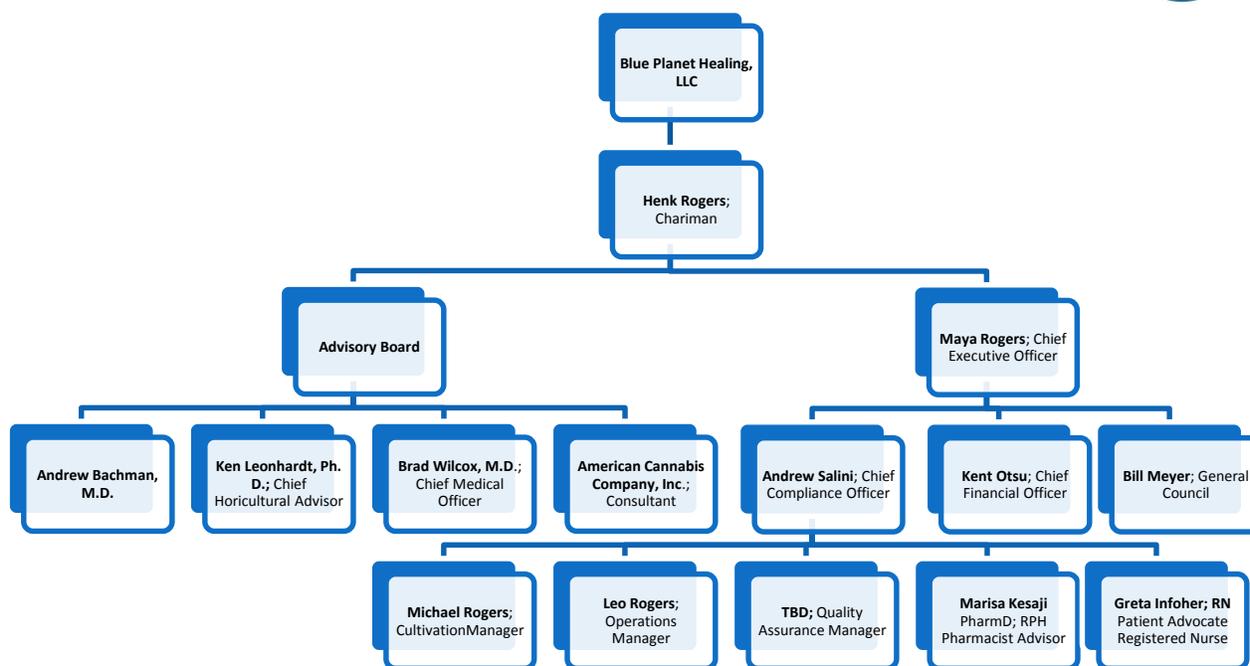
Although distinct, Blue Planet Foundation's three programmatic approaches are implemented synergistically with activities in each approach reinforcing the others. By addressing community needs in each category, Blue Planet Foundation is the leader that is unifying Hawaii's transformation to 100% clean energy with precision and determination.

BPH will operate a Dispensary Facilities (as that term is defined to include cultivation, processing/manufacturing and dispensing marijuana and manufactured marijuana products in full legal compliance with the State of Hawai'i. BPH will cultivate, manufacture and dispense marijuana and manufactured marijuana products for dispensing to qualifying and registered medical marijuana patients in the State of Hawai'i. BPH will ensure compliance with all applicable state and county law and regulations while becoming a valuable member of the business community and surrounding areas.

BPH's focus will be on cultivating the highest quality medical marijuana for the Hawai'ian medical marijuana industry and to operate safe, patient-friendly retail dispensing locations. Through the use of established industry best practices pertaining to the cultivation of marijuana and manufacturing of marijuana products, BPH will cultivate and manufacture high quality marijuana and manufactured marijuana products at the registered dispensary facilities. BPH will cultivate all marijuana on the registered production facility utilizing various cultivation techniques and methodologies including True Living Organics (TLO), Integrated Pest Management (IPM), sustainable and environmentally friendly operations and other programs and policies to ensure compliance with state law. The BPH registered dispensary premises will be within a structure to prevent unauthorized entry and ensure no activities or operations can be seen or viewed from the exterior of the facility BPH will also manufacture marijuana products of the highest quality, including oils and oil extracts, capsules, lozenges, pills, tinctures, ointments, and skin lotions. The patient-centric retail dispensing operations will focus on patient accessibility and safety and be conducted according to all state and county law.

For more information, visit [www.blueplanetfoundation.org](http://www.blueplanetfoundation.org)

## **Management and Organization** **Organizational Hierarchy Chart**



## Blue Planet Healing Organizational Members

### **Henk B. Rogers** – *Sole Applicant, Chairman & Spokesperson*

Considered one of the visionaries of computer games, Henk Rogers helped change the face of the industry as the entrepreneur responsible for bringing the Tetris® game to the United States and world market. Under Henk’s direct leadership, the Tetris game has become one of the world’s top-selling video game brands with hundreds of millions of products sold, and after 30 years since its “birth,” that number is still growing. Today Rogers serves as Managing Director of The Tetris Company, the exclusive licensor of the Tetris brand and Chairman of Blue Planet Software, the sole agent for the Tetris franchise, founder of Blue Planet Foundation, a nonprofit clean energy advocate, and founder of Blue Startups, Hawai’i’s first venture accelerator.

A heart attack in 2005 gave Henk the opportunity to rethink the rest of his life and reevaluate the purpose of his life’s work. Henk is determined to end the use of carbon-based fuel on the planet, starting with fossil fuel use in Hawai’i, his adopted home. To fulfill his mission, Henk established Blue Planet Foundation, which has become the frontline organization in the fight for indigenous renewable energy in Hawai’i. As Blue Planet Foundation’s principal and visionary philanthropist, Henk Rogers is committed to the mission of stewarding the environment through developing non-carbon, clean energy sources. He is personally devoted to helping our planet reduce and eventually eliminate its dependence on fossil fuels.

Furthermore in 2015, Henk founded Blue Planet Energy Systems, becoming a leader in energy storage solution systems home and commercial usage.

Henk’s community recognitions include:



- 2015 – Hawai‘i Business Magazine, CEO of the Year
- 2015 – Honorary Doctorate of Human Letters, University of Hawai‘i
- 2014 – Hawai‘i Institute for Public Affairs (HIPA) Ho‘ulu Award
- 2013 – Hawai‘i Business News Business Leadership Award Finalist
- 2011 – Hawai‘i Business Innovation Showcase “City & Council of Honolulu” Finalist
- 2010 – Hawai‘i Business Magazine “Five for Today” leadership recognition
- 2009 – Hawai‘i Venture Capital Association “Entrepreneur of the Year”
- 2008 – Hawai‘i Venture Capital Association “Venture Capital Deal of the Year” Honorable Mention – Avatar Reality

Henk currently sits on the board of East West Center Foundation, is the Chairman of Science Engineering Expo - Innovation Technologies (Chairman, SEE-IT), as well as the Chairman of Pacific International Space Center Exploration Systems (PISCES).

**Other Affiliations:**

Honorary Consul of Netherlands, Waialae Country Club, Waikiki Yacht Club, Honolulu Club, Sunrise Rotary, University of Hawai‘i, College of Engineering Dean’s Advisory Council, Plaza Club.

**Personal:**

Rogers and his wife Akemi currently share their time between residences in Honolulu and Kailua-Kona, Hawai‘i. They have four children: Maya, Julie, Michael and Leonard.

In his spare time, Rogers is an avid photographer, world traveler, and designer, and he enjoys playing squash and golf.

**Maya Rogers Kiyomura – Chief Executive Officer**

Maya Rogers Kiyomura is President and CEO of Blue Planet Software, the sole agent for the Tetris® brand. With a history that spans more than 30 years, Tetris is one of the leading and most distinctive video game brands and franchises in the world. Rogers has spent the last eight years leading the Tetris brand’s worldwide business initiatives, including and more than 12 years in the video game industry in Japan, China and the U.S. Prior to Tetris, Rogers steered cross culturalization and development efforts with Sony Computer Entertainment America and American Honda.

In 2012, Maya co-founded Blue Startups, Hawai‘i’s first venture accelerator that helps early stage startups with investments and mentoring. Fifty companies have gone through the Blue Startups program and received capital from the Blue Ventures Fund, and have attracted approximately \$25



million in funding. In March 2015, Blue Startups placed #17 in TechCrunch's annual ranking of top US accelerators.

Prior to Tetris, Maya held management roles with Sony Computer Entertainment America, where she steered localization efforts for games such as the Gran Turismo and Hot Shots Golf franchises. Rogers began her career working with cars at American Honda before making the switch over to working on virtual cars at SCEA.

Maya is a board member with the American Red Cross Hawai'i Chapter, and is a member of the Tiffany Circle Society of Women Leaders, a national Red Cross program comprised of women leaders and philanthropists who dedicate their time and talents to support community Red Cross efforts. Rogers also serves as a member of the advancement committee and advisory board of the Smithsonian Asian Pacific American Center. She is also actively involved in eGlobal Family, an organization that links orphaned and vulnerable children in developing countries to compassionate and responsible supporters. The Rogers family is also a proud member of the Family Business Center of Hawaii, part of the Pacific Asian Center for Entrepreneurship at UH Manoa Shidler College of Business.

In March 2015, Maya was awarded "20 for the Next 20" recognition by Hawai'i Business Magazine as one of 20 emerging leaders who have made major contributions to the state of Hawai'i, and are expected to have a significant impact on the state over the next two decades. In 2016, Pacific Business News honored Maya with the Women to Watch recognition.

Maya currently is involved with the State of Hawaii's Workforce Development task force, which is tasked to come up with plans to increase jobs under the Workforce Investment and Opportunity Act (WIOA), passed by signed into law in 2014. She also is working with the Chamber of Commerce Economic Development and Innovation Committee to provide advice from the entrepreneurial community.

Maya grew up in Japan and the US, and currently resides in Hawai'i. She holds a B.S. in Business Administration and an MBA from Pepperdine University.

**Kent Otsu** – *Chief Financial Officer*

Kent Otsu is Chief Financial Officer (CFO) of Blue Planet Software (BPS), the sole agent for the iconic video game Tetris. As CFO, he oversees all administrative and financial matters for BPS including accounting, tax reporting and compliance, and budgeting. In addition, Kent oversees legal and human resources for BPS. Kent and his team also provide similar services to all companies under the direction of Henk Rogers which include Blue Startups, a nationally-recognized accelerator, and Blue Planet Foundation, a non-profit organization dedicated to end the use of carbon-based fuels in Hawai'i.

Prior to working at BPS, Kent worked for KPMG in Honolulu where he worked on financial audits of electric utilities, healthcare and real estate entities, and he earned his Certificate of Public Accounting at this time. He then spent 12 years as Controller for LVMH Fashion Group Hawai'i, whose brands include Louis Vuitton, Celine and Fendi. His responsibilities included producing financial statements in accordance with GAAP and IFRS, income tax reporting and compliance,



and overseeing all audits including State Income Tax, General Excise Tax, Department of Labor, Internal Revenue Service and US Customs. In addition, Kent was responsible for creating and maintaining internal controls over cash and inventory, which included procedures around the point-of-sale, and inventory receiving, transferring, and physical counts.

Kent graduated from Iolani School, and then attended University of Colorado - Boulder where he earned a Bachelor of Science in Accounting. Today, Kent enjoys spending his free time with Debbie, his wife of 21 years, and his daughters Jessica and Deanna. He also enjoys an occasional round of golf, and supporting his alma mater, Iolani School.

**Andrew Salini** – *Chief Compliance Officer & Chief Operations Officer*

Andrew Salini has acted as the Chief Operations Officer & Chief Strategist at High Country Healing's Retail & Cultivation Facilities from 2014 to present. Andrew's management experiences include HCH operations, retail/cultivation/financial strategy and analytics, as well as brand and business development. Formerly, Andrew was the Chief Strategist at EMF Fixed Income Fund from 2011-2014, specializing in fixed income relative value arbitrage. He was also previously an Associate at Credit Suisse in the Fixed Income Division of the investment bank from 2010-2011 and began his career at Deutsche Bank Securities where he was an Associate Proprietary Trader and Portfolio Manager in the [Global Finance & Foreign Exchange Division](#) from 2006 to 2009.

Andrew received an A.B. in Economics, a Certificate in Finance, and a Certificate in French Language & Culture from Princeton University in 2006. He is an academic All-American in Baseball and is Princeton Baseball's All-time hits leader, 3-time Ivy League Champion and a 2002 Graduate of Phillips Academy in Andover, MA.

**William G. Meyer, III** – *General Council*

Mr. Meyer began practicing business law in Hawai'i in 1979. His practice emphasizes intellectual property law (including copyright, trademark and right of publicity licensing and registration, entertainment, trade secret, art and advertising matters); government relations; real estate matters; and related dispute resolution including litigation, arbitration and mediation.

For more than three decades, Mr. Meyer has provided creative legal and business guidance to a broad spectrum of individuals, companies and educational institutions, both in Hawai'i and on the mainland, including intellectual property owners, licensors and licensees such as artists, writers, photographers, television and film producers, composers, software and game developers, publishers, advertisers, broadcasters, art gallery owners, entertainers, recording artists, musicians, record labels, architects, scientists, apparel designers and merchandisers. Mr. Meyer's clients have included the University of Hawai'i at Mānoa, the University of Hawai'i at Hilo, national and international entertainment companies and many of Hawai'i's top recording artists, record labels and filmmakers.

Mr. Meyer's government relations work has promoted the diversification of Hawai'i's economy through the adoption of legislation which has enhanced the development of the creative and high tech industries. Mr. Meyer's real estate related practice has focused on the resolution of complex



disputes involving real estate development and sales transactions, land use, eminent domain, construction defects, government bid disputes and real estate broker issues.

Mr. Meyer has taught at the William S. Richardson School of Law, University of Hawai`i at Mānoa; the Pacific New Media Workshop, University of Hawai`i at Mānoa; and the Hawai`i Music Institute at Windward Community College and served as a court appointed mediator for the United States District Court for the District of Hawai`i in connection with intellectual property issues. Mr. Meyer is past Chair of the Intellectual Property & Technology Section of the Hawai`i State Bar Association, and a frequent speaker on intellectual property, music, art, advertising, e-commerce and Internet law topics, and has authored numerous articles and other materials on these topics, including continuing legal education materials for the Hawai`i State Bar Association and other organizations and publishers. Mr. Meyer was selected for inclusion in the 2008, 2009, 2010, 2011, 2012, 2013, 2014 and 2015 “Hawai`i Super Lawyers” in intellectual property and is peer review rated “AV” (preeminent) by Martindale-Hubbell, the highest rating available for legal ability and professional ethics.

Mr. Meyer is active in community organizations dedicated to the promotion of literacy, the preservation of Hawai`i’s host culture and the arts, devotes time to a pro bono practice which assists creative individuals with their legal and business issues and mentors young lawyers interested in the creative industries. Mr. Meyer has served on the Board of Governors of the Hawai`i Academy of Recording Arts, a Hawai`i non-profit organization, which each year presents the “Nā Hōkū Hanohano Awards” (which is similar to the Grammy® Awards and recognizes outstanding achievement in the recording arts in the State of Hawai`i) and the annual Lifetime Achievement Awards (which honors those who have made significant contributions to the music, culture and related arts of Hawai`i and/or the host culture of Hawai`i). See <[www.nahokuhanohano.org](http://www.nahokuhanohano.org)>. Mr. Meyer also serves on the Board of the Kaua`i Music Festival, the oldest and largest songwriters conference in the State of Hawai`i (see <[www.kauaimusicfestival.com](http://www.kauaimusicfestival.com)>) and acts as special counsel to the Hawai`i International Film Festival.

**Michael Rogers—*Cultivation Manager***

Michael Rogers holds a deep passion for sustainability and human welfare from his former career running an international gemstone trading business. Michael spent much time in the bush of Africa and Madagascar creating deep relationships with the poorest people of the world learning firsthand about the lives and woes of the “bottom billion”, at which point Michael made a decision to study sustainable agriculture and community development to improve people’s lives. Michael folded his business and attended the University of Hawai`i at Mānoa where he earned a degree in Plant Production and Management from the department of Tropical Plants and Soil Sciences in the College of Tropical Agriculture and Human Resources (CTAHR). During his time at the university, Michael was highly active in extracurricular activities being the president of the Horticultural Society, publishing articles regarding genetics and plant disease management, and creating a community composting facility with forced aeration to accelerate the composting process.

He is a certified permacultural designer and has work experience at a modern 2,500 acre farm where he was responsible for irrigation management, soil conservation projects, native plant



landscaping, plant disease management, and tractor operation. Currently, Michael serves on the board of advisors for Kumuola Foundation, a local non-profit organization based on a farm in the rainforests of Mānoa whose mission is to promote sustainable island living through agriculture, community, education, and practice of Hawai‘ian arts. Michael has a deep understanding of Hawai‘ian culture having a long history of dancing hula and receiving honors at the Merrie Monarch Hula Festival.

**Leo Rogers—Operations Manager**

Leo Rogers is a graduate of Roosevelt High School, and attended the University of Hawaii where he studied Kinesiology and Rehab Science. Being fully bilingual, Rogers spent 8 years working in the hospitality industry in various positions working both as a front-end and a back-end operator. He now works for Blue Planet Software as a project coordinator where he manages various projects including, digital assets, events, websites, and so on. His education, multi-cultural background, and years of experience working with customers, allows him to operate while having the medical patients best interest in mind.

**Advisory Board Members**

**Ken W. Leonhardt, Ph. D**

Ken has considerable experience in plant breeding, having created and introduced over 100 new varieties to Hawai‘i growers. Ken’s professional research focus is on polyploidy induction and creating sterility (seedless clones). Tetraploid forms of 22 species have been created. Only 2 other labs in the US focus on this kind of research (Dr. Ranney at North Carolina State U, and Dr. Contreas at Oregon State U). Tetraploid forms of Marijuana will have higher concentrations of CBDs and THCs.

Ken has familiarity with all sectors of agribusiness in Hawai‘i for 43 years and has acted as a crop science educator for the past 39 years. He was the owner/operator of a commercial ornamental plant nursery for 13 years (1975-1988).

As Chairman of the undergraduate program at the UH department of Tropical Plant and Soil Sciences, Ken is familiar with the top graduates, thus when BPH is looking to hire technicians with a crop science background, Ken will be able to source the top candidates. Ken also sits on the board of advisors for Medical & Product Testing – Hawai‘i MDs.

**Bradley J. Willcox, MD, M.Sc**

Bradley J. Willcox M.D., M.Sc. trained in Medicine at the University of Toronto, Internal Medicine at the Mayo Clinic, and Geriatric Medicine at Harvard Medical School. Dr. Willcox is Principal Investigator of the National Institute on Aging-funded Kuakini Hawai‘i Lifespan Study and Kuakini Hawai‘i Healthspan Study, which are ancillary studies on aging from the Kuakini Honolulu Heart Program. He is also Professor and Director of Research at the Department of Geriatric Medicine, John A. Burns School of Medicine, University of Hawai‘i, located on the Kuakini Health System campus. Dr. Willcox is the Co-Principal Investigator of the Okinawa Centenarian Study and has been investigating mechanisms of aging for almost two decades with this study. Clinically, he runs the Long Term Care Hospitalist Program at The Queen’s Medical Center, where he is a three time nominee for Physician of the Year.



Dr. Willcox’s research teams have identified several important genetic and environmental risk factors for aging and aging-related chronic diseases. His research team in Okinawa identified the first longevity-associated gene, and his research team in Hawai’i was the first to identify the association of the FOXO3 gene with human longevity and he has greater than 150 peer-reviewed scientific publications.

Dr. Willcox is on the Editorial Board of several leading gerontological journals, including the Journals of Gerontology. He has been recognized with a Dorothy Dillon Eweson Award for Advances in Aging Research, the Henry Christian Award from the American Federation for Medical Research, a Director’s Citation from the Centers for Medicare and Medicaid Services, and other honors. Dr. Willcox is also the author of a New York Times best-selling book on healthy aging, *The Okinawa Program*. His work has appeared in cover articles of *Time Magazine*, *National Geographic*, and on *Oprah*, *Good Morning America*, *NOVA Science*, *BBC*, and other media.

## **Consultants**



### **American Cannabis Company, Inc. (“ACC”) Company Profile**

BPH has hired and retained American Cannabis Company, Inc. (“ACC”), a marijuana-industry consulting firm that offers advisory and consultation services related to establishing operations, the implementation and execution of the operating plan, staff training, compliance, and other critical operational needs. ACC collectively brings over twenty years of knowledge and practice operating within the regulated, legal medical marijuana industry. The company has particular expertise in marijuana cultivation methods on a commercial scale and manufactures multiple industry-specific cultivation and retail solutions. As BPH’s consulting partner, ACC will help ensure that BPH has the knowledge and expertise necessary to establish compliant operations rapidly while achieving its quality goals for the brands it produces for qualifying patients in the State of Hawai’i.

### **Executive Summary**

- Based in Denver, Colorado
- Consult, advise, & provide equipment and supplies to businesses entering or currently operating in *regulated* cannabis industries
- Currently serve clients in 14 states & Canada
- Have assisted clients in winning 10+ licenses in 5 five states
  - Business & operational plans, pro-forma, market study, & application
  - Facility design, equipment selection, & construction management
  - Facility roll-out, employee training, & on-going cultivation management
  - On-going retail, operational, & compliance monitoring

### **Industry Successes**



American Cannabis Company					Cumulative
Year	State	W	L	Total	Client W %
2013	Connecticut	1	0	1	100%
2013	Massachusetts	1	2	3	50%
2014	Nevada	6	1	7	73%
2014	Minnesota	1	0	1	75%
2014	Illinois	2	4	6	61%
<b>Total</b>		<b>11</b>	<b>7</b>	<b>17</b>	<b>61%</b>

### **ACC Vision**

We are redefining society's relationship with cannabis through responsible stewardship.

### **ACC Mission Statement**

With our expert teams we establish and service regulated cannabis markets globally providing best in industry solutions that continue to exceed the requirements of the evolving cannabis industry thus ensuring our client's success through superior service and deep industry knowledge.

### **ACC Core Values**

1. Accountability & Professionalism
2. Integrity
3. Open, Transparent, & Respectful Communication
4. Passionate Teamwork
5. Sustainability

### **About The American Cannabis Company**

American Cannabis Company (ACC) was founded to meet the needs of the rapidly developing cannabis industry, including: medical, commercial and industrial hemp operators. We are experienced in cultivation, infused products and retail operations within regulated cannabis markets, as well as, establishing successful companies within the emerging limited licenses markets. From merit based applications, to facility design and deployment, to managing ongoing operations ACC has the experience and expertise to guide your business in the competitive cannabis space. Currently, we've operated in nine states and in the country of Canada. Our company focuses on providing services and products to the cannabis industry through our two operating divisions:



### **Company Ownership & Legal Entity**

American Cannabis Company, Inc. is a Delaware corporation with its headquarters in Denver, Colorado. ACC Inc. is a public company and trades under the stock ticker AMMJ on the OTCQB stock exchange.

### **Services, Equipment & Supplies**

Through its two divisions American Cannabis Consulting and The Trade Winds, American Cannabis Company provides its customers a full solution for success. From bringing your idea to a reality to ensuring it performs beyond expectation, ACC has the people, partners and products to ensure success.

### **ACC Services**

American Cannabis Consulting is the premier advisory agency for those seeking to achieve success in the highly competitive and rapidly expanding commercial cannabis industry.

Whether you're preparing to enter the market or already have a footprint, our team of industry leaders can help your business reach its potential while meeting the necessary regulatory framework. With first-hand experience in regulated commercial Cannabis cultivation since 2009 and backed by accomplishments in related industries such as healthcare and horticulture, we have the knowledge and resources to guide you through every aspect of growing your Cannabis business.

### **Cannabis Industry Research & Design**

Our knowledgeable team identifies needs in the marketplace and develops next generation products to fill those needs. Our in-house products include:



- The Cultivation Cube™: The foundation for a complete, commercial-scale grow operation, the Cultivation Cube provides exceptional environmental control, speed-to-market, production, space efficiency, lean manufacturing and security.



- SoHum Living Soil™: A 100% natural growing medium, SoHum Soil prevents an improper balance of nutrients, improves plant immunity, and is more cost-effective than traditional soil and fertilizer growth methods.



- The Satchel™: The Satchel is a pouch-like case for Cannabis and Cannabis-infused products that was designed to meet regulatory compliance with laws that require child-resistant exit packaging for licensed medicinal and recreational Cannabis businesses.

## **ACC Equipment & Supplies**

From cultivation necessities to retail goods to ancillary products like office supplies and cleaning agents, The Trade Winds can address your business' needs quickly and cost-effectively. The products we carry are carefully selected by our professionals and represent best-in-class solutions for the developing commercial cannabis markets. We continue to strive to realize solutions that improve our Client's business operations.

American Cannabis Company is proud to offer compliant, solution-based products and services to commercial cannabis cultivation and cannabis retail businesses.

## **ACC Management Consulting**

With hands-on experience in commercial cannabis cultivation, the team at American Cannabis Company has the knowledge and resources to help your crop and your business realize their potential. From Cultivation, through processing and into retail sales, our team has firsthand knowledge and experience.

Our goal is to lead you through a successful development and launch process, and to work with you to help your cultivation business grow into the future. As part of the design and build out of your business, our advisory services will focus on key elements that include:

- Business and operational plan
- Pro-forma financials
- Business plan writing
- Standard operating procedures



- Protocol based workflow
- Retail Strategies
- Retail Operations
- Regulatory compliance
- Market modeling and forecasting
- Security and safety measures
- Equipment and technology purchasing
- Quality control
- Direct staffing and/or recruitment and training
- Facility design and build-out
- Construction Management
- Patient centric strain selection
- Methodology selection
- Perpetual harvest and workflow requirements to meet patient demand
- Environmental controls
- Integrated pest management

**Andrew W. Bachman, MD, FACEP**



**LeafLine Labs, LLC, cultivates, processes, and distributes medical cannabis formulations in Minnesota.**

Founded in 2014 by Board-Certified Emergency Medicine physician, Andrew Bachman, MD, and his team, LeafLine Labs, LLC, is registered to cultivate, process, and distribute medical cannabis formulations in Minnesota’s “extraction-only” medical program. It provides expertly-crafted medicine and compassionate care for suffering patients with currently approved conditions such as cancer with specified complications, glaucoma, HIV/AIDS, Tourette’s Syndrome, ALS, Intractable Seizure Disorders, Muscle Spastic Conditions (e.g., Multiple Sclerosis), Crohn’s Disease, Terminal Illness, and Intractable Pain.

LeafLine Labs actively cultivates dozens of selected medical cannabis strains in a specifically-designed and newly-constructed 42,000 SF pharmaceutical-grade facility, ideally situated on 24 acres, optimized for plant health, production, sustainability and reproducibility. All medicinal compounds are then efficiently separated from the fibrous plant material using industry-leading scientific techniques and technology by our medically-experienced extraction team, which allows for innovative medicine formulation with NO harsh diluents, additives or toxic solvents employed.

Every lot of “whole plant extract” medicine is rigorously tested for chemical composition, potential contamination, consistency and purity at one of only two independent, state-sanctioned



and regulated laboratories in Minnesota. Our medication formulations contain standardized, proprietary cannabinoid profiles, including set ratios of CBD, THC, etc., that aid in the treatment of a variety of medical conditions and ameliorate a variety of medical symptoms for Minnesota's suffering patients with qualifying conditions. The final preparations are then clearly packaged as capsules, oils for vaporization, syrups & suspensions, tinctures, and sublingual sprays, and labelled accordingly to pharmaceutical-grade specifications.

LeafLine Labs' Headquarters and primary production facility is located in the Minneapolis/St. Paul suburb of Cottage Grove, MN, with our flagship cannabis care center opened in Eagan, MN, on July 1, 2015. A care center in St. Cloud, MN, (in close proximity to one of the nation's largest V.A. Hospitals) is nearing completion presently, with subsequent care centers in St. Paul and Hibbing, MN, slated to open by July 1, 2016. LeafLine Labs is well-supported & well-capitalized with nearly \$16M raised through vetted and approved investors to date, many of whom are physicians and/or professional caregivers in Minnesota and beyond.

#### **Marisa Kesaji** - Pharmacist Consultant

Marisa Kesaji, a graduate of Roosevelt High School (Summa Cum Laude) received her Doctor of Pharmacy (PharmD) degree from the University of Southern California. Kesaji has extensive experience as a registered pharmacist in both Hawai'i and California. Being a former Chief Pharmacist, she will be able to help develop policies and procedures to ensure safety and monitoring of products.

#### **Greta Inofer, R.N.** – Patient Advocacy Nurse

With over 5 years of experience as registered nurse, Greta's brings with her expertise in case management, care coordinating, private practice clinic, skilled nursing, and dermatology. She currently works as a registered nurse as a case manager, facilitating face-to-face patient visits to ensure that their current medicinal needs are met. As a health and wellness coach, Greta also bring her skills to work with individuals on how to be healthier mentally and physically through proper nutrition and functional fitness. Prior to this, Greta managed administrative operations at a care home, maintaining 26 staff members at a 24 bed facility. It was there where she established and implemented care protocol ensuring all regulations were met. Greta is recognized as an excellent team leader and problem solver with expertise in health and wellness, quality, utilization, and risk management. Greta is a member of the American Cannabis Nurses Association, the only nursing educational and advocacy organization representing endocannabinoid therapeutics in the United States.

#### **Licensing Agreements**

To further strengthen BPH's operational strategy, BPH has entered into an agreement with UNDRNWMNGMNT, LLC. ("UNM"), an established marijuana product manufacturing-licensing company headquartered in Colorado since 2010. Under its agreement with UNM, BPH will have the exclusive right, in Hawai'i, to manufacture marijuana infused products using UNM's proprietary techniques and processes. UNM will also provide consultation and serve as an advisor to BPH in all aspects of manufacturing marijuana products. UNM licenses its proprietary manufacturing methods, industry experience and compliance services to clients in several states. UNM specializes in pharmaceutical-grade marijuana extraction, production, formulation,



packaging and branding of dosed and tested products for regulated MM markets. UNM has been consistently recognized by dispensaries, physicians and patients for the quality and consistency of the MM products created using their proprietary techniques. MM industry experts have also awarded UNM multiple honors for the quality of their products and approach toward patient education and the safe use of MM.

UNM currently operates within Colorado's legal marijuana industry and will provide deep industry knowledge and experience to BPH upon deployment of BPH manufacturing operations. BPH will utilize established standard operating procedures, extraction methods, and recipes for the manufacturing of all marijuana products.

### **Mission Statement**

To provide relief that Hawai'i patients deserve through high quality, sustainable, and responsibly grown medical cannabis.

### **Goals and Objectives**

In order to fulfill the mission statement, BPH has a set of goals and objectives that guide the business.

1. Develop a dispensary environment that gives the most access and relief to the patients
  - a. Dispensary shall be located in a location with ample parking at a central location
  - b. Dispensary shall have a welcoming look and feel that provides the patient with comfort through their retailing experience
  - c. Patient will be supported with professional consult and education
  - d. Product will be offered at an affordable price
  - e. Patient needs will be met with the availability of most appropriate and high quality medicine
2. Develop a cultivation and manufacturing facility that is sustainable and responsible
  - a. Quality of the products produced shall meet the highest standards for the benefit of the patients
  - b. High biosecurity standards will be put in place to minimize introduction of pests and disease
  - c. All product will be subject to high standards of cleanliness and consistency as a medical grade product
  - d. Create a safe working environment with zero work-related accidents
  - e. Achieve maximum energy efficiency and use clean energy sources
  - f. Create a sustainable material flow where inputs and wastes are minimized
  - g. Wastes are collected and disposed of in a secure manner
3. Inventory will be tracked, secured, and kept clean at all times
4. Every facility and transportation of product will be entirely secure 24/7
5. BPH will continuously strive to achieve excellence and everyday will be an improvement of the last
  - a. The most latest and reliable medical information will be sought after and implemented to benefit the patients
  - b. New technologies and methodologies will be sought after and implemented to benefit the patients



- c. Regular employee training will cover all aspects of their operations as well as promote a corporate culture of human resource development and community development

### **Business Philosophy**

BPH's business philosophy is to cultivate, produce, manufacture, and dispense marijuana and manufactured marijuana products of the highest quality and with the highest regard for health, safety, security and efficacy for registered employees, business partners and qualifying patients.

### **Business Market**

The marijuana and manufactured marijuana products offered by BPH will be intended for retail dispensing to qualifying, registered patients and primary caregivers in Hawai'i. The end consumer of the products produced by BPH will be registered patients in the State of Hawai'i. Currently there are more than 12,000 qualified, registered medical marijuana patients within the state of Hawai'i. The current business market for BPH products is further explained within BPH's financial pro-forma model. The financial pro-forma model is a separate, additional document detailing financial forecasts, ROI, growth opportunities and estimated capital requirements.

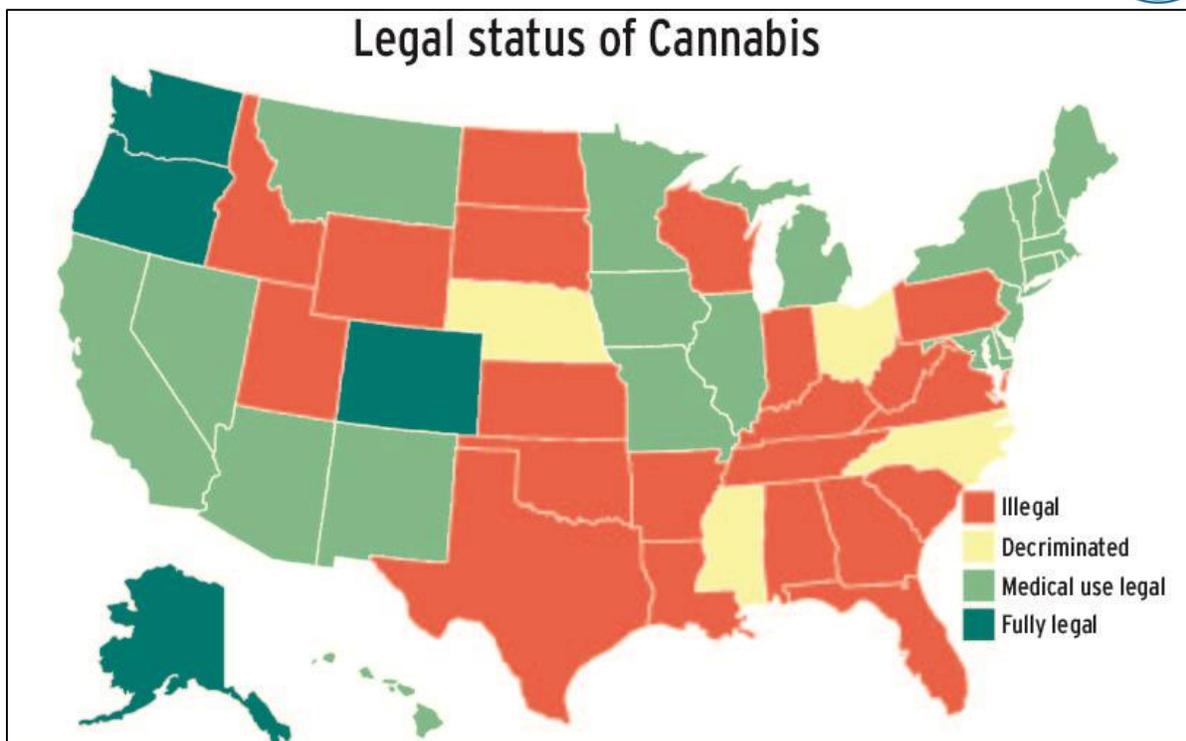
### **Industry Description**

The medical marijuana industry is an industry experiencing rapid growth and advancement. There are currently 23 states and the District of Columbia with medical marijuana laws on the books, 3 states with pending medical marijuana legislation and the states of Colorado, Washington, Oregon and Alaska with legal recreational marijuana laws.

With advances in modern medical research and marijuana research; we feel the medical marijuana market will continue to expand and develop in the years to come. More states each year are drafting legislation for medical marijuana as well as recreational use of marijuana and this trend does not show signs of decline.

### **History**

In 1996, nearly 60 years after the US government outlawed marijuana, California became the first state to legalize marijuana for medical use. Since then, 22 additional states as well as Washington DC have followed suit, bringing the total to 24.



\* <http://universe.byu.edu/2015/06/27/advocates-of-medical-marijuana-fight-for-its-legalization-in-utah/>

Despite the growing number of states involved, the medical marijuana industry remained fairly small for years, with only a limited number of dispensaries, primarily in California, operating under the constant threat of government raids.

A big breakthrough came in 2009 in the form of the “Ogden Memo,” a document instructing federal prosecutors to refrain from focusing their resources on prosecuting medical marijuana operations in states with medical marijuana laws. (<http://www.justice.gov/opa/blog/memorandum-selected-united-state-attorneys-investigations-and-prosecutions-states>)

This led to the opening of several thousand dispensaries across the country. For the next few years, the industry became very erratic due to numerous legal limitations on both the federal and local level. Due to the constant changing regulations and the reluctance from the investor community, the 2011 “breakout year” never materialized. The industry shrank by an estimated 15-20% as hundreds of dispensaries closed and patient numbers dropped.

The industry persisted through 2012 and the momentum rapidly changed. The US Department of Justice released the 2013 “Cole Memo”, which essentially authorized the medical marijuana industry. (<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>) Several new states began legalizing medical marijuana while other states that were in a holding pattern moved forward with plans to allow dispensaries to open up under tight regulations. Massachusetts was one of the states that made significant progress with their dispensary programs, setting the stage for 2014.



Medical marijuana states showed growth in 2014 from both former medical marijuana markets as well as new ones that just started awarding business licenses. The federal government released new guidance for financial institutions when dealing with medical marijuana dispensaries, providing relief for the industry; the FinCEN Memo.

([http://www.fincen.gov/statutes\\_regs/guidance/pdf/FIN-2014-G001.pdf](http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2014-G001.pdf).)

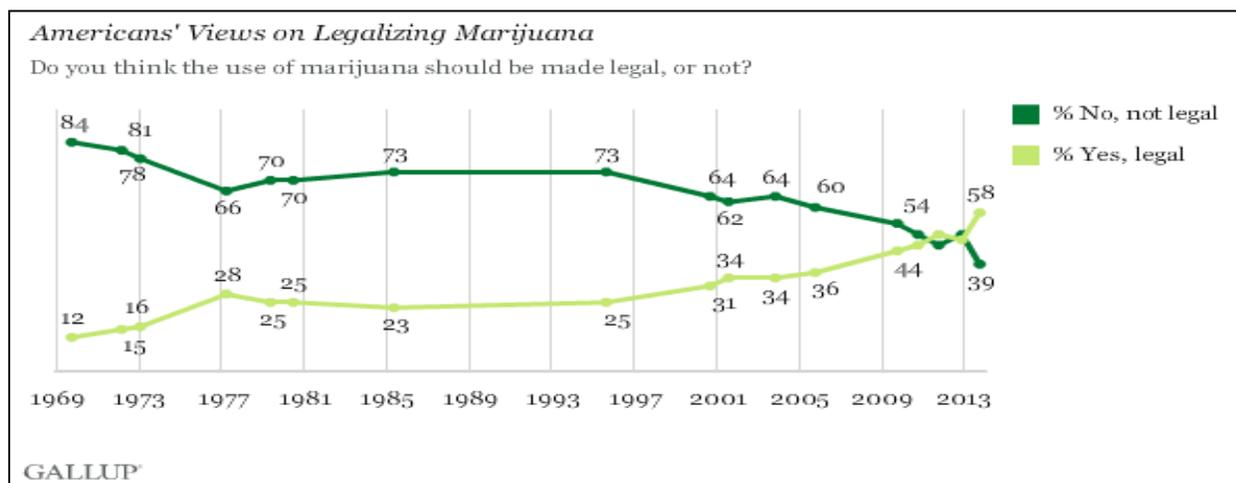
The FinCEN memo provides clarity to enhance the availability of financial services for marijuana businesses promoting greater financial transparency in the marijuana industry mitigating the dangers associated with conducting an all-cash business. The memos guidance also helps financial institutions file reports that contain information important to law enforcement.

### Trends in Social Acceptance

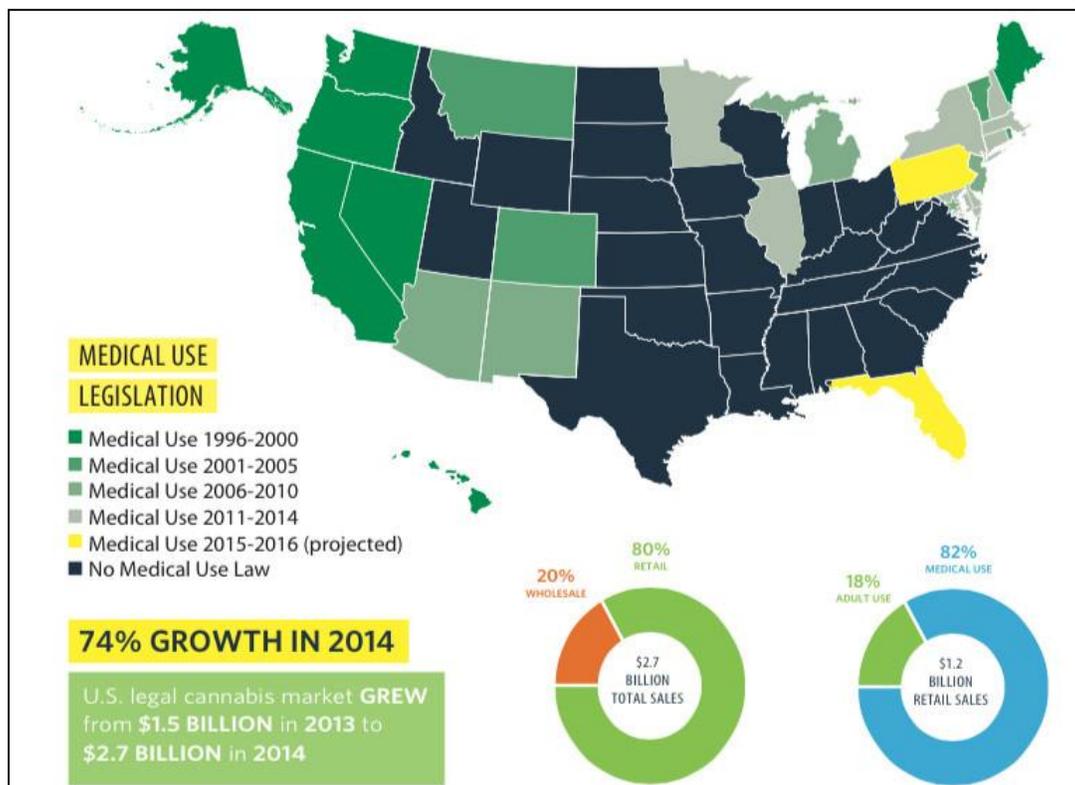
The unique therapeutic properties of pharmaceutically active compounds embedded within the marijuana plant genus have been globally neglected and overlooked for most of the 20th century, due to the classification of the plant and its active cannabinoid ingredients as “Schedule I” substances that allegedly have no medical use or benefit.

In recent years, public opinion on this matter has changed rapidly as more and more social awareness groups have promoted the full or partial legalization of the marijuana plant, while a substantial amount of scientific data, that illustrate the medical benefits of marijuana, has been generated by clinical and basic science researchers.

This social consciousness change has been dramatically illustrated by a poll performed in 2013, in which, for the first time in decades, a majority of Americans polled for approval of legalization of marijuana in the United States.



\* <http://www.thefiscaltimes.com/Columns/2014/01/03/Why-Legalizing-Marijuana-Smart-Fiscal-Move>



\* [http://www.huffingtonpost.com/2015/01/26/marijuana-industry-fastest-growing\\_n\\_6540166.html](http://www.huffingtonpost.com/2015/01/26/marijuana-industry-fastest-growing_n_6540166.html)

### **Company Strengths and Core Competencies**

BPH strengths and core competencies will be the cultivation and manufacturing process and techniques utilized by BPH. The cultivation techniques utilized by BPH will produce high grade medical marijuana of pharmaceutical quality for the qualifying patients of Hawai‘i. Through the adoption of well-established cultivation processes and methodologies from BPH’s operating partners HCH and HCH’s experience within the regulated marijuana industry will prove most beneficial for BPH’s success with organization goals and objectives.

BPH intends to produce and dispense medical marijuana and manufactured marijuana products of the highest pharmaceutical grade quality. BPH’s operating partner HCH will spearhead the implementation and execution of organization plans and goals pertaining to cultivation and retail dispensing operations. HCH brings years of knowledge and practice within the legal medical marijuana industry to the table. HCH currently operates three (3) medical marijuana retail dispensary locations and three (3) recreational marijuana stores and six (6) production centers in Colorado, all in full legal compliance with state and county law.

HCH will bring operational knowledge and experience to BPH and will become the “boots on the ground” for the deployment of BPH cultivation and retail dispensary operations. HCH will fully prepare BPH registered employees on all aspects of the business before commencing any operations. Training and education will be all encompassing; covering regulatory compliance, seed-to-sale tracking, patient advocacy, Point-of-Sale training, security and diversion, health and



safety, sanitation, transportation, also including all cultivation processes and applications, manufacturing of edibles and infused products.

A patient-centric focus at the retail dispensing locations will set BPH apart from other registered retail dispensary locations. All dispensing registered employees will receive training and education to acquire vast knowledge regarding medical marijuana; including genetic and strain varieties, recommended dosage rates, possible effects, etc. This will allow dispensing registered employees to be able to offer recommendations suited for each individual qualified patient.

BPH also has strengths in the high tech industry that would be vital in placing the company at the fore front of the industry. BPH intends to utilize its expertise to create smart, efficient, and effective systems at every aspect of its operations including energy efficiency, controlled cultivation, manufacturing, and patient outreach.

### **Legal Form of Ownership**

BPH is a Limited Liability Company (“LLC”). BPH chose this entity form for various reasons including the taxation structure of an LLC. A Limited Liability Company is a legal form of a company that provides limited liability to the owners. An LLC is a business structure that combines the pass-through taxation of a partnership or sole proprietorship with the limited liability of a corporation.

Hawai‘ian residents own 77.75% of the total ownership interest of BPH.



## Products and Services

The products offered by BPH will be a wide variety of marijuana strains as well as a vast product line of manufactured marijuana products including oils and oil extracts, tinctures, topicals such as skin lotions and ointments, capsules, pills and lozenges. BPH goal is to legally source high quality marijuana strain varieties that are specifically geared towards the treatment and alleviation of symptoms associated with qualified medical marijuana patients.

BPH intends to produce pharmaceutical grade marijuana products that unlock the palliative properties of the plant and deepen our understanding of the endocannabinoid system and its role in human health. We have a three point strategy to achieve this. First we will produce products with stringent quality standards. Next, selecting strains/genetics with desirable palliative qualities and from these produce product options that don't conflict with a doctor's normal ethical treatment protocols such as smoking or eating unhealthy foods. The strains intended to be utilized will be high in cannabidiol (CBD) or have Tetrahydrocannabinol/cannabidiol (THC:CBD) ratios that have demonstrated efficacy for qualifying conditions. Finally, through production and product strategies coupled with rigorous testing we will overcome one of the most significant hurdles for the medical marijuana industry, which is consistency of dosage and cannabinoid profile.

The cultivation of marijuana will include a wide variety of marijuana strains; all strains will be unique and have different medical values and benefits. Marijuana varieties will include different strains from indica, sativa, hybrid and CBD dominant genetics. Patients will experience different desired effects from different marijuana variety strains and genetics.

BPH will process the high grade medical marijuana produced into various manufactured marijuana products using only high quality ingredients for final products. BPH has entered into a licensing agreement with UNM, a well-known manufacturer of marijuana-infused products. UNM currently has legal operations in full compliance with the regulations in Colorado. UNM will provide established operational procedures, methods and recipes for BPH manufacturing operations allowing BPH to deploy operations with pre-established, proven recipes. This will allow BPH to immediately start manufacturing marijuana products that are consistent and reproducible for qualifying patients.

### **Marijuana Flower**

- *Description*—BPH intends to cultivate and dispense approximately 10-15 strains of marijuana ranging from those with a high level of THC and low level CBD to those with a high level of CBD and low level of THC. These strains will include Indica varieties, Sativa varieties, and hybrid strains that will be a blended variety with effects similar from both sativa and indica varieties.
  - Besides appearance, indica and sativa plants are commonly believed to have different effects on their user. These effects include sativa being more uplifting and energetic, and best suited for day use while Indica is considered more relaxing and calming and is best suited for night use.
- *Benefits*—the evidence is overwhelming that medical marijuana can relieve certain types of pain, nausea, vomiting and other symptoms caused by such illnesses as multiple



sclerosis, cancer and AIDS – or by the medical compounds frequently used to treat them. Additionally, it has proven benefit in the management of post-traumatic stress disorder.

- *Strengths*—medical marijuana can treat symptoms remarkably safely and considered less toxic than many pharmaceuticals.
- *Weaknesses*—because marijuana is federally illegal, there has not been enough scientific research done to determine the true effectiveness of the medicine. Patients are not able to get exact dosing recommendations from medical professionals.

### **Medical Manufactured marijuana Products and Concentrates**

BPH will create products that are convenient for administration of the active ingredient, medical marijuana. Our goal is to create various dosage forms that will make administration of medical marijuana convenient, easy, and palatable for qualified, registered patients in Hawai'i.

- *Product Description*—manufactured marijuana products are made with marijuana as an ingredient. They can come in the form of oils and oil extracts, capsules, pills, lozenges, sublingual tinctures, and topical(s) such as skin lotions or ointments.
- *Product Benefits*—the benefit of manufactured marijuana products is that they offer patients an alternate delivery means to experience the effects of cannabinoids without smoking or vaporizing marijuana. Alternative ingestion methods that offer consumers cannabinoid delivery formats other than smoking are one of the fastest growing segments of the marijuana industry.
- *Product Strengths*—an easily administered option for taking medical marijuana products. It improves dosing calibration and benefits from the convenience of portability.
- *Product Weaknesses*—it can take longer to feel the effects of the medical marijuana product. It is often considered to have stronger effects than inhalation of medical marijuana products.

### **Products Blue Planet Healing intends to produce include:**

#### **1) Inhalable Marijuana Products**

**a. Raw Flower:** Multiple genetics and strain varieties of indica, sativa, and hybrid marijuana will be cultivated. Different medicinal values and benefits will be obtained through different indica, sativa, and hybrid marijuana strains. Raw flower will typically be smoked or vaporized by qualified patients.

- Indica marijuana strain varieties
- Sativa marijuana strain varieties
- Hybrid marijuana strain varieties
  - Flower products will be packaged in quantities of:
    - a. 1 gram packages (1 gram)
    - b. 1/16<sup>th</sup> packages (1.75 grams)
    - c. 1/8<sup>th</sup> packages (3.5 grams)
    - d. Ounce packages (28.35 grams)

**b. Marijuana Concentrates:** Marijuana concentrates are a concentrated form of marijuana, the concentrated form is very potent and high in THC content.



Marijuana concentrates are made from extracting the cannabinoids from the marijuana plant material. Marijuana concentrates can be made into various forms and products including but not limited to CO<sub>2</sub> oil and oil extracts, sublingual tinctures, capsules and topical(s) like skin lotions or ointments. Once extracted, the concentrated marijuana oil will be used to make all BPH manufactured marijuana products.

- CO<sub>2</sub> Oil and Oil Extracts
  - Pre-filled vaporizer cartridges (250 mg and 500 mg)
  - Pre-filled metered dosage syringe
  - Shatter (1g quantity)
  - Wax (1g quantity)
- Ingestible Marijuana Products
  - Capsules
  - Pills
  - Lozenges
  - Tinctures
- Topicals
  - Skin lotions
  - Ointments

## 2) Ingestible Marijuana Products

- a. **Sublingual Tinctures:** Tinctures are a form of liquid ingestible marijuana. Tinctures will be consumed by placing the liquid tincture under the patients tongue, drinking the liquid tincture alone or mixing the tincture with tea or some other beverage.
- b. **Pill-Form/Capsules:** Edible pill form marijuana products will be beneficial to patients that cannot or prefer to not vaporize marijuana. Medical marijuana patients will ingest the edible pills in order to receive the medicinal benefits of marijuana.

## 3) Topical Marijuana Products—*ointments and skin lotions*

- a. **Topical(s):** Topical(s) will include ointments and lotions that can be utilized by medical marijuana patients looking to alleviate ailments through topical use. Topical(s) are rubbed on the skin or area needed by a medical marijuana patient.

## Quality of Products

Cultivating marijuana of the highest quality will be the driving force behind BPH's marijuana cultivation efforts. The marijuana is being cultivated for medicinal purposes; qualifying, registered patients in the State of Hawai'i with debilitating medical conditions will be consuming the marijuana to alleviate ailments and as such we believe in utilizing natural cultivation methodologies and techniques to produce marijuana of the highest quality. All marijuana cultivated by BPH will be free of any residual contaminates or pests and will pass all required state testing standards.



BPH will identify State-licensed testing laboratories located in Hawai‘i to conduct product testing on every batch of marijuana cultivated as well as all manufactured marijuana products batches as required by regulations. BPH will utilize a quality management program to ensure there are no deviations in the cultivation or manufacturing processes.

### **Product Pricing**

BPH’s will endeavor to make medical marijuana and manufactured marijuana products affordable and accessible to the registered patients of Hawai‘i. BPH has created a financial pro-forma model that details estimated pricing for cultivated marijuana and manufactured marijuana products. This financial model is a separate, additional document that can be seen in full for a more detailed breakdown of the pricing strategies.

Pricing for all BPH marijuana and manufactured marijuana products will be based on the current fair market value of said items. Pricing will also be computed to ensure BPH is profitable and able to continue operations and pursue growth strategies. Different pricing structures and strategies will be utilized by BPH for determining pricing on cultivated marijuana and processed manufactured marijuana products. Pricing structures will be identified upon deployment of operations to ensure all cost associated with the marijuana product or the manufactured marijuana products are captured to, at a minimum, be able to recoup the cost of production.

**Cultivated Marijuana:** Pricing will be based on cost of production, harvest yield, cost of dispensing, and fair market value of marijuana. The pricing model used to forecast cultivated medical marijuana pricing was based from numbers and figures from the regulated marijuana market in Colorado.

**Manufactured Marijuana Products:** Pricing will be based on cost of production, cost of dispensing, and fair market value for manufactured marijuana products. The pricing model used to forecast processed medical manufactured marijuana products pricing is based upon publically available data and use figures from the regulated marijuana market in Colorado.

*\*Please see financial pro-forma model for a detailed breakdown of BPH estimated pricing structures.*

BPH will also develop and implement a patient hardship program. The patient hardship program will be created for the purpose of helping state registered patients obtain medical marijuana in the situations where said patients cannot financially afford the medication.

### **Patient Hardship Pricing Program**

BPH will coordinate with registered dispensary customers (i.e. qualifying, registered patients) to provide financial assistance to patients who are unable to afford medicinal marijuana and/or manufactured marijuana products. BPH will strive to ensure that financial issues do not prevent qualifying patients from seeking or receiving care. BPH will use the Federal Poverty Level as a guide to provide discounted medicine to individuals who meet the policy’s criteria. BPH will rely upon the Census Bureau’s definition of a family and family income when computing federal poverty level guidelines. If the qualifying patient’s income and household falls within 300% of the published guidelines, the qualifying patient will be provided medicine at a reduced cost according to the following conditions:



1. For those qualified patients who are between 0 to 300% of the federally recognized poverty level the price will be at a 30% reduction;
2. For those qualified patients who are at or below the federally recognized poverty level the price will be 50% to 75% reduced, depending on circumstance;
3. For hospice patients, veteran's home residents, and veterans, there shall be a reduced price, depending upon the financial circumstance.

Eligibility will be based upon a determination of financial needs in accordance with the policy. In order to receive financial hardship benefits, qualifying patients must fill out a required application. The application will include mandatory attachments that document proof of income. Applicant will have the option to submit all of the following documents: W-2, paycheck stubs, income tax return, forms from Medicaid or other state-funded medical assistance programs, or forms from employers or welfare agencies. Other circumstances that will be taken into consideration are bankruptcy settlements and catastrophic situations (death, disability in family, divorce). Applicants without the above mentioned proof must provide documentation that shows the patient is unable to pay their medical marijuana bills and still be able to pay for other basic necessities. It shall not take into account age, gender, race, social or immigrant status, sexual orientation, or religious affiliation. This application must be completed annually in order to be placed in the BPH financial hardship program. Any denial of the discount/no cost request will be documented as such, and instructions for reconsideration will be provided by the BPH. All applicants and their records will be kept confidential. Patients are expected to contribute to the cost of care based on their ability to pay. This policy assures access to medicine and protects the assets of financially needy qualifying patients. Individuals with the financial means to pay for medicine shall be urged to do so within the guidelines of federal law. BPH shall notify qualifying patients of its financial assistance policy by posting notices at the registered dispensary locations and on the company website and providing the information directly to qualifying patients.

### **Proposed Location**

The proposed location BPH is considering for the production center is located in the county of Honolulu. The proposed location BPH is considering for the retail dispensing locations will also be located in the county of Honolulu. BPH will ensure locations meet all zoning requirements and that all applicable state and county law will be complied with. There will be ample parking on site for registered employees at the cultivation/production facility; there will also be ample parking for registered employees and qualifying patients and customers at the retail dispensing locations. Both locations will be of adequate size and space for the cultivation, manufacturing and dispensing of marijuana and manufactured marijuana products.

Proposed Dispensary Location – BPH has secured a retail dispensary location at the Ala Moana Medical Building, located at 1441 Kapiolani Blvd (<http://www.alamoanacenter.com/Leasing/Ala-Moana-Building.aspx>), on the corner of Keeaumoku and Kona streets. This space in the medical building offers the following amenities:

- Easy access – excellent location for patients being in the Kapiolani corridor in the heart of Honolulu, adjacent to Ala Moana shopping center



- Accessibility by public transport – Ala Moana shopping center is a major hub for TheBus, the rail will have a station at Ala Moana, as well as many taxi services have stalls
- Accessible parking – offers free customer parking with 297 stalls on site, as well as the adjacent Ala Moana shopping center offers ample parking (over 11,000 stalls)
- Security - in addition to the BPH’s own security, the medical building offers 24-hour security on premises
- Welcoming dispensary look & feel – the dispensary location will focus first and foremost on the patient’s comfort and accessibility.
- The dispensary location will be clinical, using medical grade furniture, ADA compliant.



## Operational Plan

Operations is an area of greatest significance to BPH. Success will be dependent on navigating a complex series of actions and adaptations. BPH has enlisted the help of expert consultants and operators to provide and follow detailed operating procedures. In addition, these operators and consultants have aided our careful and innovative building designs. The focus in Operations will be continuous improvement, product safety and customer satisfaction. BPH will foster communication between registered employees and track performance measurement in all areas to optimize efficiency and effectiveness. We will strive to maximize product yields and potency using best practices gleaned from across the regulated marijuana industry.

### **Education and Training**

BPH will utilize the operational experience and knowledge from HCH to provide extensive training and education for all registered employees. All BPH employees will receive extensive training prior to commencing work in any BPH registered dispensary facility. Registered employees will be required to read the relevant state and county law pertaining to medical marijuana in order to have a general understanding of the laws and regulation with which that they must comply. Training for all cultivation and retail dispensing operations will be provided by our operating partners HCH, training will also be provided from selected 3<sup>rd</sup> party security vendor Securitas, BioTrackTHC™ inventory control systems and POS vendors, UNM for manufacturing operations and CO<sub>2</sub> extraction machine vendors, and other subject matter experts. Training will include an extensive hands-on approach and the use of Standard Operating Procedures (SOP's) and various other materials and methods as deemed appropriate.

BPH will utilize targeted training materials and programs for different operations occurring at BPH licensed facilities. There will be specific training for registered employees involved within cultivation operations, processing/manufacturing operations, and retail dispensing operations. Ongoing and cross-functional training will be continued as operations commence. All registered employees will also be required to receive training on general sanitary requirements. Registered employees will be required to read and agree to comply with the company Employee Handbook, SOP's, and other materials BPH deems necessary prior to commencing work in any BPH facilities.

HCH will fully prepare facility staff on all aspects of the business before operations are commenced. Training and education will be all-encompassing, covering regulatory compliance, seed-to-sale tracking, patient service and advocacy, point-of-sale training, dispensing, security and diversion prevention, health and safety protocols, sanitation, transportation, also including all cultivation, extraction and manufacturing processes, and organizational functioning within a vertically-integrated operation. Registered employee training will cover but not be limited to the following:

- Standard Operating Procedures (SOP's)
  - Cultivation Operations SOP's
    - Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH cultivation operations.
  - Manufacturing Infused Products (MIP) Operations SOP's



- Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH manufacturing infused products operations.
- Retail Dispensing Operations SOP's
  - Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH retail dispensing operations.
- Log Sheets and Templates
  - Numerous log sheets and templates for proper record keeping and documentation for all operations including cultivation, MIP, and dispensing
- Responsible vendor training
- Patient education information
- On-site training
- Initial job training
- Job shadowing
- Employee educational information

**Laws and Regulations/Compliance Training**—Adhering to all state, county, and company regulations is of utmost importance to create an end product with efficacy for patients. All BPH registered employees will be required to have a general knowledge of all applicable laws and regulations dealing with the regulated cultivation, manufacturing, and dispensing of medical marijuana and manufactured marijuana products.

- **Federal Laws**— BPH management will make available to its employees copies of various Federal laws and memos concerning medical marijuana, including:
  - *Controlled Substances Act:*  
<http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm>
  - *Ogden Memo:* <http://www.justice.gov/opa/blog/memorandum-selected-untied-state-attorneys-investigations-and-prosecutions-states>
  - *Cole Memo:*  
<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>
  - *FinCEN Memo:* [http://www.fincen.gov/statutes\\_regs/guidance/pdf/FIN-2014-G001.pdf](http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2014-G001.pdf)
- **Policies Regarding Regulations**—it is the duty of BPH management to ensure regulatory requirements are followed at all times by all registered employees. Management shall maintain a zero tolerance policy for any infractions that would violate state, local, or company-level regulatory measures.
- **Current Regulations**—access to the current State of Hawai'i medical marijuana laws and regulations will be provided to all BPH employees prior to commencing work in any BPH facilities.



- **State of Hawai'i Regulations**—The State of Hawai'i laws and regulations regulating the medical marijuana industry can be obtained from State of Hawai'i Department of Health
  - <http://health.Hawai'i.gov/medicalmarijuana/submenu/doh-medical-use-of-marijuana-administrative-rules-effective-july-18-2015/>
- **New Regulations**—All new regulations shall be followed as of their effective date. Training of new employees regarding newly enacted State regulatory measures shall take place before the effective date of said newly enacted State regulation(s) in order to ensure that all team members have a complete understanding of such measures and can fully comply with the same.
- **Confidentiality**—Patient and/or caregiver confidentiality is of the utmost importance. All patient and/or caregiver records are to be considered confidential. All registered employees must ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) laws.
  - The confidentiality policy that will be put in place within all BPH facilities requires all employees and former employees to maintain confidentiality with respect to information and records pertaining to BPH operations. Confidential information will include but not be limited to:
    - Qualifying patient and/or primary caregiver personal records (HIPAA)
    - Company financial records
    - Company human resource records
    - Registered employee records or personal information
    - Operation activities
      - Cultivation methods/techniques
      - Production methods/techniques
  - The confidentiality policy is a legal requirement and respects the rights of employees and the importance of sensitive company information. Prior to commencing work at any BPH facilities, all employees and volunteers will be required to agree to and sign a Confidentiality Agreement Form.
    - **Breach of Confidentiality**—defined as “the disclosure of information, intentionally or unintentionally, to an individual or entity that is not entitled to said information.”
      - The disclosure of confidential information may result in disciplinary action and/or immediate job termination.

**ServSafe Training**—ServSafe is a training program for the food service industry, which teaches basic food safety for preparing and serving food. The program teaches about foodborne illness, how to prevent and how to train employees in food sanitation. This program will help employees become aware of good personal hygiene practices and safety measures to be utilized for the manufacturing of marijuana products.



BPH will require that all employees involved with processing operations will be required to complete ServSafe Safe Food Handlers training. Employees will be required to complete the ServSafe training course and successfully pass the competency test to become ServSafe certified prior to commencing work within the facility. ServSafe will help educate and train employees on personal hygiene, food safety, sanitation, and cleaning procedures and protocols.

Employees will be required to pass the ServSafe exam with at least a 75% passing score in order to be certified. Upon completion of the ServSafe course and successfully passing the exam, employees will receive a ServSafe certification that will be valid for three (3) to five (5) years.

**Responsible Vendor Program Training**— BPH will utilize a training program developed by ACC entitled “The Responsible Vendor Program”. This program is intended to help train dispensary operations staff members on different activities and information needed for daily operations. “The Responsible Vendor Program” will train employees on different educational content and materials, including but not limited to:

- Proper checking of identification and spotting false IDs
- Understanding the conduct, rules, and regulations of a licensed cannabis establishment
- Governing enforcement agencies: Their roles and how all licensed employees should work with them
- Cannabis plant biological structure and native geography
- Cannabis quality control, variety types and their various effects
- The medicinal value of marijuana and its extracts
- Methods of consumption
- Identifying indicators of intoxication

The program will aid in training and educating all BPH employees on different aspects of marijuana as a medicine. Retail dispensary employees will gain information on the various marijuana strains and products offered, their medicinal benefit, possible side effects, delivery methods, and other relevant information. This will help dispensary employees identify and recommend marijuana varieties and forms for different patients to help treat their specific qualified condition. All BPH retail dispensary registered employees will be trained on “The Responsible Vendor Program.”

**Security Measures/Protocols Training**—all BPH registered employees will receive extensive training detailing facility security measures and protocols. Security measures and protocols are explained in more detail within the Standard Operating Procedures Security Plan.

**Laws and Regulations/Compliance Training**—Adhering to all state, county laws and company specific regulations is of utmost importance to create an end product with the highest efficacy for patients. All BPH registered employees will be required to read current state law and have a basic



knowledge and understanding of the laws and regulations they must comply with in daily operations. Compliance training is detailed more thoroughly in the SOP's.

**Point of Sale (POS) Training**—BioTrackTHC™ will provide the inventory control system and POS computer systems to be utilized in all BPH registered dispensary facilities. BioTrackTHC™ will provide initial training on the systems. POS training efforts will be supported by HCH and their deep understanding and experience with BioTrackTHC™ systems. POS training is covered in more detail in the Retail SOP's.

**Patient Advocacy Training**—Qualifying patients are the reason for the medical marijuana industry and therefore proper patient advocacy training is essential in order to have a successful retail dispensing operation. Patient confidentiality is of utmost importance; any and all patient information is confidential and is to remain secured on location. Any unauthorized release of patient information will be grounds for immediate job termination. Patient advocacy and confidentiality are explained in more detail within the Standard Operating Procedures.

**Training Record**— BPH management team will be responsible for maintaining training records for each registered employee. Such records will include, at a minimum, documentation of all required training for the different operations and functions including:

- The name of the person receiving the training;
- The dates of the training;
- A general description of the topics covered;
- The name of the person supervising the training; and
- The signatures of the person receiving the training and the facility manager.

All registered employees will receive training prior to beginning work within any BPH registered dispensary facility. A continuing education program will aid in developing registered employees and preparing them for further advancement within the company. It is the responsibility of management to ensure training takes place for all registered employees prior to commencing work within any BPH registered dispensary facility.

### **Cultivation and Manufacturing**

Production will consist of the entire marijuana cultivation process from seed germination and propagation to harvesting, curing, and packaging. Production will also consist of marijuana processing for the manufacturing of marijuana products. The production process and procedures are explained in detail in the SOPs. The SOPs will cover all cultivation processes as well as all manufacturing marijuana product operations.

#### *Methods of Production:*

- *Marijuana Cultivation:* Various cultivation techniques will be utilized within the cultivation facility. See the separate, additional Cultivation SOPs document for more information on cultivation techniques.



- *Manufacturing Marijuana Products:* Processing techniques and procedures for manufactured marijuana products are explained in detail in the separate, additional Manufactured Marijuana Products SOP document.

### **Production Center Location**

All marijuana cultivation and manufacturing of marijuana products will be conducted at BPH's registered production centers. BPH will ensure that all facilities will comply with applicable zoning laws, are secured and at a minimum meet or exceed all state and county law pertaining to facility security requirements.

The initial production facility will be located in Kapolei Business Park, Phase 2. Kapolei offers the unique environmental advantages of being both relatively dry and offering some of the best sunlight exposure. Sunlight will be used for directly providing diffused natural light through the white translucent roof and for capturing the energy through Photovoltaic (PV) panels. As dehumidification is one of the largest power draws at the facility, being able to vent out humid air and intake dry outdoor air. Sensors will allow the climate control computer system to determine the optimum timing in the day when the humidity and temperatures are at a combined low to intake air that decreases the combined power draw of the AC and the dehumidifiers the most.

**Square Footage**—the production center will be approximately 24,000 sq ft consisting of a 16,000 sq ft main warehouse space, 3,000 sq ft secondary warehouse, and 5,000 sq ft of office space split into two floors. The building sits on a 50,000 sq ft lot where the remainder of the land will feature shaded parking with PV panels on the roof, climate appropriate landscaping, and a loading area.

**Type of Building**—the production center will be a newly constructed warehouse building featuring modern building materials that increase HVAC efficiency. The walls will be made of metal Structural Insulated Panels (SIPs) which are high insulation solid foam core sandwiched between rigid metal panels. The high insulation of the walls will decrease the power demand on the HVAC system.

Water absorbs heat and hot air rises. Roof ventilation at the ridge of the roof will open at optimal times to vent out hot air through a insect proof mesh screen of 300 micron mesh size or less. This will release the hottest and most humid air from the interior from the building. Air intake will occur at the lowest points of the walls from the coolest side of the building at the time. The intake air will be filtered and run through a UVA and/or ozone air sterilizing unit to eliminate incoming pests and pathogens.

**Zoning**—The facility is located on I-2 zoned land. I-2 means that the land is classified for intensive industrial use, allowing for a large amount of power (3-phase, 480V) to be pulled to the building, a necessity for a large power use facility. Nursery productions are allowed on agricultural lands and industrial lands, and thus making this facility on the most ideally zoned land.

**Construction Costs**—current estimates are around \$7.5 million



## **Quality Control**

BPH will utilize industry best practices developed for established operations within Colorado’s regulated marijuana industry and quality assurance programs to continuously measure and improve customer satisfaction. Customer satisfaction will be a top priority of BPH as we want to cultivate, manufacture and dispense marijuana and manufactured marijuana of the highest quality. BPH will utilize a patient feedback form to gather feedback and input from qualifying patients regarding our marijuana products, manufactured marijuana products, the qualifying patients’ overall experience, and feedback regarding the retail dispensary location, registered employees, and any other information or comments qualifying patients wish to provide to BPH. This patient feedback form will be reviewed by BPH in order to assess the qualifying patient feedback to continuously improve our process and products to offer qualifying patients the best experience possible when procuring from BPH.

To ensure qualifying patient and public safety, BPH has committed to establish, document, implement and maintain an appropriate Quality Management System. To this end, BPH is committed to the following Quality Management Principles:

- Customer Focus; Leadership; Involvement of People; Process Approach; System Approach to Management; Continual Improvement; Factual Approach to Decision Making; Mutually Beneficial Supplier Relationships

To assure adequate establishment, implementation, documentation and maintenance of the Quality Management System (“QMS”), BPH has taken guidance from ISO 9001 and will hire a full-time Manager of Quality Management who is certified as a Manager of Quality and Organizational Excellence by the American Society of Quality. The Manager of Quality Management will be responsible for using the guidance from ISO 9001 to develop the appropriate QMS for BPH in accordance with Hawai‘i state regulations. BPH’s Quality Management System will be based from the QMS document which is as an additional document and can be viewed upon request.

*Cultivation Operations*—Quality control measures will be created and implemented within the cultivation facility to ensure quality and consistency of products produced within the facility. BPH will utilize established and proven SOP’s for all cultivation operations. The SOP’s have been developed and tested within Colorado’s regulated medical marijuana market by our retained marijuana industry consultants ACC. BPH will use standard operating procedures (SOP’s) to promote good growing and handling practices including:

- All aspects of:
  - Irrigation, propagation, cultivation, fertilization;
  - Harvesting, drying, curing;
  - Rework or reprocessing;
  - Packaging, labeling, and handling of medical marijuana products, byproduct; and
  - Waste products, and the control thereof, to promote good growing and handling practices.

BPH will require that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical marijuana has received the training, education, or experience



necessary to perform assigned functions; and will also require that all employees practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

Automated climate controls developed through data tracking with a robust sensor system and analysis will develop an increasingly consistent and optimal cultivation system over time. BPH takes quality and excellence seriously and will always look for ways to operate at a higher level.

BPH will require employees to follow the protocol for Receipt of Material including:

- BPH shall quarantine received material that will be used to produce marijuana and/or manufactured marijuana products
- BPH shall inspect materials for defects and contamination.
- Material may not be released from quarantine by a BPH until the material:
  - Passes inspection; and
  - Is determined to be acceptable for use as intended.

*Manufacturing Operations*—Quality control measures will be created and implemented within manufacturing operations to ensure quality and consistency of products produced within the facility. BPH will utilize established and proven SOP's for all processing operations. The SOP's have been developed and tested within Colorado's regulated medical marijuana market by UNM, a licensed manufacturer of marijuana products in Colorado, Nevada and Arizona. BPH and UNM have a licensing agreement which will enable BPH access to recipes, methods and other intellectual property required for successful manufacturing operations.

*Dispensing Operations*—Quality control measures will be created and implemented within the retail dispensing locations to ensure quality and consistency of products dispensed to qualified, registered patients. BPH will utilize established and proven SOPs for all dispensing operations. The SOPs have been developed and tested within Colorado's regulated medical marijuana market by HCH.

## **Inventory**

All BPH registered dispensary facilities will need to maintain inventories on-site for the cultivation, manufacturing and/or retail dispensing processes. There will essentially be two unique process within the cultivation facility; cultivating and manufacturing, each with differing processes and needing different on-hand inventories. The retail dispensary locations will have marijuana and manufactured marijuana products as on-hand inventory for dispensing to qualified patients.

### **Cultivation Inventory**

- Cultivation equipment
- Plant fertilizer
- Pesticides
- Fungicides
- Insecticides
- Growing mediums
- Cleaning supplies



- Etc.

### **Manufacturing Inventory**

- Raw marijuana materials
- Kitchen equipment
- Extraction equipment
- Packaging materials
- Labeling materials
- Etc.

### **Retail Dispensing Inventory**

- Packaged marijuana
- Packaged manufactured marijuana products
- Exit packaging supplies
- Cleaning supplies
- Etc.

### **Inventory Value**

Valuation of on-hand inventories will be based on current fair market value for said inventories, the exact inventory values will be determined upon deployment of operations.

### **Inventory Management and Control**

BPH will utilize a perpetual inventory system in all operations—cultivation, processing/manufacturing, and retail dispensing. BPH will utilize a marijuana industry specific system from BioTrackTHC™ that will have the capabilities of linking all operational inventories together to operate as a vertically integrated business operation. Inventory control measures will be created and implemented to ensure inventory quantities are accurate and for state required seed-to-sale tracking of all marijuana and manufactured marijuana products. Proper inventory controls ensure the right amount of inventory is on hand and in production so as not to negatively impact the company and the market in general.

The inventory control system that will have the ability to identify and track all marijuana products from the time the marijuana is propagated from a seed or cutting to the time it is delivered to a retail dispensary location and dispensed to a qualified, registered patient or primary caregiver.

The inventory control system will be designed so that it can promptly identify a discrepancy in any marijuana or manufactured marijuana product stock. The system will deter loss from theft or diversion since every gram of marijuana and manufactured marijuana product will be logged and tracked through the inventory control system. The system will be capable of tracking marijuana products from a qualified, registered patient or primary caregiver back to the source of the marijuana product in the case of the development of a serious adverse event. The inventory control system will be utilized in tandem with the Product Recall Policy developed in case the need for a product recall should ever arise.

During the cultivation process all marijuana plants being cultivated will be tagged with a unique tag ID number. This tag will remain with the marijuana plant throughout its entire lifecycle. The



IG tag information will be input into the inventory control system to correlate with the attached marijuana plant. The information in the system will be changed and updated as the plant matures through its lifecycle.

### **Suppliers**

BPH will utilize numerous different suppliers for the cultivation process and for the manufacturing of medical marijuana edibles and manufactured marijuana products. Suppliers for cultivation activity will consist of a network of gardening equipment retailers and wholesalers. Suppliers for manufacturing activity will consist of grocery retailers and wholesalers, restaurant equipment companies.

BPH's suppliers will be identified upon successfully obtaining Hawai'i state licensure and the subsequent deployment of operations. BPH will use expertise provided by the American Cannabis Company, Inc. to minimize costs while obtaining high quality equipment. On a macro level BPH anticipates the need, at minimum, for the following suppliers:

- Security and surveillance equipment
- Cultivation equipment
- Processing equipment
- Dispensing equipment
- Inventory tracking equipment
- Building materials and equipment
- Point of sale equipment
- Packaging equipment

### **Distribution Channels**

BPH only distribute its medical marijuana through its registered Retail Dispensing Locations, vertically integrated with BPH operations. BPH intends to cultivate and manufacture marijuana and manufactured marijuana products for dispensing to state qualifying and registered medical marijuana patients and primary caregivers.

### **Transportation**

This section details how BPH will transport medical marijuana products to the retail dispensary(s). All applicable state and county law pertaining to the transportation of medical marijuana products will be strictly followed by all BPH team members.

**Transportation Agent Requirements**—all agents responsible for transporting marijuana products or manufactured marijuana products must:

- 1) Possess a current and valid state-issued marijuana industry worker license;
- 2) Possess a current and valid government-issued driver's license;
- 3) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or manufactured marijuana products pursuant to regulation, all transporting agents shall:



- 1) Carry a copy of the *manifest/trip plan* with him or her for the duration of the trip;
- 2) Wear their registered employee identification card;
- 3) Use a vehicle without any marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or manufactured marijuana products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation; and
- 5) Ensure that the marijuana products or manufactured marijuana products are not at all visible to the public.
- 6) Ensure there are at least two agents at any moment on a delivery, one of which will sit with the marijuana products to ensure a high level of security

**Delivery**—Transporting agents arrive at the dispensary location receiving the marijuana product(s).

- 1) Transporting agents arrive at the transportation destination
- 2) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the transport manifest/trip plan
- 3) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

### **Post-Delivery**

**Post-Delivery Protocol**—after transporting marijuana products or manufactured marijuana products, pursuant to the regulations the registered employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.

**Documentation of Delivery**—both the transporting dispensing facility agent and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Department for review upon request. The dispensary agent shall record in the inventory control each item dispensed including batch number and the weight and quantity of the marijuana and/or manufactured marijuana products that were dispensed.

**Deviations from Transportation Plan**—the transporting registered employee shall immediately report all diversion due to loss or theft of marijuana or manufactured marijuana products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the Department as required per state law. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



## **Compliance**

BPH will ensure compliance with all state and local laws and regulations, specifically H.B. 321, Chapter 329D and Administrative Rule §11-850. BPH will make all books, records, and production and dispensing facilities available to the Department or its authorized representatives for monitoring, audits, and on-site inspections at any time upon request. BPH will only cultivate, manufacture and dispense approved medical marijuana products, per requirements set forth in §11-850-71, §11-850-72 and §329D-10, in an enclosed, secure indoor facility located in the State of Hawai‘i and in the County of Honolulu. BPH will not grow marijuana or manufacture marijuana products at any site other than the production centers approved by the Department. BPH will not dispense medical marijuana or manufactured marijuana products from the production center and will only dispense marijuana and manufactured marijuana products to qualifying, registered patients and primary caregivers from retail dispensary locations.

**Registered Employees**—all employees hired and retained by BPH will be free of any criminal felony convictions and their hiring will be conditioned upon successfully passing a background check and comprehensive drug screen.

**Visitors and Activity at a Licensed Dispensary**—all visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

**Qualifying Patient Intake**—Qualifying patients and caregivers wishing to purchase products at a BPH retail dispensing location will need to have a valid state medical marijuana registration card. Patients entering the retail dispensary location will not be allowed beyond a “holding area” until a BPH employee verifies the validity of each patient’s medical marijuana registration card through the state electronic verification system. After the verification process has been completed, the patient and/or caregiver will be allowed entry into the retail dispensing portion of the premises.

The retail dispensing location manager will create and maintain a database within the inventory control system for inventory and tracking purposes. This will enable registered employees to adhere to all laws regarding the quantities of marijuana and manufactured marijuana products registered patients and/or primary caregivers are allowed to have and purchase in a given time period.

**Qualifying, Registered Patient Verification**—registered employees will verify each and every qualifying patient’s and/or primary caregiver’s state-issued medical marijuana license prior to entry into the retail dispensing center. The electronic verification process will need to be completed for every single patient and/or caregiver *EVERY* time they wish to purchase products at the facility.

- 1) **Medical Marijuana License**—Accept patient and/or caregivers state-issued medical marijuana license



- a. Ensure the state-issued medical marijuana license is current (check expiration date on License)
- 2) **Government-Issued ID**—Patients and/or caregivers must also have a current and valid government-issued ID (passport, Driver’s License)
  - a. Ensure that the state-issued ID is current (check expiration date on ID)
- 3) **Verification**—Verify the validity of the state-issued medical marijuana license
  - a. Verify validity of the medical marijuana license through the state electronic verification system
- 4) **Access**—Allow or deny access to the qualified patient and/or primary caregiver
  - a. Allow entry to retail dispensary location if the patient and/or caregiver has a valid state-issued medical marijuana license.
  - b. Deny entry to retail dispensary location if the patient and/or caregiver does not have a valid state-issued medical marijuana license.
    - i. If you feel the patient and/or caregiver is trying to use a fake or fraudulent medical marijuana license; confiscate said medical marijuana license and contact required Hawai’i state authorities.

**Dispensing Procedure**— BPH will implement and follow specific security procedures and policies for all RDL operations including: written SOPs for admitting registered patients and primary caregivers with valid government-issued photo identification cards issued pursuant to HRS Chapter 329 into the secure rooms for sales. BPH will design and construct each RDL with separate, secure room(s) for sales wherein marijuana and manufactured marijuana products are secured and locked in display cases for viewing. As required by HAR §11-850-53(3), BPH will follow written policies and procedures to ensure that a maximum occupancy limit ratio is maintained in all secured sales rooms of two customers to every one RDL employee. BPH will store all marijuana products within a locked room, vault or in a locked container securely affixed to a wall or floor. All RDLs shall have exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities.

BPH will ensure compliance with all regulatory requirements prior to dispensing any marijuana or manufactured marijuana products, BPH will ensure compliance with the following dispensing procedures:

- BPH’s registered employees shall dispense marijuana and manufactured marijuana products only to a qualified, registered patient or primary caregiver who has presented a government-issued identification card.
- Before any distribution of medical marijuana, BPH’s dispensary agent(s) shall verify that:
  - The qualified, registered patient or caregiver is currently registered with the Department;
  - The amount of marijuana and/or manufactured marijuana products that have already been dispensed does not exceed sales limits established by the regulations.
    - Four (4) ounces within a consecutive fifteen (15) day period
    - Eight (8) ounces within a consecutive thirty (30) day period
- BPH’s dispensary agent(s) may provide information on:
  - The available types of marijuana, marijuana varieties, and manufactured marijuana products



- Methods by which medical marijuana can be used; and
- How unused marijuana may be returned for disposal.
- Registered employees may decline to dispense marijuana and/or manufactured marijuana products to a qualified, registered patient or caregiver if, in the opinion of the registered employee, the qualified patient or caregiver appears to be visually impaired.
- BPH will not distribute any samples of marijuana or manufactured marijuana products or offer any marijuana products free of charge.

### **Packaging and Labeling**

BPH will package all marijuana and manufactured marijuana products on site at the production center within opaque, child resistant packaging that will protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.

BPH will package all marijuana and manufactured marijuana products in child resistant packaging prior to dispensing said product to a qualified, registered patient or caregiver. Child-resistant packaging is special packing used to reduce the risk of children ingesting dangerous items. For BPH's purposes, child-resistant packaging will be used to reduce the risk of children ingesting marijuana and/or manufactured marijuana products.

**Cultivation and Manufacturing Packaging**—BPH will pre-package all products containing marijuana and manufactured marijuana products in child-resistant and opaque containers at the production center prior to being shipped to BPH retail dispensary locations. The packaging will be constructed of tamper-evident opaque material and sealed with tamper-evident tape.

**Retail Dispensary Packaging**—BPH will package all medical marijuana and manufactured marijuana products in child-resistant packaging. We also intend to take our child-resistant packaging to the next level and utilize best practices from Colorado's medical marijuana industry in that we will also require all marijuana products leaving BPH retail dispensary locations to be placed in a child-resistant exit package. BPH will also utilize exit packaging for all marijuana and manufactured marijuana products leaving retail dispensary locations. The exit packaging will be child resistant and opaque and aid in product safety. Exit packing is not required under current Hawai'i regulations, however BPH intends to use exit packaging as an industry best practice.

**Labeling**—BPH will label all marijuana and manufactured marijuana products as required by state law. BPH will not label any marijuana product or manufactured marijuana product as organic. All labels will use only black lettering on a white background with no pictures or graphics. BPH will utilize the inventory control and POS system to generate all product and qualified patient labels. BioTrackTHC's inventory control and POS system will be able to automatically generate both the product-specific and patient-specific labels as required by Hawai'i regulations. BPH will ensure that every marijuana and manufactured marijuana product package will be affixed with the required labels containing all required information on said label.

BPH will ensure that the information printed on the package shall be in English, in black lettering at least one-sixteenth of an inch high. BPH will print a product-specific label for every package of marijuana and/or manufactured marijuana products as well as a patient-specific label for all



qualified, registered patient prior to dispensing said product. If requested by a qualified, registered patient or caregiver, BPH may also print a label in another language. BPH will not distribute a package of marijuana and/or manufactured marijuana products without a label securely attached. BPH will state on all labels of a package the following as required under current regulations:

- Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
  - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
  - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
- The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
- The batch number and date of packaging;
- A computer tracking inventory identification number barcode generated by tracking software;
- Date of harvest or manufacture and a "use by date";
- Instructions for use;
- The phrases "For medical use only" and "Not for resale or transfer to another person";
- The following warnings:
  - "This product may be unlawful outside of the State of Hawai'i and is unlawful to possess or use under federal law";
  - "This product has intoxicating effects and may be habit forming";
  - "Smoking is hazardous to your health";
  - "There may be health risks associated with consumption of this product";
  - "This product is not recommended for use by women who are pregnant or breast feeding";
  - "Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug"; and
  - "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"
- A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
- The name of the laboratory that performed the testing

BPH labels will not contain any false or misleading statement or design or include any statement, image or design that may not be included on the package.

### **Waste Disposal**

BPH will utilize marijuana industry best practices to properly dispose of medical marijuana waste. Adherence to all applicable state and county laws pertaining to the destruction and disposal of marijuana waste within the facility is very important to ensure no marijuana waste products are being diverted. All medical marijuana waste, byproducts, and undesired products will be destroyed and disposed of according to all applicable state and county law. Facility management will ensure



proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state law. Record all required information on the *Marijuana Waste Log Sheet*.

**Disposal**—Disposal of any marijuana product waste must be rendered unusable and unrecognizable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.

### **Hours of Operation**

BPH hours of operation within the facilities may vary depending on the numerous factors such as types of operations being performed, the time of year, environmental factors such as weather and temperatures, etc. Hours of operation will fall within the state allowed hours of operation per regulations. BPH retail dispensary locations will remain closed during Hawai‘i state holidays and federal holidays. These State holidays will be represented by the days shown in the figure below which was obtained from the State of Hawai‘i Department of Human Resources Development website.

<b>Retail Dispensary Location(s)</b>	<b>Hours of Operation</b>	
	<b>Open</b>	<b>Close</b>
<i>Monday</i>	8:00	8:00
<i>Tuesday</i>	8:00	8:00
<i>Wednesday</i>	8:00	8:00
<i>Thursday</i>	8:00	8:00
<i>Friday</i>	8:00	8:00
<i>Saturday</i>	8:00	8:00
<i>Sunday</i>	CLOSED	CLOSED



## Year 2016 HAWAII STATE HOLIDAYS

<u>(Hawaii Rev. Statutes, Sec. 8-1)</u>	<u>Day Observed in 2016</u>	<u>Official Date Designated in Statute/Constitution</u>
New Year's Day.....	Jan. 1 Friday.....	The first day in January
Dr. Martin Luther King, Jr. Day.....	Jan. 18 Monday.....	The third Monday in January
Presidents' Day.....	Feb. 15 Monday.....	The third Monday in February
Prince Jonah Kuhio Kalaniana'ole Day.....	Mar. 25 Friday.....	The twenty-sixth day in March
Good Friday.....	Mar. 25 Friday.....	The Friday preceding Easter Sunday
Memorial Day.....	May 30 Monday.....	The last Monday in May
King Kamehameha I Day.....	June 10 Friday.....	The eleventh day in June
Independence Day.....	July 4 Monday.....	The fourth day in July
Statehood Day.....	Aug. 19 Friday.....	The third Friday in August
Labor Day.....	Sept. 5 Monday.....	The first Monday in September
General Election Day.....	Nov. 8 Tuesday.....	The first Tuesday in Nov. following the first Monday of even-numbered years. ( <i>Hawaii State Constitution, Article 2 – Section 8</i> )
Veterans' Day.....	Nov. 11 Friday.....	The eleventh day in November
Thanksgiving.....	Nov. 24 Thursday.....	The fourth Thursday in November
Christmas.....	Dec. 26 Monday.....	The twenty-fifth day in December

\* <http://dhrd.Hawaii.gov/state-observed-holidays/>

### **Adverse Events/Product Recall Policy**

BPH will liaise with its retained marijuana industry consultant ACC in the event of the emergence of an adverse event or the need for a product recall. ACC has developed previous adverse event and product recall policies and standard operating procedures to educate, train and guide businesses how to handle such situations. BPH and ACC will together develop an adverse event and product recall policy customized for the state of Hawai'i. Below highlights some of the information that will be included in our policy.

#### *How to Recall Medical Marijuana Products*

Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by Hawai'i state law will ensure a streamlined recall process if ever necessary.

#### *Corrective Action Plan (CAP)*

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and necessary steps to be taken by the facility once a product recall is required. A typical CAP includes five (5) primary steps:

1. Step One: Industry Notification
2. Step Two: Public Notification



3. Step Three: Procurement
4. Step Four: Documentation and Record Retention
5. Step Five: Disposal

### **Retail Operations**

All BPH retail dispensary locations will be selected and designed with patient safety, environment and accessibility in mind and will be ADA compliant featuring handicapped parking, handicap accessibility and restrooms. The retail dispensary locations will fulfill these goals:

- Develop a dispensary environment that gives the most access and relief to the patients
  - Dispensary shall be located in a location with ample parking at a central location
  - Dispensary shall have a welcoming look and feel that provides the patient with comfort through their retailing experience
  - Patient will be supported with professional consult and education
  - Dispensary will be secure at all times
  - Product will be offered at an affordable price
  - Patient needs will be met with the availability of most appropriate and high quality medicine

### **Retail Dispensary Locations**

BPH will ensure that all facilities comply with all applicable zoning laws.

The initial retail dispensing location will be located on the third floor of the Ala Moana Building in room 304, on the corner facing Ala Moana Mall across the mall level parking lot. There is ample parking at the 7 level parking structure right in front of the Ala Moana building. This location offers super accessibility from its central location in town, connection to the largest and busiest shopping mall in the state, unmatched parking availability, the busiest bus depot, and being in a large medical building with a large bank located on the ground floor.

**Square Footage**— 1832 sq ft with approximately 90 ft of parking lot frontage with a built in reception area and desk.

**Type of Building**—A concrete building with 23 floors built on 31,000 sq ft of land. The building is equipped with 6 elevators and central air conditioning. The building has security guards stationed 24/7 and the parking structure is closed at night with security guards, making the facility inaccessible during the night.

### **Daily Retail Processes**

The daily retail processes are explained in more detail in the Retail Standard Operating Procedures which is a separate, additional document that can be viewed upon request. Below is a high-level overview of various process involved with the daily retail dispensary location operations.

**Opening Responsibilities**—the opening responsibilities will primarily be comprised of getting the retail sales floor ready for the day. This will be detailed in the Retail SOP's.



**Closing Responsibilities**—the closing responsibilities will primarily be comprised of closing the retail sales floor and securing product for safe storage throughout the night. Closing responsibilities will be detailed in the Retail SOP’s.

**Patient Intake**—Patients wishing to patron the retail dispensing location will need to have a valid state medical marijuana patient license. Before entry into the retail dispensing location team members will verify the validity of each patient’s medical marijuana license through the state electronic verification system. After the verification process the patient will be allowed entry into the retail dispensing location.

**Dispensing/Sales Procedure**—the sales procedure needs to be completely accurate for every sales transaction. If sales records are not accurate inventory will have discrepancies and could result in compliance issues. Retail team members will go through extensive training on the POS system and the sales process before commencing operations. The sales procedure is explained in the Retail SOP’s.

**Customer Service**—Customer service policies will be created to ensure good working relationships with dispensing organizations and licensed patients within the State of Hawai’i. These procedures will cover requirements for handling customer complaints and returns of products. BPH is focused on patient well-being with a focus on patients’ medical history and symptoms to recommend the right products for an optimal outcome. BPH will solicit and respond to patient feedback after using our products to further improve effectiveness and patient satisfaction.

### **Legal Environment**

The legal environment surrounding BPH and the medical marijuana industry in the State of Hawai’i will be discussed in this section. Various state laws are discussed in more detail within the Standard Operating Procedures, Employee Manuals, Code of Conduct, etc.

**Licensing**—BPH will ensure that all required state and county licensing are acquired and in good standing prior to launching any cultivation, processing, or dispensing of medical marijuana. All required licensure will be kept on-site at the location facility and clearly displayed.

**Permits**—BPH will ensure all required permits are obtained prior to beginning any tasks or projects. Permits will be obtained for all construction projects or any other work requiring a permit.

**State Law**—BPH will ensure full compliance with all applicable law involving HRS Chapter 329D and HAR Chapter 11-850.

**Zoning**—BPH will ensure that all facility locations are in properly zoned and approved areas for medical marijuana cultivation, processing and dispensary operations.

**Building Codes**—BPH will ensure that all building codes are properly followed and enforced by all contractors, construction crews, or maintenance workers.



**Insurance**—BPH will ensure it is protected with all required and applicable forms of insurance. Insurance will include, but not be limited to, general liability insurance and workers compensation insurance.

### **Recruiting, Benefits, Hiring, Loss of Personnel**

BPH will properly train all of its employees before they are permitted to work in any BPH facility operations.

Prior to being offered an employment position with BPH, all potential applicants will be required to pass a background check to ensure the potential applicant does not have any criminal felony convictions or have been convicted of the crimes listed in HAR §11-850 (2)-(6) and otherwise is of good moral character.

BPH intends to offer competitive wages and salaries, as well as benefits packages that include paid time off and health insurance, to all employees. Exact compensation and benefits plans and packages are in the process of being developed. It is BPH's goal to pay salaries that are, at a minimum, equitable and commensurate with salaries paid for similar work within the labor market. Accordingly, positions will generally be classified and then assigned a salary range that defines a minimum and maximum pay rate. An employee's salary may advance within the salary range as the result of performance reviews, promotions, market conditions and other business considerations. Such increases in pay are considered merit adjustments which are not guaranteed and may vary in timing and degree from employee to employee.

In accordance with State legal requirements, employees will be compensated for hours worked in excess of forty (40) hours per week. Non-exempt employees will be paid one and one-half times their regular rate of pay for hours worked in excess of forty (40) hours in a workweek. Overtime pay is based on actual hours worked. Paid time off for holidays and vacations does not count as "hours worked" for overtime purposes. Any overtime hours worked by a non-exempt employees will be required to be approved in advance by the employee's supervisor. Non-exempt employees are not to work before, beyond or outside their normal working hours without such prior approval. Employees who fail to work scheduled overtime or who work overtime without prior authorization from a supervisor may be subject to disciplinary action, up to and including termination of employment.

**Number of Employees**—exact number of employees employed by BPH is to be determined upon deployment of operations and the establishment of personnel requirements; the breakdown of these requirements can be seen below within the job description section.

**Type of Labor**—the team at BPH will comprise skilled, unskilled, and professional workers. The various positions within the organization will call for different laborers with different skill sets. The cultivation manager will need to be very skilled in the cultivation of marijuana, whereas an entry-level cultivation laborer will likely be unskilled and trained to the job requirements and functions.

**Pay Structure**—BPH will determine this upon deployment of operations and the establishment of personnel requirements. Employee compensation will be competitive with industry standards



**Job Termination**—all termination actions will follow standard procedures. Basic steps include:

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e. employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges, or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel
4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e. mutual separation and key personnel is always welcome back at SFN facilities under visitor status, employee is no longer allowed on the premise, and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was vacated. Key personnel positions will need to be filled as soon as possible by management without compromising the quality of potential candidates.

### **HR Compliance**

BPH will utilize an Employee Handbook/manual that is compliant with all Hawai'i labor laws and will be utilized at all facilities. All registered employees will be required to read the Employee Handbook prior to commencing work in any BPH registered dispensary facility. The Employee Handbook will outline various company policies that must be followed. The handbook will also explain all Human Resources (HR) functions, employee benefits, and other company programs and policies.

### **Workplace Policies**

Prior to the deployment of any operations, BPH will develop and implement multiple workplace policies including an Employee Handbook, Drug and Alcohol Free Workplace Policy, Personal Hygiene Policy, and Code of Conduct. All BPH registered employees will be required to adhere to all policies and programs while employed for BPH.

**Employee Handbook**—BPH will develop and implement an Employee Handbook that will highlight the policies and procedures that employees will need to adhere to while working for



BPH. All employees will be required to read and sign the Employee Handbook prior to commencing work in any BPH facility.

**Drug and Alcohol Free Workplace Policy**—BPH will develop and implement a Drug and Alcohol Free Workplace Policy that will highlight the policies and procedures that employees will need to adhere to while working in any BPH facility. All employees will be required to read and sign the Drug and Alcohol Free Workplace Policy prior to commencing work in any BPH facility.

**Personal Hygiene Policy**—BPH will develop and implement a Personal Hygiene Policy that will highlight the personal hygiene policies and procedures that employees will need to adhere to while working for BPH. All employees will be required to read and sign the Personal Hygiene Policy prior to commencing work in any BPH facility.

**Code of Conduct**—BPH will develop and implement a Code of Conduct that will highlight the policies and procedures relating to employee conduct and ethics that will need to adhere to while working for BPH. All employees will be required to read and sign the Code of Conduct prior to commencing work in any BPH facility.

### **Job Descriptions, Personnel Development and Reviews**

Below details BPH’s employment structure for four (4) distinct operations of the organization 1) cultivation operations 2) manufacturing operations 3) retail dispensary operations and 4) security operations. The information displayed below details the anticipated organizational employment positions, the job descriptions and a potential number of employees for each job description upon deployment of operations.

**TBD, Sustainability Manager**

This person reports to the Chief Operations Oversee sustainable projects from design and build of the facilities, responsible for efficiencies and detecting issues that may related. Remain current with new technologies pertaining to sustainable and renewable technologies.

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#### **1) Cultivation Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Chief Operating Officer: Andrew Salini; Responsible for overall operation of entire facility; oversight of cultivation operational activities, processing operational activities, and security operational activities. All department managers will report directly to the GM.*
  - *Security Clearance: Restricted Area Access*
  - *Employees at Full Capacity: 1*
- *Cultivation Manager: Michael Rogers; Responsible for oversight of cultivation operational activities. Must ensure compliance with all laws and regulations and maintain accurate records and documentation. All cultivation department manager report directly to the Cultivation Manager. Reports directly to the General Manager.*



- *Security Clearance:* Restricted Area Access
- *Employees at Full Capacity:* 1
  
- *Vegetative Manager:* Responsible for oversight of all vegetative areas. Responsible for proper record keeping and documentation. Reports directly to Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Laborers are responsible for daily cultivation activities within the vegetative areas. Reports directly to the vegetative manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 4/TBD
  
- *Flowering Manager:* Responsible for oversight of all flowering areas, proper record keeping, and documentation. Reports directly to the Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Responsible for daily cultivation activities within the flowering area. Reports to the flowering assistant manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 8/TBD
  
- *Harvest Manager:* Responsible for oversight of all harvesting processes. Direct supervision of all managers in the harvest process. Reports directly to the Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
- *Trim/Cure Manager:* Responsible for oversight of trimming process and laborers, proper record keeping, and documentation and responsible for oversight of curing process and laborers, proper record keeping and documentation. Reports to the harvest manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Responsible for daily trimming activities and duties as well as responsible for daily curing activities. Reports to the trim/cure manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 8/TBD
  
  - *Packaging and Labeling Manager:* Responsible for oversight of packaging and labeling activities, laborers and proper record keeping, and documentation.
    - *Security Clearance:* Restricted Area Access
    - *Employees at Full Capacity:* 1



- *Laborer(s)*: Responsible for daily packaging and labeling activities. Reports to the packaging and labeling manager.
  - *Security Clearance*: Limited Area Access
  - *Employees at Full Capacity*: 6/TBD

## **2) Manufacturing Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Director of Manufacturing*: Responsible for oversight of entire infused products area and processes. Direct supervision of all department managers within the infused products area. Reports directly to the facility GM.
  - *Security Clearance*: Restricted Area Access
  - *Employees at Full Capacity*: 1
  - *Infused Products Manager*: Responsible for oversight of kitchen area and activities, laborers and proper record keeping, and documentation. Reports directly to MIP Manager.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: Responsible for daily kitchen activities and duties. Reports to kitchen manager.
      - *Security Clearance*: Limited Area Access
      - *Employees at Full Capacity*: 2/TBD
  - *Extraction Manager*: Responsible for oversight of daily extraction processes, laborers and proper record keeping, and documentation. Reports to the infused products manager.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: Responsible for daily extraction processes and activities. Reports to the extraction manager.
      - *Security Clearance*: Limited Area Access
      - *Employees at Full Capacity*: 4/TBD
  - *Packaging and Labeling Manager*: Responsible for oversight of packaging and labeling activities, laborers and proper record keeping, and documentation.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: responsible for daily packaging and labeling activities. Reports to packaging and labeling manager.
      - *Security Clearance*: Limited Area Access



- *Employees at Full Capacity: 6/TBD*

### **3) Retail Dispensary Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Director of Dispensary Operations:* Responsible for entire facility operations, ensuring full compliance with state law, organizational goals and objectives, etc.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
- *Assistant Manager(s):* Oversees daily retail operations, reports directly to GM
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full capacity:* 2/TBD
- *Patient Advocacy Manager:* Responsible for educating patients with information regarding the use of medical marijuana, etc. Reports to the assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 2/TBD
- *Sales Floor Supervisor(s):* Responsible for oversight of dispensary sales agents and supervision of sales floor activity.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 4/TBD
- *Dispensary Agent(s):* Responsible for daily sales procedures, customer service, patient education, etc. Reports directly to assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 30/TBD
- *Intake Specialist(s):* Responsible for patient check-ins, reports to the assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 4/TBD

### **4) Security Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Security Manager:* Responsible for security operations at the licensed facility. Responsible for oversight of security agents and transportation agents.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1



- *Security Agent(s)*: Responsible for facility entry protocol; ensuring proper identification of any visitors and ensures said visitors have proper security clearance to enter.
  - *Security Clearance*: Restricted Area Access
  - *Employees at Full Capacity*: 1
  
- *Transportation Agent(s)*: Responsible for transporting marijuana and manufactured marijuana products to BPH registered retail dispensary locations.
  - *Security Clearance*: Limited Area Access
  - *Employees at Full Capacity*: 2/TBD

**Personnel Development**—BPH management will be responsible for making a commitment to the on-going education and professional development of BPH registered employees. Once commencing work within a BPH facility, there will be multiple opportunities for continuing education and advancement within the organization. BPH management will be responsible for establishing a development path where registered employees learn from experience and work directly with their crew leaders to learn all aspects of their job. Crossover opportunities will be available and encouraged so employees can learn other areas of the business if they wish to advance to another department, such as a trimmer learning the basics of processing or growing.

In addition to comprehensive training records, BPH management will be responsible for tracking employee development through the use of a development checklist. The development checklist provides a clear visual of the level of training an employee has received as well as their eligibility for additional responsibilities. Once minimum training levels have been reached, crew leaders and management will foster further development of individual employees. Employees may view their progress and choose to take a roll in their own development through expressing interest in learning new processes and utilizing provided reading materials to advance their knowledge. As procedures and topics are mastered, employees will earn “checks” on the development checklist from their crew leaders and production facility management.

**Performance Reviews**—BPH will implement periodic performance reviews that will be utilized to evaluate registered employee performance on an individual level. Employee performance reviews will be conducted on a semi-annual basis and maintained within the registered employees personnel file.

## **Personal Financial Statement**

*Include personal financial statements for each owner and major stockholder, showing assets and liabilities held outside the business and personal net worth. Owners will often have to draw on personal assets to finance the business, and these statements will show what is available. Bankers and investors usually want this information as well.*

## **Startup Expenses and Capitalization**

*You will have many startup expenses before you even begin operating your business. It’s important to estimate these expenses accurately and then to plan where you will get sufficient capital. This*



*is a research project, and the more thorough your research efforts, the less chance that you will leave out important expenses or underestimate them.*

*Even with the best of research, however, opening a new business has a way of costing more than you anticipate. There are two ways to make allowances for surprise expenses. The first is to add a little “padding” to each item in the budget. The problem with that approach, however, is that it destroys the accuracy of your carefully wrought plan. The second approach is to add a separate line item, called contingencies, to account for the unforeseeable. This is the approach we recommend.*

*Talk to others who have started similar businesses to get a good idea of how much to allow for contingencies. If you cannot get good information, we recommend a rule of thumb that contingencies should equal at least 20 percent of the total of all other start-up expenses.*

*Explain your research and how you arrived at your forecasts of expenses. Give sources, amounts, and terms of proposed loans. Also explain in detail how much will be contributed by each investor and what percent ownership each will have.*

## **Financial Plan**

### **Blue Planet Healing - Pro Forma Narrative**

#### **Introduction**

As state medical marijuana markets across the US step into the community of regulated businesses, the qualified applicants that are fortunate enough to exhibit their merit and be awarded the initial licenses must recognize and act upon their concomitant responsibilities as pioneers in this emerging and evolving space. This means taking the necessary steps to ensure ethical, sustainable, and safe business practices are implemented with the needs of patients in mind. To accomplish this end, expectations cannot be inexorable. A critical element in achieving success in any new market is maintaining flexible market forecasts. In other words, operators in a market undergoing initial self-discovery would be wise to some degree to expect the unexpected. Delayed reactionary behaviors to unforeseen market dynamics could jeopardize the health of the entity, the industry, and most importantly the safety of patients and compliance with law.

When establishing our business plan, CPM, and quantitative market forecasts, Blue Planet Healing, LLC (“BPH”) has done so with an open frame of mind as BPH feels that will provide the operational agility to confront market dynamics as they unfold. As detailed below, BPH’s analysis incorporates and references the lessons learned from other states in the emerging medical marijuana industry, but does so while recognizing Hawai‘i is still its own unique place, with its own unique set of variables (demographics, cultural attitudes, etc.). Only then can BPH respond to changes in the regulatory scheme or market conditions should they exhibit a degree of variance from the base case, whether that is weaker demand and lower initial patient participation or excess demand and greater participation.

BPH’s collective experience in multiple fields including software, medicine, finance, sustainable energy, real estate, legal and, most importantly the regulated medical marijuana industry, make it



uniquely equipped to confront both the known and unknown challenges of Hawai‘i’s nascent medical marijuana market. BPH has the experience and is prepared to respond according to market conditions.

Specifically, as it relates to medical marijuana, BPH’s High Country Healing (HCH) and American Cannabis Consulting (ACC) consultants have an established 6+ year track record in Colorado’s medical marijuana market. Since 2009, HCH has successfully navigated the tumultuous waters of perpetual regulatory and structural market change. Over this entire time, HCH has operated successfully and achieved a blemish free record of operational compliance in both the medical and recreational marijuana cultivation and dispensing businesses. Part of HCH’s dedication to excellence has been a commitment by HCH to educate its employees, and by extension its patients regarding the safe and efficacious use of medical marijuana (see .edu attachments “X”). HCH is one of the first dispensaries in Colorado to enroll its employees in “Responsible Vendor Training” in 2015 by the Trichome Institute as soon as the curriculums were validated and sanctioned by the State of Colorado’s Marijuana Enforcement Division (MED).

It is this rich experience in the medical marijuana industry that cautions us against overconfidently forecasting market conditions. If BPH’s expectations are inflexible, this will inhibit the type of reactions required in order to maintain public and patient safety according to the law. BPH’s business plan, CPM, and attached financial projections reflect BPH’s initial assumptions on the growth of the medical marijuana market in Hawai‘i based on empirical analysis, industry experience, and an understanding of the host cultural and local attitudes towards marijuana in Hawai‘i.

### Medical Marijuana Patient Adoption Rates – Current & Forecast

Currently, there are approximately **2,836** duly registered medical marijuana patients on the island of Oahu as of 10/31/15, representing a significantly smaller number of registered patients than the other less densely populated islands (Hawai‘i, Kauai, and Maui). This can be interpreted as reflecting a variance in social norms regarding medical marijuana between the urban professional business center of Honolulu and the more rural communities of the neighbor islands.

**Figure 1: Hawai‘i Medical Marijuana (329) Registry Program**

Valid for October 31, 2015

County	MMJ Patients	Population	% Card Holders
Hawai‘i	4,998	196,520	2.54%
Maui	2,979	165,228	1.80%
<i>Oahu</i>	<i>2,893</i>	<i>1,000,715</i>	<i>0.29%</i>
Kauai	1,686	71,320	2.36%



<b>Total</b>	12,499	1,433,783	0.87%
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\* [http://files.hawaii.gov/dbedt/economic/data\\_reports/2040-long-range-forecast/2040-long-range-forecast.pdf](http://files.hawaii.gov/dbedt/economic/data_reports/2040-long-range-forecast/2040-long-range-forecast.pdf)

Current data indicates that **2.54%** and **2.36%** respectively, of the Hawai‘i and Kauai County population, are duly registered card-holding medical marijuana patients. Thus, these are approximately 9x as many residents holding medical marijuana cards on said islands, as a percentage of the population, compared to Oahu island, where just **0.29%** of the population are currently registered in the program. Only 1.8% of Maui’s population are registered patients.

### **Lessons from the Colorado Experiment**

Colorado, for example, which provides the largest and most robust data sample for legal marijuana markets, started at a similarly modest initial medical patient base as Oahu (0.1% adoption state-wide) before the introduction of a legal dispensary system (“LDS”) in mid-2009. After just two years of profound growth, the Colorado MMJ patient base peaked at **2.5%** of the population base in Q4 2011 before leveling out at **2.2%**, where it stands today.

As Figure 2 below illustrates, there was a decline from 2.5% towards 2% in Colorado’s market, but this simply reflects the State’s inability to expediently process patient card renewals because the LDS’s success was grossly underestimated. For instance, the actual market size was 111% greater than initial projections by the Colorado Center for Law and Policy. Nevertheless, Colorado adapted and allowed for patients awaiting renewal to continue to purchase MM as it expanded its operational capacity. In any event, the key takeaway is that Colorado’s adoption rate grew from just **0.1%** to over **2.0%** in just two-years. This greater than 2% adoption rate is currently the highest seen in any U.S. state medical MM market. Oregon, California, Michigan and Washington, fall into the second tier, with patient adoption rates between 1.4% and 2%.

Looking through the lens of nominal data, Colorado experienced impressive growth in the medical marijuana patient base from 5,000 patients under the caregiver framework in late-2009, to 125,000 patients in Q4 2011, with a population of just over 5 million residents. Extrapolating from this data, Hawai‘i medical marijuana companies and the State would be wise to prepare to handle significant patient registration volumes, but at the same time must not fall victim to heuristic based assessments and succumb to availability bias. To assume that Hawai‘i would experience similarly profound growth is not a base case.

Synthesizing the data from the mainland with the county data in Hawai‘i, one could logically extrapolate that the patient adoption rate on the Hawai‘i Island is relatively close to saturation with some reasonable potential for growth on the margin coinciding with onset of a regulated dispensary network. On the other hand, Oahu has much more significant potential for growth in the long-run, even if peak adoption rates eventually reach levels seen in the other counties in Hawaii or other states across the nation. As a result, BPH sees the greatest need in Oahu for seasoned operators who can leverage their experience in the medical marijuana industry to respond to a burgeoning market in a timely and compliant manner. This offers the best opportunity for patients to receive safe access to medicine without risking product quality or patient safety.



BPH's analysis for Oahu reflects an expectation for a healthy growing medical marijuana patient base in 2016 as citizens anticipate the opening of retail dispensing locations in the second half of the year. As the program matures and stigma recedes, we suspect an increase in the adoption rates moving into 2017 to just under 1% and acceleration in 2H 2018 (to 1.5%) as additional licensees and reciprocity comes into play. Eventually, in BPH's base case forecast, it sees a peak adoption rate of around **2.8%** by 2020. This peak adoption rate in the program is consistent with the current patient base level in other counties in Hawai'i and is the base case for Oahu. BPH is cautiously optimistic that participation will be *higher* given the already meaningful participation in the caregiver framework despite the lack of a regulated LDS network. Other market simulations project participation rates +/- 20% from this level and BPH's flexible cultivation methodologies and sufficient financial resources illustrate an ability to adapt to conditions within these bounds plus a contingency buffer for anomalous statistical outcomes. Nevertheless, we also felt it prudent to engage in more rigorous stress testing scenario analysis.

### **Market Share – 2018 Reciprocity & New Licensees**

Additionally, BPH's analysis assumes that BPH's market presence will grow with the growth of the overall market, but with declining market share over time as more medical marijuana businesses are awarded licenses and come online in 2018. The base case reflects a capture of 1/3 of the market share until other LDS's come online as early as mid-2018, and dropping to high single digits shortly thereafter. These assumptions are in response to increased demand from both the growth in the patient base as well as a modest influx of tourists from other states that can participate in the state's reciprocity program, which is set to take effect as early as July, 2018.

BPH has factored in the State's desire to meet patient need by having no more than one dispensing location per 500 registered patients, but through collective experience and planning, BPH is preparing to handle volumes well in excess of 500 patients should market demand outpace the LDS network. Long-term, if this **2.8%** peak participation level were achieved as expected, that would theoretically result in a maximum of 40 dispensing locations in the county of Oahu by 2021 at the time of market maturation.

Reciprocity will bring very marginal additional tourism business to the state starting in mid-2018, and will be less of a driver of the market than de-stigmatization on the island itself. To capture the impact of reciprocity on the market, we looked at the monthly tourism data from the mainland and distilled how many medical marijuana patients were represented from each state that currently has a medical marijuana program. Subsequently, using average visit lengths (9.54 days) and cannabis consumption patterns, we were able to estimate the marginal revenue generation from these customers. Specifically, the bulk of this tourism injection will come from the mainland Pacific region (CA, AK, WA, OR, NV), which is largely comprised of states with medical marijuana programs. We factored in growth in the patient bases from each of these states, particularly California, which has significant potential for growth once its regulatory scheme is more firmly established in coming years. Nevertheless, we estimate the impact of medical marijuana patient reciprocity to initially be marginal at best, but contribute in larger fashion in longer-term forecasts.

### **Price of Medical Marijuana**



A major driving motivation of BPH team is to provide sustainably produced, pharmaceutical quality, and affordable medicine to patients in need. If Hawai‘i’s market emerges with prohibitive prices, it will deleteriously impact those in need most and potentially incentivize black market consumption. The medical marijuana movement, is not about capturing market share in a new potentially lucrative industry, rather, it is about educating patients, researching medical marijuana, and illuminating upon the values and benefits of what BPH feels is the most healing plant on earth. To share in the healing powers of this plant, BPH is dedicating resources to employee and customer education as well as research.

These initiatives, like research and education, will absorb financial resources, but BPH feels they are vital as the more we understand the plant and its benefits, the closer we are to optimizing patient health and well being. The effects of this positive feedback loop, will reverberate through society as a whole. Therefore, when it comes to product pricing, BPH realizes that if BPH is fortunate to be one of the initial players in this market, we seek to offer reasonably priced medicine as dictated by market dynamics and internal financial considerations. A significantly regulated market framework, will naturally require marginally more costly medicine than the caregiver framework currently provides. According to [priceofweed.com](http://priceofweed.com), a high quality ounce of medical marijuana costs **\$302/oz** in Hawai‘i while low quality is at **\$270/oz**. This is higher than the national average and prices seen in Colorado (\$250/oz), but elevated utility costs and the cost of labor in Hawai‘i versus other states are likely key contributors to sustaining higher than average prices.

As it is BPH’s goal to produce pharmaceutical grade medical marijuana, its base forecast reflects prices in line with current high quality ounces on Hawai‘i (**\$302/oz**, or **\$10.96/g**). However, BPH examined multiple other simulations with lower prices per ounce (down to \$150/oz) in order to better understand the operational feasibility of price fluctuations. An overarching theme of BPH’s approach to this new market is to have an open mind with respect to market dynamics. Thus are preparing to manage price volatility, with a predetermined understanding of what such price variances could mean for the bottom line and the health of the organization. BPH feels confident that its business acumen, expertise in medical marijuana, and deep financial resources position it favorably to deliver high quality medicine to those in need, while being able to weather considerable market volatility.

## **Consumption Behaviors**

In additional to forecasting the patient base, another key consideration is the consumption pattern of those patients. Unlike Colorado at the onset of its market, with numerous states medical



marijuana programs already online, there is a more robust empirical data set to use to cross-reference demand assumptions.

In Colorado, for example, a large part of the State’s underestimation of initial demand was expectations on the “heavy user” (daily user) segment of the population. According to the 2014 National Survey on Drug Use and Health, 23% of the user population in Colorado consumes almost daily, compared with just 17% nationwide.

The mosaic of data and cultural attitudes in Hawai‘i as exemplified by the relatively high adoption rate state-wide before the onset of a true regulated dispensary framework, suggests that relatively high consumption rates by the daily user segment of the patient base will be higher than the national average of 17% but not necessarily higher than 23%. Therefore, in BPH’s forecasts BPH chose to be conservative and baked in higher than average use, but also ran multiple scenario analysis to account for some variance (again, bullish and bearish scenarios +/- 20% in addition to more rigorous stress testing).

### Demographics

One of the key differentiators of Hawai‘i’s current duly registered medical marijuana patient base is the age distribution. As it relates to gender, Hawai‘i is consistent with many other states including Colorado, showing roughly 2/3 (68% vs. 64% in CO) of the base being male and 1/3 (32% vs. 36% in CO) being female. Yet, which age group represents the largest share of patients reflects an interesting contrast to other states. In Hawai‘i, the largest cohort of patients comes from the 56-65 year old segment (27.6%) vs. the 21-30 year old segment in Colorado (23.2%). This data is heat-mapped in Figure X below for illustrative purposes.

**Figure 3: Hawai‘i Medical Marijuana Patient Distribution**

(by Age)

<b>AGE</b>	<b># of Patients</b>	<b>Percentage of Base</b>
<b>&lt;17</b>	25	<b>0.20%</b>
<b>18-25</b>	573	<b>4.58%</b>
<b>26-36</b>	2,098	<b>16.79%</b>
<b>36-45</b>	2,084	<b>16.67%</b>



<b>46-55</b>	2,381	<b>19.05%</b>
<b>56-65</b>	3,450	<b>27.60%</b>
<b>66-75</b>	1,681	<b>13.45%</b>
<b>76-99</b>	207	<b>1.66%</b>
<b>Total</b>	12,499	

The larger proportion of the patient base in the 55-65yo demographic is consistent with experience in Colorado from the onset of the LDS program. For instance, in 2009 when HCH first opened its doors, a higher percentage of patients were near retirement age. Further anecdotal evidence reflects that medical marijuana was selected as an organic remedy following many years (decades) of battling the side effects of synthetic pharmaceutical prescriptions, mainly opiates. Pain relief, after all, is by far the most common mentioned reason for consuming medical marijuana. 92% of patients in Hawai‘i and 94% of patients in Colorado list this as justification for obtaining their medical marijuana cards.

Taking this one step further, it is the belief of BPH, through HCH and ACC’s real-time experience in the industry in Colorado and other states, that this older segment of the population consumes a larger proportion of infused products (oils, pills, lozenges) rather than inhaled products (flower) for actual and perceived health reasons. For instance, the longer duration and intensity of ingested medication (4-6h of relief vs. 1-2h for inhaled) make it a superior choice to address physical pain, auto-immune, and neuropathic conditions and thus a welcomed remedy for many elder patients. BPH’s collective realization of this dynamic was an important consideration in its partnership with Chief Medical Officer (CMO) Dr. Bradley Willcox, who as a UH affiliated scientist and researcher has deep experience in the area of geriatrics and gerontology.

While this assessment is not empirically robust, it does hint as to how things might unfold and thus caution and prepare BPH for a different set of circumstances than are currently reflected in today’s data. Qualitative experience oftentimes is shunned over the more concrete and tangible nature of quantitative analysis due to BPH’s collective desire for control and greater comfort with numbers than abstract ideas, yet quantitative approaches too have their own pitfalls such as data mining and confirmation bias.

Even though the cumulative consumption basket is challenging to quantify with precision, current evidence signals to us that we should be prepared to offer a relatively greater selection of products in the infused category in anticipation of larger initial demand. It was also a motivating factor in creating a vast array of non-inhaled, infused products, including sprays, lozenges, oils, and pills. This distinction between flower and infused products is quite significant to BPH’s business plan as the different product sets have varying costs of production and shelf life. For example, medical marijuana that is grown to be smoked, requires much greater dedication to the nuances of growing the plant to produce the proper flower structure as well as terpene (essential oil) yields, while



infused products (pills, lozenges, oils) place the greatest emphasis on simple trichome (cannabinoid) production.

So, looking ahead, it is critical for BPH to maintain accurate up-to-date empirical data on the patient base on Oahu in order to better serve the patient's medical needs and forecast their needs with greater accuracy. For instance, the current adoption rate in Oahu County is just 0.29%. The expectation is for this to increase roughly 10x within 5 years. It is possible that the 26-36yo segment experiences more significant growth, which would redistribute consumption patterns over time, yet, perhaps the most likely outcome is that the 55-65yo segment that grows most significantly.

According to the most recent census data, which shows Oahu County expected to grow at **0.6%** per annum from 2015-2020, **16.1%** of the Hawaiian population is over 65, versus **14.5%** as the national average. Colorado, on the other hand, is younger, with just **12.7%** above the age of 65. Using this data as a guide and not gospel, BPH reasonably anticipates a relatively higher consumption of infused products compared to inhaled products, especially at the onset. Yet again, BPH feels it is absolutely critical to maintain meticulous oversight on each of these market variables to ensure BPH's greatest chances at continuing to provide medicine to patients in need and react to market developments in real-time.

### **Cultivation Methodologies – Maintaining Flexibility**

Under Hawai'i law, all licensees are restricted to 3,000 plants per cultivation center, for a maximum of 6,000 plants. Additional licensees are set to be considered by the State at the end of 2017 for launch in mid-2018 should market conditions dictate the need for extra capacity. But what if demand surpasses the needs of patients before additional licenses are awarded in 2018? BPH, for one, is ready to confront such challenges by maintaining flexible cultivation methodologies that allow for varying plant counts per light (and thus plant size) in order to meet excess demand. Through the collective experience of HCH and ACC, BPH is prepared to confront these challenges and efficiently adapt to shifting market dynamics. It is BPH's goal with its initial production centers to maintain a high level of flexibility in production to meet many potential demand scenarios while BPH moves towards the longer goal of building a state of the art, sustainable cultivation facility, leveraging BPH's team's depth of experience in energy.

### **Summary**

BPH's collective track record in various realms of business, including the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of the Hawaiian medical marijuana market. BPH's approach is not inexorable, nor is it dogmatic. BPH's initial cultivation center is strategically poised to navigate the volatility of a new market while sewing the seeds of the long term vision of Hawaii's 2015 CEO of the Year, Henk Rogers, which is to create the gold standard for sustainable cultivation practices in the medical marijuana industry.

While BPH acknowledges the uncertainties of a new market, the base case assumptions are grounded in over 6 years of experience within the marijuana industry and a combination of



qualitative and quantitative analysis of the Hawaii market. BPH has evaluated initial market conditions and made calculated estimations on the market's development from the awarding of licenses in April 2016. BPH's analysis factored in consumption patterns, demographics, population growth, reciprocity, and more to achieve a base case forecast, which was then subjected to rigorous stress testing.

Armed with the knowledge gained from both experience in Colorado and analysis of the Hawaii market, BPH feels confident in its ability to deliver pharmaceutical grade, sustainably produced medical marijuana to Hawaii consumers in 2016. BPH has the business acumen and deep financial resources to accomplish its goal and the passion to share what BPH believes to be the most healing plant on earth with those who are suffering and in need.

*are expressed as a percent of total sales.) Include all assumptions upon which your break-even calculation is based.*

## **Security and Diversion Plan**

BPH recognizes the importance of incorporating security considerations into every aspect of its operational activities in order to ensure the safety of both BPH's customers and the public and that none of the MM produced by the Company is diverted for distribution outside the statutory framework contained in HRS Chapters 329 and 329D. BPH also understands that the failure to comply with the security requirements of Hawai'i law jeopardizes not only the safety of the public, BPH's customers and a license issued to BPH under Chapter 329D, but also Hawai'i's MM program itself which remains subject to scrutiny by federal authorities pursuant to the Cole Memorandum.

In order to implement a comprehensive and holistic approach to the management of all activities involving the chain of custody of MM, including activities in BPH's RDLs and PCs and in connection with the authorized transportation of MM, BPH will engage the services of Securitas, one of the largest security companies in the world. With over 300,000 employees and operations in over 50 countries Securitas is the Company that the State of Hawai'i has entrusted to provide security services for all of Hawai'i's airports. After comprehensive due diligence, BPH selected Securitas as its security services provider not only because it is one of the oldest and most respected security companies in operation today but because it also has experience designing and installing security systems in MM facilities in other states. BPH has reviewed with Securitas the requirements of HRS §329D (6) and (7) and HAR §11-850-51, §11-850-52 and §11-850-53. Securitas will provide security system consultation, design, and management services which fully comply with the foregoing provisions of law including all requirements regarding: access control; surveillance; and intrusion deterrence, detection and response.

BPH will also utilize written security SOPs developed from best practices currently used in MM operations in Colorado which fully comply with Hawai'i law.

**Video Surveillance System.** Securitas will design video surveillance systems at each of BPH's RDLs and PCs that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will



clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

**Alarm System.** Each RDL and PC operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

**System Failure.** In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

**Other Security Measures.** All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH-approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

**Production Center Specific Security Measures.** In addition to all the above mentioned and all other security measures required by HRS Chapter 329D and HAR Chapter 11-850, BPH will utilize a perimeter security fence around each PC that surrounds the entire premise sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any marijuana in any form as required by HAR §1185052 (1). In addition, BPH will secure all marijuana and manufactured marijuana products in a locked room, vault or container which is securely fixed to a wall or the floor to ensure product safety and to prevent theft.



**Retail Dispensary Location Specific Security.** BPH will implement and follow specific security procedures and policies for all RDL operations including: written SOPs for admitting registered patients and primary caregivers with valid government-issued photo identification cards issued pursuant to HRS Chapter 329 into the secure rooms for sales. BPH will design and construct each RDL with separate, secure room(s) for sales wherein marijuana and manufactured marijuana products are secured and locked in display cases for viewing.

As required by HAR §11-850-53(3), BPH will follow written policies and procedures to ensure that a maximum occupancy limit ratio is maintained in all secured sales rooms of two customers to everyone RDL employee. BPH will store all marijuana products within a locked room, vault or in a locked container securely affixed to a wall or floor. All RDLs shall have exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities.

**Transportation Security.** BPH will utilize HCH's experience and knowledge in the development and implementation of transportation policies and procedures based on industry best practices from current operations in Colorado's regulated marijuana industry which are fully compliant with HRS §329D-7(7) and HAR §11-850-36.

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees. 3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH's tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.



**Security Lighting**—Securitas will ensure the installation and maintenance of exterior security lights around the entire perimeter of the facility to allow surveillance in low light conditions and deter potential intrusion.

**Security Perimeter Fencing**—Securitas will install new perimeter security fencing at the cultivation/production facility locations to deter unwanted and unauthorized access to the facility.

**On-Site Electronic Monitoring**—BPH facility security rooms will have a large screen call-up monitor and a video printer capable of immediately producing a clear still photo from all video cameras.

**Commercial Grade Door Locks**—Securitas ensure the use of commercial-grade, non-residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas.

**Safes and Product Storage**—BPH will utilize commercial grade safes for product storage. Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana and manufactured marijuana products.

**Restricted and Limited Access Areas**—Management will maintain policies and procedures that limit access to the areas within facilities to only approved authorized personnel or visitors being accompanied at all times by a facility employee.

**Policies and Procedures**—Additional policies and procedures will prevent loitering, aid in electronic monitoring, and be utilized to ensure automatic electronic notification of local law enforcement agencies of any unauthorized breach of security at BPH facilities.

**Facility Layout/Site Diagram**—a facility layout/site diagram will be maintained on site at the Cultivation facility that will clearly define each area of the facility. The site diagram will be updated as soon as any changes are made to ensure a current facility layout.

**Inventory Management**—Inventory management is a critical factor within the organization. The tracking of all medical marijuana from seed to sale will be done through inventory management through the use of template log sheets, BioTrackTHC™ computer systems and Point-of-Sale systems (POS).

**Incident Management**—an effective incident reporting procedure includes identification, limiting liability, and prevention. BPH will maintain an ongoing Incident Report Log (IRL) both physically and digitally.

**Emergency Protocol**— BPH will establish emergency protocols to be implemented organization wide. Employees of the organization will be fully trained on emergency protocols before beginning employment with the company. Emergencies protocols will be developed for robbery or theft, fire emergency, chemical spill, and for other emergencies as needed. Emergency protocols are explained in more detail in the SOP's.

**Local Authorities**—BPH will establish relationships with local authorities to ensure quick response teams will be dispatched to all dispensary facilities when an alarm is raised.



## **Community Plan**

As an organization we realize that when we begin operations we will become a member of the surrounding communities and as such we want to become a valuable and productive member within said communities. Safety for our employees and the surrounding communities is of utmost importance to our organization. With the presence of our facility and the security systems planned for the facility and surrounding area, should help to reduce crime. We have plans to develop and implement community outreach programs. Such programs and events will include food and clothing drives for local food banks, churches, and others. A plan to donate a certain percentage of yearly profits to schools and infrastructure of the surrounding community is also in development. BPH will also adhere to the 'Good Neighbor Policy' at all facility locations.

### **Good Neighbor Policy**

The facility management team is committed to building and maintaining good relationships with all of its neighbors – including local business improvement districts, building owners, small businesses, and residents alike. The facility team shall make every effort respect the perspectives of our neighbors and to address their concerns. The following steps shall be made to ensure any concerns within the community are addressed:

- Introduction meetings with all surrounding businesses, building owners, and residents.
- Educational information sessions to discuss the benefits of marijuana and the company's overall mission and goals.
- Open feedback channels so any new concerns can be immediately addressed through our website, telephone, or mail.
- Complete compliance with all state and local ordinances.
- Non-obtrusive business practices shall ensure our business is discreet and operates like any other business.
- No blatant signage with offensive symbols or verbiage.
- Unmarked discreet transportation vehicles.

In addition, the facility will use carbon air filters to ensure no noxious odors from production are released into the surrounding neighborhoods.

### **Environmental Impact Plan**

Conservation and the reduction of our carbon footprint within the communities we operate in will be a primary objective of the organization. This will be implemented throughout the entire organization and at every facility. We will look for new and innovative ways to reduce our carbon footprint within every facility of the organization. 'Reduce, Reuse and Recycle' will be implemented on an organization-wide scale.

Environmental sustainability is of the highest priority in order to promote a sustainable community and ensure the impact of business is positive and influential in achieving future environmental goals. In order to reach this goal we have contracted designers, engineers and consultants who shall design intelligently, utilize energy intelligently, and strive for procedures that lead to zero waste. Various factors will be considered thoroughly when planning equipment, procedures, and methodology: Air quality, climate, ecological health, energy efficiency, water

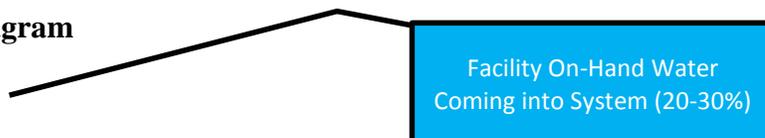


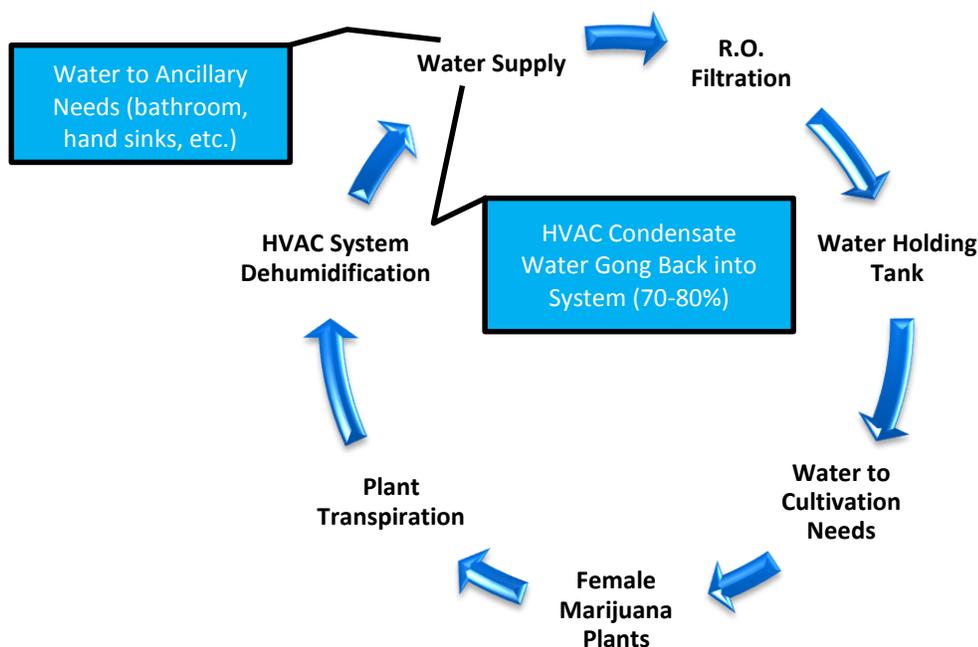
quality, transportation, and waste.

**Energy Conservation**—BPH has unique access to technologies through its team members and the network of scientists and engineers that allow the creation of a sustainable operation. BPH recognizes that power consumption by marijuana producers in other states have been a significant concern for the local government, community members, and the utility companies. Reports estimate California’s 3% to 5% of total power consumption is drawn by the marijuana cultivation industry. With cooperation from alternative energy companies, bioengineering companies, and tech companies, BPH will design and construct a cultivation facility of the highest efficiency and sustainability without sacrificing quality of the produced product. Natural sunlight diffused through a solid non see-through translucent roof with an infrared blocking coating will provide much of the light required for growing. Next generation dimmable LED grow lights, 20% more efficient than conventional LED grow lights in the market in 2015, tailored for hybrid use will supplement the diffused light with precise wavelengths optimal for the current growth stages of the plants. Every environmental factor is monitored by a robust sensor system with over 80 types of sensors that communicate in real time to each of the lights, HVAC equipment, irrigation equipment, and to the cultivation employees; allowing for a real time automatic and/or remote manual control of every aspect of the indoor cultivation environment. Plant biology and conditions will be monitored in order to optimally control the reaction of the plants to the environment and vice versa, allowing the creation of a system in which the plants and the facility will breathe at the same rhythm. By controlling light quality and quantity at the transition of light periods, the system can eliminate a bulk of the spike in relative humidity caused by the transpiration by controlling the closure of the stomata, the pores on the leaf surfaces. The level of precision , monitoring, and control will allow for a massive reduction in power demands by the cultivation facility. The reduced demands will be easily met with renewable energy sources that could include but not limited to solar, wind, hydro power, and hydrogen fuel cells coupled with the advanced energy storage solutions offered by BPES to create the world’s first sustainable marijuana cultivation facility using 100% renewable energy.

**Water Conservation**—In keeping with the sustainable approach, BPH will be collecting moisture from the air through dehumidification with the HVAC system and diverting it back to the Reverse Osmosis (RO) System to re-water the plants. As plants grow, they transpire approximately 70%-80% of the water they drink into the air and this raises humidity levels. As the environmental control systems maintain the parameters needed for optimal plant growth, the HVAC system will be required to provide adequate dehumidification. This dehumidification would produce condensate that typically would be discharged outdoors or in the sewer system as waste water, but BPH will be recapturing this condensate and piping it back to the RO System to be filtered and sent back to out to water the plants. This significantly reduces water consumption to provide environmental and financial benefits.

### Cultivation Facility Water Flow Diagram





BPH management will also create and implement an employee conservation plan. The employee conservation plan will detail specific actions employees can take for conservation efforts to try and reduce their carbon footprint. A possible reward program may be created and implemented to reward facility employees for conservation efforts.

**Employee Conservation:** Team members of BPH will be encouraged to recycle all paper and plastic waste products. Energy efficient lights and equipment will also be utilized within the facility. We will also create programs within the organization that will encourage and reward employees for their personal conservation efforts; such as carpooling and riding a bike to work. Waste products from the facility will be composted on site or mixed with biodegradable products for disposal.

### **Community Benefits Program**

Blue Planet Healing, LLC. (BPH) will contribute a percentage (to be determined after six months of operation) of net profit to organizations with tax-exempt status under Section 501 (c)(3) of the U.S. Internal Revenue Code working to strengthen the community. BPH will direct its contributions to areas that the Board of Directors believe are important to the future of community development, education, and human services. BPH's first priority is to support programs and organizations whose chief purpose is health and community education.

BPH will support organizations and programs that support **education**, specifically programs that:

- Work to eliminate pre-K – 12<sup>th</sup> grade achievement gap in public education through curriculum-based or school-sponsored programs
- Support post-secondary education
- Support booster programs for drug abuse prevention, awareness, and treatment



BPH will support organizations and programs that support **health**, specifically programs that:

- Support research into cures and treatments for qualifying conditions
- Support further research into effective marijuana treatments of qualifying conditions
- Support programs that will improve the health of the community

BPH will support the improvement of low and moderate income communities through programs that:

- Create and sustain affordable housing
- Facilitate literacy
- Provide job training and workforce development
- Revitalize and stabilize community
- Education

BPH will consider requests from organizations that work to enhance community diversity through **arts and culture** and provide:

- Access to and participation in cultural experiences for low and moderate income individuals
- Availability of a broad array of artistic opportunities and venues that reflect the community's diversity

BPH will consider requests from organizations that work to enhance a community's quality of life through projects involving **civic engagement** through:

- Public policy
- Community beautification
- Civic leadership
- Citizen education
- Cultural diversity

BPH is committed to building strong **environmental practices** through programs that:

- Conserve natural resources
- Protect endangered species
- Preserve the environment

BPH will consider requests from social and **human service organizations** that:

- Enable and sustain independence for individuals and families
- Ensure access to health education programs and quality health care

If organizations meet BPH's eligibility requirements and fit in with our philanthropic goals and objectives, we will accept requests and review them throughout the year. Local decisions are made with priority.

### **Substance Abuse and Prevention**

BPH intends to be pro-active in recognizing and preventing substance abuse. In the event that, based on data collected or observation, a potential substance abuse problem is identified; the



patient will be notified and provided with a list of local providers for patient assistance, drug and alcohol treatment and family services that patients may access without BPH involvement. It is at dispensary's agent discretion the extent to which they will provide additional assessment, evaluation, counseling, and/or referral for treatment. BPH employees will be provided training on identifying substance abuse problems.

BPH dispensary staff members will be trained on the physical effects of marijuana on the human body, recognizing the signs of marijuana impairment and what to do should the team member feel that dispensing medical marijuana to a patient and/or caregiver is not in their best interest and could result in negative consequences. All BPH professional staff members have the authority to deny dispensing medical marijuana and/or medical manufactured marijuana products to any Hawai'i qualified, registered patient or caregiver if they reasonably suspect there could be substance abuse problems with said patient or caregiver.



## Appendices

- Financial Pro-Forma Model
- Standard Operating Procedures
  - Cultivation
  - Manufacturing
  - Retail dispensing
  - Log Sheets
- Employee Handbook
- Security Plan



## **Attachment 1.2** **Financial Plan**

### **Blue Planet Healing LLC - Pro Forma Narrative**

#### **Introduction**

As state medical marijuana markets across the US step into the community of regulated businesses, the qualified applicants that are fortunate enough to exhibit their merit and be awarded the initial licenses must recognize and act upon their concomitant responsibilities as pioneers in this emerging and evolving space. This means taking the necessary steps to ensure ethical, sustainable, and safe business practices are implemented with the needs of patients in mind. To accomplish this end, expectations cannot be inexorable. A critical element in achieving success in any new market is maintaining flexible market forecasts. In other words, operators in a market undergoing initial self-discovery would be wise to some degree to expect the unexpected. Delayed reactionary behaviors to unforeseen market dynamics could jeopardize the health of the entity, the industry, and most importantly the safety of patients and compliance with law.

When establishing our business plan, CPM, and quantitative market forecasts, Blue Planet Healing, LLC (“BPH”) has done so with an open frame of mind as BPH feels that will provide the operational agility to confront market dynamics as they unfold. As detailed below, BPH’s analysis incorporates and references the lessons learned from other states in the emerging medical marijuana industry, but does so while recognizing Hawai‘i is still its own unique place, with its own unique set of variables (demographics, cultural attitudes, etc.). Only then can BPH respond to changes in the regulatory scheme or market conditions should they exhibit a degree of variance from the base case, whether that is weaker demand and lower initial patient participation or excess demand and greater participation.

BPH’s collective experience in multiple fields including software, medicine, finance, sustainable energy, real estate, legal and, most importantly the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of Hawai‘i’s nascent medical marijuana market. BPH has the experience and is prepared to respond according to market conditions.

Specifically, as it relates to medical marijuana, BPH’s High Country Healing (HCH) and American Cannabis Consulting (ACC) consultants have an established 6+ year track record in Colorado’s medical marijuana market. Since 2009, HCH has successfully navigated the tumultuous waters of perpetual regulatory and structural market change. Over this entire time, HCH has operated successfully and achieved a blemish free record of operational compliance in both the medical and recreational marijuana cultivation and dispensing businesses. Part of HCH’s dedication to excellence has been a commitment by HCH to educate its employees, and by extension its patients regarding the safe and efficacious use of medical marijuana (see .edu attachments “X”). HCH is one of the first dispensaries in Colorado to enroll its employees in “Responsible Vendor Training” in



## **Attachment 1.2**

2015 by the Trichome Institute as soon as the curriculums were validated and sanctioned by the State of Colorado’s Marijuana Enforcement Division (MED).

It is this rich experience in the medical marijuana industry that cautions us against overconfidently forecasting market conditions. If BPH’s expectations are inflexible, this will inhibit the type of reactions required in order to maintain public and patient safety according to the law. BPH’s business plan, CPM, and attached financial projections reflect BPH’s initial assumptions on the growth of the medical marijuana market in Hawai‘i based on empirical analysis, industry experience, and an understanding of the host cultural and local attitudes towards marijuana in Hawai‘i.

### **Medical Marijuana Patient Adoption Rates – Current & Forecast**

Currently, there are approximately **2,836** duly registered medical marijuana patients on the island of Oahu as of 10/31/15, representing a significantly smaller number of registered patients than the other less densely populated islands (Hawai‘i, Kauai, and Maui). This can be interpreted as reflecting a variance in social norms regarding medical marijuana between the urban professional business center of Honolulu and the more rural communities of the neighbor islands.

**Figure 1: Hawai‘i Medical Marijuana (329) Registry Program**

Valid for October 31, 2015<sup>1</sup>

<b>County</b>	<b>MMJ Patients</b>	<b>Population<sup>2</sup></b>	<b>% Card Holders</b>
Hawai‘i	4,998	196,520	2.54%
Maui	2,979	165,228	1.80%
<b><i>Oahu</i></b>	<b><i>2,893</i></b>	<b><i>1,000,715</i></b>	<b><i>0.29%</i></b>
Kauai	1,686	71,320	2.36%
<b>Total</b>	<b>12,499</b>	<b>1,433,783</b>	<b>0.87%</b>

\* [http://files.hawaii.gov/dbedt/economic/data\\_reports/2040-long-range-forecast/2040-long-range-forecast.pdf](http://files.hawaii.gov/dbedt/economic/data_reports/2040-long-range-forecast/2040-long-range-forecast.pdf)

Current data indicates that **2.54%** and **2.36%** respectively, of the Hawai‘i and Kauai County population, are duly registered card-holding medical marijuana patients. Thus, these are approximately 9x as many residents holding medical marijuana cards on said islands, as a percentage of the population, compared to Oahu island, where just **0.29%** of the population are currently registered in the program. Only 1.8% of Maui’s population are registered patients.

### **Lessons from the Colorado Experiment**

<sup>1</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>

<sup>2</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>



## **Attachment 1.2**

Colorado, for example, which provides the largest and most robust data sample for legal marijuana markets, started at a similarly modest initial medical patient base as Oahu (0.1% adoption state-wide) before the introduction of a legal dispensary system (“LDS”) in mid-2009. After just two years of profound growth, the Colorado MMJ patient base peaked at **2.5%** of the population base in Q4 2011 before leveling out at **2.2%**, where it stands today.

As Figure 2 below illustrates, there was a decline from 2.5% towards 2% in Colorado’s market, but this simply reflects the State’s inability to expediently process patient card renewals because the LDS’s success was grossly underestimated. For instance, the actual market size was 111% greater than initial projections by the Colorado Center for Law and Policy. Nevertheless, Colorado adapted and allowed for patients awaiting renewal to continue to purchase MM as it expanded its operational capacity. In any event, the key takeaway is that Colorado’s adoption rate grew from just **0.1%** to over **2.0%** in just two-years. This greater than 2% adoption rate is currently the highest seen in any U.S. state medical MM market. Oregon, California, Michigan and Washington, fall into the second tier, with patient adoption rates between 1.4% and 2%.<sup>3</sup>

Looking through the lens of nominal data, Colorado experienced impressive growth in the medical marijuana patient base from 5,000 patients under the caregiver framework in late-2009, to 125,000 patients in Q4 2011, with a population of just over 5 million residents. Extrapolating from this data, Hawai‘i medical marijuana companies and the State would be wise to prepare to handle significant patient registration volumes, but at the same time must not fall victim to heuristic based assessments and succumb to availability bias. To assume that Hawai‘i would experience similarly profound growth is not a base case.

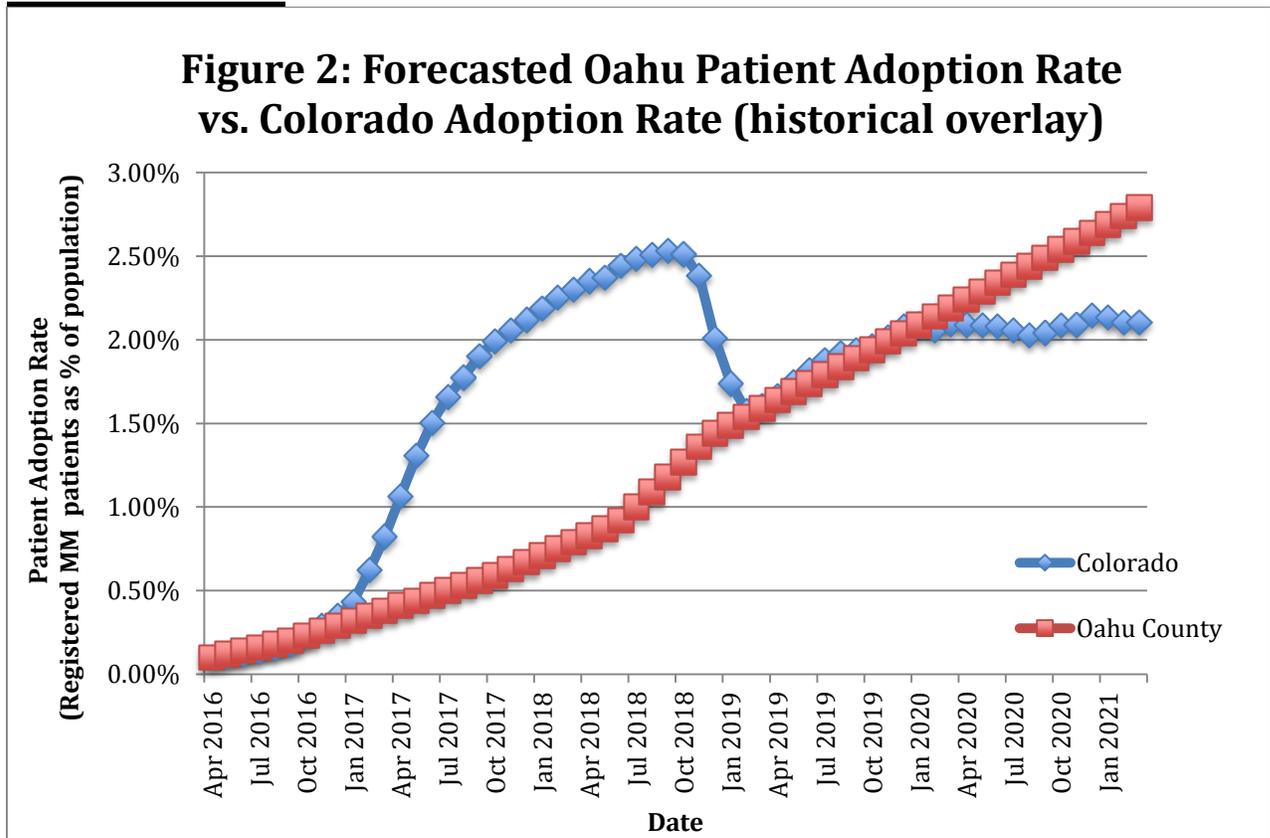
Synthesizing the data from the mainland with the county data in Hawai‘i, one could logically extrapolate that the patient adoption rate on the Hawai‘i Island is relatively close to saturation with some reasonable potential for growth on the margin coinciding with onset of a regulated dispensary network. On the other hand, Oahu has much more significant potential for growth in the long-run, even if peak adoption rates eventually reach levels seen in the other counties in Hawaii or other states across the nation. As a result, BPH sees the greatest need in Oahu for seasoned operators who can leverage their experience in the medical marijuana industry to respond to a burgeoning market in a timely and compliant manner. This offers the best opportunity for patients to receive safe access to medicine without risking product quality or patient safety.

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<sup>3</sup> <http://medicalmarijuana.procon.org/view.resource.php?resourceID=005889>



## Attachment 1.2



BPH’s analysis for Oahu reflects an expectation for a healthy growing medical marijuana patient base in 2016 as citizens anticipate the opening of retail dispensing locations in the second half of the year. As the program matures and stigma recedes, we suspect an increase in the adoption rates moving into 2017 to just under 1% and acceleration in 2H 2018 (to 1.5%) as additional licensees and reciprocity comes into play. Eventually, in BPH’s base case forecast, it sees a peak adoption rate of around **2.8%** by 2020. This peak adoption rate in the program is consistent with the current patient base level in other counties in Hawai‘i and is the base case for Oahu. BPH is cautiously optimistic that participation will be *higher* given the already meaningful participation in the caregiver framework despite the lack of a regulated LDS network. Other market simulations project participation rates +/- 20% from this level and BPH’s flexible cultivation methodologies and sufficient financial resources illustrate an ability to adapt to conditions within these bounds plus a contingency buffer for anomalous statistical outcomes. Nevertheless, we also felt it prudent to engage in more rigorous stress testing scenario analysis.

### Market Share – 2018 Reciprocity & New Licensees

Additionally, BPH’s analysis assumes that BPH’s market presence will grow with the growth of the overall market, but with declining market share over time as more medical marijuana businesses are awarded licenses and come online in 2018. The base case reflects a capture of 1/3 of the market share until other LDS’s come online as early as



## **Attachment 1.2**

mid-2018, and dropping to high single digits shortly thereafter. These assumptions are in response to increased demand from both the growth in the patient base as well as a modest influx of tourists from other states that can participate in the state's reciprocity program, which is set to take effect as early as July, 2018.

BPH has factored in the State's desire to meet patient need by having no more than one dispensing location per 500 registered patients, but through collective experience and planning, BPH is preparing to handle volumes well in excess of 500 patients should market demand outpace the LDS network. Long-term, if this **2.8%** peak participation level were achieved as expected, that would theoretically result in a maximum of 40 dispensing locations in the county of Oahu by 2021 at the time of market maturation.

Reciprocity will bring very marginal additional tourism business to the state starting in mid-2018, and will be less of a driver of the market than de-stigmatization on the island itself. To capture the impact of reciprocity on the market, we looked at the monthly tourism data from the mainland and distilled how many medical marijuana patients were represented from each state that currently has a medical marijuana program. Subsequently, using average visit lengths (9.54 days<sup>4</sup>) and cannabis consumption patterns<sup>5</sup>, we were able to estimate the marginal revenue generation from these customers. Specifically, the bulk of this tourism injection will come from the mainland Pacific region (CA, AK, WA, OR, NV), which is largely comprised of states with medical marijuana programs. We factored in growth in the patient bases from each of these states, particularly California, which has significant potential for growth once its regulatory scheme is more firmly established in coming years. Nevertheless, we estimate the impact of medical marijuana patient reciprocity to initially be marginal at best, but contribute in larger fashion in longer-term forecasts.

### **Price of Medical Marijuana**

A major driving motivation of BPH team is to provide sustainably produced, pharmaceutical quality, and affordable medicine to patients in need. If Hawai'i's market emerges with prohibitive prices, it will deleteriously impact those in need most and potentially incentivize black market consumption. The medical marijuana movement, is not about capturing market share in a new potentially lucrative industry, rather, it is about educating patients, researching medical marijuana, and illuminating upon the values and benefits of what BPH feels is the most healing plant on earth. To share in the healing powers of this plant, BPH is dedicating resources to employee and customer education as well as research.

These initiatives, like research and education, will absorb financial resources, but BPH feels they are vital as the more we understand the plant and its benefits, the closer we are to optimizing patient health and well being. The effects of this positive feedback loop,

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<sup>4</sup> <http://dbedt.hawaii.gov/visitor/>

<sup>5</sup> <https://www.colorado.gov/pacific/sites/default/files/Market%20Size%20and%20Demand%20Study,%20July%209,%202014%5B1%5D.pdf>



## **Attachment 1.2**

will reverberate through society as a whole. Therefore, when it comes to product pricing, BPH realizes that if BPH is fortunate to be one of the initial players in this market, we seek to offer reasonably priced medicine as dictated by market dynamics and internal financial considerations. A significantly regulated market framework, will naturally require marginally more costly medicine than the caregiver framework currently provides. According to [priceofweed.com](http://priceofweed.com), a high quality ounce of medical marijuana costs **\$302/oz** in Hawai‘i while low quality is at **\$270/oz**. This is higher than the national average and prices seen in Colorado (\$250/oz), but elevated utility costs and the cost of labor in Hawai‘i versus other states are likely key contributors to sustaining higher than average prices.

As it is BPH’s goal to produce pharmaceutical grade medical marijuana, its base forecast reflects prices in line with current high quality ounces on Hawai‘i (**\$302/oz**, or **\$10.96/g**). However, BPH examined multiple other simulations with lower prices per ounce (down to \$150/oz) in order to better understand the operational feasibility of price fluctuations. An overarching theme of BPH’s approach to this new market is to have an open mind with respect to market dynamics. Thus are preparing to manage price volatility, with a predetermined understanding of what such price variances could mean for the bottom line and the health of the organization. BPH feels confident that its business acumen, expertise in medical marijuana, and deep financial resources position it favorably to deliver high quality medicine to those in need, while being able to weather considerable market volatility.

### **Consumption Behaviors**

In addition to forecasting the patient base, another key consideration is the consumption pattern of those patients. Unlike Colorado at the onset of its market, with numerous states medical marijuana programs already online, there is a more robust empirical data set to use to cross-reference demand assumptions.

In Colorado, for example, a large part of the State’s underestimation of initial demand was expectations on the “heavy user” (daily user) segment of the population. According to the 2014 National Survey on Drug Use and Health, 23% of the user population in Colorado consumes almost daily, compared with just 17% nationwide.

The mosaic of data and cultural attitudes in Hawai‘i as exemplified by the relatively high adoption rate state-wide before the onset of a true regulated dispensary framework, suggests that relatively high consumption rates by the daily user segment of the patient base will be higher than the national average of 17% but not necessarily higher than 23%. Therefore, in BPH’s forecasts BPH chose to be conservative and baked in higher than average use, but also ran multiple scenario analysis to account for some variance (again, bullish and bearish scenarios +/- 20% in addition to more rigorous stress testing).

### **Demographics**



## **Attachment 1.2**

One of the key differentiators of Hawai‘i’s current duly registered medical marijuana patient base is the age distribution. As it relates to gender, Hawai‘i is consistent with many other states including Colorado, showing roughly 2/3 (68% vs. 64% in CO) of the base being male and 1/3 (32% vs. 36% in CO) being female<sup>6</sup>. Yet, which age group represents the largest share of patients reflects an interesting contrast to other states. In Hawai‘i, the largest cohort of patients comes from the 56-65 year old segment (27.6%) vs. the 21-30 year old segment in Colorado (23.2%). This data is heat-mapped in Figure X below for illustrative purposes.

**Figure 3: Hawai‘i Medical Marijuana Patient Distribution  
(by Age)**

<b>AGE</b>	<b># of Patients</b>	<b>Percentage of Base</b>
<17	25	0.20%
18-25	573	4.58%
26-36	2,098	16.79%
36-45	2,084	16.67%
46-55	2,381	19.05%
56-65	3,450	27.60%
66-75	1,681	13.45%
76-99	207	1.66%
<b>Total</b>	<b>12,499</b>	

The larger proportion of the patient base in the 55-65yo demographic is consistent with experience in Colorado from the onset of the LDS program. For instance, in 2009 when HCH first opened its doors, a higher percentage of patients were near retirement age. Further anecdotal evidence reflects that medical marijuana was selected as an organic remedy following many years (decades) of battling the side effects of synthetic pharmaceutical prescriptions, mainly opiates. Pain relief, after all, is by far the most common mentioned reason for consuming medical marijuana. 92% of patients in Hawai‘i and 94% of patients in Colorado list this as justification for obtaining their medical marijuana cards.

Taking this one step further, it is the belief of BPH, through HCH and ACC’s real-time experience in the industry in Colorado and other states, that this older segment of the population consumes a larger proportion of infused products (oils, pills, lozenges) rather than inhaled products (flower) for actual and perceived health reasons. For instance, the longer duration and intensity of ingested medication (4-6h of relief vs. 1-2h for inhaled)

<sup>6</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>



## **Attachment 1.2**

make it a superior choice to address physical pain, auto-immune, and neuropathic conditions and thus a welcomed remedy for many elder patients. BPH's collective realization of this dynamic was an important consideration in its partnership with Chief Medical Officer (CMO) Dr. Bradley Willcox, who as a UH affiliated scientist and researcher has deep experience in the area of geriatrics and gerontology.

While this assessment is not empirically robust, it does hint as to how things might unfold and thus caution and prepare BPH for a different set of circumstances than are currently reflected in today's data. Qualitative experience oftentimes is shunned over the more concrete and tangible nature of quantitative analysis due to BPH's collective desire for control and greater comfort with numbers than abstract ideas, yet quantitative approaches too have their own pitfalls such as data mining and confirmation bias.

Even though the cumulative consumption basket is challenging to quantify with precision, current evidence signals to us that we should be prepared to offer a relatively greater selection of products in the infused category in anticipation of larger initial demand. It was also a motivating factor in creating a vast array of non-inhaled, infused products, including sprays, lozenges, oils, and pills. This distinction between flower and infused products is quite significant to BPH's business plan as the different product sets have varying costs of production and shelf life. For example, medical marijuana that is grown to be smoked, requires much greater dedication to the nuances of growing the plant to produce the proper flower structure as well as terpene (essential oil) yields, while infused products (pills, lozenges, oils) place the greatest emphasis on simple trichome (cannabinoid) production.

So, looking ahead, it is critical for BPH to maintain accurate up-to-date empirical data on the patient base on Oahu in order to better serve the patient's medical needs and forecast their needs with greater accuracy. For instance, the current adoption rate in Oahu County is just 0.29%. The expectation is for this to increase roughly 10x within 5 years. It is possible that the 26-36yo segment experiences more significant growth, which would redistribute consumptions patterns over time, yet, perhaps the most likely outcome is that the 55-65yo segment that grows most significantly.

According to the most recent census data, which shows Oahu County expected to grow at **0.6%** per annum from 2015-2020, **16.1%** of the Hawaiian population is over 65, versus **14.5%** as the national average. Colorado, on the other hand, is younger, with just **12.7%** above the age of 65. Using this data as a guide and not gospel, BPH reasonably anticipates a relatively higher consumption of infused products compared to inhaled products, especially at the onset. Yet again, BPH feels it is absolutely critical to maintain meticulous oversight on each of these market variables to ensure BPH's greatest chances at continuing to provide medicine to patients in need and react to market developments in real-time.

### **Cultivation Methodologies – Maintaining Flexibility**



## **Attachment 1.2**

Under Hawai'i law, all licensees are restricted to 3,000 plants per cultivation center, for a maximum of 6,000 plants. Additional licensees are set to be considered by the State at the end of 2017 for launch in mid-2018 should market conditions dictate the need for extra capacity. But what if demand surpasses the needs of patients before additional licenses are awarded in 2018? BPH, for one, is ready to confront such challenges by maintaining flexible cultivation methodologies that allow for varying plant counts per light (and thus plant size) in order to meet excess demand. Through the collective experience of HCH and ACC, BPH is prepared to confront these challenges and efficiently adapt to shifting market dynamics. It is BPH's goal with its initial production centers to maintain a high level of flexibility in production to meet many potential demand scenarios while BPH moves towards the longer goal of building a state of the art, sustainable cultivation facility, leveraging BPH's team's depth of experience in energy.

### **Summary**

BPH's collective track record in various realms of business, including the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of the Hawaiian medical marijuana market. BPH's approach is not inexorable, nor is it dogmatic. BPH's initial cultivation center is strategically poised to navigate the volatility of a new market while sewing the seeds of the long term vision of Hawaii's 2015 CEO of the Year, Henk Rogers, which is to create the gold standard for sustainable cultivation practices in the medical marijuana industry.

While BPH acknowledges the uncertainties of a new market, the base case assumptions are grounded in over 6 years of experience within the marijuana industry and a combination of qualitative and quantitative analysis of the Hawaii market. BPH has evaluated initial market conditions and made calculated estimations on the market's development from the awarding of licenses in April 2016. BPH's analysis factored in consumption patterns, demographics, population growth, reciprocity, and more to achieve a base case forecast, which was then subjected to rigorous stress testing.

Armed with the knowledge gained from both experience in Colorado and analysis of the Hawaii market, BPH feels confident in its ability to deliver pharmaceutical grade, sustainably produced medical marijuana to Hawaii consumers in 2016. BPH has the business acumen and deep financial resources to accomplish its goal and the passion to share what BPH believes to be the most healing plant on earth with those who are suffering and in need.

## **Attachment 1.3**



### **Blue Planet Healing LLC (“BPH”) Personal Profiles**

#### **Henk Rogers—Sole Applicant, Chairman & Spokesperson**

BPH’s individual applicant, Henk Rogers ("Henk") is an internationally recognized entrepreneur, philanthropist and community leader who was recognized as Hawai‘i’s 2015 CEO of the Year. A longtime resident of Hawai‘i who studied computer science at the University of Hawai‘i, Henk has skillfully assembled a dynamic group of individuals with the necessary education, training, skills and real life experience necessary and advisable to start and successfully operate a business that will accomplish the statutory goals of HRS Chapter 329D.

Considered one of the visionaries of computer games, Henk Rogers helped change the face of the industry as the entrepreneur responsible for bringing the Tetris® game to the United States and world market. Under Henk’s direct leadership, the Tetris game has become one of the world’s top-selling video game brands with hundreds of millions of products sold, and after 30 years since its “birth,” that number is still growing. Today Rogers serves as Managing Director of The Tetris Company, the exclusive licensor of the Tetris brand and Chairman of Blue Planet Software, the sole agent for the Tetris franchise, founder of Blue Planet Foundation, a nonprofit clean energy advocate, and founder of Blue Startups, Hawai‘i’s first venture accelerator.

A heart attack in 2005 gave Henk the opportunity to rethink the rest of his life and reevaluate the purpose of his life’s work. Henk is determined to end the use of carbon-based fuel on the planet, starting with fossil fuel use in Hawai‘i, his adopted home. To fulfill his mission, Henk established Blue Planet Foundation, which has become the frontline organization in the fight for indigenous renewable energy in Hawai‘i. As Blue Planet Foundation’s principal and visionary philanthropist, Henk Rogers is committed to the mission of stewarding the environment through developing non-carbon, clean energy sources. He is personally devoted to helping our planet reduce and eventually eliminate its dependence on fossil fuels.

Furthermore in 2015, Henk founded Blue Planet Energy Systems, becoming a leader in energy storage solution systems home and commercial usage.

Henk’s community recognitions include:

- 2015 – Hawai‘i Business Magazine, CEO of the Year
- 2015 – Honorary Doctorate of Human Letters, University of Hawai‘i
- 2014 – Hawai‘i Institute for Publish Affairs (HIPA) Ho‘ulu Award
- 2013 – Hawai‘i Business News Business Leadership Award Finalist
- 2011 – Hawai‘i Business Innovation Showcase “City & Council of Honolulu” Finalist
- 2010 – Hawai‘i Business Magazine “Five for Today” leadership recognition
- 2009 – Hawai‘i Venture Capital Association “Entrepreneur of the Year”
- 2008 – Hawai‘i Venture Capital Association “Venture Capital Deal of the Year”  
Honorable Mentioned – Avatar Reality



HIGH COUNTRY HEALING

## **High Country Healing (“HCH”) Company Profile**

### **High Country Healing Overview**

- Medical Cannabis Cultivation and Dispensing since 2009
- Opened 2 of Colorado's first 20 recreational cannabis dispensaries on 1/1/2014
- Corporate mission statement is to sustainably grow some of the world's premier pharmaceutical grade cannabis for the connoisseur. Compassion, Caring, and Education are core values of High Country Healing (HCH)... as highlighted by the HCH's Free CBD oil program for those with a dire medical need, Sommelier ("Interpening") and Compliance training for all staff.
- Currently operating 3 medical and 3 recreational dispensaries: Vail, Silverthorne, Alma, and CO Springs (multiple locations)
- Currently operating 4 cultivation facilities, the largest is 22,000 square feet (organic soil and various hydroponic techniques)
- Grows over 60+ varieties of high quality pharmaceutical grade cannabis, including rare CBD-rich genetics
- CBD oil program provides free CBD-oil to cancer patients and those suffering from various forms of epilepsy, auto-immune diseases, chronic pain syndrome, PTSD etc.
- *High Times* Magazine's (leading cannabis culture magazine) most featured dispensary brand of all time (known for exceptional flower quality).
- As featured in *The Cannabist*, MSNBC's *Pot Barons*, *The Denver Post*, *The Guardian* (UK), *Skiing*, *Powder*, and *Ski Magazines*, *Yo Beat*, *Dope Directory*
- Perfect record of compliance spanning 6-years of constant and significant regulatory change with zero security issues. Certificate of good standing.
- One of Colorado's first dispensary chains to formally train staff and receive RVT (Responsible Vendor Training) Status
- Rigorously complies and exceeds all security protocol required by the state of Colorado.

### **Andrew J. Salini – Chief Operating Officer - Operations, Finance, & Strategy**

- COO & Chief Strategist at High Country Healing's Retail & Cultivation Facilities, 2014-Present
- *Management*: HCH operations, retail/cultivation/financial strategy & analytics, brand, and business development
- Formerly, Vice President, Strategist & Portfolio Management at EMF Fixed Income Fund, \$500mm AUM, 2011-2014
- Associate, Credit Suisse Fixed Income Strategy & Research, 2010-2011
- Associate, Deutsche Bank Securities, Global Finance & Foreign Exchange, Proprietary Trader & Portfolio Manager, 2006-2009
- Received a A.B. in Economics, Princeton University, 2002-2006



- Received Certificates in both Finance and French Language & Culture from Princeton University, 2002-2006
- Academic All-American in Baseball, Princeton Baseball's All-time hits leader, & 3-time Ivy League Champion
- Graduated, Phillips Academy Andover, 2002

### Andrew Salini Narrative Resume

Mr. Salini graduated Princeton University in 2006 with a degree in Economics, with certificates in Finance and French Language & Culture in 2006. He was also a 4-year letterman and starter for the Varsity Baseball team, where he was part of 3 Ivy-League Championship teams ('03, '04, '06) making 3 College World Series Tournament appearances. Mr. Salini also holds the all-time record for most hits in a career in Princeton baseball history.

Following graduation, Mr. Salini started his career in investment banking as an Associate at Deutsche Bank in the Global Finance and Foreign Exchange division where he worked until 2009. His responsibilities included portfolio management and proprietary trading of fixed income derivatives and currencies. From 2010 to 2011, Mr. Salini joined the Credit Suisse Fixed Income team in their investment bank before transitioning to the hedge fund business as the lead Strategist for EMF, a fixed income relative value fund with as much as \$500 AUM where he worked until 2014 before joining High Country Healing.

Mr. Salini developed a niche in finance through his ability to distill the quantitative nuances of the fixed income markets. His professional experience has thus always focused on the details and intricacies of a highly complex and highly regulated market place. This detail-orientation and meticulous approach to work made him a natural fit to step into the COO role at High Country Healing. His role has included overseeing and optimizing all operations and compliance functions and offering market analysis and strategy to help steer HCH through the tumultuous waters of ever-changing regulatory landscape of this blossoming new cannabis industry.

As a researcher by training, Mr. Salini took a deep dive into the medicinal benefits of cannabis following conversations with Mr. Brown in 2009. His resulting conviction sparked a desire to be a part of the movement to share the wonderful healing powers of this giving plant with the world to help end suffering. After losing his mother to breast cancer in 2009 after a 10 year battle, and seeing the deleterious and lingering effects of cancer on his father, he joined the HCH team in 2014 and has not looked back since.



## **Attachment 1.5**

# **UNDRNWMNGMNT LLC (“UNM”) Profile**

### **MANUFACTURING QUALIFICATIONS**

To strengthen Blue Planet Healing’s operational strategy we have entered into an agreement with UNDRNWMNGMNT, LLC (“UNM”), a marijuana product-licensing company headquartered in Colorado. Under this agreement we will license their product lines and they will provide consultation and serve as advisors in all areas of manufacturing marijuana products.

These professionals have operated an award-winning infused-product company since 2010. They have expanded to license their products, industry experience and compliance services into several states. They specialize in pharmaceutical-grade extraction, production, formulation, packaging and branding of their dosed and tested products for medical marijuana markets. They have been consistently recognized for the quality and consistency of their approach in the medical marijuana arena by dispensaries, physicians and patients. Medical marijuana industry experts have also awarded UNM multiple honors for the quality of their products and approach toward education and safe use.

The principals of UNM have deep experience in the medical-marijuana industry. They have founded a research lab, production center, a dispensary and cultivation facilities. They are also currently active in multiple states working within strict regulatory standards. In 2006, one of the principals founded a national nutraceutical company. That company must comply with FDA regulations and oversight as well as international quality and safety standards that maintain strictly-established dosing amounts within microgram tolerances. We feel the broad spectrum of experience the UNM principals possess will assist us to create products of the level of purity, quality and consistency currently demanded of this industry. Through this relationship, our Company will have access to their methods, best practices, branding experience, production technology, SOPs, training programs and other proprietary elements.

Collaborating with state government, our licensors have helped shape public policy with respect to many cannabis-product issues including child-resistant packaging and consistent dosing. In Colorado, they were selected by the Colorado Marijuana Enforcement Division to participate in multiple state-level ‘Working Groups’. These Working Groups consisted of various State agencies, marijuana-industry representatives, representatives from the Governor’s Office, law enforcement and opposition groups. The working groups were organized to develop functional regulation and refine existing regulation for the marijuana industry. Cooperation and communication with regulatory agencies will be essential in a successful launch of a medical-marijuana framework in Hawaii and we will engage their experience to assist and support this process.

Our licensor has established and maintained strategic long-term working and research relationships with suppliers for equipment, packaging, ingredients, solvents and other materials and components integral to operations. Based on years of on-going testing, they have vetted and sourced the highest quality suppliers that fit reliably into their supply chains. These relationships afford them the ability to optimize the areas of cost, quality and service. This experience with suppliers will be leveraged in our manufacturing facility’s operations.



## **Attachment 1.5**

Our facility will be equipped with a closed-loop Sub/Supercritical Extraction unit. Other equipment will include but is not limited to: kitchen, lab, packaging equipment, certified scales, and a GC testing unit. Our licensors have researched and sourced the necessary equipment to manufacture, package, store, and ship our final products. We have selected equipment with power needs and physical footprints which fit to the planned facility. By planning every step of the manufacturing process from equipment, facility-layout, supply-chain, and employee training, to the formulations of the final products we have developed a stable, safe and scalable business model.

The conceptual product descriptions, labels, manufacturing information, process flow diagrams, standard operating procedures and other pertinent information relating to our manufacturing plan are included in the attachments to this section.

## **Attachment 1.6**



### **Blue Planet Healing LLC (“BPH”) Personal Profiles**

#### **Maya Rogers—Chief Executive Officer**

Maya Rogers ("Maya") will be the CEO of BPH. For the last several years she has helmed Blue Planet Software, one of Hawai‘i's most successful high tech companies, through the highly complex and competitive high-tech world with international sophistication and a sense of local pride and style. As the Business Development Manager of Blue Startups, Hawai‘i's premier Business Accelerator Organization and a 2015 top 20 US Accelerator, Maya assists and trains promising start-up entrepreneurs to compete on a global scale using a mentor driven model that reaches networks throughout Hawai‘i, Asia and Silicon Valley.

Maya Rogers Kiyomura is President and CEO of Blue Planet Software, the sole agent for the Tetris® brand. With a history that spans more than 30 years, Tetris is one of the leading and most distinctive video game brands and franchises in the world. Rogers has spent the last eight years leading the Tetris brand’s worldwide business initiatives, including and more than 12 years in the video game industry in Japan, China and the U.S. Prior to Tetris, Rogers steered cross culturalization and development efforts with Sony Computer Entertainment America and American Honda.

In 2012, Maya co-founded Blue Startups, Hawai‘i’s first venture accelerator that helps early stage startups with investments and mentoring. Fifty companies have gone through the Blue Startups program and received capital from the Blue Ventures Fund, and have attracted approximately \$25 million in funding. In March 2015, Blue Startups placed #17 in TechCrunch’s annual ranking of top US accelerators. Prior to Tetris, Maya held management roles with Sony Computer Entertainment America, where she steered localization efforts for games such as the Gran Turismo and Hot Shots Golf franchises. Rogers began her career working with cars at American Honda before making the switch over to working on virtual cars at SCEA.

Maya is a board member with the American Red Cross Hawai‘i Chapter, and is a member of the Tiffany Circle Society of Women Leaders, a national Red Cross program comprised of women leaders and philanthropists who dedicate their time and talents to support community Red Cross efforts. Rogers also serves as a member of the advancement committee and advisory board of the Smithsonian Asian Pacific American Center. She is also actively involved in eGlobal Family, an organization that links orphaned and vulnerable children in developing countries to compassionate and responsible supporters. In March 2015, Maya was awarded “20 for the Next 20” recognition by Hawai‘i Business Magazine as one of 20 emerging leaders who have made major contributions to the state of Hawai‘i, and are expected to have a significant impact on the state over the next two decades. In 2016, Pacific Business News honored Maya with the Women to Watch recognition.

Maya grew up in Japan and the US, and currently resides in Hawai‘i. She holds a B.S. in Business Administration and an MBA from Pepperdine University.

## **Attachment 1.7**



### **Blue Planet Healing LLC (“BPH”) Personal Profiles**

#### **Kent Otsu—Chief Financial Officer**

BPH's Chief Financial Officer, Kent Otsu, has significant finance experience working for some of Hawai'i's most notable companies and will be the executive responsible for the financial control and planning of BPH. Kent will oversee all financial and accounting functions including: (1) cash control, (2) preparing budgets and financial statements, (3) coordinating financing (4) monitoring expenditures and liquidity, (5) managing tax issues, (6) reporting financial performance to the board, (7) providing timely financial data to the CEO and (8) working with appropriate financial and other government regulators.

Kent Otsu is Chief Financial Officer (CFO) of Blue Planet Software (BPS), the sole agent for the iconic video game Tetris. As CFO, he oversees all administrative and financial matters for BPS including accounting, tax reporting and compliance, and budgeting. In addition, Kent oversees legal and human resources for BPS. Kent and his team also provide similar services to all companies under the direction of Henk Rogers which include Blue Startups, a nationally-recognized accelerator, and Blue Planet Foundation, a non-profit organization dedicated to end the use of carbon-based fuels in Hawai'i.

Prior to working at BPS, Kent worked for KPMG in Honolulu where he worked on financial audits of electric utilities, healthcare and real estate entities, and he earned his Certificate of Public Accounting at this time. He then spent 12 years as Controller for LVMH Fashion Group Hawai'i, whose brands include Louis Vuitton, Celine and Fendi. His responsibilities included producing financial statements in accordance with GAAP and IFRS, income tax reporting and compliance, and overseeing all audits including State Income Tax, General Excise Tax, Department of Labor, Internal Revenue Service and US Customs. In addition, Kent was responsible for creating and maintaining internal controls over cash and inventory, which included procedures around the point-of-sale, and inventory receiving, transferring, and physical counts.

Kent graduated from Iolani School, and then attended University of Colorado - Boulder where he earned a Bachelor of Science in Accounting. Today, Kent enjoys spending his free time with Debbie, his wife of 21 years, and his daughters Jessica and Deanna. He also enjoys an occasional round of golf, and supporting his alma mater, Iolani School.

## **Attachment 1.8**



### **Blue Planet Healing LLC (“BPH”) Personal Profiles**

#### **Bradley J. Willcox, MD, M.Sc—Medical Director Advisor**

Dr. Bradley Willcox M.D., a UH affiliated scientist, researcher and practicing physician who will act as BPH's Chief Medical Advisor ("CMA") and, among other things, provide guidance to BPH regarding the latest credible scientific research involving MM and will act as the Company's information gatekeeper in connection with the preparation and dissemination of medical and scientific information to registered patients as permitted by the Department of Health, State of Hawai‘i ("DOH"). Dr. Willcox is an investigator in the area of geriatrics and gerontology at the Pacific Health Research and Education Institute and is a clinical assistant professor in the Department of Geriatric Medicine at the John A. Burns School of Medicine, University of Hawai‘i. As his attached profile attests, Dr. Willcox's education, training, background and experience make him particularly well suited to provide scientific and medical guidance to a MM dispensary business. DOH has recently compiled and published information regarding the demographics of the roughly 12,000+ MM patients in the State of Hawai‘i. The DOH data indicates that an overwhelming number of these patients use MM to alleviate pain from (their physician certified) debilitating medical condition. Accordingly, it appears that a substantial number of Hawai‘i's registered MM patients use MM to treat symptoms associated with many of the chronic diseases that afflict Hawai‘i's kūpuna. Dr. Willcox's medical and scientific background nicely fits this demographic. In addition, the recent expansion of the definition of "debilitating medical condition," for which physicians may prescribe MM, to include "post-traumatic stress disorder" increases the relevance of Dr. Willcox's skill set to BPH's mission.

Bradley J. Willcox M.D., M.Sc. trained in Medicine at the University of Toronto, Internal Medicine at the Mayo Clinic, and Geriatric Medicine at Harvard Medical School. Dr. Willcox is Principal Investigator of the National Institute on Aging-funded Kuakini Hawai‘i Lifespan Study and Kuakini Hawai‘i Healthspan Study, which are ancillary studies on aging from the Kuakini Honolulu Heart Program. He is also Professor and Director of Research at the Department of Geriatric Medicine, John A. Burns School of Medicine, University of Hawai‘i, located on the Kuakini Health System campus. Dr. Willcox is the Co-Principal Investigator of the Okinawa Centenarian Study and has been investigating mechanisms of aging for almost two decades with this study. Clinically, he runs the Long Term Care Hospitalist Program at The Queen’s Medical Center, where he is a three time nominee for Physician of the Year.

Dr. Willcox’s research teams have identified several important genetic and environmental risk factors for aging and aging-related chronic diseases. His research team in Okinawa identified the first longevity-associated gene, and his research team in Hawai‘i was the first to identify the association of the FOXO3 gene with human longevity and he has greater than 150 peer-reviewed scientific publications.

## **Attachment 1.8**

Dr. Willcox is on the Editorial Board of several leading gerontological journals, including the Journals of Gerontology. He has been recognized with a Dorothy Dillon Eweson Award for Advances in Aging Research, the Henry Christian Award from the American Federation for Medical Research, a Director's Citation from the Centers for Medicare and Medicaid Services, and other honors. Dr. Willcox is also the author of a New York Times best-selling book on healthy aging, The Okinawa Program. His work has appeared in cover articles of Time Magazine, National Geographic, and on Oprah, Good Morning America, NOVA Science, BBC, and other media.



## **Attachment 1.9**



# MEMO

To: **Ms. Maya Rogers**  
From: **Andrew W. Bachman, MD, FACEP**  
Date: **Wednesday, January 27, 2016**  
Subject: **Blue Planet Healing Medical Cannabis Application**

Dear Ms. Rogers,

Please find attached the documentation, as discussed, supporting your Blue Planet Healing application to be filed with the Hawaii State Department of Health and demonstrating my enthusiastic commitment to personally serve as a consultant on your Advisory Board in the capacity of Global Operations & Emerging Market Advisor providing expertise ranging from cultivation to caregiving. This role will focus on developing a successful, sustainable, responsible and positively impactful company and novel healthcare sector for the State of Hawaii by providing proven industry expertise in medicinal cannabis extraction & formulation, regulatory compliance, pesticide-free medically-oriented hydroponic cultivation, clinical care center delivery & design, public relations & provider/patient education & outreach with a professed and Board-Certified foundation in patient caregiving throughout.

LeafLine Labs, LLC, one of only two registered cultivators, extractors, formulators, distributors, and care delivery entities in Minnesota's vertically-integrated, extraction-only Medical Cannabis Program, appropriately-regulated by Minnesota's Department of Health (MDH), similarly commits as an entity to serve as a consultant supporting same and the Advisory Board role outlined above.

AWB

Andrew W. Bachman, MD, FACEP  
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612.432.6998 (C)



## Attachment 1.9



### **Andrew Bachman, MD, FACEP** **Founder**

*When you know better, do better.* These words by Maya Angelou inspire Andrew Bachman's approach to medicine and caregiving. Because after more than a decade working as an emergency medicine doctor, Bachman saw firsthand the shortcomings of available pharmaceutical therapies. This insight led him to research alternative and complementary options, including medical cannabis. Bachman's vision for LeafLine Labs is to bring safe, consistent and high-quality medical cannabis to the people of Minnesota. It's a new model for health care, one grown from the roots of early medicine, that brings patients and caregivers together in the same space to facilitate more natural, compassionate interactions. A Minnesota native, Bachman completed his emergency medicine residency at Hennepin County



## **Attachment 1.9**

Medical Center, received his medical degree from Georgetown University School of Medicine and earned an undergraduate degree in biology from Amherst College.

### **LeafLine Labs**

#### **LeafLine Labs, LLC, cultivates, processes, and distributes medical cannabis formulations in Minnesota.**

Founded in 2014 by Board-Certified Emergency Medicine physician, Andrew Bachman, MD, and his team, LeafLine Labs, LLC, is registered to cultivate, process, and distribute medical cannabis formulations in Minnesota’s “extraction-only” medical program. It provides expertly-crafted medicine and compassionate care for suffering patients with currently approved conditions such as cancer with specified complications, glaucoma, HIV/AIDS, Tourette’s Syndrome, ALS, Intractable Seizure Disorders, Muscle Spastic Conditions (e.g., Multiple Sclerosis), Crohn’s Disease, Terminal Illness, and Intractable Pain.

LeafLine Labs actively cultivates dozens of selected medical cannabis strains in a specifically-designed and newly-constructed 42,000 SF pharmaceutical-grade facility, ideally situated on 24 acres, optimized for plant health, production, sustainability and reproducibility. All medicinal compounds are then efficiently separated from the fibrous plant material using industry-leading scientific techniques and technology by our medically-experienced extraction team, which allows



## **Attachment 1.9**

for innovative medicine formulation with NO harsh diluents, additives

or toxic  
solvents  
employed.

Every lot of “whole plant extract” medicine is rigorously tested for chemical composition, potential contamination, consistency and purity at one of only two independent, state-sanctioned and regulated laboratories in Minnesota. Our medication formulations contain standardized, proprietary cannabinoid profiles, including set ratios of CBD, THC, etc., that aid in the treatment of a variety of medical conditions and ameliorate a variety of medical symptoms for Minnesota’s suffering patients with qualifying conditions. The final preparations are then clearly packaged as capsules, oils for vaporization, syrups & suspensions, tinctures, and sublingual sprays, and labelled accordingly to pharmaceutical-grade specifications.

LeafLine Labs’ Headquarters and primary production facility is located in the Minneapolis/St. Paul suburb of Cottage Grove, MN, with our flagship cannabis care center opened in Eagan, MN, on July 1, 2015. A care center in St. Cloud, MN, (in close proximity to one of the nation’s largest V.A. Hospitals) is nearing completion presently, with subsequent care centers in St. Paul and Hibbing, MN, slated to open by July 1, 2016. LeafLine Labs is well-supported & well-capitalized with nearly \$16M raised through vetted and approved investors to date, many of whom are physicians and/or professional caregivers in Minnesota and beyond.



Attachment 1.9





## Attachment 1.9



## Attachment 1.9





## Attachment 1.9



The story of a girl and her family fighting Dravet Syndrome.

# Life-changing progress.

MEET AMELIA





## Attachment 1.10

# Inhofer, Greta

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### Objective

Highly skilled Registered Nurse and case manager with more than 5 years of nursing experience, including case management, care coordinating, private practice clinic, skilled nursing, and dermatology. Recognized as an excellent team leader and problem solver with expertise in health and wellness, quality, utilization, and risk management.

### Experience

#### RN CASE MANAGER, HEALTHWAYS HAWAII/HMSA — 2015-PRESENT

Provided care coordination for patients considered to be high risk for readmissions. Facilitated face to face visits as needed, provided case management services for individual needs. Filled the gaps in members continues care after transitioning home from the hospital.

#### HEALTH AND WELLNESS COACH—2012-PRESENT

Provide one on one education, tools, and encouragement to individuals on how to be healthier physically and mentally through proper nutrition and functional fitness.

#### RN CARE HOME OPERATOR, MANOA COTTAGES - 2012-2014

Evaluated clinical care services and all administrative operations and activities. Managed a 24 bed facility with 26 staff members. Maintained the structure and staffing of the facility to effectively meet the needs of the residents. Established and implemented care protocol ensuring all regulations were met.

#### DERMATOLOGY RN, SODERSTROM DERMATOLOGY - 2010-2012

Worked alongside a very well respected physician, performing many clinical functions and roles of a general nursing RN, including taking detailed patient health histories, routine examinations and screenings for serious problems such as skin cancer. Assisted in the operating room with surgeries. Certified to use laser therapy to treat autoimmune skin disorders such as vitiligo and psoriasis.

### Skills & Abilities

- Great communicator and excellent interpersonal skills
- Strong leadership skills
- Strong teaching skills
- Enjoy public speaking
- Volunteer with Oahu Medical Reserve
- Volunteer with Project Hawaii
- Strong desire to make a difference in the community of Oahu

### Education

Black Hawk College, Moline Illinois - Nursing- 2010



# Attachment 1.11

## MARISA YURI KESAJI, PHARM.D, RPH



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### EDUCATION

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<b>University of Southern California</b> Doctor of Pharmacy	8/2001 - 5/2005
<b>University of Southern California</b> Undergraduate Studies-Trojans Admission Pre-Pharmacy (TAP) Program	8/1999 - 5/2001

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### PROFESSIONAL OVERVIEW

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- Currently in the Administrator In Training Program at The Plaza Assisted Living
  - Established and enforced policies and procedures to promote cost-effective, appropriate and safe medication use
  - Developed and implemented store programs to help meet sales objectives and increase prescription volume
  - Supervised staff pharmacists, pharmacy technicians and pharmacy ancillary on the day-to-day operations of the pharmacy
  - Ensured pharmacy personnel follow company policies, state and federal regulations, HIPAA and Occupational Safety and Health Administration directives
  - Reviewed monthly financial statistics and maintained expenditures within budget guidelines
  - Monitored and oversaw pharmacy's inventory, placed orders with vendors, logged and tracked all invoices and verified all drug orders received
  - Oversaw third party billing, claims processing and collections
  - Collaborated with front store manager on company initiatives in order to drive sales and increase profitability
  - Maintained all state and federal record keeping for legend drugs and controlled substances
  - Assisted in the hiring, promoting and termination process of pharmacy personnel
  - Coached and mentored pharmacy staff on basic pharmacy operations and how to provide outstanding customer service
  - Reviewed and accurately interpreted physicians orders, prepared compounds and dispensed medications in compliance with company policy, pharmacy procedure and all state and federal laws
  - Evaluated medication contraindications due to allergies, incompatibilities, drug-drug, drug-food or drug-disease interactions
  - Consulted with health care providers to prevent allergic and/or adverse drug reactions and provided dosing recommendations in order to improve patient outcomes
- 

### EXPERIENCE

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<b>Administrator In Training</b> The Plaza Assisted Living – Honolulu, HI	8/2015-Present
<b>Chief Pharmacist / Pharmacy Manager</b> Prince Kuhio Pharmacy – Honolulu, HI *Pharmacy Manager for 2 locations	12/2013-1/2015
<b>Staff Pharmacist</b> CVS Pharmacy – Honolulu, HI Target – Pacoima, CA	8/2007-12/2013 9/2006-7/2007
<b>Pharmacy Manager</b> CVS Pharmacy – Los Angeles, CA	1/2006-9/2006
<b>Staff Pharmacist</b> Sav-On Pharmacy – Los Angeles, CA	7/2005-12/2005

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### CERTIFICATIONS

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<b>Hawaii Board of Pharmacy, License Number: PH2596</b>	Valid until 12/2017
<b>APhA Certified Immunizing Pharmacist</b>	4/2011-Present
<b>American Heart Association BLS for Healthcare Providers (CPR and AED) Certified</b>	Valid until 6/2016

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## **Attachment 1.11**

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### REFERENCES

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Available upon request

## **Attachment 1.12**



### **Blue Planet Healing LLC (“BPH”) Personal Profiles**

#### **Dr. Kenneth Leonhardt, Ph.D.—Director of Horticulture Advisor**

Dr. Kenneth Leonhardt, Ph.D., also a UH affiliated scientist, will act as the Company’s Chief Horticultural Advisor ("CH") and provide BPH with guidance regarding the best horticultural practices necessary to economically produce quality pharmaceutical grade MM for Hawai’i’s patients. Dr. Leonhardt will work closely with BPH’s Cultivation Manager.

Ken has considerable experience in plant breeding, having created and introduced over 100 new varieties to Hawai’i growers. Ken’s professional research focus is on polyploidy induction and creating sterility (seedless clones). Tetraploid forms of 22 species have been created. Only 2 other labs in the US focus on this kind of research (Dr. Ranney at North Carolina State U, and Dr. Contrearras at Oregon State U). Tetraploid forms of Marijuana will have higher concentrations of CBDs and THCs.

Ken has familiarity with all sectors of agribusiness in Hawai’i for 43 years and has acted as a crop science educator for the past 39 years. He was the owner/operator of a commercial ornamental plant nursery for 13 years (1975-1988).

As Chairman of the undergraduate program at the UH department of Tropical Plant and Soil Sciences, Ken is familiar with the top graduates, thus when BPH is looking to hire technicians with a crop science background, Ken will be able to source the top candidates. Ken also sits on the board of advisors for Medical & Product Testing – Hawai’i MDs.

## **Attachment 1.13**



### **Blue Planet Healing LLC (“BPH”) Personal Profiles**

#### **Michael Rogers—Cultivation Manager**

Michael Rogers holds a deep passion for sustainability and human welfare from his former career running an international gemstone trading business. Michael spent much time in the bush of Africa and Madagascar creating deep relationships with the poorest people of the world learning firsthand about the lives and woes of the “bottom billion”, at which point Michael made a decision to study sustainable agriculture and community development to improve people’s lives. Michael folded his business and attended the University of Hawai‘i at Mānoa where he earned a degree in Tropical Plants and Soil Sciences with a focus on Plant Production and Management. During his time at the university, Michael was highly active in extracurricular activities being the president of the Horticultural Society, publishing articles regarding genetics and plant disease management, and creating a community composting facility.

He is a certified permacultural designer and has work experience at a modern 2,500 acre farm where he was responsible for irrigation management, soil conservation projects, native plant landscaping, plant disease management, and tractor operation. Currently, Michael serves on the board of advisors for Kumuola Foundation, a local non-profit organization based on a farm in the rainforests of Mānoa whose mission is to promote sustainable island living through agriculture, community, education, and practice of Hawai‘ian arts. Michael has a deep understanding of Hawai‘ian culture having a long history of dancing hula and receiving honors at the Merrie Monarch Hula Festival.



## **Blue Planet Healing LLC (“BPH”) Personal Profiles**

### **Greg Anton, Esq.,--Legal Counsel**

Attorney Greg Anton has been a champion of medical cannabis patients for over 35 years; working to help insure safe access to this valuable medicine. Greg has litigated issues of cannabis law at all levels of State and Federal courts, including the US Supreme Court. (In 2015 he achieved a landmark legal victory with an unprecedented ruling that his client can distribute medical cannabis without Federal interference).

Besides working with state and local government officials to develop safe, effective regulations; Greg has provided legal counsel to all aspects of the medical cannabis industry. Greg represents the first licensed medical cannabis dispensary in the United States.



## Application Response: Question 2

One of the challenges faced by all applicants is navigating the complexities inherent in preparing to launch a new era business that is subject to conflicting yet strict federal and state laws and requires the immediate and continued infusion of significant financial and other resources without the benefit of traditional banking and other financial services. Added to that complexity is the fact that the new business must be operational as soon as practicable after the law allows, yet applicants cannot legally engage in the core activities made legal under Chapter 329D until they are duly licensed and a multitude of legal and regulatory conditions precedent have been met. These challenges require careful and creative planning.

Blue Planet Healing LLC's ("BPH") regulated marijuana industry consultants, American Cannabis Company Inc. ("ACC") and High Country Healing ("HCH") will help BPH navigate the complexities of its regulated marijuana business operations. HCH possesses the knowledge and experience of operating in the regulated marijuana industry and will serve as the "boots on the ground" for BPH's operations. If BPH is awarded a license, Andrew Salini from HCH will relocate to Honolulu for the deployment and implementation of BPH's operating plans.

### **Timeline.**

BPH's plan for opening and operating its retail dispensing locations ("RDL") and production centers ("PC") will utilize the Critical Path Method ("CPM") planning technique widely used by businesses and other enterprises when a project consists, as is the case here, of a number of contingent activities that must be completed, or are substantially completed, before said subsequent activities can start. This approach is essential when a project contains a multitude of disparate but interlocking parts. Using CPM can simplify an otherwise complex web of activities into a cohesive and logical roadmap to achieve the ultimate objective involved. Use of CPM allows BPH to analyze how long this project will take to complete based upon a number of variables and



Application Response: Question 2

to identify which activities are "mission critical" meaning that they must be done on time or the overall project will take longer.

If awarded a dispensary license, BPH will not begin dispensing marijuana and manufactured marijuana products sooner than July 15, 2016. Not less than thirty (30) days prior to producing or manufacturing any marijuana or manufactured marijuana products at BPH's licensed PCs, BPH will submit to Department of Health ("DOH"), the information set forth in HAR §11-850-32 (a) and allow DOH to inspect the premises in order to determine BPH's ability to comply with the requirements of HAR Chapter 11-850 and HRS Chapter 329D. BPH will not commence any cultivation or manufacturing operations within the licensed PC until DOH approves the facility. Not less than sixty (60) days prior to opening a licensed RDL for business, BPH will submit to DOH, the information set forth in HAR §11-850-33(a) and allow DOH to inspect the premise to determine BPH's ability to comply with requirements of HAR Chapter 11-850 and HRS Chapter 329D. BPH's RDLs will not possess or dispense marijuana or manufactured marijuana products until the Department approves BPH's facilities.

BPH will complete and submit an Application for Controlled Substances pursuant to HAR §11-850-22(a). BPH will provide proof of the Narcotics Enforcement Division certificate to DOH within seven (7) days of receiving the certificate and will notify DOH immediately if the certificate is suspended or revoked. BPH will maintain the certificate throughout the licensing period and will renew its certificate upon expiration as required.

BPH's CPM is essential to BPH's objective of striking the right balance between the "race to open" and establishing and maintaining the highest standards of safety for BPH's customers and the public. In this regard, BPH's CPM is infused with the insights and experience HCH has gained as a result of its experience in planning, opening and operating its dispensaries in the State of



### Application Response: Question 2

Colorado with appropriate adjustments based upon considerations regarding Hawai‘i’s medical marijuana (“MM”) patient population and demographics, and Hawai‘i’s unique real estate and labor markets and business regulatory environment. (A copy of BPH's high-level CPM plan, including a timeline for opening a RDL, is attached as "2.1")

### Operations.

BPH will conduct all of its operations according to its Business Plan (See Attachment “2.2”), Financial Plan (See Attachment “2.3”) and written Standard Operating Procedures (“SOPs”); (See Attachment “2.4”; “2.5”; and “2.6”) developed by BPH based, in large measure, on the SOPs successfully developed and utilized by HCH in Colorado with additional input and assistance from one of BPH's outside MM consultants, ACC (see profile attached as "2.7"). ACC has nationwide experience assisting start-up MM dispensaries in the formation of their compliant operations. In addition, BPH's Chief Medical Officer (“CMO”), Chief Horticulture Advisor (“CHA”), other technical advisers and legal team have collaborated with HCH and ACC in developing SOPs to mirror the requirements of Hawai‘i law. These living document will be revised as dictated by operations and regulatory alignments. By using SOPs, BPH will put in place procedures that are a set of step-by-step instructions designed to achieve a predictable, standardized, desired results that can deliver phytopharmaceutical grade MM. SOPs are especially important in industries involving food and drug safety considerations, both of which are of paramount importance here. SOPs specific to certain designated activities of BPH such as: security requirements; criminal background checks; inventory tracking, security and sales; maintaining as confidential customer information; lab testing; compliance with requirements regarding signage, packaging, labeling and chain of custody of products; disposal and destruction



## Application Response: Question 2

of MM; and ensuring product safety in accordance with Hawai'i law are addressed in and are attached to the sections of this application which concern such considerations.

### **Regulatory Compliance.**

BPH will ensure compliance with all state and county laws and regulations, specifically HRS Chapter 329D and HAR Chapter 11-850. BPH will make all books, records, and production and dispensing facilities available to DOH or its authorized representatives for monitoring, audits, and on-site inspections at any time upon request. BPH will only cultivate, manufacture and dispense approved medical marijuana products, in accordance with HAR §11-850-71, §11-850-72 and HRS §329D-10, in an enclosed, secure indoor facility located on Oahu. BPH will not grow marijuana or manufacture marijuana products at any site other than the PCs approved by DOH. BPH will not dispense medical marijuana or manufactured marijuana products from any PC and will only dispense marijuana and manufactured marijuana products to registered patients and primary caregivers from RDLs.

### **Community Plan.**

As an organization, BPH realizes that it will be part of the surrounding community in which it operates. As such, BPH wants to become a valuable and productive member of that community. Safety for its employees and the surrounding communities is of utmost importance to BPH. BPH intends to develop and implement community outreach programs to help enrich the communities it operates in. Such programs and events may include food and clothing drives for local food banks, churches, and other charitable organizations. BPH intends to develop a charitable contribution program that will contribute a percentage (to be determined after six months of operations) of net profit to 501(c)(3) organizations working to strengthen the community. BPH will direct its contributions to areas that BPH believes are important to the future of community development,



## Application Response: Question 2

education, and human services. BPH's first priority is to support programs and organizations whose chief purpose is health and community education.

### **Environmental Impact Plan.**

Conservation and the reduction of BPH's carbon footprint will be a primary objective. 'Reduce, Reuse and Recycle' will be implemented on an organization-wide scale with environmental sustainability being one of BPH's highest priorities. In order to reach this goal, BPH has contracted with designers, engineers, and consultants who will design and utilize energy intelligently, and strive for procedures that minimize waste. Various factors will be thoroughly considered when planning equipment, procedures, and methodology such as: air quality, climate, ecological health, energy efficiency, water quality, transportation, and waste.

### **Good Neighbor Policy.**

BPH is committed to building and maintaining good relationships with all of its neighbors—local business improvement districts, building owners, small businesses, and residents alike. The BPH team shall make every effort to respect our neighbors and to address their concerns. The following steps will ensure any community concerns are addressed: 1) Introduction meetings with all surrounding businesses, building owners, and residents; 2) Educational information sessions to discuss the company's overall mission and goals; 3) Open feedback channels so any new concerns can be immediately addressed through BPH website, telephone, or mail; 4) Complete compliance with all state laws and regulations and county ordinances; 5) Non-obtrusive business practices that ensure BPH's business operates discretely; and 6) Unmarked discrete transportation vehicles. BPH will adhere to the 'Good Neighbor Policy' at all facility locations.

As evidence of our long standing commitment to the communities we operate in we have attached a letter of support from Hawai'i's former governor. (See Attachment "2.8")



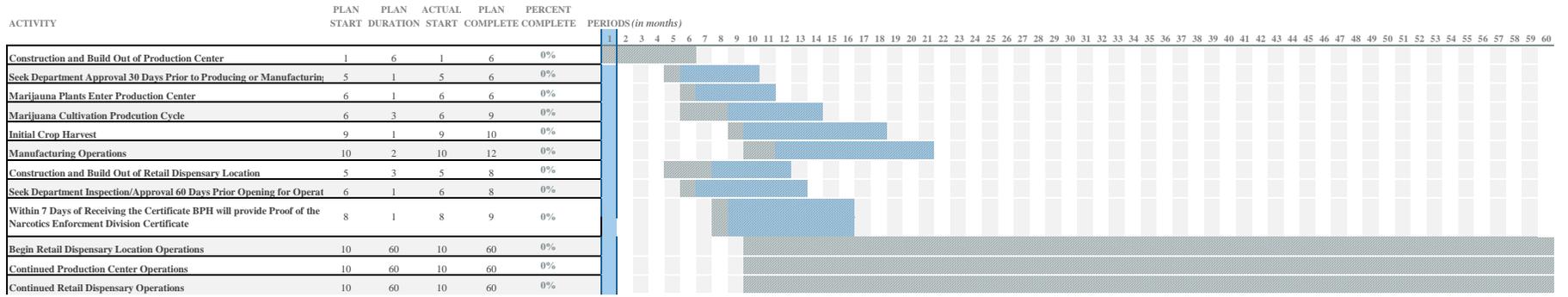
Application Response: Question 2

Attachment 2.1



Blue Planet Healing LLC: *Critical Path Method*

Period Highlight | Plan Actual % Complete Actual (beyond plan) % Complete (beyond plan)





# **BUSINESS PLAN**

Medical Marijuana Cultivation, Manufactured  
Marijuana Products and Retail Dispensing Facilities



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# Executive Summary

## Mission Statement

"To provide relief that Hawai'i patients deserve through the highest quality, sustainable, and responsibly grown medical cannabis."

Hawaii is the most beautiful and pleasant place to live in the US if not the world. The weather is perfect, nature is beautiful, culture is rich, and most importantly; the people live with aloha. Residents of Hawaii know how lucky we are to live in paradise. However, the universe works in mysterious ways, and we do not always get everything we want. Many of us either know of people close to us or are themselves suffering from health issues that prevent them from enjoying their lives, or live in constant pain. Many of these ailments have no known cure or require prescription drugs with devastating side effects. For the first time in history, Hawaii has the opportunity to improve the quality of lives of these with varieties of medicinal marijuana that were researched and developed to provide direct relief to these patients. Blue Planet Healing was formed to provide relief that Hawaii patients deserve through the highest quality, sustainable, and responsibly grown medical marijuana.

Blue Planet Healing, LLC. (BPH) is a family owned local company dedicated to improving the quality of lives of the people of Hawaii. The company is comprised of highly experienced and talented individuals that gathered under the cause of improving the lives of our neighbors. It is an organization that allows them to achieve what they alone can not. These members bring together with them expertise in business, medicine, horticulture, community, sustainability, technology and the medical marijuana industry to create a team that will set the bar in the medical marijuana industry. BPH will create a patient centric medical marijuana dispensary system that brings the most benefit to the patients while being professional and innovative.

BPH along with its consultants, bring the highest quality of products and services to the patients. Colorado has the most mature medical marijuana industry in the United States. BPH's team include a member recognized to produce the highest quality medicinal marijuana and a member recognized to produce the highest quality marijuana manufactured products. Their experience navigating through the constantly evolving industry and regulations will be vital to BPH.

BPH includes in its mission a notion for a sustainable operation. As Marijuana production is such a heavy consumer of electricity, BPH has taken the concept of sustainability and stewardship into its mission. The unique experiences and background in clean energy, software, and other technologies, BPH has the capability to turn this industry from the heaviest of polluters to one of the cleanest.

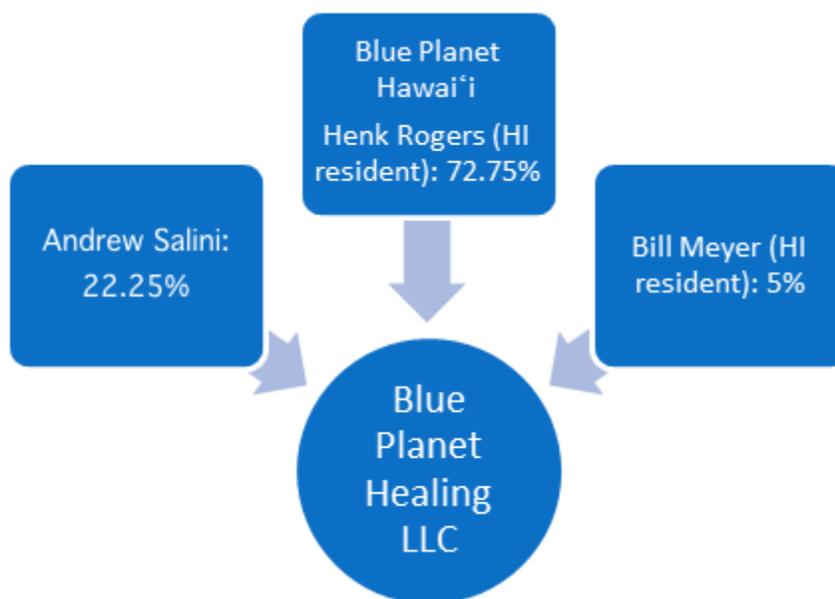


Following the mission with conviction and fortitude, BPH will be the most beneficial operator of a medical marijuana dispensary business for the people of the state of Hawaii and the medical marijuana industry globally.

## Company Profile

Blue Planet Healing, LLC., (“BPH”) a family owned company, and is uniquely qualified to operate a business whose sole mission is to provide, to duly registered patients, in strict compliance with Hawai‘i law, safe and consistent pharmaceutical grade marijuana in the form of unprocessed flower buds and the marijuana infused products permitted pursuant to Hawai‘i Revised Statutes (“HRS”) § 329D-10 and § 11-850-72 of the Hawai‘i Administrative Rules (“HAR”).

BPH is owned by Rogers Medicinals, LLC and High Country Healing Hawaii LLC, and Bill Meyer. The total ownership interest of BPH by Hawai‘i residents is 77.75% as shown below.



In order to accomplish this mission, BPH has assembled a team of highly qualified professionals with long histories and deep roots in the local business, medical, scientific, horticultural, and legal communities. This talented group of individuals comprise the core BPH team and possess vast knowledge and business experience in: regulated industries; horticulture: commercial manufacturing; operating a medical marijuana business which includes experience with retail sales, protecting confidential customer information, secure inventory control and tracking and the utilization of 24-hour security monitoring. BPH’s core team members have the ability and experience required to successfully operate a business. BPH has created this business plan and financial plan (financial pro-forma model) for the guidance, implementation and deployment of its organizational and operational goals and objectives.



BPH's individual applicant, Henk Rogers ("Henk") is an internationally recognized entrepreneur, philanthropist and community leader who was recognized as Hawai'i's 2015 CEO of the Year. A longtime resident of Hawai'i who studied computer science at the University of Hawai'i, Henk has skillfully assembled a dynamic group of individuals with the necessary education, training, skills and real life experience necessary and advisable to start and successfully operate a business that will accomplish the statutory goals of HRS Chapter 329D.

In addition, BPH has unconditional access to all of the necessary financial resources needed to execute its startup and roll out plans.

In addition to Henk, the owners/principals ("Principals") of BPH include Andrew Salini, who is a Princeton University in Economics and Finance and the Chief Operating Officer of High Country Healing ("HCH"), which is one of the first medical marijuana ("MM") dispensaries in the State of Colorado. Andrew will act as BPH's Chief Operations Officer ("COO").

Over the last 6 years, HCH has successfully, cultivated, produced and distributed high quality pharmaceutical grade MM in full compliance with Colorado's laws and regulatory scheme which, among other things, requires: maintaining strict inventory control, tracking and reporting; and protecting confidential customer information. HCH operates three Colorado based MM retail dispensing locations ("RDL"), as that term is defined in HRS § 329D-1, and three recreational marijuana ("RM") stores all under the watchful eye of a comprehensive and effective 24 hour security monitoring system. HCH employs and manages a team of over 57 skilled workers in its operations.

As a result of their development and implementation of a comprehensive financial and business plan, HCH has grown from one RDL and Production Center ("PC"), as that term is defined in HRS § 329D-1, to three (3) RDLs and three (3) RM stores (consisting of ≈9,000 sq. ft.) and three PCs and three (3) RM production centers (consisting of ≈ 35,000 sq. ft.). HCH has obtained high profile recognition within the industry for its quality products and kudos from Colorado's law enforcement community for its exemplary behavior and legal and regulatory compliance. HCH brings extensive knowledge and experience in: regulated industries; horticulture; commercial manufacturing; operating a medical marijuana business which includes experience with retail sales and other relevant experience to BPH for the successful operation of its business.

To further strengthen BPH's operational strategy, BPH has entered into a consulting agreement with UNDRNWMNGMNT, LLC. ("UNM"), an established marijuana product manufacturing-licensing company headquartered in Colorado since 2010. Under its agreement with UNM, BPH will have the exclusive right, in Hawai'i, to manufacture marijuana infused products using UNM's proprietary techniques and processes. UNM will also provide consultation and serve as an advisor to BPH in all aspects of manufacturing marijuana products. UNM licenses its proprietary manufacturing methods, industry experience and compliance services to clients in several states.



UNM specializes in pharmaceutical-grade marijuana extraction, production, formulation, packaging and branding of dosed and tested products for regulated MM markets. UNM has been consistently recognized by dispensaries, physicians and patients for the quality and consistency of the MM products created using their proprietary techniques. MM industry experts have also awarded UNM multiple honors for the quality of their products and approach toward patient education and the safe use of MM.

The other principals of BPH will all bring additional relevant expertise and business acumen to the table.

Maya Rogers Kiyomura ("Maya") will be the CEO of BPH. For the last several years she has helmed Blue Planet Software, one of Hawai'i's most successful high tech companies, through the highly complex and competitive high-tech world with international sophistication and a sense of local pride and style. As co-founder and Partner of Blue Startups, Hawai'i's premier Business Accelerator Organization and a 2015 top 20 US Accelerator, Maya assists and trains promising start-up entrepreneurs to compete on a global scale using a mentor driven model that reaches networks throughout Hawai'i, Asia and Silicon Valley.

BPH's Chief Financial Officer, Kent Otsu, has significant finance experience working for some of Hawai'i's most notable companies and will be the executive responsible for the financial control and planning of BPH. Kent will oversee all financial and accounting functions including: (1) cash control, (2) preparing budgets and financial statements, (3) coordinating financing (4) monitoring expenditures and liquidity, (5) managing tax issues, (6) reporting financial performance to the board, (7) providing timely financial data to the CEO and (8) working with appropriate financial and other government regulators.

BPH's distinguished Board of Advisors includes:

1) Dr. Bradley Willcox M.D., a UH affiliated scientist, researcher and practicing physician who will act as BPH's Chief Medical Advisor ("CMA") and, among other things, provide guidance to BPH regarding the latest credible scientific research involving MM and will act as the Company's information gatekeeper in connection with the preparation and dissemination of medical and scientific information to registered patients as permitted by the Department of Health, State of Hawai'i ("DOH"). Dr. Willcox is an investigator in the area of geriatrics and gerontology at the Pacific Health Research and Education Institute and is a clinical assistant professor in the Department of Geriatric Medicine at the John A. Burns School of Medicine, University of Hawai'i. As his attached profile attests, Dr. Willcox's education, training, background and experience make him particularly well suited to provide scientific and medical guidance to a MM dispensary business. DOH has recently compiled and published information regarding the demographics of the roughly 12,000+ MM patients in the State of Hawai'i. The DOH data indicates that an overwhelming number of these patients use MM to alleviate pain from (their physician certified) debilitating medical condition. Accordingly, it appears that a substantial number of Hawai'i's registered MM patients use MM to treat symptoms associated with many of the chronic diseases that afflict Hawai'i's kūpuna. Dr. Willcox's medical and scientific background nicely fits this



demographic. In addition, the recent expansion of the definition of "debilitating medical condition," for which physicians may prescribe MM, to include "post-traumatic stress disorder" increases the relevance of Dr. Willcox's skill set to BPH's mission.

2) Dr. Andrew Bachman, M.D. is a co-founder of LeafLine Labs, a MM research and manufacturing company located in Minnesota. Dr. Bachman earned his medical degree from Georgetown University School of Medicine and his undergraduate degree in biology from Amherst College and will provide advice and guidance to BPH regarding early stage development of its MM dispensary operations.

3) Greta Inofer, R.N. is a registered nurse with over five years experience in patient case management and care coordination. Under the guidance of Dr. Willcox, Greta will facilitate dissemination of patient information and provide face-to-face patient consultation regarding the safe use of MM.

4) Dr. Marisa Kesaji, Pharm.D. is a graduate of Roosevelt High School (Summa Cum Laude) received her Doctor of Pharmacy from the University of Southern California. Dr. Kesaji will provide advice and guidance to BPH regarding pharmacological issues and working in consultation with BPH's CMO and CHA.

5) Dr. Kenneth Leonhardt, Ph.D., also a UH affiliated scientist, will act as the Company's Chief Horticultural Advisor ("CH") and provide BPH with guidance regarding the best horticultural practices necessary to economically produce quality pharmaceutical grade MM for Hawai'i's patients. Dr. Leonhardt will work closely with BPH's Cultivation Manager.

BPH's Cultivation Manager will be Michael Rogers a graduate in Horticulture Science from the College of Tropical Agriculture at the University of Hawai'i at Mānoa.

Finally, BPH has engaged a team of local business and regulatory attorneys and a nationally recognized cannabis law attorney, Greg Anton, Esq. to provide the legal advice, counsel and guidance necessary to assure that BPH complies with all applicable state laws and regulations and understands the complexities inherent in operating a business that is legal under state law but in violation of the federal Controlled Substances Act (21 USC § 801 et. seq.). Attorney Greg Anton has been a champion of medical cannabis patients for over 35 years; working to help ensure safe access to this valuable medicine. Greg has litigated issues of cannabis law at all levels of State and Federal courts, including the US Supreme Court. (In 2015 he achieved a landmark legal victory with an unprecedented ruling that his client can distribute medical cannabis without Federal interference). Besides working with state and local government officials to develop safe, effective regulations; Greg has provided legal counsel to all aspects of the medical cannabis industry. Greg represents the first licensed medical cannabis dispensary in the United States.

This highly credentialed and competent team possesses the required business savvy and will provide the necessary training, guidance and oversight to the employees, contractors, and vendors of BPH to ensure that BPH is not only successful from a business standpoint but that it sets the standard for excellence in patient care and safety for Hawai'i's registered MM patients.



## Company mission statement

Mission Statement: To provide relief that Hawai'i patients deserve through the highest quality, sustainable, and responsibly grown medical cannabis.

We hold patient safety as number one, and are committed to providing a safe, consistent, high quality medical marijuana to the registered patients. How we will differ from others will be in the care in which the medical marijuana will be grown. Our operating partners, High Country Healing, has won several awards for its quality product. They make up our core team and will be bringing their cultivation expertise. We have also recruited on our team a Chief Horticultural Advisor, an established Ph.D at the University of Hawai'i

## Blue Planet Software

The Tetris brand is one of the leading and most distinctive video game brands and franchises in the world with over 500 million mobile downloads, and over a billion games played online per year. In the game's 31 year history, Tetris has partnered with the likes of Electronic Arts, Ubisoft, Sega and Hasbro and continues to be one of the most widely recognized video games of all time.

Some other interesting facts of Tetris:

- Tetris is played in more than 185 countries
- Tetris has been translated into more than 50 languages
- Tetris has been released on over 50 platforms
- Over 35 million units of Tetris were sold for the original Game Boy platform
- More than 23 billion games of Tetris Battle on Facebook have been played to date, making it one of the social platform's most popular games
- Hundreds of millions of Tetris products have been sold around the world.

Blue Planet Software, Inc. (BPS), the sole Agent for Tetris, was established in Hawaii 20 years ago. Currently, with a dozen employees all based in downtown Honolulu, BPS continues to develop the Tetris brand identity that millions of fans have grown to love. As its sole agent, BPS delivers brand consistency and represents Tetris in all licensing relationships including the following:

- Product ideation
- Product quality assurance and approvals
- Promotional and public relations support
- Global Intellectual property protection

For more information, visit [www.tetris.com](http://www.tetris.com)

## Blue Planet Energy Systems



Founded in 2015, Blue Planet Energy Systems is a Honolulu based energy storage company. Working in partnership with Sony, Blue Planet Energy has created the “Blue Ion” solution which combines solar, energy storage and an energy efficiency management software to help homes and businesses become energy self-sufficient. Blue Ion is used to help homes and business maximize renewable energy, shift energy from low energy periods to peak periods and provide standby power protecting against black-outs.

Henk Rogers provided the vision and inspiration behind Blue Planet Energy Systems. In his Hawai‘i homes, Henk installed solar panels and reduced his energy consumption with efficient lighting and electric vehicles but after doing so he felt there was more that could be done. So he began exploring different battery technologies by purchasing and installing different options. In Sony he found a technology that was safe, powerful and cool.

He struck a relationship with Sony’s corporate leadership and negotiated an exclusive relationship to resell Sony’s industry leading and proprietary Fortelion™ chemistry.

Today Blue Planet Energy is one of the leaders in Energy Storage with its Blue Ion systems deployed in homes, commercial facilities in Hawai‘i and California.

For more information, visit [www.blueplanetenergy.com](http://www.blueplanetenergy.com)

## **Blue Startups**

Blue Startups is a Honolulu-based venture accelerator founded by Henk Rogers and Maya Rogers Kiyomura. Blue Startups invests and provides hands-on mentorship to capital-efficient and scalable-technology companies, including Internet, software, mobile, gaming and e-commerce. Blue Startups is a nexus of entrepreneurial activity not only in Hawai‘i, but also between Asia and the Continental U.S.

Blue Startups concentrates on helping scalable-technology companies including web, software, mobile, gaming and e-commerce compete on a global scale. A member of the Global Accelerator Network, Blue Startups follows the Techstars mentor-driven accelerator model, reaching networks in Hawai‘i, Asia and the Silicon Valley.

Blue Startups has a network of more than 80 mentors reaching from Hawaii and Japan to Silicon Valley. The interaction of mentors with teams will assist in developing Hawai‘i as a node of entrepreneurship by bringing in expertise, capital and other resources from across the Pacific. Our premise is that people make innovation happen, that growth follows effective execution, and that sustained success will require access to global resources.

Blue Startups has 50 companies in its portfolio to date, has deployed over \$1 million dollars in funding, and the companies have gone on to raising over \$25 million in follow-on funding. Over 75% of the companies have received outside capital, and the average raise of each graduate company is \$500,000. Today, Blue Startups is ranked as top 20 accelerators in the U.S. as ranked by TechCrunch.



For more information, visit: [www.bluestartups.com](http://www.bluestartups.com).

## **Blue Planet Foundation**

Henk founded the Blue Planet Foundation in 2007 as a 501(c)(3) nonprofit organization. Blue Planet Foundation's mission is to clear the path for 100% clean energy, starting in Hawaii. Blue Planet Foundation's vision is a world powered by abundant renewable energy that sustains all life on Earth. The Foundation focuses on implementing transformative clean energy policy and developing innovative and scalable energy engagement programs by directing its efforts in three areas of change: (1) encouraging leaders to make policy changes that accelerate cost-effective, secure, renewable energy; (2) engaging communities through smart, replicable renewable energy and energy efficiency solutions; and (3) inspiring everyone, through creative communications, to believe in the power and possibility of a future beyond fossil fuels. By leveraging activities in these three programmatic areas of advocacy, action, and awareness, Blue Planet Foundation is making meaningful change on an issue that touches every aspect of our lives and economy.

### *Advocacy*

Blue Planet Foundation's advocacy work seeks to implement innovative legislative and regulatory policy solutions to remove barriers and accelerate the transition to 100% clean energy. The Foundation advocates at the state legislature and Public Utilities Commission and acts as a resource at conferences and in working groups like the Hawaii Clean Energy Initiative. Blue Planet Foundation also convenes world renowned experts to help decision leaders make smart policy choices. In 2015, Blue Planet Foundation led the campaign to pass the nation's first 100% renewable energy requirement, as well as a community renewables bill that could dramatically increase access to renewable power.

### *Action*

Blue Planet Foundation's action programs provide tools to the community to control their energy consumption and allow them to support renewable energy. A clear example of this is the Foundation's WEfficiency crowdfunding program. Since its launch in 2014, WEfficiency has enabled individuals to fund projects that will displace 200,000 gallons of oil, avoid 5 million pounds of carbon pollution, and save local nonprofits \$1.2 million. Nonprofits such as YWCA, Damien Memorial School, Boys & Girls Club, and others have used WEfficiency to decrease their carbon footprints while increasing their capacities to serve our community.

### *Awareness*

Blue Planet Foundation's awareness initiatives engage communities in a new conversation about energy, helping to build understanding about the damage caused by fossil fuels and the solutions available through renewable energy and smarter energy use. Blue Planet Foundation tracks Hawaii's progress toward 100% clean energy with its Energy Report Card, published annually in print and online. Developed to inform decision leaders and the public, the report evaluates the annual progress in five categories of energy transformation: transportation, efficiency,



renewables, smart grid, and economics. Blue Planet Foundation also increases awareness through its Island Pulse kiosks. The kiosks help make the invisible, visible, by providing a real-time breakdown of our energy use as well as the sources of that energy (solar, wind, coal, etc.). The Island Pulse was developed in partnership with Hawaiian Electric, who provided the energy data for the first time publicly.

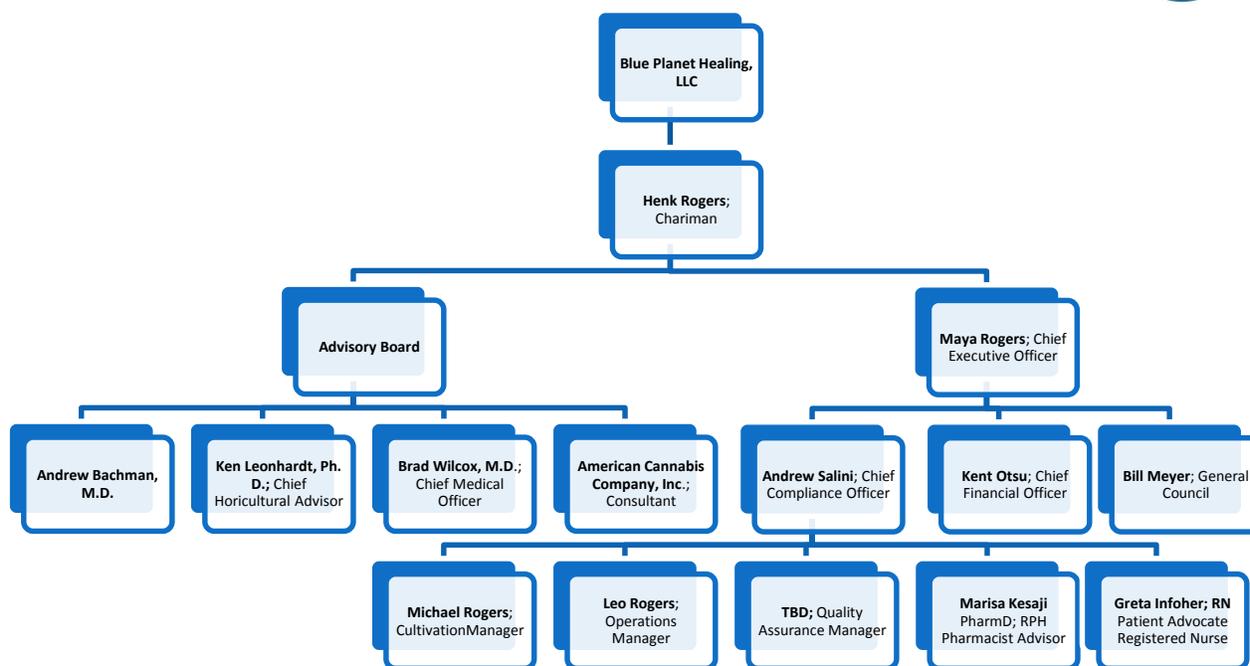
Although distinct, Blue Planet Foundation's three programmatic approaches are implemented synergistically with activities in each approach reinforcing the others. By addressing community needs in each category, Blue Planet Foundation is the leader that is unifying Hawaii's transformation to 100% clean energy with precision and determination.

BPH will operate a Dispensary Facilities (as that term is defined to include cultivation, processing/manufacturing and dispensing marijuana and manufactured marijuana products in full legal compliance with the State of Hawai'i. BPH will cultivate, manufacture and dispense marijuana and manufactured marijuana products for dispensing to qualifying and registered medical marijuana patients in the State of Hawai'i. BPH will ensure compliance with all applicable state and county law and regulations while becoming a valuable member of the business community and surrounding areas.

BPH's focus will be on cultivating the highest quality medical marijuana for the Hawai'ian medical marijuana industry and to operate safe, patient-friendly retail dispensing locations. Through the use of established industry best practices pertaining to the cultivation of marijuana and manufacturing of marijuana products, BPH will cultivate and manufacture high quality marijuana and manufactured marijuana products at the registered dispensary facilities. BPH will cultivate all marijuana on the registered production facility utilizing various cultivation techniques and methodologies including True Living Organics (TLO), Integrated Pest Management (IPM), sustainable and environmentally friendly operations and other programs and policies to ensure compliance with state law. The BPH registered dispensary premises will be within a structure to prevent unauthorized entry and ensure no activities or operations can be seen or viewed from the exterior of the facility BPH will also manufacture marijuana products of the highest quality, including oils and oil extracts, capsules, lozenges, pills, tinctures, ointments, and skin lotions. The patient-centric retail dispensing operations will focus on patient accessibility and safety and be conducted according to all state and county law.

For more information, visit [www.blueplanetfoundation.org](http://www.blueplanetfoundation.org)

## **Management and Organization** **Organizational Hierarchy Chart**



## Blue Planet Healing Organizational Members

### **Henk B. Rogers** – *Sole Applicant, Chairman & Spokesperson*

Considered one of the visionaries of computer games, Henk Rogers helped change the face of the industry as the entrepreneur responsible for bringing the Tetris® game to the United States and world market. Under Henk’s direct leadership, the Tetris game has become one of the world’s top-selling video game brands with hundreds of millions of products sold, and after 30 years since its “birth,” that number is still growing. Today Rogers serves as Managing Director of The Tetris Company, the exclusive licensor of the Tetris brand and Chairman of Blue Planet Software, the sole agent for the Tetris franchise, founder of Blue Planet Foundation, a nonprofit clean energy advocate, and founder of Blue Startups, Hawai’i’s first venture accelerator.

A heart attack in 2005 gave Henk the opportunity to rethink the rest of his life and reevaluate the purpose of his life’s work. Henk is determined to end the use of carbon-based fuel on the planet, starting with fossil fuel use in Hawai’i, his adopted home. To fulfill his mission, Henk established Blue Planet Foundation, which has become the frontline organization in the fight for indigenous renewable energy in Hawai’i. As Blue Planet Foundation’s principal and visionary philanthropist, Henk Rogers is committed to the mission of stewarding the environment through developing non-carbon, clean energy sources. He is personally devoted to helping our planet reduce and eventually eliminate its dependence on fossil fuels.

Furthermore in 2015, Henk founded Blue Planet Energy Systems, becoming a leader in energy storage solution systems home and commercial usage.

Henk’s community recognitions include:



- 2015 – Hawai‘i Business Magazine, CEO of the Year
- 2015 – Honorary Doctorate of Human Letters, University of Hawai‘i
- 2014 – Hawai‘i Institute for Public Affairs (HIPA) Ho‘ulu Award
- 2013 – Hawai‘i Business News Business Leadership Award Finalist
- 2011 – Hawai‘i Business Innovation Showcase “City & Council of Honolulu” Finalist
- 2010 – Hawai‘i Business Magazine “Five for Today” leadership recognition
- 2009 – Hawai‘i Venture Capital Association “Entrepreneur of the Year”
- 2008 – Hawai‘i Venture Capital Association “Venture Capital Deal of the Year” Honorable Mention – Avatar Reality

Henk currently sits on the board of East West Center Foundation, is the Chairman of Science Engineering Expo - Innovation Technologies (Chairman, SEE-IT), as well as the Chairman of Pacific International Space Center Exploration Systems (PISCES).

**Other Affiliations:**

Honorary Consul of Netherlands, Waialae Country Club, Waikiki Yacht Club, Honolulu Club, Sunrise Rotary, University of Hawai‘i, College of Engineering Dean’s Advisory Council, Plaza Club.

**Personal:**

Rogers and his wife Akemi currently share their time between residences in Honolulu and Kailua-Kona, Hawai‘i. They have four children: Maya, Julie, Michael and Leonard.

In his spare time, Rogers is an avid photographer, world traveler, and designer, and he enjoys playing squash and golf.

**Maya Rogers Kiyomura – Chief Executive Officer**

Maya Rogers Kiyomura is President and CEO of Blue Planet Software, the sole agent for the Tetris® brand. With a history that spans more than 30 years, Tetris is one of the leading and most distinctive video game brands and franchises in the world. Rogers has spent the last eight years leading the Tetris brand’s worldwide business initiatives, including and more than 12 years in the video game industry in Japan, China and the U.S. Prior to Tetris, Rogers steered cross culturalization and development efforts with Sony Computer Entertainment America and American Honda.

In 2012, Maya co-founded Blue Startups, Hawai‘i’s first venture accelerator that helps early stage startups with investments and mentoring. Fifty companies have gone through the Blue Startups program and received capital from the Blue Ventures Fund, and have attracted approximately \$25



million in funding. In March 2015, Blue Startups placed #17 in TechCrunch's annual ranking of top US accelerators.

Prior to Tetris, Maya held management roles with Sony Computer Entertainment America, where she steered localization efforts for games such as the Gran Turismo and Hot Shots Golf franchises. Rogers began her career working with cars at American Honda before making the switch over to working on virtual cars at SCEA.

Maya is a board member with the American Red Cross Hawai'i Chapter, and is a member of the Tiffany Circle Society of Women Leaders, a national Red Cross program comprised of women leaders and philanthropists who dedicate their time and talents to support community Red Cross efforts. Rogers also serves as a member of the advancement committee and advisory board of the Smithsonian Asian Pacific American Center. She is also actively involved in eGlobal Family, an organization that links orphaned and vulnerable children in developing countries to compassionate and responsible supporters. The Rogers family is also a proud member of the Family Business Center of Hawaii, part of the Pacific Asian Center for Entrepreneurship at UH Manoa Shidler College of Business.

In March 2015, Maya was awarded "20 for the Next 20" recognition by Hawai'i Business Magazine as one of 20 emerging leaders who have made major contributions to the state of Hawai'i, and are expected to have a significant impact on the state over the next two decades. In 2016, Pacific Business News honored Maya with the Women to Watch recognition.

Maya currently is involved with the State of Hawaii's Workforce Development task force, which is tasked to come up with plans to increase jobs under the Workforce Investment and Opportunity Act (WIOA), passed by signed into law in 2014. She also is working with the Chamber of Commerce Economic Development and Innovation Committee to provide advice from the entrepreneurial community.

Maya grew up in Japan and the US, and currently resides in Hawai'i. She holds a B.S. in Business Administration and an MBA from Pepperdine University.

**Kent Otsu** – *Chief Financial Officer*

Kent Otsu is Chief Financial Officer (CFO) of Blue Planet Software (BPS), the sole agent for the iconic video game Tetris. As CFO, he oversees all administrative and financial matters for BPS including accounting, tax reporting and compliance, and budgeting. In addition, Kent oversees legal and human resources for BPS. Kent and his team also provide similar services to all companies under the direction of Henk Rogers which include Blue Startups, a nationally-recognized accelerator, and Blue Planet Foundation, a non-profit organization dedicated to end the use of carbon-based fuels in Hawai'i.

Prior to working at BPS, Kent worked for KPMG in Honolulu where he worked on financial audits of electric utilities, healthcare and real estate entities, and he earned his Certificate of Public Accounting at this time. He then spent 12 years as Controller for LVMH Fashion Group Hawai'i, whose brands include Louis Vuitton, Celine and Fendi. His responsibilities included producing financial statements in accordance with GAAP and IFRS, income tax reporting and compliance,



and overseeing all audits including State Income Tax, General Excise Tax, Department of Labor, Internal Revenue Service and US Customs. In addition, Kent was responsible for creating and maintaining internal controls over cash and inventory, which included procedures around the point-of-sale, and inventory receiving, transferring, and physical counts.

Kent graduated from Iolani School, and then attended University of Colorado - Boulder where he earned a Bachelor of Science in Accounting. Today, Kent enjoys spending his free time with Debbie, his wife of 21 years, and his daughters Jessica and Deanna. He also enjoys an occasional round of golf, and supporting his alma mater, Iolani School.

**Andrew Salini – Chief Compliance Officer & Chief Operations Officer**

Andrew Salini has acted as the Chief Operations Officer & Chief Strategist at High Country Healing's Retail & Cultivation Facilities from 2014 to present. Andrew's management experiences include HCH operations, retail/cultivation/financial strategy and analytics, as well as brand and business development. Formerly, Andrew was the Chief Strategist at EMF Fixed Income Fund from 2011-2014, specializing in fixed income relative value arbitrage. He was also previously an Associate at Credit Suisse in the Fixed Income Division of the investment bank from 2010-2011 and began his career at Deutsche Bank Securities where he was an Associate Proprietary Trader and Portfolio Manager in the [Global Finance & Foreign Exchange Division](#) from 2006 to 2009.

Andrew received an A.B. in Economics, a Certificate in Finance, and a Certificate in French Language & Culture from Princeton University in 2006. He is an academic All-American in Baseball and is Princeton Baseball's All-time hits leader, 3-time Ivy League Champion and a 2002 Graduate of Phillips Academy in Andover, MA.

**William G. Meyer, III – General Council**

Mr. Meyer began practicing business law in Hawai'i in 1979. His practice emphasizes intellectual property law (including copyright, trademark and right of publicity licensing and registration, entertainment, trade secret, art and advertising matters); government relations; real estate matters; and related dispute resolution including litigation, arbitration and mediation.

For more than three decades, Mr. Meyer has provided creative legal and business guidance to a broad spectrum of individuals, companies and educational institutions, both in Hawai'i and on the mainland, including intellectual property owners, licensors and licensees such as artists, writers, photographers, television and film producers, composers, software and game developers, publishers, advertisers, broadcasters, art gallery owners, entertainers, recording artists, musicians, record labels, architects, scientists, apparel designers and merchandisers. Mr. Meyer's clients have included the University of Hawai'i at Mānoa, the University of Hawai'i at Hilo, national and international entertainment companies and many of Hawai'i's top recording artists, record labels and filmmakers.

Mr. Meyer's government relations work has promoted the diversification of Hawai'i's economy through the adoption of legislation which has enhanced the development of the creative and high tech industries. Mr. Meyer's real estate related practice has focused on the resolution of complex



disputes involving real estate development and sales transactions, land use, eminent domain, construction defects, government bid disputes and real estate broker issues.

Mr. Meyer has taught at the William S. Richardson School of Law, University of Hawai`i at Mānoa; the Pacific New Media Workshop, University of Hawai`i at Mānoa; and the Hawai`i Music Institute at Windward Community College and served as a court appointed mediator for the United States District Court for the District of Hawai`i in connection with intellectual property issues. Mr. Meyer is past Chair of the Intellectual Property & Technology Section of the Hawai`i State Bar Association, and a frequent speaker on intellectual property, music, art, advertising, e-commerce and Internet law topics, and has authored numerous articles and other materials on these topics, including continuing legal education materials for the Hawai`i State Bar Association and other organizations and publishers. Mr. Meyer was selected for inclusion in the 2008, 2009, 2010, 2011, 2012, 2013, 2014 and 2015 “Hawai`i Super Lawyers” in intellectual property and is peer review rated “AV” (preeminent) by Martindale-Hubbell, the highest rating available for legal ability and professional ethics.

Mr. Meyer is active in community organizations dedicated to the promotion of literacy, the preservation of Hawai`i’s host culture and the arts, devotes time to a pro bono practice which assists creative individuals with their legal and business issues and mentors young lawyers interested in the creative industries. Mr. Meyer has served on the Board of Governors of the Hawai`i Academy of Recording Arts, a Hawai`i non-profit organization, which each year presents the “Nā Hōkū Hanohano Awards” (which is similar to the Grammy® Awards and recognizes outstanding achievement in the recording arts in the State of Hawai`i) and the annual Lifetime Achievement Awards (which honors those who have made significant contributions to the music, culture and related arts of Hawai`i and/or the host culture of Hawai`i). See <[www.nahokuhanohano.org](http://www.nahokuhanohano.org)>. Mr. Meyer also serves on the Board of the Kaua`i Music Festival, the oldest and largest songwriters conference in the State of Hawai`i (see <[www.kauaimusicfestival.com](http://www.kauaimusicfestival.com)>) and acts as special counsel to the Hawai`i International Film Festival.

#### **Michael Rogers—*Cultivation Manager***

Michael Rogers holds a deep passion for sustainability and human welfare from his former career running an international gemstone trading business. Michael spent much time in the bush of Africa and Madagascar creating deep relationships with the poorest people of the world learning firsthand about the lives and woes of the “bottom billion”, at which point Michael made a decision to study sustainable agriculture and community development to improve people’s lives. Michael folded his business and attended the University of Hawai`i at Mānoa where he earned a degree in Plant Production and Management from the department of Tropical Plants and Soil Sciences in the College of Tropical Agriculture and Human Resources (CTAHR). During his time at the university, Michael was highly active in extracurricular activities being the president of the Horticultural Society, publishing articles regarding genetics and plant disease management, and creating a community composting facility with forced aeration to accelerate the composting process.

He is a certified permacultural designer and has work experience at a modern 2,500 acre farm where he was responsible for irrigation management, soil conservation projects, native plant



landscaping, plant disease management, and tractor operation. Currently, Michael serves on the board of advisors for Kumuola Foundation, a local non-profit organization based on a farm in the rainforests of Mānoa whose mission is to promote sustainable island living through agriculture, community, education, and practice of Hawai‘ian arts. Michael has a deep understanding of Hawai‘ian culture having a long history of dancing hula and receiving honors at the Merrie Monarch Hula Festival.

**Leo Rogers—Operations Manager**

Leo Rogers is a graduate of Roosevelt High School, and attended the University of Hawaii where he studied Kinesiology and Rehab Science. Being fully bilingual, Rogers spent 8 years working in the hospitality industry in various positions working both as a front-end and a back-end operator. He now works for Blue Planet Software as a project coordinator where he manages various projects including, digital assets, events, websites, and so on. His education, multi-cultural background, and years of experience working with customers, allows him to operate while having the medical patients best interest in mind.

**Advisory Board Members**

**Ken W. Leonhardt, Ph. D**

Ken has considerable experience in plant breeding, having created and introduced over 100 new varieties to Hawai‘i growers. Ken’s professional research focus is on polyploidy induction and creating sterility (seedless clones). Tetraploid forms of 22 species have been created. Only 2 other labs in the US focus on this kind of research (Dr. Ranney at North Carolina State U, and Dr. Contreas at Oregon State U). Tetraploid forms of Marijuana will have higher concentrations of CBDs and THC’s.

Ken has familiarity with all sectors of agribusiness in Hawai‘i for 43 years and has acted as a crop science educator for the past 39 years. He was the owner/operator of a commercial ornamental plant nursery for 13 years (1975-1988).

As Chairman of the undergraduate program at the UH department of Tropical Plant and Soil Sciences, Ken is familiar with the top graduates, thus when BPH is looking to hire technicians with a crop science background, Ken will be able to source the top candidates. Ken also sits on the board of advisors for Medical & Product Testing – Hawai‘i MDs.

**Bradley J. Willcox, MD, M.Sc**

Bradley J. Willcox M.D., M.Sc. trained in Medicine at the University of Toronto, Internal Medicine at the Mayo Clinic, and Geriatric Medicine at Harvard Medical School. Dr. Willcox is Principal Investigator of the National Institute on Aging-funded Kuakini Hawai‘i Lifespan Study and Kuakini Hawai‘i Healthspan Study, which are ancillary studies on aging from the Kuakini Honolulu Heart Program. He is also Professor and Director of Research at the Department of Geriatric Medicine, John A. Burns School of Medicine, University of Hawai‘i, located on the Kuakini Health System campus. Dr. Willcox is the Co-Principal Investigator of the Okinawa Centenarian Study and has been investigating mechanisms of aging for almost two decades with this study. Clinically, he runs the Long Term Care Hospitalist Program at The Queen’s Medical Center, where he is a three time nominee for Physician of the Year.



Dr. Willcox’s research teams have identified several important genetic and environmental risk factors for aging and aging-related chronic diseases. His research team in Okinawa identified the first longevity-associated gene, and his research team in Hawai’i was the first to identify the association of the FOXO3 gene with human longevity and he has greater than 150 peer-reviewed scientific publications.

Dr. Willcox is on the Editorial Board of several leading gerontological journals, including the Journals of Gerontology. He has been recognized with a Dorothy Dillon Eweson Award for Advances in Aging Research, the Henry Christian Award from the American Federation for Medical Research, a Director’s Citation from the Centers for Medicare and Medicaid Services, and other honors. Dr. Willcox is also the author of a New York Times best-selling book on healthy aging, *The Okinawa Program*. His work has appeared in cover articles of *Time Magazine*, *National Geographic*, and on *Oprah*, *Good Morning America*, *NOVA Science*, *BBC*, and other media.

## **Consultants**



### **American Cannabis Company, Inc. (“ACC”) Company Profile**

BPH has hired and retained American Cannabis Company, Inc. (“ACC”), a marijuana-industry consulting firm that offers advisory and consultation services related to establishing operations, the implementation and execution of the operating plan, staff training, compliance, and other critical operational needs. ACC collectively brings over twenty years of knowledge and practice operating within the regulated, legal medical marijuana industry. The company has particular expertise in marijuana cultivation methods on a commercial scale and manufactures multiple industry-specific cultivation and retail solutions. As BPH’s consulting partner, ACC will help ensure that BPH has the knowledge and expertise necessary to establish compliant operations rapidly while achieving its quality goals for the brands it produces for qualifying patients in the State of Hawai’i.

### **Executive Summary**

- Based in Denver, Colorado
- Consult, advise, & provide equipment and supplies to businesses entering or currently operating in *regulated* cannabis industries
- Currently serve clients in 14 states & Canada
- Have assisted clients in winning 10+ licenses in 5 five states
  - Business & operational plans, pro-forma, market study, & application
  - Facility design, equipment selection, & construction management
  - Facility roll-out, employee training, & on-going cultivation management
  - On-going retail, operational, & compliance monitoring

### **Industry Successes**



American Cannabis Company					Cumulative
Year	State	W	L	Total	Client W %
2013	Connecticut	1	0	1	100%
2013	Massachusetts	1	2	3	50%
2014	Nevada	6	1	7	73%
2014	Minnesota	1	0	1	75%
2014	Illinois	2	4	6	61%
<b>Total</b>		<b>11</b>	<b>7</b>	<b>17</b>	<b>61%</b>

### **ACC Vision**

We are redefining society's relationship with cannabis through responsible stewardship.

### **ACC Mission Statement**

With our expert teams we establish and service regulated cannabis markets globally providing best in industry solutions that continue to exceed the requirements of the evolving cannabis industry thus ensuring our client's success through superior service and deep industry knowledge.

### **ACC Core Values**

1. Accountability & Professionalism
2. Integrity
3. Open, Transparent, & Respectful Communication
4. Passionate Teamwork
5. Sustainability

### **About The American Cannabis Company**

American Cannabis Company (ACC) was founded to meet the needs of the rapidly developing cannabis industry, including: medical, commercial and industrial hemp operators. We are experienced in cultivation, infused products and retail operations within regulated cannabis markets, as well as, establishing successful companies within the emerging limited licenses markets. From merit based applications, to facility design and deployment, to managing ongoing operations ACC has the experience and expertise to guide your business in the competitive cannabis space. Currently, we've operated in nine states and in the country of Canada. Our company focuses on providing services and products to the cannabis industry through our two operating divisions:



### **Company Ownership & Legal Entity**

American Cannabis Company, Inc. is a Delaware corporation with its headquarters in Denver, Colorado. ACC Inc. is a public company and trades under the stock ticker AMMJ on the OTCQB stock exchange.

### **Services, Equipment & Supplies**

Through its two divisions American Cannabis Consulting and The Trade Winds, American Cannabis Company provides its customers a full solution for success. From bringing your idea to a reality to ensuring it performs beyond expectation, ACC has the people, partners and products to ensure success.

### **ACC Services**

American Cannabis Consulting is the premier advisory agency for those seeking to achieve success in the highly competitive and rapidly expanding commercial cannabis industry.

Whether you're preparing to enter the market or already have a footprint, our team of industry leaders can help your business reach its potential while meeting the necessary regulatory framework. With first-hand experience in regulated commercial Cannabis cultivation since 2009 and backed by accomplishments in related industries such as healthcare and horticulture, we have the knowledge and resources to guide you through every aspect of growing your Cannabis business.

### **Cannabis Industry Research & Design**

Our knowledgeable team identifies needs in the marketplace and develops next generation products to fill those needs. Our in-house products include:



- The Cultivation Cube™: The foundation for a complete, commercial-scale grow operation, the Cultivation Cube provides exceptional environmental control, speed-to-market, production, space efficiency, lean manufacturing and security.



- SoHum Living Soil™: A 100% natural growing medium, SoHum Soil prevents an improper balance of nutrients, improves plant immunity, and is more cost-effective than traditional soil and fertilizer growth methods.



- The Satchel™: The Satchel is a pouch-like case for Cannabis and Cannabis-infused products that was designed to meet regulatory compliance with laws that require child-resistant exit packaging for licensed medicinal and recreational Cannabis businesses.

## **ACC Equipment & Supplies**

From cultivation necessities to retail goods to ancillary products like office supplies and cleaning agents, The Trade Winds can address your business' needs quickly and cost-effectively. The products we carry are carefully selected by our professionals and represent best-in-class solutions for the developing commercial cannabis markets. We continue to strive to realize solutions that improve our Client's business operations.

American Cannabis Company is proud to offer compliant, solution-based products and services to commercial cannabis cultivation and cannabis retail businesses.

## **ACC Management Consulting**

With hands-on experience in commercial cannabis cultivation, the team at American Cannabis Company has the knowledge and resources to help your crop and your business realize their potential. From Cultivation, through processing and into retail sales, our team has firsthand knowledge and experience.

Our goal is to lead you through a successful development and launch process, and to work with you to help your cultivation business grow into the future. As part of the design and build out of your business, our advisory services will focus on key elements that include:

- Business and operational plan
- Pro-forma financials
- Business plan writing
- Standard operating procedures



- Protocol based workflow
- Retail Strategies
- Retail Operations
- Regulatory compliance
- Market modeling and forecasting
- Security and safety measures
- Equipment and technology purchasing
- Quality control
- Direct staffing and/or recruitment and training
- Facility design and build-out
- Construction Management
- Patient centric strain selection
- Methodology selection
- Perpetual harvest and workflow requirements to meet patient demand
- Environmental controls
- Integrated pest management

**Andrew W. Bachman, MD, FACEP**



**LeafLine Labs, LLC, cultivates, processes, and distributes medical cannabis formulations in Minnesota.**

Founded in 2014 by Board-Certified Emergency Medicine physician, Andrew Bachman, MD, and his team, LeafLine Labs, LLC, is registered to cultivate, process, and distribute medical cannabis formulations in Minnesota’s “extraction-only” medical program. It provides expertly-crafted medicine and compassionate care for suffering patients with currently approved conditions such as cancer with specified complications, glaucoma, HIV/AIDS, Tourette’s Syndrome, ALS, Intractable Seizure Disorders, Muscle Spastic Conditions (e.g., Multiple Sclerosis), Crohn’s Disease, Terminal Illness, and Intractable Pain.

LeafLine Labs actively cultivates dozens of selected medical cannabis strains in a specifically-designed and newly-constructed 42,000 SF pharmaceutical-grade facility, ideally situated on 24 acres, optimized for plant health, production, sustainability and reproducibility. All medicinal compounds are then efficiently separated from the fibrous plant material using industry-leading scientific techniques and technology by our medically-experienced extraction team, which allows for innovative medicine formulation with NO harsh diluents, additives or toxic solvents employed.

Every lot of “whole plant extract” medicine is rigorously tested for chemical composition, potential contamination, consistency and purity at one of only two independent, state-sanctioned



and regulated laboratories in Minnesota. Our medication formulations contain standardized, proprietary cannabinoid profiles, including set ratios of CBD, THC, etc., that aid in the treatment of a variety of medical conditions and ameliorate a variety of medical symptoms for Minnesota’s suffering patients with qualifying conditions. The final preparations are then clearly packaged as capsules, oils for vaporization, syrups & suspensions, tinctures, and sublingual sprays, and labelled accordingly to pharmaceutical-grade specifications.

LeafLine Labs’ Headquarters and primary production facility is located in the Minneapolis/St. Paul suburb of Cottage Grove, MN, with our flagship cannabis care center opened in Eagan, MN, on July 1, 2015. A care center in St. Cloud, MN, (in close proximity to one of the nation’s largest V.A. Hospitals) is nearing completion presently, with subsequent care centers in St. Paul and Hibbing, MN, slated to open by July 1, 2016. LeafLine Labs is well-supported & well-capitalized with nearly \$16M raised through vetted and approved investors to date, many of whom are physicians and/or professional caregivers in Minnesota and beyond.

#### **Marisa Kesaji** - Pharmacist Consultant

Marisa Kesaji, a graduate of Roosevelt High School (Summa Cum Laude) received her Doctor of Pharmacy (PharmD) degree from the University of Southern California. Kesaji has extensive experience as a registered pharmacist in both Hawai‘i and California. Being a former Chief Pharmacist, she will be able to help develop policies and procedures to ensure safety and monitoring of products.

#### **Greta Inofer, R.N.** – Patient Advocacy Nurse

With over 5 years of experience as registered nurse, Greta’s brings with her expertise in case management, care coordinating, private practice clinic, skilled nursing, and dermatology. She currently works as a registered nurse as a case manager, facilitating face-to-face patient visits to ensure that their current medicinal needs are met. As a health and wellness coach, Great also bring her skills to work with individuals on how to be healthier mentally and physically through proper nutrition and functional fitness. Prior to this, Greta managed administrative operations at a care home, maintaining 26 staff members at a 24 bed facility. It was there where she established and implemented care protocol ensuring all regulations were met. Greta is recognized as an excellent team leader and problem solver with expertise in health and wellness, quality, utilization, and risk management. Greta is a member of the American Cannabis Nurses Association, the only nursing educational and advocacy organization representing endocannabinoid therapeutics in the United States.

#### **Licensing Agreements**

To further strengthen BPH’s operational strategy, BPH has entered into an agreement with UNDRNWMNGMNT, LLC. (“UNM”), an established marijuana product manufacturing-licensing company headquartered in Colorado since 2010. Under its agreement with UNM, BPH will have the exclusive right, in Hawai‘i, to manufacture marijuana infused products using UNM’s proprietary techniques and processes. UNM will also provide consultation and serve as an advisor to BPH in all aspects of manufacturing marijuana products. UNM licenses its proprietary manufacturing methods, industry experience and compliance services to clients in several states. UNM specializes in pharmaceutical-grade marijuana extraction, production, formulation,



packaging and branding of dosed and tested products for regulated MM markets. UNM has been consistently recognized by dispensaries, physicians and patients for the quality and consistency of the MM products created using their proprietary techniques. MM industry experts have also awarded UNM multiple honors for the quality of their products and approach toward patient education and the safe use of MM.

UNM currently operates within Colorado's legal marijuana industry and will provide deep industry knowledge and experience to BPH upon deployment of BPH manufacturing operations. BPH will utilize established standard operating procedures, extraction methods, and recipes for the manufacturing of all marijuana products.

### **Mission Statement**

To provide relief that Hawai'i patients deserve through high quality, sustainable, and responsibly grown medical cannabis.

### **Goals and Objectives**

In order to fulfill the mission statement, BPH has a set of goals and objectives that guide the business.

1. Develop a dispensary environment that gives the most access and relief to the patients
  - a. Dispensary shall be located in a location with ample parking at a central location
  - b. Dispensary shall have a welcoming look and feel that provides the patient with comfort through their retailing experience
  - c. Patient will be supported with professional consult and education
  - d. Product will be offered at an affordable price
  - e. Patient needs will be met with the availability of most appropriate and high quality medicine
2. Develop a cultivation and manufacturing facility that is sustainable and responsible
  - a. Quality of the products produced shall meet the highest standards for the benefit of the patients
  - b. High biosecurity standards will be put in place to minimize introduction of pests and disease
  - c. All product will be subject to high standards of cleanliness and consistency as a medical grade product
  - d. Create a safe working environment with zero work-related accidents
  - e. Achieve maximum energy efficiency and use clean energy sources
  - f. Create a sustainable material flow where inputs and wastes are minimized
  - g. Wastes are collected and disposed of in a secure manner
3. Inventory will be tracked, secured, and kept clean at all times
4. Every facility and transportation of product will be entirely secure 24/7
5. BPH will continuously strive to achieve excellence and everyday will be an improvement of the last
  - a. The most latest and reliable medical information will be sought after and implemented to benefit the patients
  - b. New technologies and methodologies will be sought after and implemented to benefit the patients



- c. Regular employee training will cover all aspects of their operations as well as promote a corporate culture of human resource development and community development

### **Business Philosophy**

BPH's business philosophy is to cultivate, produce, manufacture, and dispense marijuana and manufactured marijuana products of the highest quality and with the highest regard for health, safety, security and efficacy for registered employees, business partners and qualifying patients.

### **Business Market**

The marijuana and manufactured marijuana products offered by BPH will be intended for retail dispensing to qualifying, registered patients and primary caregivers in Hawai'i. The end consumer of the products produced by BPH will be registered patients in the State of Hawai'i. Currently there are more than 12,000 qualified, registered medical marijuana patients within the state of Hawai'i. The current business market for BPH products is further explained within BPH's financial pro-forma model. The financial pro-forma model is a separate, additional document detailing financial forecasts, ROI, growth opportunities and estimated capital requirements.

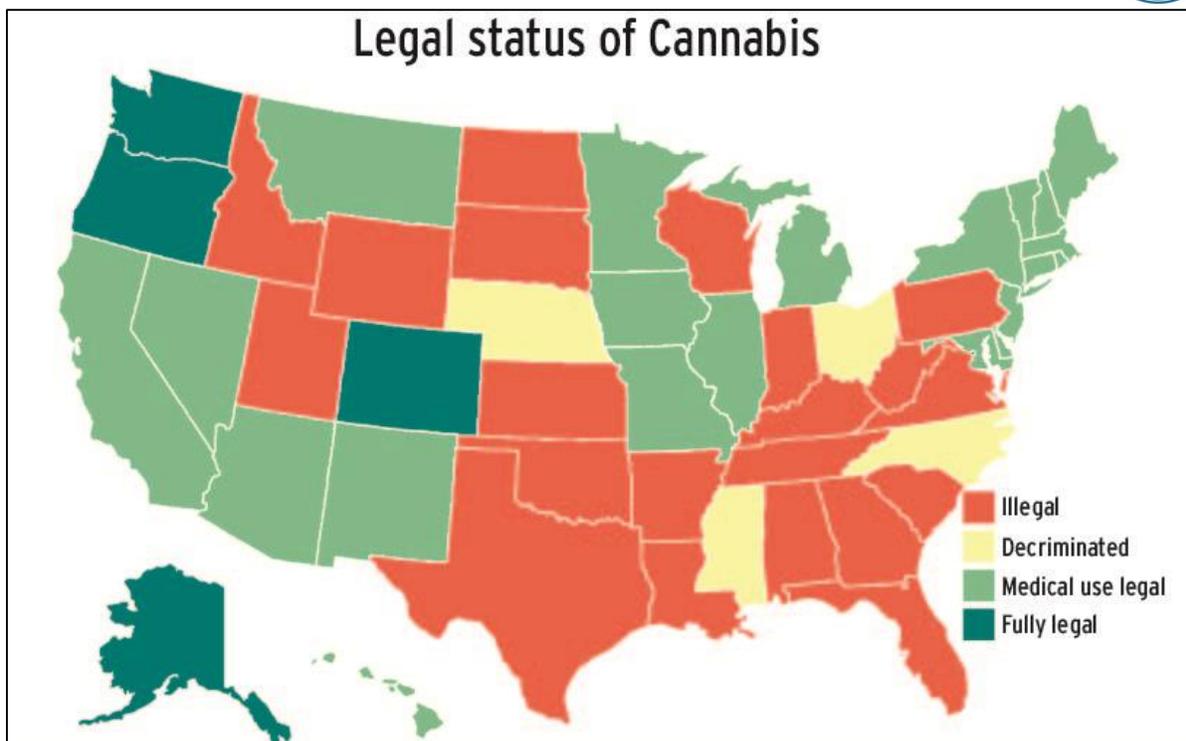
### **Industry Description**

The medical marijuana industry is an industry experiencing rapid growth and advancement. There are currently 23 states and the District of Columbia with medical marijuana laws on the books, 3 states with pending medical marijuana legislation and the states of Colorado, Washington, Oregon and Alaska with legal recreational marijuana laws.

With advances in modern medical research and marijuana research; we feel the medical marijuana market will continue to expand and develop in the years to come. More states each year are drafting legislation for medical marijuana as well as recreational use of marijuana and this trend does not show signs of decline.

### **History**

In 1996, nearly 60 years after the US government outlawed marijuana, California became the first state to legalize marijuana for medical use. Since then, 22 additional states as well as Washington DC have followed suit, bringing the total to 24.



\* <http://universe.byu.edu/2015/06/27/advocates-of-medical-marijuana-fight-for-its-legalization-in-utah/>

Despite the growing number of states involved, the medical marijuana industry remained fairly small for years, with only a limited number of dispensaries, primarily in California, operating under the constant threat of government raids.

A big breakthrough came in 2009 in the form of the “Ogden Memo,” a document instructing federal prosecutors to refrain from focusing their resources on prosecuting medical marijuana operations in states with medical marijuana laws. (<http://www.justice.gov/opa/blog/memorandum-selected-united-state-attorneys-investigations-and-prosecutions-states>)

This led to the opening of several thousand dispensaries across the country. For the next few years, the industry became very erratic due to numerous legal limitations on both the federal and local level. Due to the constant changing regulations and the reluctance from the investor community, the 2011 “breakout year” never materialized. The industry shrank by an estimated 15-20% as hundreds of dispensaries closed and patient numbers dropped.

The industry persisted through 2012 and the momentum rapidly changed. The US Department of Justice released the 2013 “Cole Memo”, which essentially authorized the medical marijuana industry. (<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>) Several new states began legalizing medical marijuana while other states that were in a holding pattern moved forward with plans to allow dispensaries to open up under tight regulations. Massachusetts was one of the states that made significant progress with their dispensary programs, setting the stage for 2014.



Medical marijuana states showed growth in 2014 from both former medical marijuana markets as well as new ones that just started awarding business licenses. The federal government released new guidance for financial institutions when dealing with medical marijuana dispensaries, providing relief for the industry; the FinCEN Memo. ([http://www.fincen.gov/statutes\\_regs/guidance/pdf/FIN-2014-G001.pdf](http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2014-G001.pdf).)

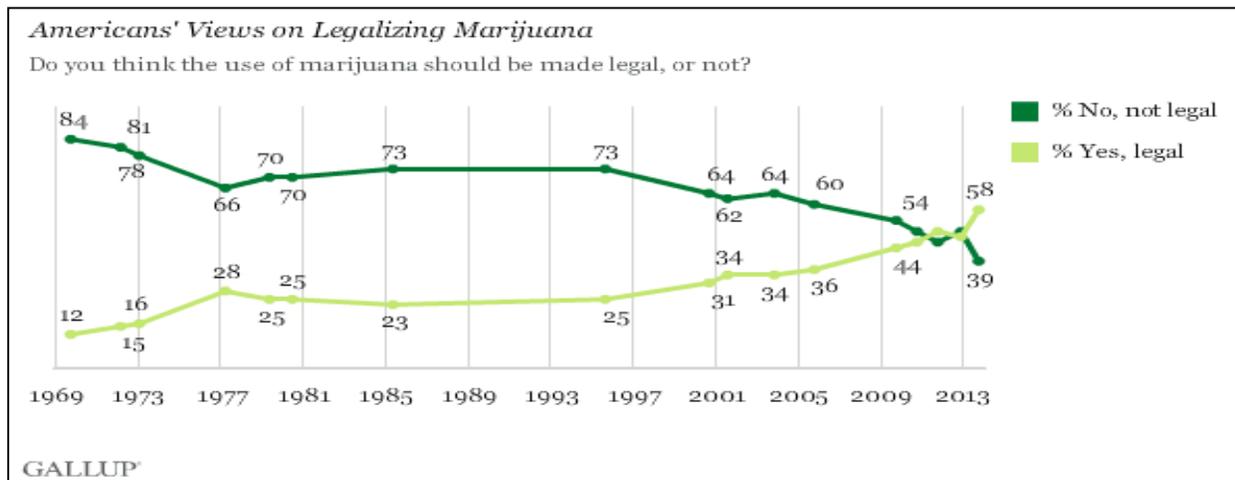
The FinCEN memo provides clarity to enhance the availability of financial services for marijuana businesses promoting greater financial transparency in the marijuana industry mitigating the dangers associated with conducting an all-cash business. The memos guidance also helps financial institutions file reports that contain information important to law enforcement.

### Trends in Social Acceptance

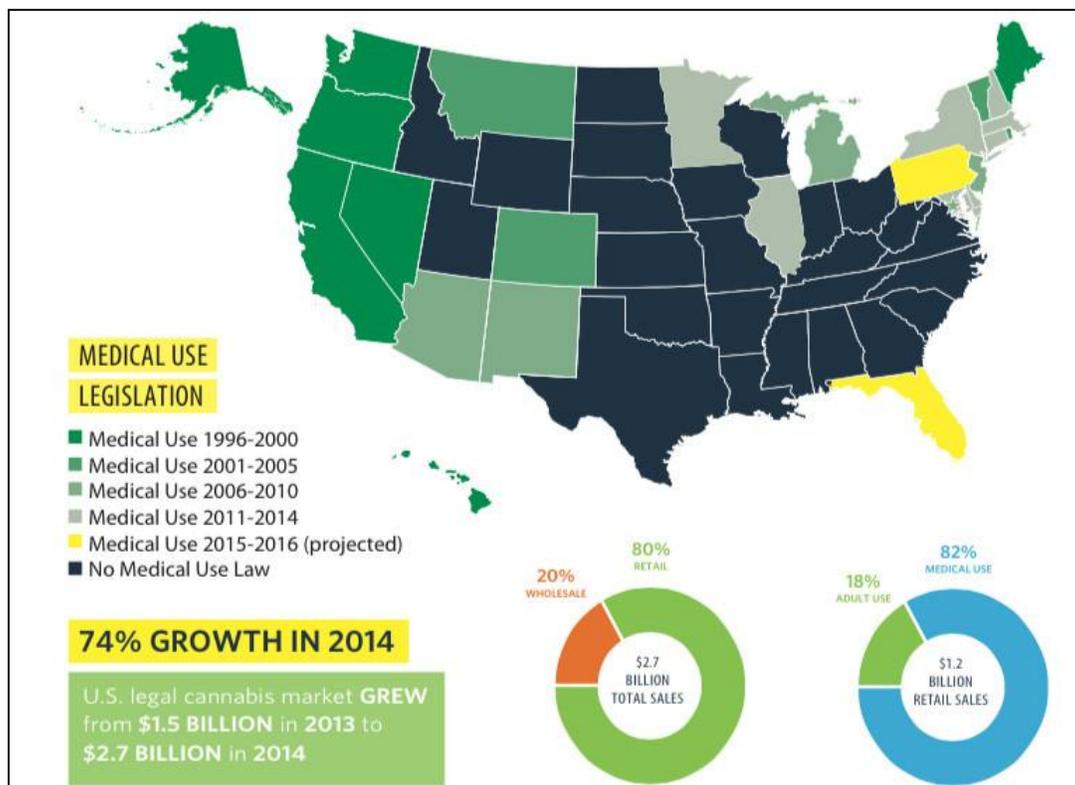
The unique therapeutic properties of pharmaceutically active compounds embedded within the marijuana plant genus have been globally neglected and overlooked for most of the 20th century, due to the classification of the plant and its active cannabinoid ingredients as “Schedule I” substances that allegedly have no medical use or benefit.

In recent years, public opinion on this matter has changed rapidly as more and more social awareness groups have promoted the full or partial legalization of the marijuana plant, while a substantial amount of scientific data, that illustrate the medical benefits of marijuana, has been generated by clinical and basic science researchers.

This social consciousness change has been dramatically illustrated by a poll performed in 2013, in which, for the first time in decades, a majority of Americans polled for approval of legalization of marijuana in the United States.



\* <http://www.thefiscaltimes.com/Columns/2014/01/03/Why-Legalizing-Marijuana-Smart-Fiscal-Move>



\* [http://www.huffingtonpost.com/2015/01/26/marijuana-industry-fastest-growing\\_n\\_6540166.html](http://www.huffingtonpost.com/2015/01/26/marijuana-industry-fastest-growing_n_6540166.html)

### **Company Strengths and Core Competencies**

BPH strengths and core competencies will be the cultivation and manufacturing process and techniques utilized by BPH. The cultivation techniques utilized by BPH will produce high grade medical marijuana of pharmaceutical quality for the qualifying patients of Hawai‘i. Through the adoption of well-established cultivation processes and methodologies from BPH’s operating partners HCH and HCH’s experience within the regulated marijuana industry will prove most beneficial for BPH’s success with organization goals and objectives.

BPH intends to produce and dispense medical marijuana and manufactured marijuana products of the highest pharmaceutical grade quality. BPH’s operating partner HCH will spearhead the implementation and execution of organization plans and goals pertaining to cultivation and retail dispensing operations. HCH brings years of knowledge and practice within the legal medical marijuana industry to the table. HCH currently operates three (3) medical marijuana retail dispensary locations and three (3) recreational marijuana stores and six (6) production centers in Colorado, all in full legal compliance with state and county law.

HCH will bring operational knowledge and experience to BPH and will become the “boots on the ground” for the deployment of BPH cultivation and retail dispensary operations. HCH will fully prepare BPH registered employees on all aspects of the business before commencing any operations. Training and education will be all encompassing; covering regulatory compliance, seed-to-sale tracking, patient advocacy, Point-of-Sale training, security and diversion, health and



safety, sanitation, transportation, also including all cultivation processes and applications, manufacturing of edibles and infused products.

A patient-centric focus at the retail dispensing locations will set BPH apart from other registered retail dispensary locations. All dispensing registered employees will receive training and education to acquire vast knowledge regarding medical marijuana; including genetic and strain varieties, recommended dosage rates, possible effects, etc. This will allow dispensing registered employees to be able to offer recommendations suited for each individual qualified patient.

BPH also has strengths in the high tech industry that would be vital in placing the company at the fore front of the industry. BPH intends to utilize its expertise to create smart, efficient, and effective systems at every aspect of its operations including energy efficiency, controlled cultivation, manufacturing, and patient outreach.

### **Legal Form of Ownership**

BPH is a Limited Liability Company (“LLC”). BPH chose this entity form for various reasons including the taxation structure of an LLC. A Limited Liability Company is a legal form of a company that provides limited liability to the owners. An LLC is a business structure that combines the pass-through taxation of a partnership or sole proprietorship with the limited liability of a corporation.

Hawai‘ian residents own 77.75% of the total ownership interest of BPH.



## Products and Services

The products offered by BPH will be a wide variety of marijuana strains as well as a vast product line of manufactured marijuana products including oils and oil extracts, tinctures, topicals such as skin lotions and ointments, capsules, pills and lozenges. BPH goal is to legally source high quality marijuana strain varieties that are specifically geared towards the treatment and alleviation of symptoms associated with qualified medical marijuana patients.

BPH intends to produce pharmaceutical grade marijuana products that unlock the palliative properties of the plant and deepen our understanding of the endocannabinoid system and its role in human health. We have a three point strategy to achieve this. First we will produce products with stringent quality standards. Next, selecting strains/genetics with desirable palliative qualities and from these produce product options that don't conflict with a doctor's normal ethical treatment protocols such as smoking or eating unhealthy foods. The strains intended to be utilized will be high in cannabidiol (CBD) or have Tetrahydrocannabinol/cannabidiol (THC:CBD) ratios that have demonstrated efficacy for qualifying conditions. Finally, through production and product strategies coupled with rigorous testing we will overcome one of the most significant hurdles for the medical marijuana industry, which is consistency of dosage and cannabinoid profile.

The cultivation of marijuana will include a wide variety of marijuana strains; all strains will be unique and have different medical values and benefits. Marijuana varieties will include different strains from indica, sativa, hybrid and CBD dominant genetics. Patients will experience different desired effects from different marijuana variety strains and genetics.

BPH will process the high grade medical marijuana produced into various manufactured marijuana products using only high quality ingredients for final products. BPH has entered into a licensing agreement with UNM, a well-known manufacturer of marijuana-infused products. UNM currently has legal operations in full compliance with the regulations in Colorado. UNM will provide established operational procedures, methods and recipes for BPH manufacturing operations allowing BPH to deploy operations with pre-established, proven recipes. This will allow BPH to immediately start manufacturing marijuana products that are consistent and reproducible for qualifying patients.

### **Marijuana Flower**

- *Description*—BPH intends to cultivate and dispense approximately 10-15 strains of marijuana ranging from those with a high level of THC and low level CBD to those with a high level of CBD and low level of THC. These strains will include Indica varieties, Sativa varieties, and hybrid strains that will be a blended variety with effects similar from both sativa and indica varieties.
  - Besides appearance, indica and sativa plants are commonly believed to have different effects on their user. These effects include sativa being more uplifting and energetic, and best suited for day use while Indica is considered more relaxing and calming and is best suited for night use.
- *Benefits*—the evidence is overwhelming that medical marijuana can relieve certain types of pain, nausea, vomiting and other symptoms caused by such illnesses as multiple



sclerosis, cancer and AIDS – or by the medical compounds frequently used to treat them. Additionally, it has proven benefit in the management of post-traumatic stress disorder.

- *Strengths*—medical marijuana can treat symptoms remarkably safely and considered less toxic than many pharmaceuticals.
- *Weaknesses*—because marijuana is federally illegal, there has not been enough scientific research done to determine the true effectiveness of the medicine. Patients are not able to get exact dosing recommendations from medical professionals.

### **Medical Manufactured marijuana Products and Concentrates**

BPH will create products that are convenient for administration of the active ingredient, medical marijuana. Our goal is to create various dosage forms that will make administration of medical marijuana convenient, easy, and palatable for qualified, registered patients in Hawai'i.

- *Product Description*—manufactured marijuana products are made with marijuana as an ingredient. They can come in the form of oils and oil extracts, capsules, pills, lozenges, sublingual tinctures, and topical(s) such as skin lotions or ointments.
- *Product Benefits*—the benefit of manufactured marijuana products is that they offer patients an alternate delivery means to experience the effects of cannabinoids without smoking or vaporizing marijuana. Alternative ingestion methods that offer consumers cannabinoid delivery formats other than smoking are one of the fastest growing segments of the marijuana industry.
- *Product Strengths*—an easily administered option for taking medical marijuana products. It improves dosing calibration and benefits from the convenience of portability.
- *Product Weaknesses*—it can take longer to feel the effects of the medical marijuana product. It is often considered to have stronger effects than inhalation of medical marijuana products.

### **Products Blue Planet Healing intends to produce include:**

#### **1) Inhalable Marijuana Products**

**a. Raw Flower:** Multiple genetics and strain varieties of indica, sativa, and hybrid marijuana will be cultivated. Different medicinal values and benefits will be obtained through different indica, sativa, and hybrid marijuana strains. Raw flower will typically be smoked or vaporized by qualified patients.

- Indica marijuana strain varieties
- Sativa marijuana strain varieties
- Hybrid marijuana strain varieties
  - Flower products will be packaged in quantities of:
    - a. 1 gram packages (1 gram)
    - b. 1/16<sup>th</sup> packages (1.75 grams)
    - c. 1/8<sup>th</sup> packages (3.5 grams)
    - d. Ounce packages (28.35 grams)

**b. Marijuana Concentrates:** Marijuana concentrates are a concentrated form of marijuana, the concentrated form is very potent and high in THC content.



Marijuana concentrates are made from extracting the cannabinoids from the marijuana plant material. Marijuana concentrates can be made into various forms and products including but not limited to CO<sub>2</sub> oil and oil extracts, sublingual tinctures, capsules and topical(s) like skin lotions or ointments. Once extracted, the concentrated marijuana oil will be used to make all BPH manufactured marijuana products.

- CO<sub>2</sub> Oil and Oil Extracts
  - Pre-filled vaporizer cartridges (250 mg and 500 mg)
  - Pre-filled metered dosage syringe
  - Shatter (1g quantity)
  - Wax (1g quantity)
- Ingestible Marijuana Products
  - Capsules
  - Pills
  - Lozenges
  - Tinctures
- Topicals
  - Skin lotions
  - Ointments

## 2) Ingestible Marijuana Products

- a. **Sublingual Tinctures:** Tinctures are a form of liquid ingestible marijuana. Tinctures will be consumed by placing the liquid tincture under the patients tongue, drinking the liquid tincture alone or mixing the tincture with tea or some other beverage.
- b. **Pill-Form/Capsules:** Edible pill form marijuana products will be beneficial to patients that cannot or prefer to not vaporize marijuana. Medical marijuana patients will ingest the edible pills in order to receive the medicinal benefits of marijuana.

## 3) Topical Marijuana Products—*ointments and skin lotions*

- a. **Topical(s):** Topical(s) will include ointments and lotions that can be utilized by medical marijuana patients looking to alleviate ailments through topical use. Topical(s) are rubbed on the skin or area needed by a medical marijuana patient.

## Quality of Products

Cultivating marijuana of the highest quality will be the driving force behind BPH's marijuana cultivation efforts. The marijuana is being cultivated for medicinal purposes; qualifying, registered patients in the State of Hawai'i with debilitating medical conditions will be consuming the marijuana to alleviate ailments and as such we believe in utilizing natural cultivation methodologies and techniques to produce marijuana of the highest quality. All marijuana cultivated by BPH will be free of any residual contaminates or pests and will pass all required state testing standards.



BPH will identify State-licensed testing laboratories located in Hawai‘i to conduct product testing on every batch of marijuana cultivated as well as all manufactured marijuana products batches as required by regulations. BPH will utilize a quality management program to ensure there are no deviations in the cultivation or manufacturing processes.

### **Product Pricing**

BPH’s will endeavor to make medical marijuana and manufactured marijuana products affordable and accessible to the registered patients of Hawai‘i. BPH has created a financial pro-forma model that details estimated pricing for cultivated marijuana and manufactured marijuana products. This financial model is a separate, additional document that can be seen in full for a more detailed breakdown of the pricing strategies.

Pricing for all BPH marijuana and manufactured marijuana products will be based on the current fair market value of said items. Pricing will also be computed to ensure BPH is profitable and able to continue operations and pursue growth strategies. Different pricing structures and strategies will be utilized by BPH for determining pricing on cultivated marijuana and processed manufactured marijuana products. Pricing structures will be identified upon deployment of operations to ensure all cost associated with the marijuana product or the manufactured marijuana products are captured to, at a minimum, be able to recoup the cost of production.

**Cultivated Marijuana:** Pricing will be based on cost of production, harvest yield, cost of dispensing, and fair market value of marijuana. The pricing model used to forecast cultivated medical marijuana pricing was based from numbers and figures from the regulated marijuana market in Colorado.

**Manufactured Marijuana Products:** Pricing will be based on cost of production, cost of dispensing, and fair market value for manufactured marijuana products. The pricing model used to forecast processed medical manufactured marijuana products pricing is based upon publically available data and use figures from the regulated marijuana market in Colorado.

*\*Please see financial pro-forma model for a detailed breakdown of BPH estimated pricing structures.*

BPH will also develop and implement a patient hardship program. The patient hardship program will be created for the purpose of helping state registered patients obtain medical marijuana in the situations where said patients cannot financially afford the medication.

### **Patient Hardship Pricing Program**

BPH will coordinate with registered dispensary customers (i.e. qualifying, registered patients) to provide financial assistance to patients who are unable to afford medicinal marijuana and/or manufactured marijuana products. BPH will strive to ensure that financial issues do not prevent qualifying patients from seeking or receiving care. BPH will use the Federal Poverty Level as a guide to provide discounted medicine to individuals who meet the policy’s criteria. BPH will rely upon the Census Bureau’s definition of a family and family income when computing federal poverty level guidelines. If the qualifying patient’s income and household falls within 300% of the published guidelines, the qualifying patient will be provided medicine at a reduced cost according to the following conditions:



1. For those qualified patients who are between 0 to 300% of the federally recognized poverty level the price will be at a 30% reduction;
2. For those qualified patients who are at or below the federally recognized poverty level the price will be 50% to 75% reduced, depending on circumstance;
3. For hospice patients, veteran's home residents, and veterans, there shall be a reduced price, depending upon the financial circumstance.

Eligibility will be based upon a determination of financial needs in accordance with the policy. In order to receive financial hardship benefits, qualifying patients must fill out a required application. The application will include mandatory attachments that document proof of income. Applicant will have the option to submit all of the following documents: W-2, paycheck stubs, income tax return, forms from Medicaid or other state-funded medical assistance programs, or forms from employers or welfare agencies. Other circumstances that will be taken into consideration are bankruptcy settlements and catastrophic situations (death, disability in family, divorce). Applicants without the above mentioned proof must provide documentation that shows the patient is unable to pay their medical marijuana bills and still be able to pay for other basic necessities. It shall not take into account age, gender, race, social or immigrant status, sexual orientation, or religious affiliation. This application must be completed annually in order to be placed in the BPH financial hardship program. Any denial of the discount/no cost request will be documented as such, and instructions for reconsideration will be provided by the BPH. All applicants and their records will be kept confidential. Patients are expected to contribute to the cost of care based on their ability to pay. This policy assures access to medicine and protects the assets of financially needy qualifying patients. Individuals with the financial means to pay for medicine shall be urged to do so within the guidelines of federal law. BPH shall notify qualifying patients of its financial assistance policy by posting notices at the registered dispensary locations and on the company website and providing the information directly to qualifying patients.

### **Proposed Location**

The proposed location BPH is considering for the production center is located in the county of Honolulu. The proposed location BPH is considering for the retail dispensing locations will also be located in the county of Honolulu. BPH will ensure locations meet all zoning requirements and that all applicable state and county law will be complied with. There will be ample parking on site for registered employees at the cultivation/production facility; there will also be ample parking for registered employees and qualifying patients and customers at the retail dispensing locations. Both locations will be of adequate size and space for the cultivation, manufacturing and dispensing of marijuana and manufactured marijuana products.

Proposed Dispensary Location – BPH has secured a retail dispensary location at the Ala Moana Medical Building, located at 1441 Kapiolani Blvd (<http://www.alamoanacenter.com/Leasing/Ala-Moana-Building.aspx>), on the corner of Keeaumoku and Kona streets. This space in the medical building offers the following amenities:

- Easy access – excellent location for patients being in the Kapiolani corridor in the heart of Honolulu, adjacent to Ala Moana shopping center



- Accessibility by public transport – Ala Moana shopping center is a major hub for TheBus, the rail will have a station at Ala Moana, as well as many taxi services have stalls
- Accessible parking – offers free customer parking with 297 stalls on site, as well as the adjacent Ala Moana shopping center offers ample parking (over 11,000 stalls)
- Security - in addition to the BPH’s own security, the medical building offers 24-hour security on premises
- Welcoming dispensary look & feel – the dispensary location will focus first and foremost on the patient’s comfort and accessibility.
- The dispensary location will be clinical, using medical grade furniture, ADA compliant.



## Operational Plan

Operations is an area of greatest significance to BPH. Success will be dependent on navigating a complex series of actions and adaptations. BPH has enlisted the help of expert consultants and operators to provide and follow detailed operating procedures. In addition, these operators and consultants have aided our careful and innovative building designs. The focus in Operations will be continuous improvement, product safety and customer satisfaction. BPH will foster communication between registered employees and track performance measurement in all areas to optimize efficiency and effectiveness. We will strive to maximize product yields and potency using best practices gleaned from across the regulated marijuana industry.

### **Education and Training**

BPH will utilize the operational experience and knowledge from HCH to provide extensive training and education for all registered employees. All BPH employees will receive extensive training prior to commencing work in any BPH registered dispensary facility. Registered employees will be required to read the relevant state and county law pertaining to medical marijuana in order to have a general understanding of the laws and regulation with which that they must comply. Training for all cultivation and retail dispensing operations will be provided by our operating partners HCH, training will also be provided from selected 3<sup>rd</sup> party security vendor Securitas, BioTrackTHC™ inventory control systems and POS vendors, UNM for manufacturing operations and CO<sub>2</sub> extraction machine vendors, and other subject matter experts. Training will include an extensive hands-on approach and the use of Standard Operating Procedures (SOP's) and various other materials and methods as deemed appropriate.

BPH will utilize targeted training materials and programs for different operations occurring at BPH licensed facilities. There will be specific training for registered employees involved within cultivation operations, processing/manufacturing operations, and retail dispensing operations. Ongoing and cross-functional training will be continued as operations commence. All registered employees will also be required to receive training on general sanitary requirements. Registered employees will be required to read and agree to comply with the company Employee Handbook, SOP's, and other materials BPH deems necessary prior to commencing work in any BPH facilities.

HCH will fully prepare facility staff on all aspects of the business before operations are commenced. Training and education will be all-encompassing, covering regulatory compliance, seed-to-sale tracking, patient service and advocacy, point-of-sale training, dispensing, security and diversion prevention, health and safety protocols, sanitation, transportation, also including all cultivation, extraction and manufacturing processes, and organizational functioning within a vertically-integrated operation. Registered employee training will cover but not be limited to the following:

- Standard Operating Procedures (SOP's)
  - Cultivation Operations SOP's
    - Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH cultivation operations.
  - Manufacturing Infused Products (MIP) Operations SOP's



- Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH manufacturing infused products operations.
- Retail Dispensing Operations SOP's
  - Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH retail dispensing operations.
- Log Sheets and Templates
  - Numerous log sheets and templates for proper record keeping and documentation for all operations including cultivation, MIP, and dispensing
- Responsible vendor training
- Patient education information
- On-site training
- Initial job training
- Job shadowing
- Employee educational information

**Laws and Regulations/Compliance Training**—Adhering to all state, county, and company regulations is of utmost importance to create an end product with efficacy for patients. All BPH registered employees will be required to have a general knowledge of all applicable laws and regulations dealing with the regulated cultivation, manufacturing, and dispensing of medical marijuana and manufactured marijuana products.

- **Federal Laws**— BPH management will make available to its employees copies of various Federal laws and memos concerning medical marijuana, including:
  - *Controlled Substances Act*:  
<http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm>
  - *Ogden Memo*: <http://www.justice.gov/opa/blog/memorandum-selected-untied-state-attorneys-investigations-and-prosecutions-states>
  - *Cole Memo*:  
<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>
  - *FinCEN Memo*: [http://www.fincen.gov/statutes\\_regs/guidance/pdf/FIN-2014-G001.pdf](http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2014-G001.pdf)
- **Policies Regarding Regulations**—it is the duty of BPH management to ensure regulatory requirements are followed at all times by all registered employees. Management shall maintain a zero tolerance policy for any infractions that would violate state, local, or company-level regulatory measures.
- **Current Regulations**—access to the current State of Hawai'i medical marijuana laws and regulations will be provided to all BPH employees prior to commencing work in any BPH facilities.



- **State of Hawai'i Regulations**—The State of Hawai'i laws and regulations regulating the medical marijuana industry can be obtained from State of Hawai'i Department of Health
  - <http://health.Hawai'i.gov/medicalmarijuana/submenu/doh-medical-use-of-marijuana-administrative-rules-effective-july-18-2015/>
- **New Regulations**—All new regulations shall be followed as of their effective date. Training of new employees regarding newly enacted State regulatory measures shall take place before the effective date of said newly enacted State regulation(s) in order to ensure that all team members have a complete understanding of such measures and can fully comply with the same.
- **Confidentiality**—Patient and/or caregiver confidentiality is of the utmost importance. All patient and/or caregiver records are to be considered confidential. All registered employees must ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) laws.
  - The confidentiality policy that will be put in place within all BPH facilities requires all employees and former employees to maintain confidentiality with respect to information and records pertaining to BPH operations. Confidential information will include but not be limited to:
    - Qualifying patient and/or primary caregiver personal records (HIPAA)
    - Company financial records
    - Company human resource records
    - Registered employee records or personal information
    - Operation activities
      - Cultivation methods/techniques
      - Production methods/techniques
  - The confidentiality policy is a legal requirement and respects the rights of employees and the importance of sensitive company information. Prior to commencing work at any BPH facilities, all employees and volunteers will be required to agree to and sign a Confidentiality Agreement Form.
    - **Breach of Confidentiality**—defined as “the disclosure of information, intentionally or unintentionally, to an individual or entity that is not entitled to said information.”
      - The disclosure of confidential information may result in disciplinary action and/or immediate job termination.

**ServSafe Training**—ServSafe is a training program for the food service industry, which teaches basic food safety for preparing and serving food. The program teaches about foodborne illness, how to prevent and how to train employees in food sanitation. This program will help employees become aware of good personal hygiene practices and safety measures to be utilized for the manufacturing of marijuana products.



BPH will require that all employees involved with processing operations will be required to complete ServSafe Safe Food Handlers training. Employees will be required to complete the ServSafe training course and successfully pass the competency test to become ServSafe certified prior to commencing work within the facility. ServSafe will help educate and train employees on personal hygiene, food safety, sanitation, and cleaning procedures and protocols.

Employees will be required to pass the ServSafe exam with at least a 75% passing score in order to be certified. Upon completion of the ServSafe course and successfully passing the exam, employees will receive a ServSafe certification that will be valid for three (3) to five (5) years.

**Responsible Vendor Program Training**— BPH will utilize a training program developed by ACC entitled “The Responsible Vendor Program”. This program is intended to help train dispensary operations staff members on different activities and information needed for daily operations. “The Responsible Vendor Program” will train employees on different educational content and materials, including but not limited to:

- Proper checking of identification and spotting false IDs
- Understanding the conduct, rules, and regulations of a licensed cannabis establishment
- Governing enforcement agencies: Their roles and how all licensed employees should work with them
- Cannabis plant biological structure and native geography
- Cannabis quality control, variety types and their various effects
- The medicinal value of marijuana and its extracts
- Methods of consumption
- Identifying indicators of intoxication

The program will aid in training and educating all BPH employees on different aspects of marijuana as a medicine. Retail dispensary employees will gain information on the various marijuana strains and products offered, their medicinal benefit, possible side effects, delivery methods, and other relevant information. This will help dispensary employees identify and recommend marijuana varieties and forms for different patients to help treat their specific qualified condition. All BPH retail dispensary registered employees will be trained on “The Responsible Vendor Program.”

**Security Measures/Protocols Training**—all BPH registered employees will receive extensive training detailing facility security measures and protocols. Security measures and protocols are explained in more detail within the Standard Operating Procedures Security Plan.

**Laws and Regulations/Compliance Training**—Adhering to all state, county laws and company specific regulations is of utmost importance to create an end product with the highest efficacy for patients. All BPH registered employees will be required to read current state law and have a basic



knowledge and understanding of the laws and regulations they must comply with in daily operations. Compliance training is detailed more thoroughly in the SOP's.

**Point of Sale (POS) Training**—BioTrackTHC™ will provide the inventory control system and POS computer systems to be utilized in all BPH registered dispensary facilities. BioTrackTHC™ will provide initial training on the systems. POS training efforts will be supported by HCH and their deep understanding and experience with BioTrackTHC™ systems. POS training is covered in more detail in the Retail SOP's.

**Patient Advocacy Training**—Qualifying patients are the reason for the medical marijuana industry and therefore proper patient advocacy training is essential in order to have a successful retail dispensing operation. Patient confidentiality is of utmost importance; any and all patient information is confidential and is to remain secured on location. Any unauthorized release of patient information will be grounds for immediate job termination. Patient advocacy and confidentiality are explained in more detail within the Standard Operating Procedures.

**Training Record**— BPH management team will be responsible for maintaining training records for each registered employee. Such records will include, at a minimum, documentation of all required training for the different operations and functions including:

- The name of the person receiving the training;
- The dates of the training;
- A general description of the topics covered;
- The name of the person supervising the training; and
- The signatures of the person receiving the training and the facility manager.

All registered employees will receive training prior to beginning work within any BPH registered dispensary facility. A continuing education program will aid in developing registered employees and preparing them for further advancement within the company. It is the responsibility of management to ensure training takes place for all registered employees prior to commencing work within any BPH registered dispensary facility.

### **Cultivation and Manufacturing**

Production will consist of the entire marijuana cultivation process from seed germination and propagation to harvesting, curing, and packaging. Production will also consist of marijuana processing for the manufacturing of marijuana products. The production process and procedures are explained in detail in the SOPs. The SOPs will cover all cultivation processes as well as all manufacturing marijuana product operations.

#### *Methods of Production:*

- *Marijuana Cultivation:* Various cultivation techniques will be utilized within the cultivation facility. See the separate, additional Cultivation SOPs document for more information on cultivation techniques.



- *Manufacturing Marijuana Products:* Processing techniques and procedures for manufactured marijuana products are explained in detail in the separate, additional Manufactured Marijuana Products SOP document.

### **Production Center Location**

All marijuana cultivation and manufacturing of marijuana products will be conducted at BPH's registered production centers. BPH will ensure that all facilities will comply with applicable zoning laws, are secured and at a minimum meet or exceed all state and county law pertaining to facility security requirements.

The initial production facility will be located in Kapolei Business Park, Phase 2. Kapolei offers the unique environmental advantages of being both relatively dry and offering some of the best sunlight exposure. Sunlight will be used for directly providing diffused natural light through the white translucent roof and for capturing the energy through Photovoltaic (PV) panels. As dehumidification is one of the largest power draws at the facility, being able to vent out humid air and intake dry outdoor air. Sensors will allow the climate control computer system to determine the optimum timing in the day when the humidity and temperatures are at a combined low to intake air that decreases the combined power draw of the AC and the dehumidifiers the most.

**Square Footage**—the production center will be approximately 24,000 sq ft consisting of a 16,000 sq ft main warehouse space, 3,000 sq ft secondary warehouse, and 5,000 sq ft of office space split into two floors. The building sits on a 50,000 sq ft lot where the remainder of the land will feature shaded parking with PV panels on the roof, climate appropriate landscaping, and a loading area.

**Type of Building**—the production center will be a newly constructed warehouse building featuring modern building materials that increase HVAC efficiency. The walls will be made of metal Structural Insulated Panels (SIPs) which are high insulation solid foam core sandwiched between rigid metal panels. The high insulation of the walls will decrease the power demand on the HVAC system.

Water absorbs heat and hot air rises. Roof ventilation at the ridge of the roof will open at optimal times to vent out hot air through a insect proof mesh screen of 300 micron mesh size or less. This will release the hottest and most humid air from the interior from the building. Air intake will occur at the lowest points of the walls from the coolest side of the building at the time. The intake air will be filtered and run through a UVA and/or ozone air sterilizing unit to eliminate incoming pests and pathogens.

**Zoning**—The facility is located on I-2 zoned land. I-2 means that the land is classified for intensive industrial use, allowing for a large amount of power (3-phase, 480V) to be pulled to the building, a necessity for a large power use facility. Nursery productions are allowed on agricultural lands and industrial lands, and thus making this facility on the most ideally zoned land.

**Construction Costs**—current estimates are around \$7.5 million



## **Quality Control**

BPH will utilize industry best practices developed for established operations within Colorado’s regulated marijuana industry and quality assurance programs to continuously measure and improve customer satisfaction. Customer satisfaction will be a top priority of BPH as we want to cultivate, manufacture and dispense marijuana and manufactured marijuana of the highest quality. BPH will utilize a patient feedback form to gather feedback and input from qualifying patients regarding our marijuana products, manufactured marijuana products, the qualifying patients’ overall experience, and feedback regarding the retail dispensary location, registered employees, and any other information or comments qualifying patients wish to provide to BPH. This patient feedback form will be reviewed by BPH in order to assess the qualifying patient feedback to continuously improve our process and products to offer qualifying patients the best experience possible when procuring from BPH.

To ensure qualifying patient and public safety, BPH has committed to establish, document, implement and maintain an appropriate Quality Management System. To this end, BPH is committed to the following Quality Management Principles:

- Customer Focus; Leadership; Involvement of People; Process Approach; System Approach to Management; Continual Improvement; Factual Approach to Decision Making; Mutually Beneficial Supplier Relationships

To assure adequate establishment, implementation, documentation and maintenance of the Quality Management System (“QMS”), BPH has taken guidance from ISO 9001 and will hire a full-time Manager of Quality Management who is certified as a Manager of Quality and Organizational Excellence by the American Society of Quality. The Manager of Quality Management will be responsible for using the guidance from ISO 9001 to develop the appropriate QMS for BPH in accordance with Hawai‘i state regulations. BPH’s Quality Management System will be based from the QMS document which is as an additional document and can be viewed upon request.

*Cultivation Operations*—Quality control measures will be created and implemented within the cultivation facility to ensure quality and consistency of products produced within the facility. BPH will utilize established and proven SOP’s for all cultivation operations. The SOP’s have been developed and tested within Colorado’s regulated medical marijuana market by our retained marijuana industry consultants ACC. BPH will use standard operating procedures (SOP’s) to promote good growing and handling practices including:

- All aspects of:
  - Irrigation, propagation, cultivation, fertilization;
  - Harvesting, drying, curing;
  - Rework or reprocessing;
  - Packaging, labeling, and handling of medical marijuana products, byproduct; and
  - Waste products, and the control thereof, to promote good growing and handling practices.

BPH will require that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical marijuana has received the training, education, or experience



necessary to perform assigned functions; and will also require that all employees practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

Automated climate controls developed through data tracking with a robust sensor system and analysis will develop an increasingly consistent and optimal cultivation system over time. BPH takes quality and excellence seriously and will always look for ways to operate at a higher level.

BPH will require employees to follow the protocol for Receipt of Material including:

- BPH shall quarantine received material that will be used to produce marijuana and/or manufactured marijuana products
- BPH shall inspect materials for defects and contamination.
- Material may not be released from quarantine by a BPH until the material:
  - Passes inspection; and
  - Is determined to be acceptable for use as intended.

*Manufacturing Operations*—Quality control measures will be created and implemented within manufacturing operations to ensure quality and consistency of products produced within the facility. BPH will utilize established and proven SOP's for all processing operations. The SOP's have been developed and tested within Colorado's regulated medical marijuana market by UNM, a licensed manufacturer of marijuana products in Colorado, Nevada and Arizona. BPH and UNM have a licensing agreement which will enable BPH access to recipes, methods and other intellectual property required for successful manufacturing operations.

*Dispensing Operations*—Quality control measures will be created and implemented within the retail dispensing locations to ensure quality and consistency of products dispensed to qualified, registered patients. BPH will utilize established and proven SOPs for all dispensing operations. The SOPs have been developed and tested within Colorado's regulated medical marijuana market by HCH.

### **Inventory**

All BPH registered dispensary facilities will need to maintain inventories on-site for the cultivation, manufacturing and/or retail dispensing processes. There will essentially be two unique process within the cultivation facility; cultivating and manufacturing, each with differing processes and needing different on-hand inventories. The retail dispensary locations will have marijuana and manufactured marijuana products as on-hand inventory for dispensing to qualified patients.

#### **Cultivation Inventory**

- Cultivation equipment
- Plant fertilizer
- Pesticides
- Fungicides
- Insecticides
- Growing mediums
- Cleaning supplies



- Etc.

### **Manufacturing Inventory**

- Raw marijuana materials
- Kitchen equipment
- Extraction equipment
- Packaging materials
- Labeling materials
- Etc.

### **Retail Dispensing Inventory**

- Packaged marijuana
- Packaged manufactured marijuana products
- Exit packaging supplies
- Cleaning supplies
- Etc.

### **Inventory Value**

Valuation of on-hand inventories will be based on current fair market value for said inventories, the exact inventory values will be determined upon deployment of operations.

### **Inventory Management and Control**

BPH will utilize a perpetual inventory system in all operations—cultivation, processing/manufacturing, and retail dispensing. BPH will utilize a marijuana industry specific system from BioTrackTHC™ that will have the capabilities of linking all operational inventories together to operate as a vertically integrated business operation. Inventory control measures will be created and implemented to ensure inventory quantities are accurate and for state required seed-to-sale tracking of all marijuana and manufactured marijuana products. Proper inventory controls ensure the right amount of inventory is on hand and in production so as not to negatively impact the company and the market in general.

The inventory control system that will have the ability to identify and track all marijuana products from the time the marijuana is propagated from a seed or cutting to the time it is delivered to a retail dispensary location and dispensed to a qualified, registered patient or primary caregiver.

The inventory control system will be designed so that it can promptly identify a discrepancy in any marijuana or manufactured marijuana product stock. The system will deter loss from theft or diversion since every gram of marijuana and manufactured marijuana product will be logged and tracked through the inventory control system. The system will be capable of tracking marijuana products from a qualified, registered patient or primary caregiver back to the source of the marijuana product in the case of the development of a serious adverse event. The inventory control system will be utilized in tandem with the Product Recall Policy developed in case the need for a product recall should ever arise.

During the cultivation process all marijuana plants being cultivated will be tagged with a unique tag ID number. This tag will remain with the marijuana plant throughout its entire lifecycle. The



IG tag information will be input into the inventory control system to correlate with the attached marijuana plant. The information in the system will be changed and updated as the plant matures through its lifecycle.

### **Suppliers**

BPH will utilize numerous different suppliers for the cultivation process and for the manufacturing of medical marijuana edibles and manufactured marijuana products. Suppliers for cultivation activity will consist of a network of gardening equipment retailers and wholesalers. Suppliers for manufacturing activity will consist of grocery retailers and wholesalers, restaurant equipment companies.

BPH's suppliers will be identified upon successfully obtaining Hawai'i state licensure and the subsequent deployment of operations. BPH will use expertise provided by the American Cannabis Company, Inc. to minimize costs while obtaining high quality equipment. On a macro level BPH anticipates the need, at minimum, for the following suppliers:

- Security and surveillance equipment
- Cultivation equipment
- Processing equipment
- Dispensing equipment
- Inventory tracking equipment
- Building materials and equipment
- Point of sale equipment
- Packaging equipment

### **Distribution Channels**

BPH only distribute its medical marijuana through its registered Retail Dispensing Locations, vertically integrated with BPH operations. BPH intends to cultivate and manufacture marijuana and manufactured marijuana products for dispensing to state qualifying and registered medical marijuana patients and primary caregivers.

### **Transportation**

This section details how BPH will transport medical marijuana products to the retail dispensary(s). All applicable state and county law pertaining to the transportation of medical marijuana products will be strictly followed by all BPH team members.

**Transportation Agent Requirements**—all agents responsible for transporting marijuana products or manufactured marijuana products must:

- 1) Possess a current and valid state-issued marijuana industry worker license;
- 2) Possess a current and valid government-issued driver's license;
- 3) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or manufactured marijuana products pursuant to regulation, all transporting agents shall:



- 1) Carry a copy of the *manifest/trip plan* with him or her for the duration of the trip;
- 2) Wear their registered employee identification card;
- 3) Use a vehicle without any marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or manufactured marijuana products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation; and
- 5) Ensure that the marijuana products or manufactured marijuana products are not at all visible to the public.
- 6) Ensure there are at least two agents at any moment on a delivery, one of which will sit with the marijuana products to ensure a high level of security

**Delivery**—Transporting agents arrive at the dispensary location receiving the marijuana product(s).

- 1) Transporting agents arrive at the transportation destination
- 2) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the transport manifest/trip plan
- 3) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

### **Post-Delivery**

**Post-Delivery Protocol**—after transporting marijuana products or manufactured marijuana products, pursuant to the regulations the registered employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.

**Documentation of Delivery**—both the transporting dispensing facility agent and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Department for review upon request. The dispensary agent shall record in the inventory control each item dispensed including batch number and the weight and quantity of the marijuana and/or manufactured marijuana products that were dispensed.

**Deviations from Transportation Plan**—the transporting registered employee shall immediately report all diversion due to loss or theft of marijuana or manufactured marijuana products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the Department as required per state law. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



## **Compliance**

BPH will ensure compliance with all state and local laws and regulations, specifically H.B. 321, Chapter 329D and Administrative Rule §11-850. BPH will make all books, records, and production and dispensing facilities available to the Department or its authorized representatives for monitoring, audits, and on-site inspections at any time upon request. BPH will only cultivate, manufacture and dispense approved medical marijuana products, per requirements set forth in §11-850-71, §11-850-72 and §329D-10, in an enclosed, secure indoor facility located in the State of Hawai‘i and in the County of Honolulu. BPH will not grow marijuana or manufacture marijuana products at any site other than the production centers approved by the Department. BPH will not dispense medical marijuana or manufactured marijuana products from the production center and will only dispense marijuana and manufactured marijuana products to qualifying, registered patients and primary caregivers from retail dispensary locations.

**Registered Employees**—all employees hired and retained by BPH will be free of any criminal felony convictions and their hiring will be conditioned upon successfully passing a background check and comprehensive drug screen.

**Visitors and Activity at a Licensed Dispensary**—all visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

**Qualifying Patient Intake**—Qualifying patients and caregivers wishing to purchase products at a BPH retail dispensing location will need to have a valid state medical marijuana registration card. Patients entering the retail dispensary location will not be allowed beyond a “holding area” until a BPH employee verifies the validity of each patient’s medical marijuana registration card through the state electronic verification system. After the verification process has been completed, the patient and/or caregiver will be allowed entry into the retail dispensing portion of the premises.

The retail dispensing location manager will create and maintain a database within the inventory control system for inventory and tracking purposes. This will enable registered employees to adhere to all laws regarding the quantities of marijuana and manufactured marijuana products registered patients and/or primary caregivers are allowed to have and purchase in a given time period.

**Qualifying, Registered Patient Verification**—registered employees will verify each and every qualifying patient’s and/or primary caregiver’s state-issued medical marijuana license prior to entry into the retail dispensing center. The electronic verification process will need to be completed for every single patient and/or caregiver *EVERY* time they wish to purchase products at the facility.

- 1) **Medical Marijuana License**—Accept patient and/or caregivers state-issued medical marijuana license



- a. Ensure the state-issued medical marijuana license is current (check expiration date on License)
- 2) **Government-Issued ID**—Patients and/or caregivers must also have a current and valid government-issued ID (passport, Driver’s License)
  - a. Ensure that the state-issued ID is current (check expiration date on ID)
- 3) **Verification**—Verify the validity of the state-issued medical marijuana license
  - a. Verify validity of the medical marijuana license through the state electronic verification system
- 4) **Access**—Allow or deny access to the qualified patient and/or primary caregiver
  - a. Allow entry to retail dispensary location if the patient and/or caregiver has a valid state-issued medical marijuana license.
  - b. Deny entry to retail dispensary location if the patient and/or caregiver does not have a valid state-issued medical marijuana license.
    - i. If you feel the patient and/or caregiver is trying to use a fake or fraudulent medical marijuana license; confiscate said medical marijuana license and contact required Hawai’i state authorities.

**Dispensing Procedure**— BPH will implement and follow specific security procedures and policies for all RDL operations including: written SOPs for admitting registered patients and primary caregivers with valid government-issued photo identification cards issued pursuant to HRS Chapter 329 into the secure rooms for sales. BPH will design and construct each RDL with separate, secure room(s) for sales wherein marijuana and manufactured marijuana products are secured and locked in display cases for viewing. As required by HAR §11-850-53(3), BPH will follow written policies and procedures to ensure that a maximum occupancy limit ratio is maintained in all secured sales rooms of two customers to every RDL employee. BPH will store all marijuana products within a locked room, vault or in a locked container securely affixed to a wall or floor. All RDLs shall have exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities.

BPH will ensure compliance with all regulatory requirements prior to dispensing any marijuana or manufactured marijuana products, BPH will ensure compliance with the following dispensing procedures:

- BPH’s registered employees shall dispense marijuana and manufactured marijuana products only to a qualified, registered patient or primary caregiver who has presented a government-issued identification card.
- Before any distribution of medical marijuana, BPH’s dispensary agent(s) shall verify that:
  - The qualified, registered patient or caregiver is currently registered with the Department;
  - The amount of marijuana and/or manufactured marijuana products that have already been dispensed does not exceed sales limits established by the regulations.
    - Four (4) ounces within a consecutive fifteen (15) day period
    - Eight (8) ounces within a consecutive thirty (30) day period
- BPH’s dispensary agent(s) may provide information on:
  - The available types of marijuana, marijuana varieties, and manufactured marijuana products



- Methods by which medical marijuana can be used; and
- How unused marijuana may be returned for disposal.
- Registered employees may decline to dispense marijuana and/or manufactured marijuana products to a qualified, registered patient or caregiver if, in the opinion of the registered employee, the qualified patient or caregiver appears to be visually impaired.
- BPH will not distribute any samples of marijuana or manufactured marijuana products or offer any marijuana products free of charge.

### **Packaging and Labeling**

BPH will package all marijuana and manufactured marijuana products on site at the production center within opaque, child resistant packaging that will protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.

BPH will package all marijuana and manufactured marijuana products in child resistant packaging prior to dispensing said product to a qualified, registered patient or caregiver. Child-resistant packaging is special packing used to reduce the risk of children ingesting dangerous items. For BPH's purposes, child-resistant packaging will be used to reduce the risk of children ingesting marijuana and/or manufactured marijuana products.

**Cultivation and Manufacturing Packaging**—BPH will pre-package all products containing marijuana and manufactured marijuana products in child-resistant and opaque containers at the production center prior to being shipped to BPH retail dispensary locations. The packaging will be constructed of tamper-evident opaque material and sealed with tamper-evident tape.

**Retail Dispensary Packaging**—BPH will package all medical marijuana and manufactured marijuana products in child-resistant packaging. We also intend to take our child-resistant packaging to the next level and utilize best practices from Colorado's medical marijuana industry in that we will also require all marijuana products leaving BPH retail dispensary locations to be placed in a child-resistant exit package. BPH will also utilize exit packaging for all marijuana and manufactured marijuana products leaving retail dispensary locations. The exit packaging will be child resistant and opaque and aid in product safety. Exit packing is not required under current Hawai'i regulations, however BPH intends to use exit packaging as an industry best practice.

**Labeling**—BPH will label all marijuana and manufactured marijuana products as required by state law. BPH will not label any marijuana product or manufactured marijuana product as organic. All labels will use only black lettering on a white background with no pictures or graphics. BPH will utilize the inventory control and POS system to generate all product and qualified patient labels. BioTrackTHC's inventory control and POS system will be able to automatically generate both the product-specific and patient-specific labels as required by Hawai'i regulations. BPH will ensure that every marijuana and manufactured marijuana product package will be affixed with the required labels containing all required information on said label.

BPH will ensure that the information printed on the package shall be in English, in black lettering at least one-sixteenth of an inch high. BPH will print a product-specific label for every package of marijuana and/or manufactured marijuana products as well as a patient-specific label for all



qualified, registered patient prior to dispensing said product. If requested by a qualified, registered patient or caregiver, BPH may also print a label in another language. BPH will not distribute a package of marijuana and/or manufactured marijuana products without a label securely attached. BPH will state on all labels of a package the following as required under current regulations:

- Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
  - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
  - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
- The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
- The batch number and date of packaging;
- A computer tracking inventory identification number barcode generated by tracking software;
- Date of harvest or manufacture and a "use by date";
- Instructions for use;
- The phrases "For medical use only" and "Not for resale or transfer to another person";
- The following warnings:
  - "This product may be unlawful outside of the State of Hawai'i and is unlawful to possess or use under federal law";
  - "This product has intoxicating effects and may be habit forming";
  - "Smoking is hazardous to your health";
  - "There may be health risks associated with consumption of this product";
  - "This product is not recommended for use by women who are pregnant or breast feeding";
  - "Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug"; and
  - "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"
- A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
- The name of the laboratory that performed the testing

BPH labels will not contain any false or misleading statement or design or include any statement, image or design that may not be included on the package.

### **Waste Disposal**

BPH will utilize marijuana industry best practices to properly dispose of medical marijuana waste. Adherence to all applicable state and county laws pertaining to the destruction and disposal of marijuana waste within the facility is very important to ensure no marijuana waste products are being diverted. All medical marijuana waste, byproducts, and undesired products will be destroyed and disposed of according to all applicable state and county law. Facility management will ensure



proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state law. Record all required information on the *Marijuana Waste Log Sheet*.

**Disposal**—Disposal of any marijuana product waste must be rendered unusable and unrecognizable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.

### **Hours of Operation**

BPH hours of operation within the facilities may vary depending on the numerous factors such as types of operations being performed, the time of year, environmental factors such as weather and temperatures, etc. Hours of operation will fall within the state allowed hours of operation per regulations. BPH retail dispensary locations will remain closed during Hawai‘i state holidays and federal holidays. These State holidays will be represented by the days shown in the figure below which was obtained from the State of Hawai‘i Department of Human Resources Development website.

<b>Retail Dispensary Location(s)</b>	<b>Hours of Operation</b>	
	<b>Open</b>	<b>Close</b>
<i>Monday</i>	8:00	8:00
<i>Tuesday</i>	8:00	8:00
<i>Wednesday</i>	8:00	8:00
<i>Thursday</i>	8:00	8:00
<i>Friday</i>	8:00	8:00
<i>Saturday</i>	8:00	8:00
<i>Sunday</i>	CLOSED	CLOSED



## Year 2016 HAWAII STATE HOLIDAYS

<u>(Hawaii Rev. Statutes, Sec. 8-1)</u>	<u>Day Observed in 2016</u>	<u>Official Date Designated in Statute/Constitution</u>
New Year's Day.....	Jan. 1 Friday.....	The first day in January
Dr. Martin Luther King, Jr. Day.....	Jan. 18 Monday.....	The third Monday in January
Presidents' Day.....	Feb. 15 Monday.....	The third Monday in February
Prince Jonah Kuhio Kalaniana'ole Day.....	Mar. 25 Friday.....	The twenty-sixth day in March
Good Friday.....	Mar. 25 Friday.....	The Friday preceding Easter Sunday
Memorial Day.....	May 30 Monday.....	The last Monday in May
King Kamehameha I Day.....	June 10 Friday.....	The eleventh day in June
Independence Day.....	July 4 Monday.....	The fourth day in July
Statehood Day.....	Aug. 19 Friday.....	The third Friday in August
Labor Day.....	Sept. 5 Monday.....	The first Monday in September
General Election Day.....	Nov. 8 Tuesday.....	The first Tuesday in Nov. following the first Monday of even-numbered years. ( <i>Hawaii State Constitution, Article 2 – Section 8</i> )
Veterans' Day.....	Nov. 11 Friday.....	The eleventh day in November
Thanksgiving.....	Nov. 24 Thursday.....	The fourth Thursday in November
Christmas.....	Dec. 26 Monday.....	The twenty-fifth day in December

\* <http://dhrd.Hawaii.gov/state-observed-holidays/>

### **Adverse Events/Product Recall Policy**

BPH will liaise with its retained marijuana industry consultant ACC in the event of the emergence of an adverse event or the need for a product recall. ACC has developed previous adverse event and product recall policies and standard operating procedures to educate, train and guide businesses how to handle such situations. BPH and ACC will together develop an adverse event and product recall policy customized for the state of Hawai'i. Below highlights some of the information that will be included in our policy.

#### *How to Recall Medical Marijuana Products*

Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by Hawai'i state law will ensure a streamlined recall process if ever necessary.

#### *Corrective Action Plan (CAP)*

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and necessary steps to be taken by the facility once a product recall is required. A typical CAP includes five (5) primary steps:

1. Step One: Industry Notification
2. Step Two: Public Notification



3. Step Three: Procurement
4. Step Four: Documentation and Record Retention
5. Step Five: Disposal

### **Retail Operations**

All BPH retail dispensary locations will be selected and designed with patient safety, environment and accessibility in mind and will be ADA compliant featuring handicapped parking, handicap accessibility and restrooms. The retail dispensary locations will fulfill these goals:

- Develop a dispensary environment that gives the most access and relief to the patients
  - Dispensary shall be located in a location with ample parking at a central location
  - Dispensary shall have a welcoming look and feel that provides the patient with comfort through their retailing experience
  - Patient will be supported with professional consult and education
  - Dispensary will be secure at all times
  - Product will be offered at an affordable price
  - Patient needs will be met with the availability of most appropriate and high quality medicine

### **Retail Dispensary Locations**

BPH will ensure that all facilities comply with all applicable zoning laws.

The initial retail dispensing location will be located on the third floor of the Ala Moana Building in room 304, on the corner facing Ala Moana Mall across the mall level parking lot. There is ample parking at the 7 level parking structure right in front of the Ala Moana building. This location offers super accessibility from its central location in town, connection to the largest and busiest shopping mall in the state, unmatched parking availability, the busiest bus depot, and being in a large medical building with a large bank located on the ground floor.

**Square Footage**— 1832 sq ft with approximately 90 ft of parking lot frontage with a built in reception area and desk.

**Type of Building**—A concrete building with 23 floors built on 31,000 sq ft of land. The building is equipped with 6 elevators and central air conditioning. The building has security guards stationed 24/7 and the parking structure is closed at night with security guards, making the facility inaccessible during the night.

### **Daily Retail Processes**

The daily retail processes are explained in more detail in the Retail Standard Operating Procedures which is a separate, additional document that can be viewed upon request. Below is a high-level overview of various process involved with the daily retail dispensary location operations.

**Opening Responsibilities**—the opening responsibilities will primarily be comprised of getting the retail sales floor ready for the day. This will be detailed in the Retail SOP's.



**Closing Responsibilities**—the closing responsibilities will primarily be comprised of closing the retail sales floor and securing product for safe storage throughout the night. Closing responsibilities will be detailed in the Retail SOP’s.

**Patient Intake**—Patients wishing to patron the retail dispensing location will need to have a valid state medical marijuana patient license. Before entry into the retail dispensing location team members will verify the validity of each patient’s medical marijuana license through the state electronic verification system. After the verification process the patient will be allowed entry into the retail dispensing location.

**Dispensing/Sales Procedure**—the sales procedure needs to be completely accurate for every sales transaction. If sales records are not accurate inventory will have discrepancies and could result in compliance issues. Retail team members will go through extensive training on the POS system and the sales process before commencing operations. The sales procedure is explained in the Retail SOP’s.

**Customer Service**—Customer service policies will be created to ensure good working relationships with dispensing organizations and licensed patients within the State of Hawai’i. These procedures will cover requirements for handling customer complaints and returns of products. BPH is focused on patient well-being with a focus on patients’ medical history and symptoms to recommend the right products for an optimal outcome. BPH will solicit and respond to patient feedback after using our products to further improve effectiveness and patient satisfaction.

### **Legal Environment**

The legal environment surrounding BPH and the medical marijuana industry in the State of Hawai’i will be discussed in this section. Various state laws are discussed in more detail within the Standard Operating Procedures, Employee Manuals, Code of Conduct, etc.

**Licensing**—BPH will ensure that all required state and county licensing are acquired and in good standing prior to launching any cultivation, processing, or dispensing of medical marijuana. All required licensure will be kept on-site at the location facility and clearly displayed.

**Permits**—BPH will ensure all required permits are obtained prior to beginning any tasks or projects. Permits will be obtained for all construction projects or any other work requiring a permit.

**State Law**—BPH will ensure full compliance with all applicable law involving HRS Chapter 329D and HAR Chapter 11-850.

**Zoning**—BPH will ensure that all facility locations are in properly zoned and approved areas for medical marijuana cultivation, processing and dispensary operations.

**Building Codes**—BPH will ensure that all building codes are properly followed and enforced by all contractors, construction crews, or maintenance workers.



**Insurance**—BPH will ensure it is protected with all required and applicable forms of insurance. Insurance will include, but not be limited to, general liability insurance and workers compensation insurance.

### **Recruiting, Benefits, Hiring, Loss of Personnel**

BPH will properly train all of its employees before they are permitted to work in any BPH facility operations.

Prior to being offered an employment position with BPH, all potential applicants will be required to pass a background check to ensure the potential applicant does not have any criminal felony convictions or have been convicted of the crimes listed in HAR §11-850 (2)-(6) and otherwise is of good moral character.

BPH intends to offer competitive wages and salaries, as well as benefits packages that include paid time off and health insurance, to all employees. Exact compensation and benefits plans and packages are in the process of being developed. It is BPH's goal to pay salaries that are, at a minimum, equitable and commensurate with salaries paid for similar work within the labor market. Accordingly, positions will generally be classified and then assigned a salary range that defines a minimum and maximum pay rate. An employee's salary may advance within the salary range as the result of performance reviews, promotions, market conditions and other business considerations. Such increases in pay are considered merit adjustments which are not guaranteed and may vary in timing and degree from employee to employee.

In accordance with State legal requirements, employees will be compensated for hours worked in excess of forty (40) hours per week. Non-exempt employees will be paid one and one-half times their regular rate of pay for hours worked in excess of forty (40) hours in a workweek. Overtime pay is based on actual hours worked. Paid time off for holidays and vacations does not count as "hours worked" for overtime purposes. Any overtime hours worked by a non-exempt employees will be required to be approved in advance by the employee's supervisor. Non-exempt employees are not to work before, beyond or outside their normal working hours without such prior approval. Employees who fail to work scheduled overtime or who work overtime without prior authorization from a supervisor may be subject to disciplinary action, up to and including termination of employment.

**Number of Employees**—exact number of employees employed by BPH is to be determined upon deployment of operations and the establishment of personnel requirements; the breakdown of these requirements can be seen below within the job description section.

**Type of Labor**—the team at BPH will comprise skilled, unskilled, and professional workers. The various positions within the organization will call for different laborers with different skill sets. The cultivation manager will need to be very skilled in the cultivation of marijuana, whereas an entry-level cultivation laborer will likely be unskilled and trained to the job requirements and functions.

**Pay Structure**—BPH will determine this upon deployment of operations and the establishment of personnel requirements. Employee compensation will be competitive with industry standards



**Job Termination**—all termination actions will follow standard procedures. Basic steps include:

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e. employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges, or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel
4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e. mutual separation and key personnel is always welcome back at SFN facilities under visitor status, employee is no longer allowed on the premise, and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was vacated. Key personnel positions will need to be filled as soon as possible by management without compromising the quality of potential candidates.

### **HR Compliance**

BPH will utilize an Employee Handbook/manual that is compliant with all Hawai'i labor laws and will be utilized at all facilities. All registered employees will be required to read the Employee Handbook prior to commencing work in any BPH registered dispensary facility. The Employee Handbook will outline various company policies that must be followed. The handbook will also explain all Human Resources (HR) functions, employee benefits, and other company programs and policies.

### **Workplace Policies**

Prior to the deployment of any operations, BPH will develop and implement multiple workplace policies including an Employee Handbook, Drug and Alcohol Free Workplace Policy, Personal Hygiene Policy, and Code of Conduct. All BPH registered employees will be required to adhere to all policies and programs while employed for BPH.

**Employee Handbook**—BPH will develop and implement an Employee Handbook that will highlight the policies and procedures that employees will need to adhere to while working for



BPH. All employees will be required to read and sign the Employee Handbook prior to commencing work in any BPH facility.

**Drug and Alcohol Free Workplace Policy**—BPH will develop and implement a Drug and Alcohol Free Workplace Policy that will highlight the policies and procedures that employees will need to adhere to while working in any BPH facility. All employees will be required to read and sign the Drug and Alcohol Free Workplace Policy prior to commencing work in any BPH facility.

**Personal Hygiene Policy**—BPH will develop and implement a Personal Hygiene Policy that will highlight the personal hygiene policies and procedures that employees will need to adhere to while working for BPH. All employees will be required to read and sign the Personal Hygiene Policy prior to commencing work in any BPH facility.

**Code of Conduct**—BPH will develop and implement a Code of Conduct that will highlight the policies and procedures relating to employee conduct and ethics that will need to adhere to while working for BPH. All employees will be required to read and sign the Code of Conduct prior to commencing work in any BPH facility.

### **Job Descriptions, Personnel Development and Reviews**

Below details BPH’s employment structure for four (4) distinct operations of the organization 1) cultivation operations 2) manufacturing operations 3) retail dispensary operations and 4) security operations. The information displayed below details the anticipated organizational employment positions, the job descriptions and a potential number of employees for each job description upon deployment of operations.

**TBD, Sustainability Manager**

This person reports to the Chief Operations Oversee sustainable projects from design and build of the facilities, responsible for efficiencies and detecting issues that may related. Remain current with new technologies pertaining to sustainable and renewable technologies.

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#### **1) Cultivation Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Chief Operating Officer: Andrew Salini; Responsible for overall operation of entire facility; oversight of cultivation operational activities, processing operational activities, and security operational activities. All department managers will report directly to the GM.*
  - *Security Clearance: Restricted Area Access*
  - *Employees at Full Capacity: 1*
- *Cultivation Manager: Michael Rogers; Responsible for oversight of cultivation operational activities. Must ensure compliance with all laws and regulations and maintain accurate records and documentation. All cultivation department manager report directly to the Cultivation Manager. Reports directly to the General Manager.*



- *Security Clearance:* Restricted Area Access
- *Employees at Full Capacity:* 1
  
- *Vegetative Manager:* Responsible for oversight of all vegetative areas. Responsible for proper record keeping and documentation. Reports directly to Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Laborers are responsible for daily cultivation activities within the vegetative areas. Reports directly to the vegetative manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 4/TBD
  
- *Flowering Manager:* Responsible for oversight of all flowering areas, proper record keeping, and documentation. Reports directly to the Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Responsible for daily cultivation activities within the flowering area. Reports to the flowering assistant manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 8/TBD
  
- *Harvest Manager:* Responsible for oversight of all harvesting processes. Direct supervision of all managers in the harvest process. Reports directly to the Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
- *Trim/Cure Manager:* Responsible for oversight of trimming process and laborers, proper record keeping, and documentation and responsible for oversight of curing process and laborers, proper record keeping and documentation. Reports to the harvest manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Responsible for daily trimming activities and duties as well as responsible for daily curing activities. Reports to the trim/cure manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 8/TBD
  
  - *Packaging and Labeling Manager:* Responsible for oversight of packaging and labeling activities, laborers and proper record keeping, and documentation.
    - *Security Clearance:* Restricted Area Access
    - *Employees at Full Capacity:* 1



- *Laborer(s)*: Responsible for daily packaging and labeling activities. Reports to the packaging and labeling manager.
  - *Security Clearance*: Limited Area Access
  - *Employees at Full Capacity*: 6/TBD

## **2) Manufacturing Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Director of Manufacturing*: Responsible for oversight of entire infused products area and processes. Direct supervision of all department managers within the infused products area. Reports directly to the facility GM.
  - *Security Clearance*: Restricted Area Access
  - *Employees at Full Capacity*: 1
  - *Infused Products Manager*: Responsible for oversight of kitchen area and activities, laborers and proper record keeping, and documentation. Reports directly to MIP Manager.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: Responsible for daily kitchen activities and duties. Reports to kitchen manager.
      - *Security Clearance*: Limited Area Access
      - *Employees at Full Capacity*: 2/TBD
  - *Extraction Manager*: Responsible for oversight of daily extraction processes, laborers and proper record keeping, and documentation. Reports to the infused products manager.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: Responsible for daily extraction processes and activities. Reports to the extraction manager.
      - *Security Clearance*: Limited Area Access
      - *Employees at Full Capacity*: 4/TBD
  - *Packaging and Labeling Manager*: Responsible for oversight of packaging and labeling activities, laborers and proper record keeping, and documentation.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: responsible for daily packaging and labeling activities. Reports to packaging and labeling manager.
      - *Security Clearance*: Limited Area Access



- *Employees at Full Capacity: 6/TBD*

### **3) Retail Dispensary Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Director of Dispensary Operations:* Responsible for entire facility operations, ensuring full compliance with state law, organizational goals and objectives, etc.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
- *Assistant Manager(s):* Oversees daily retail operations, reports directly to GM
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full capacity:* 2/TBD
- *Patient Advocacy Manager:* Responsible for educating patients with information regarding the use of medical marijuana, etc. Reports to the assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 2/TBD
- *Sales Floor Supervisor(s):* Responsible for oversight of dispensary sales agents and supervision of sales floor activity.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 4/TBD
- *Dispensary Agent(s):* Responsible for daily sales procedures, customer service, patient education, etc. Reports directly to assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 30/TBD
- *Intake Specialist(s):* Responsible for patient check-ins, reports to the assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 4/TBD

### **4) Security Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Security Manager:* Responsible for security operations at the licensed facility. Responsible for oversight of security agents and transportation agents.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1



- *Security Agent(s)*: Responsible for facility entry protocol; ensuring proper identification of any visitors and ensures said visitors have proper security clearance to enter.
  - *Security Clearance*: Restricted Area Access
  - *Employees at Full Capacity*: 1
  
- *Transportation Agent(s)*: Responsible for transporting marijuana and manufactured marijuana products to BPH registered retail dispensary locations.
  - *Security Clearance*: Limited Area Access
  - *Employees at Full Capacity*: 2/TBD

**Personnel Development**—BPH management will be responsible for making a commitment to the on-going education and professional development of BPH registered employees. Once commencing work within a BPH facility, there will be multiple opportunities for continuing education and advancement within the organization. BPH management will be responsible for establishing a development path where registered employees learn from experience and work directly with their crew leaders to learn all aspects of their job. Crossover opportunities will be available and encouraged so employees can learn other areas of the business if they wish to advance to another department, such as a trimmer learning the basics of processing or growing.

In addition to comprehensive training records, BPH management will be responsible for tracking employee development through the use of a development checklist. The development checklist provides a clear visual of the level of training an employee has received as well as their eligibility for additional responsibilities. Once minimum training levels have been reached, crew leaders and management will foster further development of individual employees. Employees may view their progress and choose to take a roll in their own development through expressing interest in learning new processes and utilizing provided reading materials to advance their knowledge. As procedures and topics are mastered, employees will earn “checks” on the development checklist from their crew leaders and production facility management.

**Performance Reviews**—BPH will implement periodic performance reviews that will be utilized to evaluate registered employee performance on an individual level. Employee performance reviews will be conducted on a semi-annual basis and maintained within the registered employees personnel file.

## **Personal Financial Statement**

*Include personal financial statements for each owner and major stockholder, showing assets and liabilities held outside the business and personal net worth. Owners will often have to draw on personal assets to finance the business, and these statements will show what is available. Bankers and investors usually want this information as well.*

## **Startup Expenses and Capitalization**

*You will have many startup expenses before you even begin operating your business. It’s important to estimate these expenses accurately and then to plan where you will get sufficient capital. This*



*is a research project, and the more thorough your research efforts, the less chance that you will leave out important expenses or underestimate them.*

*Even with the best of research, however, opening a new business has a way of costing more than you anticipate. There are two ways to make allowances for surprise expenses. The first is to add a little “padding” to each item in the budget. The problem with that approach, however, is that it destroys the accuracy of your carefully wrought plan. The second approach is to add a separate line item, called contingencies, to account for the unforeseeable. This is the approach we recommend.*

*Talk to others who have started similar businesses to get a good idea of how much to allow for contingencies. If you cannot get good information, we recommend a rule of thumb that contingencies should equal at least 20 percent of the total of all other start-up expenses.*

*Explain your research and how you arrived at your forecasts of expenses. Give sources, amounts, and terms of proposed loans. Also explain in detail how much will be contributed by each investor and what percent ownership each will have.*

## **Financial Plan**

### **Blue Planet Healing - Pro Forma Narrative**

#### **Introduction**

As state medical marijuana markets across the US step into the community of regulated businesses, the qualified applicants that are fortunate enough to exhibit their merit and be awarded the initial licenses must recognize and act upon their concomitant responsibilities as pioneers in this emerging and evolving space. This means taking the necessary steps to ensure ethical, sustainable, and safe business practices are implemented with the needs of patients in mind. To accomplish this end, expectations cannot be inexorable. A critical element in achieving success in any new market is maintaining flexible market forecasts. In other words, operators in a market undergoing initial self-discovery would be wise to some degree to expect the unexpected. Delayed reactionary behaviors to unforeseen market dynamics could jeopardize the health of the entity, the industry, and most importantly the safety of patients and compliance with law.

When establishing our business plan, CPM, and quantitative market forecasts, Blue Planet Healing, LLC (“BPH”) has done so with an open frame of mind as BPH feels that will provide the operational agility to confront market dynamics as they unfold. As detailed below, BPH’s analysis incorporates and references the lessons learned from other states in the emerging medical marijuana industry, but does so while recognizing Hawai‘i is still its own unique place, with its own unique set of variables (demographics, cultural attitudes, etc.). Only then can BPH respond to changes in the regulatory scheme or market conditions should they exhibit a degree of variance from the base case, whether that is weaker demand and lower initial patient participation or excess demand and greater participation.

BPH’s collective experience in multiple fields including software, medicine, finance, sustainable energy, real estate, legal and, most importantly the regulated medical marijuana industry, make it



uniquely equipped to confront both the known and unknown challenges of Hawai‘i’s nascent medical marijuana market. BPH has the experience and is prepared to respond according to market conditions.

Specifically, as it relates to medical marijuana, BPH’s High Country Healing (HCH) and American Cannabis Consulting (ACC) consultants have an established 6+ year track record in Colorado’s medical marijuana market. Since 2009, HCH has successfully navigated the tumultuous waters of perpetual regulatory and structural market change. Over this entire time, HCH has operated successfully and achieved a blemish free record of operational compliance in both the medical and recreational marijuana cultivation and dispensing businesses. Part of HCH’s dedication to excellence has been a commitment by HCH to educate its employees, and by extension its patients regarding the safe and efficacious use of medical marijuana (see .edu attachments “X”). HCH is one of the first dispensaries in Colorado to enroll its employees in “Responsible Vendor Training” in 2015 by the Trichome Institute as soon as the curriculums were validated and sanctioned by the State of Colorado’s Marijuana Enforcement Division (MED).

It is this rich experience in the medical marijuana industry that cautions us against overconfidently forecasting market conditions. If BPH’s expectations are inflexible, this will inhibit the type of reactions required in order to maintain public and patient safety according to the law. BPH’s business plan, CPM, and attached financial projections reflect BPH’s initial assumptions on the growth of the medical marijuana market in Hawai‘i based on empirical analysis, industry experience, and an understanding of the host cultural and local attitudes towards marijuana in Hawai‘i.

### **Medical Marijuana Patient Adoption Rates – Current & Forecast**

Currently, there are approximately **2,836** duly registered medical marijuana patients on the island of Oahu as of 10/31/15, representing a significantly smaller number of registered patients than the other less densely populated islands (Hawai‘i, Kauai, and Maui). This can be interpreted as reflecting a variance in social norms regarding medical marijuana between the urban professional business center of Honolulu and the more rural communities of the neighbor islands.

**Figure 1: Hawai‘i Medical Marijuana (329) Registry Program**

Valid for October 31, 2015

<b>County</b>	<b>MMJ Patients</b>	<b>Population</b>	<b>% Card Holders</b>
<b>Hawai‘i</b>	4,998	196,520	2.54%
<b>Maui</b>	2,979	165,228	1.80%
<b>Oahu</b>	<b>2,893</b>	<b>1,000,715</b>	<b>0.29%</b>
<b>Kauai</b>	1,686	71,320	2.36%



<b>Total</b>	12,499	1,433,783	0.87%
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\* [http://files.hawaii.gov/dbedt/economic/data\\_reports/2040-long-range-forecast/2040-long-range-forecast.pdf](http://files.hawaii.gov/dbedt/economic/data_reports/2040-long-range-forecast/2040-long-range-forecast.pdf)

Current data indicates that **2.54%** and **2.36%** respectively, of the Hawai‘i and Kauai County population, are duly registered card-holding medical marijuana patients. Thus, these are approximately 9x as many residents holding medical marijuana cards on said islands, as a percentage of the population, compared to Oahu island, where just **0.29%** of the population are currently registered in the program. Only 1.8% of Maui’s population are registered patients.

### **Lessons from the Colorado Experiment**

Colorado, for example, which provides the largest and most robust data sample for legal marijuana markets, started at a similarly modest initial medical patient base as Oahu (0.1% adoption state-wide) before the introduction of a legal dispensary system (“LDS”) in mid-2009. After just two years of profound growth, the Colorado MMJ patient base peaked at **2.5%** of the population base in Q4 2011 before leveling out at **2.2%**, where it stands today.

As Figure 2 below illustrates, there was a decline from 2.5% towards 2% in Colorado’s market, but this simply reflects the State’s inability to expediently process patient card renewals because the LDS’s success was grossly underestimated. For instance, the actual market size was 111% greater than initial projections by the Colorado Center for Law and Policy. Nevertheless, Colorado adapted and allowed for patients awaiting renewal to continue to purchase MM as it expanded its operational capacity. In any event, the key takeaway is that Colorado’s adoption rate grew from just **0.1%** to over **2.0%** in just two-years. This greater than 2% adoption rate is currently the highest seen in any U.S. state medical MM market. Oregon, California, Michigan and Washington, fall into the second tier, with patient adoption rates between 1.4% and 2%.

Looking through the lens of nominal data, Colorado experienced impressive growth in the medical marijuana patient base from 5,000 patients under the caregiver framework in late-2009, to 125,000 patients in Q4 2011, with a population of just over 5 million residents. Extrapolating from this data, Hawai‘i medical marijuana companies and the State would be wise to prepare to handle significant patient registration volumes, but at the same time must not fall victim to heuristic based assessments and succumb to availability bias. To assume that Hawai‘i would experience similarly profound growth is not a base case.

Synthesizing the data from the mainland with the county data in Hawai‘i, one could logically extrapolate that the patient adoption rate on the Hawai‘i Island is relatively close to saturation with some reasonable potential for growth on the margin coinciding with onset of a regulated dispensary network. On the other hand, Oahu has much more significant potential for growth in the long-run, even if peak adoption rates eventually reach levels seen in the other counties in Hawaii or other states across the nation. As a result, BPH sees the greatest need in Oahu for seasoned operators who can leverage their experience in the medical marijuana industry to respond to a burgeoning market in a timely and compliant manner. This offers the best opportunity for patients to receive safe access to medicine without risking product quality or patient safety.



BPH's analysis for Oahu reflects an expectation for a healthy growing medical marijuana patient base in 2016 as citizens anticipate the opening of retail dispensing locations in the second half of the year. As the program matures and stigma recedes, we suspect an increase in the adoption rates moving into 2017 to just under 1% and acceleration in 2H 2018 (to 1.5%) as additional licensees and reciprocity comes into play. Eventually, in BPH's base case forecast, it sees a peak adoption rate of around **2.8%** by 2020. This peak adoption rate in the program is consistent with the current patient base level in other counties in Hawai'i and is the base case for Oahu. BPH is cautiously optimistic that participation will be *higher* given the already meaningful participation in the caregiver framework despite the lack of a regulated LDS network. Other market simulations project participation rates +/- 20% from this level and BPH's flexible cultivation methodologies and sufficient financial resources illustrate an ability to adapt to conditions within these bounds plus a contingency buffer for anomalous statistical outcomes. Nevertheless, we also felt it prudent to engage in more rigorous stress testing scenario analysis.

### **Market Share – 2018 Reciprocity & New Licensees**

Additionally, BPH's analysis assumes that BPH's market presence will grow with the growth of the overall market, but with declining market share over time as more medical marijuana businesses are awarded licenses and come online in 2018. The base case reflects a capture of 1/3 of the market share until other LDS's come online as early as mid-2018, and dropping to high single digits shortly thereafter. These assumptions are in response to increased demand from both the growth in the patient base as well as a modest influx of tourists from other states that can participate in the state's reciprocity program, which is set to take effect as early as July, 2018.

BPH has factored in the State's desire to meet patient need by having no more than one dispensing location per 500 registered patients, but through collective experience and planning, BPH is preparing to handle volumes well in excess of 500 patients should market demand outpace the LDS network. Long-term, if this **2.8%** peak participation level were achieved as expected, that would theoretically result in a maximum of 40 dispensing locations in the county of Oahu by 2021 at the time of market maturation.

Reciprocity will bring very marginal additional tourism business to the state starting in mid-2018, and will be less of a driver of the market than de-stigmatization on the island itself. To capture the impact of reciprocity on the market, we looked at the monthly tourism data from the mainland and distilled how many medical marijuana patients were represented from each state that currently has a medical marijuana program. Subsequently, using average visit lengths (9.54 days) and cannabis consumption patterns, we were able to estimate the marginal revenue generation from these customers. Specifically, the bulk of this tourism injection will come from the mainland Pacific region (CA, AK, WA, OR, NV), which is largely comprised of states with medical marijuana programs. We factored in growth in the patient bases from each of these states, particularly California, which has significant potential for growth once its regulatory scheme is more firmly established in coming years. Nevertheless, we estimate the impact of medical marijuana patient reciprocity to initially be marginal at best, but contribute in larger fashion in longer-term forecasts.

### **Price of Medical Marijuana**



A major driving motivation of BPH team is to provide sustainably produced, pharmaceutical quality, and affordable medicine to patients in need. If Hawai‘i’s market emerges with prohibitive prices, it will deleteriously impact those in need most and potentially incentivize black market consumption. The medical marijuana movement, is not about capturing market share in a new potentially lucrative industry, rather, it is about educating patients, researching medical marijuana, and illuminating upon the values and benefits of what BPH feels is the most healing plant on earth. To share in the healing powers of this plant, BPH is dedicating resources to employee and customer education as well as research.

These initiatives, like research and education, will absorb financial resources, but BPH feels they are vital as the more we understand the plant and its benefits, the closer we are to optimizing patient health and well being. The effects of this positive feedback loop, will reverberate through society as a whole. Therefore, when it comes to product pricing, BPH realizes that if BPH is fortunate to be one of the initial players in this market, we seek to offer reasonably priced medicine as dictated by market dynamics and internal financial considerations. A significantly regulated market framework, will naturally require marginally more costly medicine than the caregiver framework currently provides. According to [priceofweed.com](http://priceofweed.com), a high quality ounce of medical marijuana costs **\$302/oz** in Hawai‘i while low quality is at **\$270/oz**. This is higher than the national average and prices seen in Colorado (\$250/oz), but elevated utility costs and the cost of labor in Hawai‘i versus other states are likely key contributors to sustaining higher than average prices.

As it is BPH’s goal to produce pharmaceutical grade medical marijuana, its base forecast reflects prices in line with current high quality ounces on Hawai‘i (**\$302/oz**, or **\$10.96/g**). However, BPH examined multiple other simulations with lower prices per ounce (down to \$150/oz) in order to better understand the operational feasibility of price fluctuations. An overarching theme of BPH’s approach to this new market is to have an open mind with respect to market dynamics. Thus are preparing to manage price volatility, with a predetermined understanding of what such price variances could mean for the bottom line and the health of the organization. BPH feels confident that its business acumen, expertise in medical marijuana, and deep financial resources position it favorably to deliver high quality medicine to those in need, while being able to weather considerable market volatility.

## **Consumption Behaviors**

In additional to forecasting the patient base, another key consideration is the consumption pattern of those patients. Unlike Colorado at the onset of its market, with numerous states medical



marijuana programs already online, there is a more robust empirical data set to use to cross-reference demand assumptions.

In Colorado, for example, a large part of the State’s underestimation of initial demand was expectations on the “heavy user” (daily user) segment of the population. According to the 2014 National Survey on Drug Use and Health, 23% of the user population in Colorado consumes almost daily, compared with just 17% nationwide.

The mosaic of data and cultural attitudes in Hawai‘i as exemplified by the relatively high adoption rate state-wide before the onset of a true regulated dispensary framework, suggests that relatively high consumption rates by the daily user segment of the patient base will be higher than the national average of 17% but not necessarily higher than 23%. Therefore, in BPH’s forecasts BPH chose to be conservative and baked in higher than average use, but also ran multiple scenario analysis to account for some variance (again, bullish and bearish scenarios +/- 20% in addition to more rigorous stress testing).

### Demographics

One of the key differentiators of Hawai‘i’s current duly registered medical marijuana patient base is the age distribution. As it relates to gender, Hawai‘i is consistent with many other states including Colorado, showing roughly 2/3 (68% vs. 64% in CO) of the base being male and 1/3 (32% vs. 36% in CO) being female. Yet, which age group represents the largest share of patients reflects an interesting contrast to other states. In Hawai‘i, the largest cohort of patients comes from the 56-65 year old segment (27.6%) vs. the 21-30 year old segment in Colorado (23.2%). This data is heat-mapped in Figure X below for illustrative purposes.

**Figure 3: Hawai‘i Medical Marijuana Patient Distribution**

(by Age)

<b>AGE</b>	<b># of Patients</b>	<b>Percentage of Base</b>
<b>&lt;17</b>	25	<b>0.20%</b>
<b>18-25</b>	573	<b>4.58%</b>
<b>26-36</b>	2,098	<b>16.79%</b>
<b>36-45</b>	2,084	<b>16.67%</b>



<b>46-55</b>	2,381	<b>19.05%</b>
<b>56-65</b>	3,450	<b>27.60%</b>
<b>66-75</b>	1,681	<b>13.45%</b>
<b>76-99</b>	207	<b>1.66%</b>
<b>Total</b>	12,499	

The larger proportion of the patient base in the 55-65yo demographic is consistent with experience in Colorado from the onset of the LDS program. For instance, in 2009 when HCH first opened its doors, a higher percentage of patients were near retirement age. Further anecdotal evidence reflects that medical marijuana was selected as an organic remedy following many years (decades) of battling the side effects of synthetic pharmaceutical prescriptions, mainly opiates. Pain relief, after all, is by far the most common mentioned reason for consuming medical marijuana. 92% of patients in Hawai‘i and 94% of patients in Colorado list this as justification for obtaining their medical marijuana cards.

Taking this one step further, it is the belief of BPH, through HCH and ACC’s real-time experience in the industry in Colorado and other states, that this older segment of the population consumes a larger proportion of infused products (oils, pills, lozenges) rather than inhaled products (flower) for actual and perceived health reasons. For instance, the longer duration and intensity of ingested medication (4-6h of relief vs. 1-2h for inhaled) make it a superior choice to address physical pain, auto-immune, and neuropathic conditions and thus a welcomed remedy for many elder patients. BPH’s collective realization of this dynamic was an important consideration in its partnership with Chief Medical Officer (CMO) Dr. Bradley Willcox, who as a UH affiliated scientist and researcher has deep experience in the area of geriatrics and gerontology.

While this assessment is not empirically robust, it does hint as to how things might unfold and thus caution and prepare BPH for a different set of circumstances than are currently reflected in today’s data. Qualitative experience oftentimes is shunned over the more concrete and tangible nature of quantitative analysis due to BPH’s collective desire for control and greater comfort with numbers than abstract ideas, yet quantitative approaches too have their own pitfalls such as data mining and confirmation bias.

Even though the cumulative consumption basket is challenging to quantify with precision, current evidence signals to us that we should be prepared to offer a relatively greater selection of products in the infused category in anticipation of larger initial demand. It was also a motivating factor in creating a vast array of non-inhaled, infused products, including sprays, lozenges, oils, and pills. This distinction between flower and infused products is quite significant to BPH’s business plan as the different product sets have varying costs of production and shelf life. For example, medical marijuana that is grown to be smoked, requires much greater dedication to the nuances of growing the plant to produce the proper flower structure as well as terpene (essential oil) yields, while



infused products (pills, lozenges, oils) place the greatest emphasis on simple trichome (cannabinoid) production.

So, looking ahead, it is critical for BPH to maintain accurate up-to-date empirical data on the patient base on Oahu in order to better serve the patient's medical needs and forecast their needs with greater accuracy. For instance, the current adoption rate in Oahu County is just 0.29%. The expectation is for this to increase roughly 10x within 5 years. It is possible that the 26-36yo segment experiences more significant growth, which would redistribute consumption patterns over time, yet, perhaps the most likely outcome is that the 55-65yo segment that grows most significantly.

According to the most recent census data, which shows Oahu County expected to grow at **0.6%** per annum from 2015-2020, **16.1%** of the Hawaiian population is over 65, versus **14.5%** as the national average. Colorado, on the other hand, is younger, with just **12.7%** above the age of 65. Using this data as a guide and not gospel, BPH reasonably anticipates a relatively higher consumption of infused products compared to inhaled products, especially at the onset. Yet again, BPH feels it is absolutely critical to maintain meticulous oversight on each of these market variables to ensure BPH's greatest chances at continuing to provide medicine to patients in need and react to market developments in real-time.

### **Cultivation Methodologies – Maintaining Flexibility**

Under Hawai'i law, all licensees are restricted to 3,000 plants per cultivation center, for a maximum of 6,000 plants. Additional licensees are set to be considered by the State at the end of 2017 for launch in mid-2018 should market conditions dictate the need for extra capacity. But what if demand surpasses the needs of patients before additional licenses are awarded in 2018? BPH, for one, is ready to confront such challenges by maintaining flexible cultivation methodologies that allow for varying plant counts per light (and thus plant size) in order to meet excess demand. Through the collective experience of HCH and ACC, BPH is prepared to confront these challenges and efficiently adapt to shifting market dynamics. It is BPH's goal with its initial production centers to maintain a high level of flexibility in production to meet many potential demand scenarios while BPH moves towards the longer goal of building a state of the art, sustainable cultivation facility, leveraging BPH's team's depth of experience in energy.

### **Summary**

BPH's collective track record in various realms of business, including the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of the Hawaiian medical marijuana market. BPH's approach is not inexorable, nor is it dogmatic. BPH's initial cultivation center is strategically poised to navigate the volatility of a new market while sewing the seeds of the long term vision of Hawaii's 2015 CEO of the Year, Henk Rogers, which is to create the gold standard for sustainable cultivation practices in the medical marijuana industry.

While BPH acknowledges the uncertainties of a new market, the base case assumptions are grounded in over 6 years of experience within the marijuana industry and a combination of



qualitative and quantitative analysis of the Hawaii market. BPH has evaluated initial market conditions and made calculated estimations on the market's development from the awarding of licenses in April 2016. BPH's analysis factored in consumption patterns, demographics, population growth, reciprocity, and more to achieve a base case forecast, which was then subjected to rigorous stress testing.

Armed with the knowledge gained from both experience in Colorado and analysis of the Hawaii market, BPH feels confident in its ability to deliver pharmaceutical grade, sustainably produced medical marijuana to Hawaii consumers in 2016. BPH has the business acumen and deep financial resources to accomplish its goal and the passion to share what BPH believes to be the most healing plant on earth with those who are suffering and in need.

*are expressed as a percent of total sales.) Include all assumptions upon which your break-even calculation is based.*

## **Security and Diversion Plan**

BPH recognizes the importance of incorporating security considerations into every aspect of its operational activities in order to ensure the safety of both BPH's customers and the public and that none of the MM produced by the Company is diverted for distribution outside the statutory framework contained in HRS Chapters 329 and 329D. BPH also understands that the failure to comply with the security requirements of Hawai'i law jeopardizes not only the safety of the public, BPH's customers and a license issued to BPH under Chapter 329D, but also Hawai'i's MM program itself which remains subject to scrutiny by federal authorities pursuant to the Cole Memorandum.

In order to implement a comprehensive and holistic approach to the management of all activities involving the chain of custody of MM, including activities in BPH's RDLs and PCs and in connection with the authorized transportation of MM, BPH will engage the services of Securitas, one of the largest security companies in the world. With over 300,000 employees and operations in over 50 countries Securitas is the Company that the State of Hawai'i has entrusted to provide security services for all of Hawai'i's airports. After comprehensive due diligence, BPH selected Securitas as its security services provider not only because it is one of the oldest and most respected security companies in operation today but because it also has experience designing and installing security systems in MM facilities in other states. BPH has reviewed with Securitas the requirements of HRS §329D (6) and (7) and HAR §11-850-51, §11-850-52 and §11-850-53. Securitas will provide security system consultation, design, and management services which fully comply with the foregoing provisions of law including all requirements regarding: access control; surveillance; and intrusion deterrence, detection and response.

BPH will also utilize written security SOPs developed from best practices currently used in MM operations in Colorado which fully comply with Hawai'i law.

**Video Surveillance System.** Securitas will design video surveillance systems at each of BPH's RDLs and PCs that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will



clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

**Alarm System.** Each RDL and PC operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

**System Failure.** In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

**Other Security Measures.** All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH-approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

**Production Center Specific Security Measures.** In addition to all the above mentioned and all other security measures required by HRS Chapter 329D and HAR Chapter 11-850, BPH will utilize a perimeter security fence around each PC that surrounds the entire premise sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any marijuana in any form as required by HAR §1185052 (1). In addition, BPH will secure all marijuana and manufactured marijuana products in a locked room, vault or container which is securely fixed to a wall or the floor to ensure product safety and to prevent theft.



**Retail Dispensary Location Specific Security.** BPH will implement and follow specific security procedures and policies for all RDL operations including: written SOPs for admitting registered patients and primary caregivers with valid government-issued photo identification cards issued pursuant to HRS Chapter 329 into the secure rooms for sales. BPH will design and construct each RDL with separate, secure room(s) for sales wherein marijuana and manufactured marijuana products are secured and locked in display cases for viewing.

As required by HAR §11-850-53(3), BPH will follow written policies and procedures to ensure that a maximum occupancy limit ratio is maintained in all secured sales rooms of two customers to everyone RDL employee. BPH will store all marijuana products within a locked room, vault or in a locked container securely affixed to a wall or floor. All RDLs shall have exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities.

**Transportation Security.** BPH will utilize HCH's experience and knowledge in the development and implementation of transportation policies and procedures based on industry best practices from current operations in Colorado's regulated marijuana industry which are fully compliant with HRS §329D-7(7) and HAR §11-850-36.

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees. 3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH's tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.



**Security Lighting**—Securitas will ensure the installation and maintenance of exterior security lights around the entire perimeter of the facility to allow surveillance in low light conditions and deter potential intrusion.

**Security Perimeter Fencing**—Securitas will install new perimeter security fencing at the cultivation/production facility locations to deter unwanted and unauthorized access to the facility.

**On-Site Electronic Monitoring**—BPH facility security rooms will have a large screen call-up monitor and a video printer capable of immediately producing a clear still photo from all video cameras.

**Commercial Grade Door Locks**—Securitas ensure the use of commercial-grade, non-residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas.

**Safes and Product Storage**—BPH will utilize commercial grade safes for product storage. Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana and manufactured marijuana products.

**Restricted and Limited Access Areas**—Management will maintain policies and procedures that limit access to the areas within facilities to only approved authorized personnel or visitors being accompanied at all times by a facility employee.

**Policies and Procedures**—Additional policies and procedures will prevent loitering, aid in electronic monitoring, and be utilized to ensure automatic electronic notification of local law enforcement agencies of any unauthorized breach of security at BPH facilities.

**Facility Layout/Site Diagram**—a facility layout/site diagram will be maintained on site at the Cultivation facility that will clearly define each area of the facility. The site diagram will be updated as soon as any changes are made to ensure a current facility layout.

**Inventory Management**—Inventory management is a critical factor within the organization. The tracking of all medical marijuana from seed to sale will be done through inventory management through the use of template log sheets, BioTrackTHC™ computer systems and Point-of-Sale systems (POS).

**Incident Management**—an effective incident reporting procedure includes identification, limiting liability, and prevention. BPH will maintain an ongoing Incident Report Log (IRL) both physically and digitally.

**Emergency Protocol**— BPH will establish emergency protocols to be implemented organization wide. Employees of the organization will be fully trained on emergency protocols before beginning employment with the company. Emergencies protocols will be developed for robbery or theft, fire emergency, chemical spill, and for other emergencies as needed. Emergency protocols are explained in more detail in the SOP's.

**Local Authorities**—BPH will establish relationships with local authorities to ensure quick response teams will be dispatched to all dispensary facilities when an alarm is raised.



## **Community Plan**

As an organization we realize that when we begin operations we will become a member of the surrounding communities and as such we want to become a valuable and productive member within said communities. Safety for our employees and the surrounding communities is of utmost importance to our organization. With the presence of our facility and the security systems planned for the facility and surrounding area, should help to reduce crime. We have plans to develop and implement community outreach programs. Such programs and events will include food and clothing drives for local food banks, churches, and others. A plan to donate a certain percentage of yearly profits to schools and infrastructure of the surrounding community is also in development. BPH will also adhere to the 'Good Neighbor Policy' at all facility locations.

### **Good Neighbor Policy**

The facility management team is committed to building and maintaining good relationships with all of its neighbors – including local business improvement districts, building owners, small businesses, and residents alike. The facility team shall make every effort respect the perspectives of our neighbors and to address their concerns. The following steps shall be made to ensure any concerns within the community are addressed:

- Introduction meetings with all surrounding businesses, building owners, and residents.
- Educational information sessions to discuss the benefits of marijuana and the company's overall mission and goals.
- Open feedback channels so any new concerns can be immediately addressed through our website, telephone, or mail.
- Complete compliance with all state and local ordinances.
- Non-obtrusive business practices shall ensure our business is discreet and operates like any other business.
- No blatant signage with offensive symbols or verbiage.
- Unmarked discreet transportation vehicles.

In addition, the facility will use carbon air filters to ensure no noxious odors from production are released into the surrounding neighborhoods.

### **Environmental Impact Plan**

Conservation and the reduction of our carbon footprint within the communities we operate in will be a primary objective of the organization. This will be implemented throughout the entire organization and at every facility. We will look for new and innovative ways to reduce our carbon footprint within every facility of the organization. 'Reduce, Reuse and Recycle' will be implemented on an organization-wide scale.

Environmental sustainability is of the highest priority in order to promote a sustainable community and ensure the impact of business is positive and influential in achieving future environmental goals. In order to reach this goal we have contracted designers, engineers and consultants who shall design intelligently, utilize energy intelligently, and strive for procedures that lead to zero waste. Various factors will be considered thoroughly when planning equipment, procedures, and methodology: Air quality, climate, ecological health, energy efficiency, water

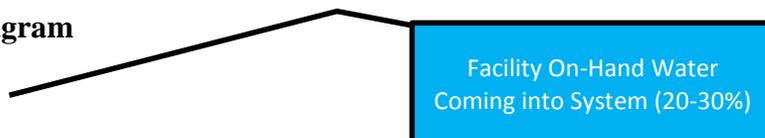


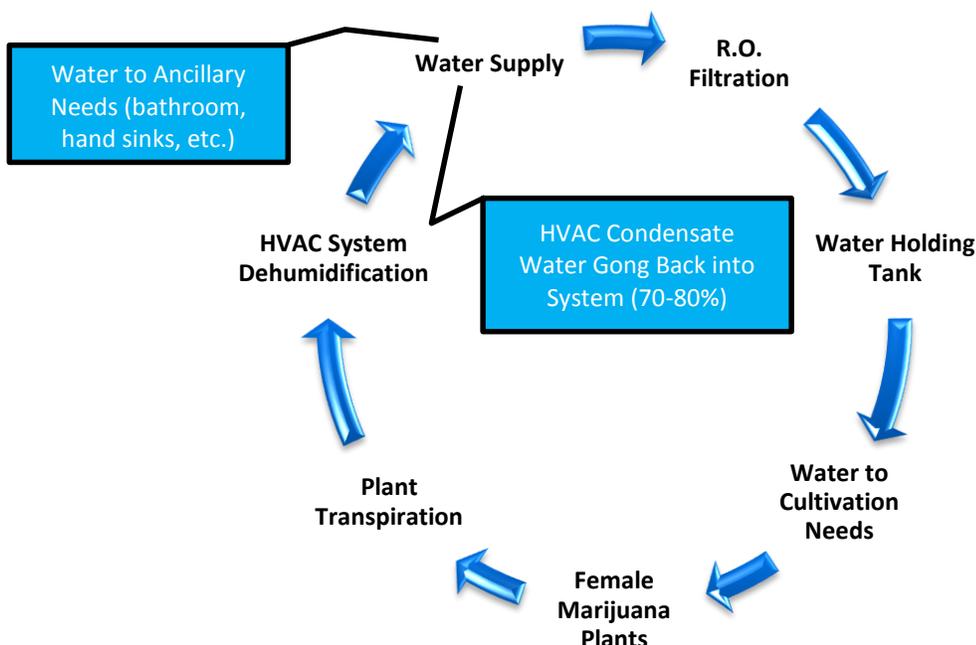
quality, transportation, and waste.

**Energy Conservation**—BPH has unique access to technologies through its team members and the network of scientists and engineers that allow the creation of a sustainable operation. BPH recognizes that power consumption by marijuana producers in other states have been a significant concern for the local government, community members, and the utility companies. Reports estimate California’s 3% to 5% of total power consumption is drawn by the marijuana cultivation industry. With cooperation from alternative energy companies, bioengineering companies, and tech companies, BPH will design and construct a cultivation facility of the highest efficiency and sustainability without sacrificing quality of the produced product. Natural sunlight diffused through a solid non see-through translucent roof with an infrared blocking coating will provide much of the light required for growing. Next generation dimmable LED grow lights, 20% more efficient than conventional LED grow lights in the market in 2015, tailored for hybrid use will supplement the diffused light with precise wavelengths optimal for the current growth stages of the plants. Every environmental factor is monitored by a robust sensor system with over 80 types of sensors that communicate in real time to each of the lights, HVAC equipment, irrigation equipment, and to the cultivation employees; allowing for a real time automatic and/or remote manual control of every aspect of the indoor cultivation environment. Plant biology and conditions will be monitored in order to optimally control the reaction of the plants to the environment and vice versa, allowing the creation of a system in which the plants and the facility will breathe at the same rhythm. By controlling light quality and quantity at the transition of light periods, the system can eliminate a bulk of the spike in relative humidity caused by the transpiration by controlling the closure of the stomata, the pores on the leaf surfaces. The level of precision , monitoring, and control will allow for a massive reduction in power demands by the cultivation facility. The reduced demands will be easily met with renewable energy sources that could include but not limited to solar, wind, hydro power, and hydrogen fuel cells coupled with the advanced energy storage solutions offered by BPES to create the world’s first sustainable marijuana cultivation facility using 100% renewable energy.

**Water Conservation**—In keeping with the sustainable approach, BPH will be collecting moisture from the air through dehumidification with the HVAC system and diverting it back to the Reverse Osmosis (RO) System to re-water the plants. As plants grow, they transpire approximately 70%-80% of the water they drink into the air and this raises humidity levels. As the environmental control systems maintain the parameters needed for optimal plant growth, the HVAC system will be required to provide adequate dehumidification. This dehumidification would produce condensate that typically would be discharged outdoors or in the sewer system as waste water, but BPH will be recapturing this condensate and piping it back to the RO System to be filtered and sent back to out to water the plants. This significantly reduces water consumption to provide environmental and financial benefits.

### Cultivation Facility Water Flow Diagram





BPH management will also create and implement an employee conservation plan. The employee conservation plan will detail specific actions employees can take for conservation efforts to try and reduce their carbon footprint. A possible reward program may be created and implemented to reward facility employees for conservation efforts.

**Employee Conservation:** Team members of BPH will be encouraged to recycle all paper and plastic waste products. Energy efficient lights and equipment will also be utilized within the facility. We will also create programs within the organization that will encourage and reward employees for their personal conservation efforts; such as carpooling and riding a bike to work. Waste products from the facility will be composted on site or mixed with biodegradable products for disposal.

### **Community Benefits Program**

Blue Planet Healing, LLC. (BPH) will contribute a percentage (to be determined after six months of operation) of net profit to organizations with tax-exempt status under Section 501 (c)(3) of the U.S. Internal Revenue Code working to strengthen the community. BPH will direct its contributions to areas that the Board of Directors believe are important to the future of community development, education, and human services. BPH's first priority is to support programs and organizations whose chief purpose is health and community education.

BPH will support organizations and programs that support **education**, specifically programs that:

- Work to eliminate pre-K – 12<sup>th</sup> grade achievement gap in public education through curriculum-based or school-sponsored programs
- Support post-secondary education
- Support booster programs for drug abuse prevention, awareness, and treatment



BPH will support organizations and programs that support **health**, specifically programs that:

- Support research into cures and treatments for qualifying conditions
- Support further research into effective marijuana treatments of qualifying conditions
- Support programs that will improve the health of the community

BPH will support the improvement of low and moderate income communities through programs that:

- Create and sustain affordable housing
- Facilitate literacy
- Provide job training and workforce development
- Revitalize and stabilize community
- Education

BPH will consider requests from organizations that work to enhance community diversity through **arts and culture** and provide:

- Access to and participation in cultural experiences for low and moderate income individuals
- Availability of a broad array of artistic opportunities and venues that reflect the community's diversity

BPH will consider requests from organizations that work to enhance a community's quality of life through projects involving **civic engagement** through:

- Public policy
- Community beautification
- Civic leadership
- Citizen education
- Cultural diversity

BPH is committed to building strong **environmental practices** through programs that:

- Conserve natural resources
- Protect endangered species
- Preserve the environment

BPH will consider requests from social and **human service organizations** that:

- Enable and sustain independence for individuals and families
- Ensure access to health education programs and quality health care

If organizations meet BPH's eligibility requirements and fit in with our philanthropic goals and objectives, we will accept requests and review them throughout the year. Local decisions are made with priority.

### **Substance Abuse and Prevention**

BPH intends to be pro-active in recognizing and preventing substance abuse. In the event that, based on data collected or observation, a potential substance abuse problem is identified; the



patient will be notified and provided with a list of local providers for patient assistance, drug and alcohol treatment and family services that patients may access without BPH involvement. It is at dispensary's agent discretion the extent to which they will provide additional assessment, evaluation, counseling, and/or referral for treatment. BPH employees will be provided training on identifying substance abuse problems.

BPH dispensary staff members will be trained on the physical effects of marijuana on the human body, recognizing the signs of marijuana impairment and what to do should the team member feel that dispensing medical marijuana to a patient and/or caregiver is not in their best interest and could result in negative consequences. All BPH professional staff members have the authority to deny dispensing medical marijuana and/or medical manufactured marijuana products to any Hawai'i qualified, registered patient or caregiver if they reasonably suspect there could be substance abuse problems with said patient or caregiver.



## Appendices

- Financial Pro-Forma Model
- Standard Operating Procedures
  - Cultivation
  - Manufacturing
  - Retail dispensing
  - Log Sheets
- Employee Handbook
- Security Plan



## **Attachment 2.2** **Financial Plan**

### **Blue Planet Healing LLC - Pro Forma Narrative**

#### **Introduction**

As state medical marijuana markets across the US step into the community of regulated businesses, the qualified applicants that are fortunate enough to exhibit their merit and be awarded the initial licenses must recognize and act upon their concomitant responsibilities as pioneers in this emerging and evolving space. This means taking the necessary steps to ensure ethical, sustainable, and safe business practices are implemented with the needs of patients in mind. To accomplish this end, expectations cannot be inexorable. A critical element in achieving success in any new market is maintaining flexible market forecasts. In other words, operators in a market undergoing initial self-discovery would be wise to some degree to expect the unexpected. Delayed reactionary behaviors to unforeseen market dynamics could jeopardize the health of the entity, the industry, and most importantly the safety of patients and compliance with law.

When establishing our business plan, CPM, and quantitative market forecasts, Blue Planet Healing, LLC (“BPH”) has done so with an open frame of mind as BPH feels that will provide the operational agility to confront market dynamics as they unfold. As detailed below, BPH’s analysis incorporates and references the lessons learned from other states in the emerging medical marijuana industry, but does so while recognizing Hawai‘i is still its own unique place, with its own unique set of variables (demographics, cultural attitudes, etc.). Only then can BPH respond to changes in the regulatory scheme or market conditions should they exhibit a degree of variance from the base case, whether that is weaker demand and lower initial patient participation or excess demand and greater participation.

BPH’s collective experience in multiple fields including software, medicine, finance, sustainable energy, real estate, legal and, most importantly the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of Hawai‘i’s nascent medical marijuana market. BPH has the experience and is prepared to respond according to market conditions.

Specifically, as it relates to medical marijuana, BPH’s High Country Healing (HCH) and American Cannabis Consulting (ACC) consultants have an established 6+ year track record in Colorado’s medical marijuana market. Since 2009, HCH has successfully navigated the tumultuous waters of perpetual regulatory and structural market change. Over this entire time, HCH has operated successfully and achieved a blemish free record of operational compliance in both the medical and recreational marijuana cultivation and dispensing businesses. Part of HCH’s dedication to excellence has been a commitment by HCH to educate its employees, and by extension its patients regarding the safe and efficacious use of medical marijuana (see .edu attachments “X”). HCH is one of the first dispensaries in Colorado to enroll its employees in “Responsible Vendor Training” in



## Attachment 2.2

2015 by the Trichome Institute as soon as the curriculums were validated and sanctioned by the State of Colorado’s Marijuana Enforcement Division (MED).

It is this rich experience in the medical marijuana industry that cautions us against overconfidently forecasting market conditions. If BPH’s expectations are inflexible, this will inhibit the type of reactions required in order to maintain public and patient safety according to the law. BPH’s business plan, CPM, and attached financial projections reflect BPH’s initial assumptions on the growth of the medical marijuana market in Hawai‘i based on empirical analysis, industry experience, and an understanding of the host cultural and local attitudes towards marijuana in Hawai‘i.

### **Medical Marijuana Patient Adoption Rates – Current & Forecast**

Currently, there are approximately **2,836** duly registered medical marijuana patients on the island of Oahu as of 10/31/15, representing a significantly smaller number of registered patients than the other less densely populated islands (Hawai‘i, Kauai, and Maui). This can be interpreted as reflecting a variance in social norms regarding medical marijuana between the urban professional business center of Honolulu and the more rural communities of the neighbor islands.

**Figure 1: Hawai‘i Medical Marijuana (329) Registry Program**

Valid for October 31, 2015<sup>1</sup>

County	MMJ Patients	Population <sup>2</sup>	% Card Holders
Hawai‘i	4,998	196,520	2.54%
Maui	2,979	165,228	1.80%
<b>Oahu</b>	<b>2,893</b>	<b>1,000,715</b>	<b>0.29%</b>
Kauai	1,686	71,320	2.36%
Total	12,499	1,433,783	0.87%

\* [http://files.hawaii.gov/dbedt/economic/data\\_reports/2040-long-range-forecast/2040-long-range-forecast.pdf](http://files.hawaii.gov/dbedt/economic/data_reports/2040-long-range-forecast/2040-long-range-forecast.pdf)

Current data indicates that **2.54%** and **2.36%** respectively, of the Hawai‘i and Kauai County population, are duly registered card-holding medical marijuana patients. Thus, these are approximately 9x as many residents holding medical marijuana cards on said islands, as a percentage of the population, compared to Oahu island, where just **0.29%** of the population are currently registered in the program. Only 1.8% of Maui’s population are registered patients.

### **Lessons from the Colorado Experiment**

<sup>1</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>

<sup>2</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>



## **Attachment 2.2**

Colorado, for example, which provides the largest and most robust data sample for legal marijuana markets, started at a similarly modest initial medical patient base as Oahu (0.1% adoption state-wide) before the introduction of a legal dispensary system (“LDS”) in mid-2009. After just two years of profound growth, the Colorado MMJ patient base peaked at **2.5%** of the population base in Q4 2011 before leveling out at **2.2%**, where it stands today.

As Figure 2 below illustrates, there was a decline from 2.5% towards 2% in Colorado’s market, but this simply reflects the State’s inability to expediently process patient card renewals because the LDS’s success was grossly underestimated. For instance, the actual market size was 111% greater than initial projections by the Colorado Center for Law and Policy. Nevertheless, Colorado adapted and allowed for patients awaiting renewal to continue to purchase MM as it expanded its operational capacity. In any event, the key takeaway is that Colorado’s adoption rate grew from just **0.1%** to over **2.0%** in just two-years. This greater than 2% adoption rate is currently the highest seen in any U.S. state medical MM market. Oregon, California, Michigan and Washington, fall into the second tier, with patient adoption rates between 1.4% and 2%.<sup>3</sup>

Looking through the lens of nominal data, Colorado experienced impressive growth in the medical marijuana patient base from 5,000 patients under the caregiver framework in late-2009, to 125,000 patients in Q4 2011, with a population of just over 5 million residents. Extrapolating from this data, Hawai‘i medical marijuana companies and the State would be wise to prepare to handle significant patient registration volumes, but at the same time must not fall victim to heuristic based assessments and succumb to availability bias. To assume that Hawai‘i would experience similarly profound growth is not a base case.

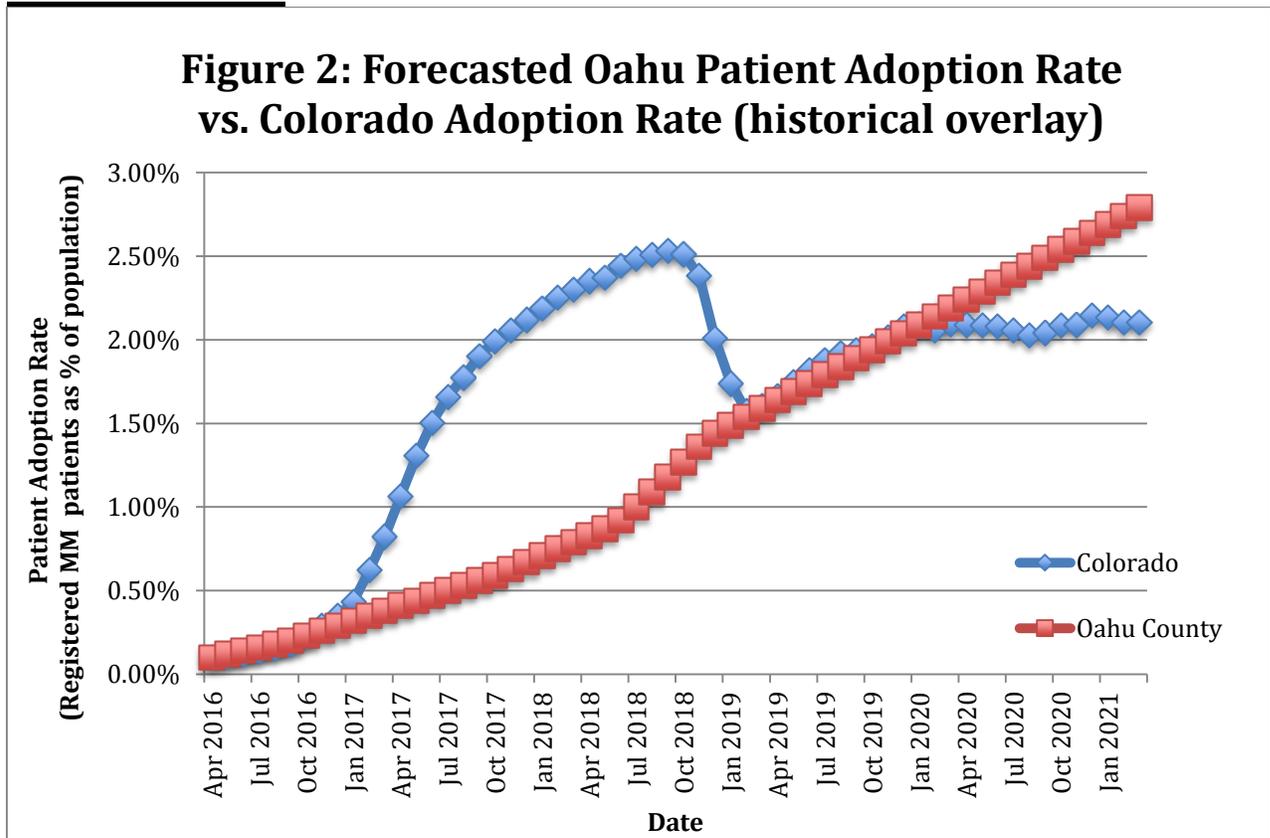
Synthesizing the data from the mainland with the county data in Hawai‘i, one could logically extrapolate that the patient adoption rate on the Hawai‘i Island is relatively close to saturation with some reasonable potential for growth on the margin coinciding with onset of a regulated dispensary network. On the other hand, Oahu has much more significant potential for growth in the long-run, even if peak adoption rates eventually reach levels seen in the other counties in Hawaii or other states across the nation. As a result, BPH sees the greatest need in Oahu for seasoned operators who can leverage their experience in the medical marijuana industry to respond to a burgeoning market in a timely and compliant manner. This offers the best opportunity for patients to receive safe access to medicine without risking product quality or patient safety.

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<sup>3</sup> <http://medicalmarijuana.procon.org/view.resource.php?resourceID=005889>



## Attachment 2.2



BPH’s analysis for Oahu reflects an expectation for a healthy growing medical marijuana patient base in 2016 as citizens anticipate the opening of retail dispensing locations in the second half of the year. As the program matures and stigma recedes, we suspect an increase in the adoption rates moving into 2017 to just under 1% and acceleration in 2H 2018 (to 1.5%) as additional licensees and reciprocity comes into play. Eventually, in BPH’s base case forecast, it sees a peak adoption rate of around **2.8%** by 2020. This peak adoption rate in the program is consistent with the current patient base level in other counties in Hawai‘i and is the base case for Oahu. BPH is cautiously optimistic that participation will be *higher* given the already meaningful participation in the caregiver framework despite the lack of a regulated LDS network. Other market simulations project participation rates +/- 20% from this level and BPH’s flexible cultivation methodologies and sufficient financial resources illustrate an ability to adapt to conditions within these bounds plus a contingency buffer for anomalous statistical outcomes. Nevertheless, we also felt it prudent to engage in more rigorous stress testing scenario analysis.

### Market Share – 2018 Reciprocity & New Licensees

Additionally, BPH’s analysis assumes that BPH’s market presence will grow with the growth of the overall market, but with declining market share over time as more medical marijuana businesses are awarded licenses and come online in 2018. The base case reflects a capture of 1/3 of the market share until other LDS’s come online as early as



## **Attachment 2.2**

mid-2018, and dropping to high single digits shortly thereafter. These assumptions are in response to increased demand from both the growth in the patient base as well as a modest influx of tourists from other states that can participate in the state's reciprocity program, which is set to take effect as early as July, 2018.

BPH has factored in the State's desire to meet patient need by having no more than one dispensing location per 500 registered patients, but through collective experience and planning, BPH is preparing to handle volumes well in excess of 500 patients should market demand outpace the LDS network. Long-term, if this **2.8%** peak participation level were achieved as expected, that would theoretically result in a maximum of 40 dispensing locations in the county of Oahu by 2021 at the time of market maturation.

Reciprocity will bring very marginal additional tourism business to the state starting in mid-2018, and will be less of a driver of the market than de-stigmatization on the island itself. To capture the impact of reciprocity on the market, we looked at the monthly tourism data from the mainland and distilled how many medical marijuana patients were represented from each state that currently has a medical marijuana program. Subsequently, using average visit lengths (9.54 days<sup>4</sup>) and cannabis consumption patterns<sup>5</sup>, we were able to estimate the marginal revenue generation from these customers. Specifically, the bulk of this tourism injection will come from the mainland Pacific region (CA, AK, WA, OR, NV), which is largely comprised of states with medical marijuana programs. We factored in growth in the patient bases from each of these states, particularly California, which has significant potential for growth once its regulatory scheme is more firmly established in coming years. Nevertheless, we estimate the impact of medical marijuana patient reciprocity to initially be marginal at best, but contribute in larger fashion in longer-term forecasts.

### **Price of Medical Marijuana**

A major driving motivation of BPH team is to provide sustainably produced, pharmaceutical quality, and affordable medicine to patients in need. If Hawai'i's market emerges with prohibitive prices, it will deleteriously impact those in need most and potentially incentivize black market consumption. The medical marijuana movement, is not about capturing market share in a new potentially lucrative industry, rather, it is about educating patients, researching medical marijuana, and illuminating upon the values and benefits of what BPH feels is the most healing plant on earth. To share in the healing powers of this plant, BPH is dedicating resources to employee and customer education as well as research.

These initiatives, like research and education, will absorb financial resources, but BPH feels they are vital as the more we understand the plant and its benefits, the closer we are to optimizing patient health and well being. The effects of this positive feedback loop,

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<sup>4</sup> <http://dbedt.hawaii.gov/visitor/>

<sup>5</sup> <https://www.colorado.gov/pacific/sites/default/files/Market%20Size%20and%20Demand%20Study,%20July%209,%202014%5B1%5D.pdf>



## **Attachment 2.2**

will reverberate through society as a whole. Therefore, when it comes to product pricing, BPH realizes that if BPH is fortunate to be one of the initial players in this market, we seek to offer reasonably priced medicine as dictated by market dynamics and internal financial considerations. A significantly regulated market framework, will naturally require marginally more costly medicine than the caregiver framework currently provides. According to priceofweed.com, a high quality ounce of medical marijuana costs **\$302/oz** in Hawai‘i while low quality is at **\$270/oz**. This is higher than the national average and prices seen in Colorado (\$250/oz), but elevated utility costs and the cost of labor in Hawai‘i versus other states are likely key contributors to sustaining higher than average prices.

As it is BPH’s goal to produce pharmaceutical grade medical marijuana, its base forecast reflects prices in line with current high quality ounces on Hawai‘i (**\$302/oz**, or **\$10.96/g**). However, BPH examined multiple other simulations with lower prices per ounce (down to \$150/oz) in order to better understand the operational feasibility of price fluctuations. An overarching theme of BPH’s approach to this new market is to have an open mind with respect to market dynamics. Thus are preparing to manage price volatility, with a predetermined understanding of what such price variances could mean for the bottom line and the health of the organization. BPH feels confident that its business acumen, expertise in medical marijuana, and deep financial resources position it favorably to deliver high quality medicine to those in need, while being able to weather considerable market volatility.

### **Consumption Behaviors**

In additional to forecasting the patient base, another key consideration is the consumption pattern of those patients. Unlike Colorado at the onset of its market, with numerous states medical marijuana programs already online, there is a more robust empirical data set to use to cross-reference demand assumptions.

In Colorado, for example, a large part of the State’s underestimation of initial demand was expectations on the “heavy user” (daily user) segment of the population. According to the 2014 National Survey on Drug Use and Health, 23% of the user population in Colorado consumes almost daily, compared with just 17% nationwide.

The mosaic of data and cultural attitudes in Hawai‘i as exemplified by the relatively high adoption rate state-wide before the onset of a true regulated dispensary framework, suggests that relatively high consumption rates by the daily user segment of the patient base will be higher than the national average of 17% but not necessarily higher than 23%. Therefore, in BPH’s forecasts BPH chose to be conservative and baked in higher than average use, but also ran multiple scenario analysis to account for some variance (again, bullish and bearish scenarios +/- 20% in addition to more rigorous stress testing).

### **Demographics**



## **Attachment 2.2**

One of the key differentiators of Hawai‘i’s current duly registered medical marijuana patient base is the age distribution. As it relates to gender, Hawai‘i is consistent with many other states including Colorado, showing roughly 2/3 (68% vs. 64% in CO) of the base being male and 1/3 (32% vs. 36% in CO) being female<sup>6</sup>. Yet, which age group represents the largest share of patients reflects an interesting contrast to other states. In Hawai‘i, the largest cohort of patients comes from the 56-65 year old segment (27.6%) vs. the 21-30 year old segment in Colorado (23.2%). This data is heat-mapped in Figure X below for illustrative purposes.

**Figure 3: Hawai‘i Medical Marijuana Patient Distribution  
(by Age)**

<b>AGE</b>	<b># of Patients</b>	<b>Percentage of Base</b>
<17	25	0.20%
18-25	573	4.58%
26-36	2,098	16.79%
36-45	2,084	16.67%
46-55	2,381	19.05%
56-65	3,450	27.60%
66-75	1,681	13.45%
76-99	207	1.66%
<b>Total</b>	<b>12,499</b>	

The larger proportion of the patient base in the 55-65yo demographic is consistent with experience in Colorado from the onset of the LDS program. For instance, in 2009 when HCH first opened its doors, a higher percentage of patients were near retirement age. Further anecdotal evidence reflects that medical marijuana was selected as an organic remedy following many years (decades) of battling the side effects of synthetic pharmaceutical prescriptions, mainly opiates. Pain relief, after all, is by far the most common mentioned reason for consuming medical marijuana. 92% of patients in Hawai‘i and 94% of patients in Colorado list this as justification for obtaining their medical marijuana cards.

Taking this one step further, it is the belief of BPH, through HCH and ACC’s real-time experience in the industry in Colorado and other states, that this older segment of the population consumes a larger proportion of infused products (oils, pills, lozenges) rather than inhaled products (flower) for actual and perceived health reasons. For instance, the longer duration and intensity of ingested medication (4-6h of relief vs. 1-2h for inhaled)

<sup>6</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>



## **Attachment 2.2**

make it a superior choice to address physical pain, auto-immune, and neuropathic conditions and thus a welcomed remedy for many elder patients. BPH's collective realization of this dynamic was an important consideration in its partnership with Chief Medical Officer (CMO) Dr. Bradley Willcox, who as a UH affiliated scientist and researcher has deep experience in the area of geriatrics and gerontology.

While this assessment is not empirically robust, it does hint as to how things might unfold and thus caution and prepare BPH for a different set of circumstances than are currently reflected in today's data. Qualitative experience oftentimes is shunned over the more concrete and tangible nature of quantitative analysis due to BPH's collective desire for control and greater comfort with numbers than abstract ideas, yet quantitative approaches too have their own pitfalls such as data mining and confirmation bias.

Even though the cumulative consumption basket is challenging to quantify with precision, current evidence signals to us that we should be prepared to offer a relatively greater selection of products in the infused category in anticipation of larger initial demand. It was also a motivating factor in creating a vast array of non-inhaled, infused products, including sprays, lozenges, oils, and pills. This distinction between flower and infused products is quite significant to BPH's business plan as the different product sets have varying costs of production and shelf life. For example, medical marijuana that is grown to be smoked, requires much greater dedication to the nuances of growing the plant to produce the proper flower structure as well as terpene (essential oil) yields, while infused products (pills, lozenges, oils) place the greatest emphasis on simple trichome (cannabinoid) production.

So, looking ahead, it is critical for BPH to maintain accurate up-to-date empirical data on the patient base on Oahu in order to better serve the patient's medical needs and forecast their needs with greater accuracy. For instance, the current adoption rate in Oahu County is just 0.29%. The expectation is for this to increase roughly 10x within 5 years. It is possible that the 26-36yo segment experiences more significant growth, which would redistribute consumptions patterns over time, yet, perhaps the most likely outcome is that the 55-65yo segment that grows most significantly.

According to the most recent census data, which shows Oahu County expected to grow at **0.6%** per annum from 2015-2020, **16.1%** of the Hawaiian population is over 65, versus **14.5%** as the national average. Colorado, on the other hand, is younger, with just **12.7%** above the age of 65. Using this data as a guide and not gospel, BPH reasonably anticipates a relatively higher consumption of infused products compared to inhaled products, especially at the onset. Yet again, BPH feels it is absolutely critical to maintain meticulous oversight on each of these market variables to ensure BPH's greatest chances at continuing to provide medicine to patients in need and react to market developments in real-time.

### **Cultivation Methodologies – Maintaining Flexibility**



## **Attachment 2.2**

Under Hawai'i law, all licensees are restricted to 3,000 plants per cultivation center, for a maximum of 6,000 plants. Additional licensees are set to be considered by the State at the end of 2017 for launch in mid-2018 should market conditions dictate the need for extra capacity. But what if demand surpasses the needs of patients before additional licenses are awarded in 2018? BPH, for one, is ready to confront such challenges by maintaining flexible cultivation methodologies that allow for varying plant counts per light (and thus plant size) in order to meet excess demand. Through the collective experience of HCH and ACC, BPH is prepared to confront these challenges and efficiently adapt to shifting market dynamics. It is BPH's goal with its initial production centers to maintain a high level of flexibility in production to meet many potential demand scenarios while BPH moves towards the longer goal of building a state of the art, sustainable cultivation facility, leveraging BPH's team's depth of experience in energy.

### **Summary**

BPH's collective track record in various realms of business, including the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of the Hawaiian medical marijuana market. BPH's approach is not inexorable, nor is it dogmatic. BPH's initial cultivation center is strategically poised to navigate the volatility of a new market while sewing the seeds of the long term vision of Hawaii's 2015 CEO of the Year, Henk Rogers, which is to create the gold standard for sustainable cultivation practices in the medical marijuana industry.

While BPH acknowledges the uncertainties of a new market, the base case assumptions are grounded in over 6 years of experience within the marijuana industry and a combination of qualitative and quantitative analysis of the Hawaii market. BPH has evaluated initial market conditions and made calculated estimations on the market's development from the awarding of licenses in April 2016. BPH's analysis factored in consumption patterns, demographics, population growth, reciprocity, and more to achieve a base case forecast, which was then subjected to rigorous stress testing.

Armed with the knowledge gained from both experience in Colorado and analysis of the Hawaii market, BPH feels confident in its ability to deliver pharmaceutical grade, sustainably produced medical marijuana to Hawaii consumers in 2016. BPH has the business acumen and deep financial resources to accomplish its goal and the passion to share what BPH believes to be the most healing plant on earth with those who are suffering and in need.



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# STANDARD OPERATING PROCEDURES

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*State Of Hawai'i Production Center—Cultivation Operations*





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**-----STATE REGULATORY COMPLIANCE DISCLOSURE-----**

*Medical cannabis facilities operate in a highly regulated industry, as such adherence to all applicable state and local laws pertaining to the cultivation, production, manufacturing, possessing and dispensing of cannabis and/or cannabis-infused products within the facility is of utmost importance. State and local laws and regulations will vary among states; it is recommended to read and have good understanding of the state and local laws and regulations in which you operate. Having a good understanding of the state and local laws is the first step in being educated on how to operate within regulations, the records and documents needed to be maintained to be in full compliance and to continue operating a cannabis business within a regulated market.*

**-----CONFIDENTIALITY DISCLOSURE-----**

“Confidential Information and Intellectual Properties” means and includes any tangible or intangible information or material that is confidential or proprietary to Consultant that Client may obtain knowledge of through, or as a result of, its relationship with Consultant. Such information shall be deemed Consultant’s Confidential Information and Intellectual Properties whether or not owned or developed by Consultant. Confidential Information and Intellectual Properties shall also include, but is not limited to, any inventions, processes, designs, formulae, trade secrets, Standard Operating Procedures, know-how, confidential information, trademarks, copyrights, service marks, domain names, computer software, data and documentation, and all similar intellectual property.

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<b>Standard Operating Procedure:</b> Standard Operating Procedures
<b>Purpose:</b> To explain the standard operating procedures needed to be adhered to within the Licensed Premise
<b>Scope:</b> To cover the education and training required pertaining to the standard operating procedures utilized within the Licensed Premise.
<b>Initial Training:</b> TBD

**Definitions**

**Standard Operating Procedure (SOP)**—a set of step-by-step instructions to achieve a predictable, standardized, desired result often within the context of a longer overall process. At its simplest, an SOP is a repeated application of unchanged processes and procedures and its documentation. These SOP’s are to be followed as directed and not deviated for the cultivation of marijuana within any Blue Planet Healing LLC (BPH) registered production centers.

**Material Change**—a material change is defined as a major deviation from the standard procedure, or changing the procedure or methodology drastically enough to notice a change. The material change is important enough to notice or to have an effect on the standard operating procedure.

**Principles of Standard Operating Procedures**

The cultivation of marijuana can be difficult for the rudimentary gardener. American Cannabis Company’s (ACC) Standard Operating Procedures (SOP’s) insure consistent production of high quality medical marijuana. BPH will utilize said SOP’s for all marijuana cultivation methodologies and operations. Understanding and abiding by the following SOP’s is mandatory for all registered employees working within BPH’s registered dispensary facilities.

The standard operating procedures must be practiced and utilized to cultivate each plant and to produce each batch of marijuana. The strict adherence to the written SOP’s will aid in BPH’s quality control program and measures. The written SOP’s have been developed within a regulated marijuana industry with the purpose of creating systems and procedures that result in a consistent and reproducible marijuana product. The cultivation process is broken down into each week of the plant’s lifecycle. Apply the following SOP instructions to the lifecycle of each plant in the facility. Do not deviate from exact instruction within these standard operating procedures.

- Failure to practice and utilize BPH’s written standard operating procedures is grounds for disciplinary action and possible job termination.

Written standard operating procedures will be utilized for all cultivation activities and operations, for the cultivation of all marijuana plants to ensure consistency of the batch with the variety and for accuracy of the day-to-day production. The written standard operating procedures will ensure consistency of batch and accuracy of day-to-day production if utilized properly and not deviated from.

- Registered employees will be required to record and maintain documentation log sheets and forms to record the cultivation process
  - Required documentation and record keeping is highlighted throughout the SOP’s and indicates which documentation log sheets and records are to be taken and maintained.
    - Registered employees will need to pay careful attention to each standard operating procedure to ensure proper documentation and record keeping
      - The documentation should demonstrate consistency of batch with the medical marijuana variety being cultivated
      - The documentation should also demonstrate the accuracy of the day-to-day production within the Licensed Premise.
- Any major deviation from the standard operating procedure defined as a material change that could impact the quality of batch must be documented, recorded and maintained on the Licensed Premise
  - Registered employees are required to document any major deviation in production of a batch from the standard operating procedure



**Deviation/Material Change to Standard Operating Procedures**

Upon recognizing the need for or making a material change to a standard operating procedure, registered employees will be required to document the material change within the *Material Change to SOP's* log sheet and update the current SOP to reflect the material change.

<b><u>Deviation/Material Change to SOP's</u></b>		
<b>Date:</b>	<b>Registered Employee:</b>	<b>Deviation in Production:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Reason for the deviation</b> ( <i>identify and describe in detail the deviation from the SOP</i> ):		
<b>SOP requiring material change:</b>		
<b>Material Change made to the SOP</b> ( <i>please describe in detail</i> ):		
<b>SOP Updated?</b> <input type="checkbox"/> YES	<b>Date Updated:</b>	<b>Update By:</b>
<b>Manager/Supervisor Awareness and Approval:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Manager/Supervisor Signature:</b>	
<b>Sample of production batch with deviation sent to independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO		<b>Sample of production batch with deviation determined to meet specifications for the variety by BPH and the independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Medical Cannabis Batch Released for Distribution?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO		<b>Additional Notes/Comments:</b>
<i>After documentation of a material change to a standard operating procedure, registered employees will be required to maintain the record of material change within a limit-access and secured area of the Licensed Premise.</i>		

**Deviations in Production—Independent Laboratory Testing**

Per State of Hawai'i regulations, BPH will not release any batch of marijuana or manufactured marijuana products if there was any deviation in production from the batch from the standard operating procedure. All medical marijuana will need to be securely held and stored until:

- The sample from the batch of marijuana and/or manufactured marijuana product with any deviation in production is sent to an independent testing laboratory for testing
  - The marijuana will not be released for distribution until after an independent testing laboratory and BPH determines, as a result of testing, that the batch meets the specifications for the variety and the determination is recorded.
- Follow *Samples for Laboratory Testing* and the *Transferring/Transporting and Shipping Medical Marijuana* standard operating procedures for procedures and requirements pertaining to laboratory testing and transport.
  - Ensure to follow Sampled for Laboratory Testing
    - Fill out and record all required documentation log sheets
      - Fill out *Material Change Samples for Laboratory Testing* log sheet (*can be seen below*)

<b><u>Material Change Samples for Laboratory Testing</u></b>					
<b>Date:</b>	<b>Employee:</b>	<b>Attribute ID #/Product Batch #/Strain:</b>	<b>Sample Quantity:</b>	<b>Sample Attribute ID # (NEW):</b>	<b>Receiving Laboratory:</b>



State Regulatory Compliance

<b>Standard Operating Procedure:</b> State Regulatory Compliance Training
<b>Purpose:</b> To explain the regulatory compliance needed to be adhered to in the State of Hawai'i.
<b>Scope:</b> To cover the regulations enacted within Hawaii pertaining to legally operating a marijuana business.
<b>Initial Training:</b> training done on individual time

**Required Documents**

- 1) State Regulations
- 2) Local/City Regulations (*if applicable*)

**The Principles of State Regulatory Compliance Training**

BPH will require all registered employees to read and become familiar with the State and Local/City regulations that have been enacted pertaining to operating a legal, licensed marijuana business.

BPH will keep a physical, up-to-date copy of any and all laws and regulation in which you must operate under at every licensed facility. Every registered employee will receive a hard copy of the laws and regulation which they can read and become familiar with.

Key State Regulations Employees Should be Familiar With:

- Who can have access to the facility
  - Visitor process
- Packaging and labeling compliances and requirements
- Allowed purchase amounts (quantities and distribution timeframe)
- Hours of allowed operation
- Inventory tracking and required record keeping
- Security procedures and protocols
- Laboratory testing requirements
- Transportation of marijuana products
- Etc.

**State of Hawaii**

- <http://health.hawaii.gov/medicalmarijuana/>



<b>Standard Operating Procedure:</b> Record Keeping and Documentation
<b>Purpose:</b> To ensure that all required marijuana cultivation records and data are properly recorded and documented. Including zone/room environments, transplant logs, IPM applications, inventory, etc.
<b>Scope:</b> Procedures covering record keeping and documentation for activities within the production center
<b>Initial Training:</b> 4-8 hours

**What is the Purpose of Record Keeping and Documentation?**

Marijuana cultivation facilities operate in a highly regulated industry, as such proper record keeping and documentation are essential within the cultivation facility. Having records of crop inputs such as growing media records and pesticide applications will aid during the cultivation process to ensure proper feedings occur and that plants are not treated with chemicals more than absolutely necessary.

**Equipment/Tools Required**

- 1) Pen or pencil
- 2) Clipboard
- 3) Log Sheets

**Principles of Record Keeping and Documentation**

Adherence to all applicable state and local laws pertaining to the cultivation of marijuana within the production center facility is of utmost importance. State and local laws and regulations will vary among states; having a good understanding of the state and local laws is the first step in being educated on the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within Hawai'i's regulated market.

Required records and documentation are noted throughout the written Standard Operating Procedures; BPH's registered employees will be required to make such records and documentation as part of their job responsibilities. Registered employees will be required to make two sets of all records and documentation; one set of records and documentation will be made within the BioTrackTHC™ inventory control system, and a second set of records and documentation will be made using physical log sheets and templates. The physical records and documentation will be maintained on at the production center within a limited access area. Failure to create and maintain records and documentation will be grounds for disciplinary action and/or job termination.

Record Keeping and documentation are noted within other SOP's where documentation is required. The SOP's will also reference which documentation records and log sheets are required to be filled out and maintained.

**Cultivation Licensed Premise Records:**

- Propagation Log
- Transplant Log
- Nutrients, Supplements and Growth Additives
- Daily Environment Documentation
- Plant Monitoring—inventory
- POS Inventory
- Inventory Reconciliation
- Daily Marijuana Products Transfer/Shipping Log
- Pest and Disease Identification
- Pesticide/Fungicide Application
- Harvested Marijuana Log
- Marijuana Waste Log
- Finished Marijuana Log

- Cleaning and Sanitation Log
- Product Recall Log
- Returned Marijuana Log
- Employee List
- Visitor Documentation Log
- Etc.

### **Secondary Records**

BPH will maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution. BPH will require registered employees to maintain secondary records on the Licensed Premise. The physical records and documentation log sheets will serve as secondary, back-up records and documentation that will be maintained independent of the inventory control system.

Per Hawaii regulations, records required to be maintained separate of the inventory control system:

- **Records of Each Distribution**
  - Records of distribution must include:
    - The name and address of the recipient retail dispensary location
    - The quantity delivered
    - The name, strength, batch number of the product
    - The date and time of distribution

### **Requirements of Secondary Records:**

- Records must be maintained independent of the inventory control system
  - Physical records will be maintained within a file cabinet, separate from the inventory control system
- Records must be searchable
  - Records will be organized and filed alphabetically according to recipient name
- Records must be secure
  - Records will be maintained within the Licensed Premise, located within a limited-access area inside a manager office equipped with an independent security alarm system. The records will be held within a lockable filing cabinet inside the secure office.
- Records must be tamper-evident
  - The file cabinet where secondary records are to be maintained will have a secure, tamper-evident locking mechanism on it.

**Records and Documents Storage Retention**—Unless otherwise specified, BPH will retain and maintain all records and duplicate sets of records for a minimum of six (6) years.

### **Duplicate Records and Off-Site Storage**

BPH will maintain duplicate sets of all records required by regulation. These duplicate copies of BPH records will be maintained at a secure, off-site location. This location will only be disclosed to personnel with proper security clearance. The off-site record storage will be secured with a security alarm and surveillance system to ensure access is limited to authorized personnel only. BPH will maintain duplicate copies of all records at a secure storage facility within Hawaii.

**Reports**—BPH can generate a list of the products and their specifications that have been offered for distribution. These reports are to be provided to the Department upon request.

- Reports can be created through the BioTrackTHC™ inventory control system
  - Within the inventory control system, BPH will be able to generate a list of all the products along with their specifications that were offered for distribution
  - This list can be generated for all products offered within specific date ranges



General Security/Diversion Prevention Training

<b>Standard Operating Procedure:</b> General Security/Diversion Prevention Training
<b>Purpose:</b> To explain the general security and diversion prevention training needed to be adhered to.
<b>Scope:</b> To understand security and diversion prevention training requirements.
<b>Initial Training:</b> 4-8 hours

**Diversion and Trafficking Prevention Training**

Diversion and trafficking prevention will primarily be done using the various security alarm and surveillance equipment installed and utilized at BPH’s production facility. The various security alarm and surveillance equipment utilized is explained in more detail within the Security Plan which is a separate, additional document that can be viewed upon request. All BPH registered employees will be trained on all security equipment, measures and policies prior to commencing work within the production center.

BPH will utilize BioTrackTHC’s inventory control system and industry best practices and policies to reduce the risk of diversion and theft of marijuana products. All marijuana plants will be tagged, recorded and tracked through the inventory control system from seed-to-sale.

The use of professional security systems from Securitas that will be installed at all of organization facilities will also help to reduce the risk to diversion, loss, theft or unauthorized access.

If any marijuana or manufactured marijuana product loss or discrepancy noticed by a registered employee, management shall be made aware of the loss immediately. Inventory discrepancies should be easily noticeable with the use of the inventory control system. The diversion or product loss must be documented on the **Product Loss** log sheet which can be seen below.

<b><u>Product Loss Log Sheet</u></b>				
<b><u>Date:</u></b>	<b><u>Product Name/Category</u></b>	<b><u>Product Attribute # or Unique ID #</u></b>	<b><u>Total Quantity</u></b> <b><u>Loss:</u></b>	<b><u>Product Loss</u></b> <b><u>Valuation:</u></b>
				\$
<b><u>Reporting</u></b> <b><u>Employee:</u></b>	<b><u>Manager/Supervisor:</u></b>	<b><u>Product Loss Due To:</u></b>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<b><u>Internal</u></b> <b><u>Investigation:</u></b>	<b><u>Required Authorities</u></b> <b><u>Notified:</u></b>	<b><u>Authorities Notified (list all) :</u></b>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<b><u>Note/Comments:</u></b>				

### **Video Surveillance System.**

Securitas will design video surveillance systems at BPH's retail dispensary facilities that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

### **Alarm System.**

Each retail dispensary location operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

### **System Failure.**

In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

### **Other Security Measures.**

All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH- approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

### **Production Center Specific Security Measures.**

In addition to all the above mentioned and all other security measures required by HRS Chapter 329D and HAR Chapter 11-850, BPH will utilize a perimeter security fence around each PC that surrounds the entire premise sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any marijuana in any form as required by HAR §1185052 (1). In addition, BPH will secure all marijuana and manufactured marijuana products in a locked room, vault or container which is securely fixed to a wall or the floor to ensure product safety and to prevent theft.

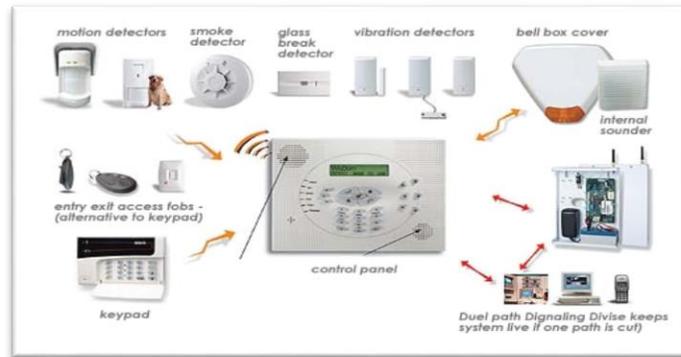
### **Transportation Security.**

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees. 3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH's tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be



packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

**Alarm Surveillance**—a primary alarm system will be installed at all BPH registered dispensary facilities by Securitas, a licensed alarm company, with an advanced security alarm system on all perimeter entry points, perimeter windows, and secured interior rooms. Motion detection equipment and camera equipment will be used to ensure the entire facility(s) is continuously safe from intrusion and product diversion.



**Video Surveillance**—an advanced video surveillance and recording system at all BPH facilities. All cameras will record in digital format and be maintained to meet the requirements outlined by State and local regulations. Video cameras will be maintained in each room and be used to identify any activity occurring within the room and be capable of recording and viewing in low light conditions. An onsite DVR and an additional offsite DVR will be utilized to store all footage; all video surveillance recording will be stored for a minimum of one year.



**Security Lighting**—security lighting around the entire perimeter of the production center to allow surveillance in low light conditions and deter potential intrusion.





**Motion Detector Alarms**—the professional security alarm system will utilize motion detectors that will detect intrusion and will automatically notify the proper authorities.



**Duress Alarms**—the security and alarm systems will utilize a duress alarm button on the alarm panels that can be pushed by employees in the case of an emergency. Different duress alarm buttons can be pushed to automatically notify the proper authority; police, fire or emergency services.



**On-Site Electronic Monitoring**—facility security rooms will have a large screen call-up monitor (at least 19”) and a video printer capable of immediately producing a clear still photo from all video cameras.



**Commercial Grade Door Locks**—commercial-grade, non- residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas. Key-card access door locks may also be utilized to further limit access at facilities.



**Safes and Product Storage**—Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana products and cash.



Perpetual Inventory Control System

**Standard Operating Procedure: Perpetual Inventory Control System**

**Purpose:** To explain the principles and concepts of the perpetual inventory control system

**Scope:** To educate and train registered employees and licensed premise employees on the perpetual inventory control system

**Initial Training:** TBD

**Principles of the Perpetual Inventory Control System**

BPH will utilize a perpetual inventory system from a regulated marijuana industry-specific inventory system provider, BioTrackTHC™. This inventory control system has been developed specifically for the regulated marijuana industry and has been customized to include all marijuana business operational needs. The systems have been designed to be user friendly, the ability to be mobile, and with inventory control capabilities to track every medical marijuana plant and product from seed to sale.

The inventory control system will be designed to have the ability to promptly identify a discrepancy in stocks of marijuana plants and products. BPH administrators of the system will be notified of a substantial reduction in an inventory stock level and be prompted to investigate the inventory levels to ensure no theft, diversion or discrepancies occurred. Administrators and users can run inventory reports from the inventory control system to check inventory stock levels that have been recorded in the inventory control system against a physical inventory audit to further determine inventory discrepancies.

**Inventory Control /POS System**—the tracking of all medical marijuana products from seed to sale will be done through inventory management through the use of template log sheets, computer systems, Secure Information Systems (SIS) and selected Point-of-Sale systems (POS). All medical marijuana plants and products are to be tagged, recorded and tracked through the inventory control system. Failure to do so can result in disciplinary action and/or job termination.



*\*Inventory control system and/or Point-of-Sale (POS) system training will be provided by an expert or consultant from the inventory control system supplier, BioTrackTHC™. This 3<sup>rd</sup> party training will be required for all BPH registered employees prior to working within the production center.*

Registered employees will be required to utilize the inventory control system to identify, record, monitor and track all medical marijuana plants and products from the time the medical marijuana is propagated from seed or cutting to the time it is delivered to a licensed dispensary, licensed processor or a qualifying patient or caregiver. The standard operating procedures detail multiple situations when plant tagging, monitoring and recording activities are required by registered employees within the production center.



Marijuana plants will be given a unique attribute number, assigned to a production batch and recorded in the inventory control system. The plant will then be given a new and unique plant tag with the plants identification and specifications and be recorded in the inventory control system, the tag will remain with the plant throughout the plants lifecycle enabling the plant to be identified and tracked.

The inventory control system intended to be utilized within BPH's production center will in the event of a serious adverse event have the ability to track any marijuana plant or product back to the originating source, including the ability of tracking marijuana from a qualifying patient back to the source of the marijuana. The marijuana believed to have caused a serious adverse event should have a product label with product information and specifications such as the product name, unique attribute number, batch number and originating entity. With this information, the marijuana product will be able to be traced back to the originating source of the medical marijuana.



OSHA Compliance

<b>Standard Operating Procedure:</b> OSHA Compliance and Training
<b>Purpose:</b> To explain the principles and concepts of OSHA regulations.
<b>Scope:</b> To understand OSHA requirements to create a safe work environment.
<b>Initial Training:</b> 4-6 hours

**OSHA Training**

Registered employees have the right to a safe workplace, and BPH intends to provide a safe work environment for all registered employees at all BPH facilities. The Occupational Safety and Health Act of 1970 (OSH Act) was passed into law as a preventative measure for workers from being killed or seriously harmed while at work. The law requires employers to provide employees with working conditions that are free from known dangers.

The OSH Act created the Occupational Safety and Health Administration (OSHA). This regulatory agency sets and enforces protective workplace safety and health standards. OSHA is also charged with providing information, training and assistance to workers and employers to educate and train individuals on workplace safety. Employees may file a complaint if they feel necessary which will result in OSHA to inspect the workplace if they feel OSHA standards are not being met or that there may be serious hazards or danger. More information on the Occupational Safety and Health Administration can be found online at the website: <https://www.osha.gov/>.

**OSHA’s Mission**—With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

**OSHA Training**—The OSHA Outreach Training Program for General Industry provides training for workers and employers on the recognition, avoidance, abatement, and prevention of safety and health hazards and dangers in workplaces in general industry. This program also provides information regarding workers' rights, employer responsibilities, and how to file a complaint. Employees can attend a 10-hour or 30-hour class delivered by OSHA-authorized trainers. The 10-hour class is intended for entry level workers, while the 30-hour class is more appropriate for supervisors or workers with some safety responsibility. OSHA training helps to ensure that workers are more knowledgeable about workplace hazards, dangers and their rights.

Under the OSH Law, employers have a responsibility to provide a safe workplace free from known hazards or dangers. The OSHA website provides a short summary of employer responsibilities with which BPH will ensure compliance.

- Provide a workplace free from serious recognized hazards and comply with standards, rules and regulations issued under the OSH Act.
- Examine workplace conditions to make sure they conform to applicable OSHA standards.
- Make sure employees have and use safe tools and equipment and properly maintain this equipment.
- Use color codes, posters, labels or signs to warn employees of potential hazards.
- Establish or update operating procedures and communicate them so that employees follow safety and health requirements.
- Employers must provide safety training in a language and vocabulary workers can understand.
- Employers with hazardous chemicals in the workplace must develop and implement a written hazard communication program and train employees on the hazards they are exposed to and proper precautions (and a copy of safety data sheets must be readily available). See the OSHA page on Hazard Communication.
- Provide medical examinations and training when required by OSHA standards.
- Post, at a prominent location within the workplace, the OSHA poster (or the state-plan equivalent) informing employees of their rights and responsibilities.
- Report to the nearest OSHA office all work-related fatalities within 8 hours, and all work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours. Call our toll-free number: 1-800-321-OSHA (6742); TTY 1-877-889-5627. [Employers under federal OSHA's jurisdiction were required to



begin reporting by Jan. 1, 2015. Establishments in a state with a state-run OSHA program should contact their state plan for the implementation date].

- Keep records of work-related injuries and illnesses. (Note: Employers with 10 or fewer employees and employers in certain low-hazard industries are exempt from this requirement.)
- Provide employees, former employees and their representative's access to the Log of Work-Related Injuries and Illnesses (OSHA Form 300). On February 1, and for three months, covered employers must post the summary of the OSHA log of injuries and illnesses (OSHA Form 300A).
- Provide access to employee medical records and exposure records to employees or their authorized representatives.
- Provide to the OSHA compliance officer the names of authorized employee representatives who may be asked to accompany the compliance officer during an inspection.
- Not discriminate against employees who exercise their rights under the Act. See our "Whistleblower Protection" webpage.
- Post OSHA citations at or near the work area involved. Each citation must remain posted until the violation has been corrected, or for three working days, whichever is longer. Post abatement verification documents or tags.
- Correct cited violations by the deadline set in the OSHA citation and submit required abatement verification documentation.
- OSHA encourages all employers to adopt an Injury and Illness Prevention Program. Injury and Illness Prevention Programs, known by a variety of names, are universal interventions that can substantially reduce the number and severity of workplace injuries and alleviate the associated financial burdens on U.S. workplaces. Many states have requirements or voluntary guidelines for workplace Injury and Illness Prevention Programs. Also, numerous employers in the United States already manage safety using Injury and Illness Prevention Programs, and we believe that all employers can and should do the same. Most successful Injury and Illness Prevention Programs are based on a common set of key elements. These include: management leadership, worker participation, hazard identification, hazard prevention and control, education and training, and program evaluation and improvement. OSHA's Injury and Illness Prevention Programs topics page contains more information including examples of programs and systems that have reduced workplace injuries and illnesses.

### **Plan for OSHA Compliance**

Below details BPH's plan for compliance with OSHA will begin by ensuring that all organizational facilities are free from known hazards and/or dangers. Although OSHA is a federal organization and we are not currently held to OSHA standards, BPH feels it is best practices to be aware of OSHA guidelines and adhere to said guideline within our operations.

All registered employees will be provided basic training covering workplace safety pertaining to identifying and preventing potential hazards and or dangers such as trip hazards. This basic training will begin with training all new employees on policies and procedures. Proper and adequate training can help to reduce workplace accidents through educating and training employees on operations, policies and procedures. Employees will be given a tour of the facility property and areas in which the employee will have access to (limited or restricted). Other training to be included in BPH's plan for OSHA compliance will include:

- Training on SOP's
- Regulatory compliance training (laws and regulations pertaining to medical marijuana cultivation, processing or dispensing)
- Basic training on workplace safety
- Recognition of potential workplace hazards or dangers



Cultivation Methodology

<b>Standard Operating Procedure:</b> Cultivation Methodology
<b>Purpose:</b> To determine and understand the cultivation techniques and methodologies to be implemented in the production center.
<b>Scope:</b> To determine the growing methodology ( <i>soil, hydro, coco, etc.</i> ) and types of equipment and systems to be implemented and utilized
<b>Initial Training:</b> TBD

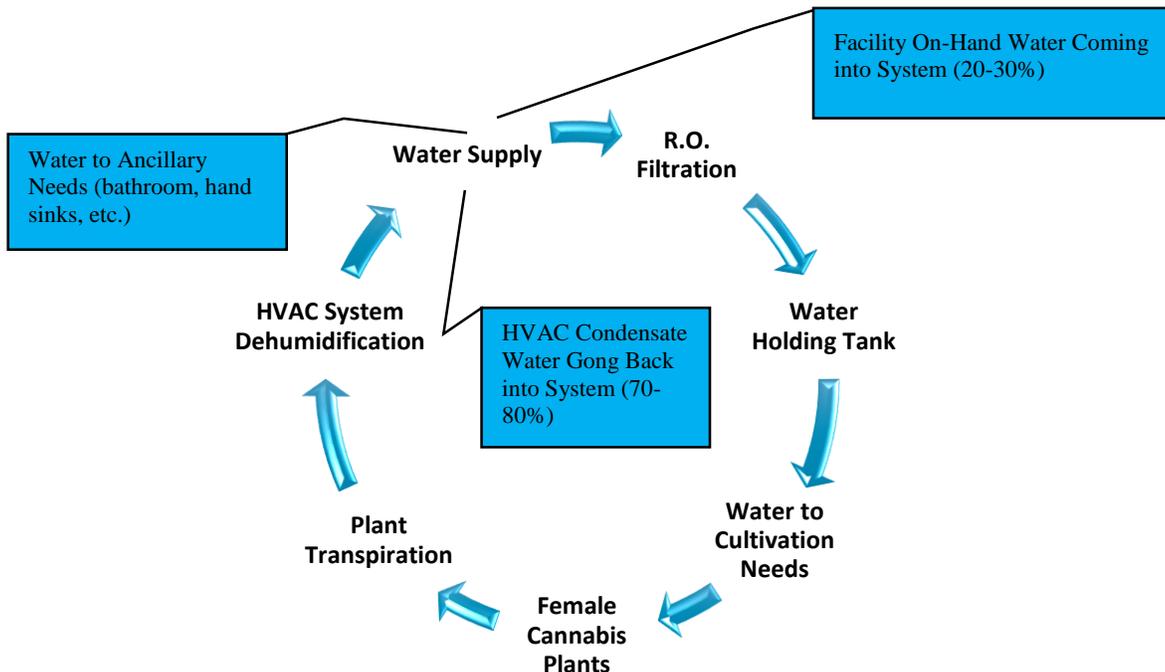
### The Principles of Cultivation Methodology

There are multiple cultivation techniques and methodologies pertaining to marijuana cultivation; ACC utilizes organic cultivation techniques and methodologies encompassing a bio-dynamic super soil, SoHum Living Soil, automated, gravity-fed watering systems from AutoPot, and roll-top benches or moveable palletized racking for increased production capacity and increased efficiency.

### Water Quality

**Water Quality Test(s)**—BPH will perform water quality tests on facility water every six (6) months at a minimum. A water sample from the cultivation facility will be sent to a water testing laboratory where an analysis of the water will be performed to determine what, if any, substances are in the water. A record of all water quality tests will be maintained on-site at the licensed premise within a file labeled “Water Quality Tests”. Water quality tests and records will be made available for inspection to the Commission upon request.

**Reverse Osmosis of Water (RO System)**—all water utilized for cultivation operations will be run through a state-of-the-art Reverse Osmosis (RO) water filtration system to ensure all contaminants have been removed from the water. The RO system will be designed according to the water quality test that will be performed at the facility as well as the RO system being designed to be able to adequately purify and supply the proper amounts of water for daily operations.





### **Growing Medium**—biodynamic soil

SoHum Living Soil is a fully-amended bio-dynamic potting mix which simplifies the growing process while maximizing yields and producing consistent quality. SoHum is a growing medium that is biodynamic, a potting mix developed to optimize the marijuana plants’ maximum genetic potential. In marijuana cultivation, the term “biodynamic” applies to the understanding that soil directly impacts plant development and emphasizes a natural approach to growing that focuses on the micro life in the soil.



- *More information on SoHum Living Soils can be viewed within the **Growing Media SOP***

### **Growing Containers/Watering System**

ACC utilizes an automated watering system and plant containers from AutoPot Automated Irrigation System. The AutoPot systems use a gravity-based irrigation network that stems from a refillable water reservoir to the individual pots. The system prevents over-watering and operator error, and requires no power supplies, water pumps or timers. AutoPots were designed to maximize the crop and save water.

The system is expandable to grow with operational needs; pot modules and additional tanks can be easily added to the watering network. When used in conjunction with complementary products like SoHum Living Soil, AutoPot Automated Irrigation System can be one of the building blocks of a completely organic grow system.

#### **Benefits of AutoPot Automated Irrigation System:**

- An energy-efficient component of a lean manufacturing system, the AutoPot system offers a number of advantages over other irrigation products:
- Delivers exactly the amount of water your plants need
- Eliminates the need for daily moisture monitoring
- Eliminates the need to manually water multiple times per week
- Requires no electricity
- Produces no leaking, runoff or other water waste
- Is readily scalable to your grow operation
- Increases plant growth by 40%

*\*Please see the **AutoPot SOP** for more information on set-up and maintenance on AutoPots.*

### **Roll-Top Benches**

Roll-top benches are utilized as a way to maximize facility cubic footage working space and allows the plants to be elevated off the ground increasing workflow efficiency and effectiveness.



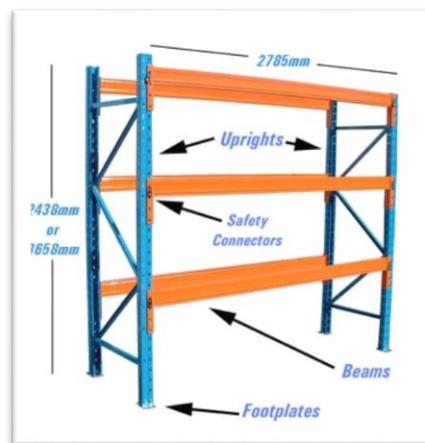
### **Tiered Two-Level Cultivation**

BPH will use a cultivation system utilizing stackable pallet racking creating 2-level cultivation rooms. The pallet racking will be stationary and secured to the floor, maximizing the facility's cubic footage. This system will allow users to maximize their facilities cubic footage resulting in increased production capacity.

Advantages to utilizing the tiered 2-level cultivation include:

- Maximizes plant canopy cubic footage
- Lights within rack footprint so no susceptibility to damage
- Easy to reach plants for maintenance purposes
- Very limited light wasted due to direct concentration above plants
- Less water consumption due to use of Auto Pots (no waste water runoff)
- Lower labor costs due to easier cleaning of lights and system
- Able to use CO<sub>2</sub>

The system will utilize standard pallet racking such as the pallet racking pictured below.





Environmental Control System

<b>Standard Operating Procedure:</b> Environmental Control System
<b>Purpose:</b> To explain the environmental control system
<b>Scope:</b> To educate and train registered employees and licensed premise personnel on the environmental control system and cultivation environmental parameters.
<b>Initial Training:</b> TBD

**Environmental Control System**

Temperature will be monitored by a computer based environmental control system. Multiple temperature sensors will be strategically situated around each cultivation room, these sensors will send data to a central computer. The environmental control system will then log this data for future reference, as well as allow the user to make adjustments, set alarms, and monitor the system from any location. Temperature will be controlled using a HVAC system sized correctly for each growing area. The environmental control system’s main computer will regulate the HVAC system. Maintaining temperatures between 72 and 78 degrees is paramount to plant health and Integrated Pest Management. High temperatures encourage the rapid growth of pests as well as increase stress to the plant. All rooms will have back up HVAC systems for redundancy.

Humidity control is the most important aspect of Integrated Pest Management in the indoor horticulture environment. High levels of humidity encourage molds and mildews, as well as create an environment perfect for the growth of insects. Multiple sensors placed in each cultivation room will monitor humidity. These sensors send data to the environmental control systems computer to be logged, trigger dehumidifiers, or set off an alarm. Humidity is controlled by either dehumidification, or ventilation. During standard operation humidity will be removed from the room using horticultural grade dehumidifiers. In the event of a high humidity alarm, a ventilation system will exhaust the room to rapidly lower humidity. Plant transpiration varies greatly between the light and dark periods in a grow room; anticipating this fluctuation is critical. Maintaining a humidity level between 20%-45% is the best defense against mold and mildew issues.

In the sterile cultivation environment, ventilation is used mainly as an emergency means to clear the air from a room. In place of typical ventilation, supplemental CO2 will be introduced to the room at strictly regulated levels. The environmental system will be tied to several sensors that can trigger the ventilation system in the event of a high reading. When the computer system senses levels of CO2, temperature, or humidity above certain set points, it will initiate the ventilation system, and clear the air out of the room. This air will be replaced by HEPA filtered air from outside of the grow room. This ventilation system will initiate at the following set points which will be adjusted seasonally according to outdoor conditions: Temperature On: 92\* Off: 84\*, Humidity On: 70% Off: 45%, CO2 On: 2000ppm Off: 800ppm.

In the indoor horticulture environment lighting control allows us to manipulate the season the plant perceives it is in. Providing 18 or more hours of light will cause vegetative growth indefinitely, this is simulating spring and summer. When the plants are provided 12 hours of light, the flowering cycle begins; this is simulating the transition from summer to autumn. An environmental control system will control the lighting system from a central computer. This system will not only control the lights according to the desired growth period, but will also reduce the amount of operating lights in the event of a high temperature alarm.

**Facility Ventilation Protection**

All intake and exhaust points on the exterior of the facility are to be screened with 350 micron insect cloth. This cloth will be supported by aluminum frames, and sealed to prevent any risk of infestation. This screen is adequate in size to control insects from entering the facility including thrips, aphids, and mites, which are the most common pests associated with marijuana. Registered employees will be required to inspect all facility ventilation protection barriers on a six (6) month basis. Registered employees may need to remove the filter in order to properly clean the filter to ensure the filter is functioning properly. Filters may need to be replaced all together. All Licensed Premise facility ventilation protection (filters/screens) inspection, cleaning, maintenance and repairs or replacements will need to be documented on the **Facility Ventilation Protection (filters/screens)** log sheet as seen below.



<b>Standard Operating Procedure:</b> Employee Dress Code and Personal Hygiene
<b>Purpose:</b> To explain the employee dress code required.
<b>Scope:</b> Covers the dress code requirements for employees.
<b>Initial Training:</b> 30 minutes

### **Principles of Employee Dress Code**

The cultivation facility is considered a “clean” room type setting and as such employees of the cultivation facility will be required to change out of street clothes and into provided work wear to be worn during all scheduled work shifts. The work wear will consist of medical-type scrubs and garden shoes.

Employees are expected to arrive at facilities and enter the locker rooms immediately after entering the facility to shower and change into provided work wear. This will reduce the cultivation areas from exposure to outside contaminants such as pests and diseases.

**Registered employees**—BPH registered employees working will be required to wear approved attire while working within the production center.

- Registered employees will be provided work attire to be worn while working within the Licensed Premise.
  - Work uniform such as scrubs
  - Closed-toe garden shoes such as Crocks
  - Hat (*optional*)

**Transportation Agents**— BPH registered employees working will be required to wear approved attire while on duty. Transportation agent work attire will differ from that of registered employees due to State regulations mandating transportation agents must not have any identifying logos or markings that could indicate ownership or possession of marijuana.

- Transportation agents will be required to wear un-identifying work attire
  - Plain jeans or khakis pants
  - Plain polo or button-up shirt
  - Closed-toe shoe

### **Personal Hygiene Policy**

This policy has been set forth in order to ensure that all employees are practicing good personal hygiene to ensure that are products are produced in safest and most sanitary means possible. The personal hygiene policy includes but is not limited to the following:

- A. Maintaining adequate personal hygiene
  - a. Arrive to work clean in appearance/clean clothes.
  - b. Showering every day is essential
  - c. Deodorant and a clean personal smell is required
- B. Men must be neatly groomed/shaven
  - a. Mustaches or beards allowed if maintained
  - b. We reserve the right to ask you to wear a beard cover if we deem it necessary
- C. Long hair must be constrained in a neat manner to avoid hair coming into contact with food items
  - a. A hat or hairnet is preferred
  - b. Jewelry of any kind is not permitted

- i. This includes earrings, rings, bracelets, watches, etc.
- D. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and
  - E. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

### **General Sanitary Requirements**

BPH will take all reasonable measures and precautions to ensure that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for medical marijuana products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.

BPH will have hand-washing facilities that are convenient and furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

That all registered employees working in direct contact with processing, preparation, weighing or repackaging of medical marijuana products shall conform to hygienic practices while on duty, including but not limited to:

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the processing, preparation, weighing or repackaging of medical marijuana products and at any other time when the hands may have become soiled or contaminated; and
- Refraining from having direct contact with preparation of medical marijuana products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical marijuana products.

Registered employees are required to ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical marijuana products are exposed. Registered employees are required to ensure that floors, walls, and ceilings are adequately cleaned and kept clean and kept in good repair.

The facility will provide adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests. Registered employees must ensure that all contact surfaces, including utensils and equipment used for the preparation of medical marijuana products shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used with medical marijuana and used in accordance with labeled instructions;

BPH requires all toxic cleaning compounds, sanitizing agents, solvents used in the production of medical marijuana and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of medical marijuana products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. That medical marijuana products that can support the rapid growth of undesirable microorganisms will be held in a manner that prevents the growth of these microorganisms; and the storage and transport of finished medical marijuana products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.



**Standard Operating Procedure:** Facility Entry Protocol and Good Growing and Handling Practices

**Purpose:** To explain how employees should enter the production center, preventative IPM measures, and procedures to follow to gain access to Limited Access Area(s).

**Scope:** Covers the steps involved for properly entering the Licensed Premise as well as good growing and handling practices

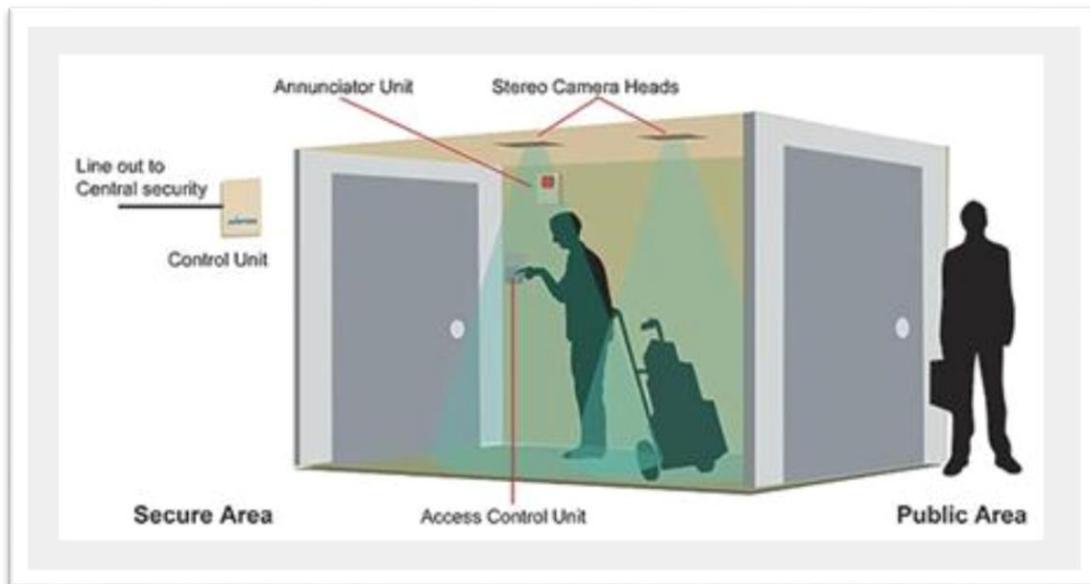
**Initial Training:** 2-4 hours

**Principles of Facility Entry Protocol**

The primary objective of having a specific facility entry protocol is to try to reduce the exposure and risk to outside contaminants from entering the facility. Containments can be anything from pests such as insects and diseases such as powdery mildew. It will be of utmost importance for employees to be mindful of where they have been immediately before arriving at the cultivation facility as this can determine the likelihood and types of contaminants possible.

Upon arriving at the cultivation facility, registered employees will enter the facility using their issued key/keycard or the like, enter the facility’s ‘entry vestibule’. This area is designed as a security measure against unwanted intruders. There will be a magnetic door that can only be opened by personnel with the proper security clearance. This door will be opened through the use of an access control unit.

***Example of a “Entry Vestibule”:***



Upon exiting the “Entry Vestibule” employees will head directly for the locker rooms where they will change out of all street clothes, take showers and change into provided work attire/uniform prior to entering the “clean” area of the cultivation facility.

**Locker Room Steps for Employees to Follow:**

1. Enter locker room
2. Remove **ALL** street clothes and place them in your locker
  - a. *ALL* clothes
  - i. Hats



- ii. Socks
    - iii. Shoes
  3. Take a shower
    - a. This is done as another preventative measure to ensure the cultivation facility is not exposed to any outside contaminants
  4. Change into provide work attire/uniform
    - a. Scrubs
    - b. Hair nets
    - c. Hat (optional)
    - d. Garden shoes

Upon successfully showering and changing into the provided work wear, employees will be ready to begin their work shift within the “clean” area of the cultivation facility.

Upon exiting the locker room, employees will go through an “air-lock” chamber to remove any remaining potential contaminants prior to entering the clean cultivation area. Upon exiting the Air-Lock chamber, the employee will be in the “clean” area of the cultivation facility.

***Example of an Air-Lock Chamber:***



**Good Growing and Handling Practices**

The indoor cultivation environment offers little help to registered employees in terms of biosecurity, so preventative maintenance and clean protocols are essential in operations. Plants are typically cultivated and arranged in close proximity and as such plants in close proximity to each other spread diseases, molds, mildews, and insects with ease in comparison to the natural growing conditions found outside. Due to this, very strict clean entry protocols, as well as quarantine, and biosecurity procedures are necessary.

The facility will be divided into a “clean zone” and a “dirty zone”.

- The clean zone represents any area where marijuana products will be whether in plant form, flower form, concentrate, or infused product.
  - All “clean zones” in the facility will require registered employees to follow the clean entry protocol to enter.
- The dirty zone represents any area where no marijuana product will ever be (excluding marijuana waiting destruction and disposal), including soil receiving, and administration offices.

**Cultivation Areas**—each cultivation chamber in the facility will have separate entry protocols, to keep from cross contaminating any possible pests from room to room. Upon entry into a cultivation room, each grower agent will put on a pair of nitrile gloves, as well as step in a disinfecting footbath. The disinfecting footbath is filled with a plant

and animal safe disinfecting solution, typically used in the animal care, and commercial greenhouse industry. This will control any contaminants on the bottom of grower agent’s feet, where the biggest risk of disease lies. Now in a cultivation chamber, it is the grower agent’s responsibility to be observant for any signs of issues. Upon exiting a cultivation room, the grower agent is required to remove gloves, and step in the disinfecting footbath upon exit.

**Example of Disinfecting Foot Mat/Bath:**



In the event that a disease, mold, mildew, or pest is found, the facility will enter quarantine protocols; refer to the **Integrated Pest management SOP**.

**Foliar Spray Applications**—during the application of foliar sprays, registered employees will be required to wear certain protective clothing depending of type of material being applied. Foliar sprays applied to plants are non-harmful in nature, and do not require protection clothing to be worn. Despite these materials being nonhazardous to plants and animals, the procedure will be to wear protective eyewear, an organic oil capable respirator, and nitrile gloves. This will protect the applicator from breathing any small particles emitted by atomizing sprayers. Sterilizing sprays applied to rooms when plants are not present will require an increased amount of protective clothing. During empty room cleaning and spraying, the applicator will wear a full body chemical suit, protective eyewear, organic chemical respirator, and nitrile gloves. This will protect the applicator from any potential hazardous materials entering eyes, touching skin, or being inhaled.

**Propagation Room(s)**—one of the most important areas of cultivation to assure strict cleanliness protocols are followed is the propagation area. In this area, very specific steps must be taken to not cross contaminate diseases. The propagation room will have a higher temperature and humidity, therefore encouraging insects, molds, and mildews to grow at an increased rate. The first procedure to assuring a clean propagation room is daily inspection of mother plants. These plants will typically be much older and larger than an average cultivation plant, and tend to have more space, and foliage to inspect. Assuring stock plants are not affected will allow you to be sure you are not starting any new clones with a pest. When propagating plants, the first step is to sterilize the work area. Wiping down all work surfaces with a 3% hydrogen peroxide solution will clean any lingering pests. All cloning equipment including clone domes, trays, scissors, and razor blades must be sterilized with hydrogen peroxide solution also. During the cloning process, scissors and razor blades will be sterilized between each strain propagated. Once cloning is completed, the work area is to be sterilized, and remain clean for the next time propagation is done. Protocols for inspecting, and maintaining clone domes are very important. Naturally all clones taken will not survive, and this unhealthy clone presents a food source for molds and mildews. During the time clones are given to grow roots, daily inspections of each dome will be required. Any mold will be removed, as well as dead leaves and clones. If a dome is found to have mold, it will be misted with 3% hydrogen peroxide solution before being closed. During these inspections it is important to clean tools between each dome to reduce the risk of spreading disease.

*\*During daily cultivation tasks, strict procedures are set to minimize risk of pest introduction, or spread. It is the responsibility of each grower agent to read and know these procedures and how they relate to their position. It will be the grower agent’s responsibility to monitor these procedures to assure they are being completed in entirety.*

**Processing/trimming**—the processing/trimming area of the facility will have procedures set in place to reduce the risk of pest and disease issues post-harvest. Post-harvest, it is very important to have strict procedures, and the plants natural resistance to pests is diminished. This wet plant material is very susceptible to mold contamination, and must be handle properly. All processing registered employees will undergo the same entry protocol including mandatory shower, and wearing medical scrubs, hairnet, beard cover if necessary, garden shoes, and clean nitrile gloves. When entering the processing room agents will first step in a sterilizing footbath to mitigate tracking pests between



areas. Prior to harvest the processing team will clean and sterilize all surfaces in the processing room with 3% hydrogen peroxide solution. Once all surfaces are sterilized, harvested plants may enter the room. During all stages of processing registered employees are required to wear nitrile gloves, hairnets, and beard covers. If harvesting more than one cultivation room, the processing room will be sterilized again prior to the next room's plants entering.

When the processing stage is complete, the registered employees responsible for monitoring the drying process will be required to follow cleanliness procedures. Prior to entering the drying room, agent will step in sterilizing footbath to stop the spread of pests on feet. When inspecting drying product, agent will wear clean nitrile gloves, hairnet, beard cover if necessary, medical scrubs and garden shoes. Product will be inspected for issues procedurally, required inventory management forms will be kept with product to monitor progress.



Limited Access Areas

<b>Standard Operating Procedure:</b> Limited Access Areas
<b>Purpose:</b> To explain Limited Access Areas, who is allowed in these areas, and procedures to follow within the Limited Access Area.
<b>Scope:</b> Covers the steps involved in escorting visitors in limited access areas.
<b>Initial Training:</b> 1 hour

### The Principles of Limited Access Areas

A Limited Access Area is a building, room, or other contiguous area upon the Licensed Premises where medical marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee. Limited Access Areas are areas within the licensee's facility where only certain people will have the required permission to access.

Limited Access Areas may have people in them without the proper permission as long as the Visitor SOPs and state regulatory required protocols are followed. Registered employees will follow the *Visitor SOP*; with allowed visitors being escorted by a registered employee at all times while in the facility and Limited Access Areas.

Limited access areas should be limited to State licensed, facility employees only. If a visitor needs to access the limited access areas, registered employees will be required to follow the written *Visitor SOP*.





Visitors

<b>Standard Operating Procedure: Visitors</b>
<b>Purpose:</b> To explain the processes involved to accept/allow visitors into the retail dispensary.
<b>Scope:</b> Covers the required steps to follow to allow visitors into the facility.
<b>Initial Training:</b> 1 hour

**Requirements**

- 1) Visitor Log Sheet
- 2) Visitor pass

Pursuant to 329D-15 and 329D-16, unauthorized access to retail dispensing locations and/or a production center is a Class C felony. Due to the strict penalties for infractions, BPH will take steps to identify all potential subcontractors, maintenance workers, and any other individual identified as needing to visit one of BPH retail dispensing locations or our production center. Such steps will allow said individuals to submit proactively to fingerprint cards and background checks and be aware of the information submitted to the Department. In order to obtain Department approval, BPH also intends to identify secondary, back-up individuals who can be utilized as resources if the primary resource is unavailable; these secondary subcontractors and resources will also be required to submit fingerprint cards and authorize consent for background investigations to ensure the individual does not have any felony convictions or other offenses listed in §11-850-17.

**The Principles of Visitor Protocol**

BPH’s visitor protocol will follow industry best practices and current regulations. There will be situations that arise that will require someone to enter the registered dispensary facility premises who is not a State-licensed industry worker or not a State-registered patient or caregiver but they will need access to the facility. Common visitors typically will be support-type businesses such as HVAC, electric and plumbing, general contractors, etc.

All visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

Approved visitors will be required to provide a BPH registered employee with a current, valid government-issued identification. The registered employee will confirm the individual is on the BPH’s Department-approved list, make a photocopy of the visitor’s ID and maintain the photocopy with the visitor log book; visitors will be required to sign in and out with a registered employee and provide a written reason for the visit (e.g. maintenance work, HVAC, repairs, etc.). Upon completing these requirements, the registered employee will issue a ‘visitor badge’ for the visitor to wear and display while at any BPH registered dispensary facility. BPH will also require a registered employee to remain with the visitor for the duration of the visit to ensure the visitor does not interact with or handle any marijuana plant, material, product, or manufactured marijuana product.

- **Government-Issued ID**—all visitors must have a current and valid government-issued ID (passport, Driver’s License, military ID)
  - Ensure that the government-issued ID is current (check expiration date on ID)
- **Verification**—Verify the validity of the government-issued ID and that the visitor is on the current Department-approved list
- **Photocopy**— Make photocopy of visitor’s government-issued ID
  - Make a photocopy of visitor’s ID; Photocopy is to remain with *Visitor Log Sheet*

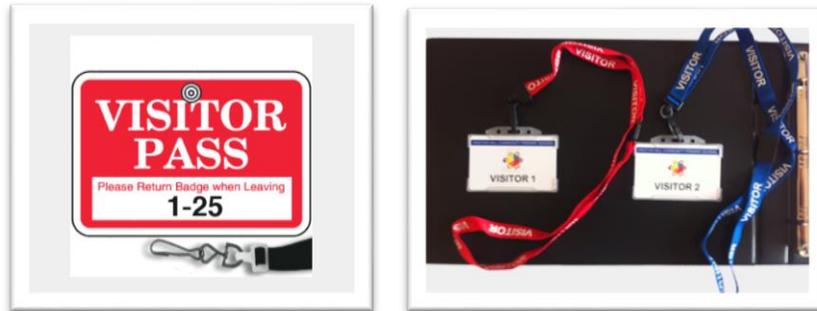


- **Access**—Allow or deny access to the facility
  - Allow entry to dispensary if the visitor has a valid government-issued ID.
  - Deny entry to the facility if the visitor does not have a valid government-issued ID.
- **Record/Documentation**—Have visitor fill out the *Visitor Log Sheet*
  - *Visitor Log Sheet* will document visitors name, company, date, time-in, time-out, signature, reason for the visit
  - Maintain photocopy of visitor ID with the *Visitor Log Sheet*
  - This record of visit must be retained and maintain on the licensed premise for a minimum of two (2) years.

**Visitor Access Process:**

- 1) Check visitors ID and credentials at the check-in station
  - a. Make photocopy of Visitor’s ID
- 2) Verify with management that visitors are expected and on the current Department-approved list
- 3) Fill out *Visitor Log Sheet*
- 4) Have said visitor sign-in and date the *Visitor Log Sheet*
- 5) Give visitor a ‘*Visitor Pass*’
- 6) When visitor is finished at the licensed premises:
  - a. Have visitor sign-out on *Visitor Log Sheet*
  - b. Collect the ‘*Visitor Pass*’ from said visitor

*Example of a Visitor Pass can be seen below:*



*Example of Visitor Sign-In Documentation Log Sheet:*

<u>Visitor Sign-In Documentation Log Sheet</u>							
<u>Date</u>	<u>Time In</u>	<u>Time Out</u>	<u>Visitor Name</u>	<u>Visitor's Company</u>	<u>Visitor Signature</u>	<u>Reason for Visit</u>	<u>Registered Employee Escort</u>



Daily Facility Evaluation

**Standard Operating Procedure: Daily Facility Evaluation**

**Purpose:** To train employees on the production center daily evaluation prior to conducting any cultivation and/or processing daily operations.

**Scope:** Explain what items, equipment and processes need to be evaluated on a daily basis prior to commencing any daily operations.

**Initial Training:** 4-6 hours

**Principles of Daily Facility Evaluation**

Adhering to a daily facility evaluation is paramount within a cultivation facility. Registered employees will be required to inspect the cultivation facility/operations on a daily bases to ensure the facility is operating optimally. The facility evaluation is done to ensure that the various cultivation room environments are optimal, to ensure no lighting or equipment is malfunctioning, and to assess the overall health of the marijuana plants.

If performed routinely on a daily bases, registered employees will become in-tune with the cultivation facility and realize potential problems and be able to address those potential problems before they become issues. The facility evaluation will be the first task completed by registered employees after completing the facility entry and clean protocols.

**Items to Evaluate:**

1. Room environment
  - a. Temperature
  - b. Humidity
  - c. CO2 level (*if applicable*)
2. Plant medium moisture
3. Lights functioning properly
4. Growing equipment functioning properly
  - a. Autopots
  - b. CO2 system(s)
  - c. Fans
  - d. HVAC system(s)
5. Signs of disease/pests
  - a. Type of disease/pest
6. Additional notes/details

*Cultivation Facility Evaluation form can be seen below:*



### Cultivation Facility Evaluation

<b>Date:</b>		<b>Time:</b>		<b>Registered Employee:</b>	
<b>Mother Room</b>					
Temp.:		Humidity:		Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO	
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO		Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO			
Overall Plant Health:					
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO		What type of disease/pest infestation?			
Notes/Details:					
Number of Plants:		POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO		Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Action Items ( <i>if any</i> ):					
Additional Notes/Details:					
<b>Propagation/Clone Room</b>					
Temp.:		Humidity:		Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO	
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO		Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO			
Overall Plant Health:					
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO		What type of disease/pest infestation?			
Notes/Details:					
Number of Plants:		POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO		Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Action Items ( <i>if any</i> ):					
Additional Notes/Details:					



Vegetative Room(s)		
Temp.:	Humidity:	Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO
Plant Vegetative Lifecycle Week:		
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO	Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Overall Plant Health:		
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO	What type of disease/pest infestation?	
Notes/Details:		
Number of Plants:	POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO	Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO
Action Items ( <i>if any</i> ):		
Additional Notes/Details:		
Flowering Room(s)		
Temp.:	Humidity:	Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO
CO2 Level:	Plant Flowering Lifecycle Week:	
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO	Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Overall Plant Health:		
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO	What type of disease/pest infestation?	
Notes/Details:		
Number of Plants:	POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO	Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO
Action Items ( <i>if any</i> ):		
Additional Notes/Details:		



Receipt of Material

<b>Standard Operating Procedure: Receipt of Materials</b>
<b>Purpose:</b> Explain procedure and requirements for receiving raw materials
<b>Scope:</b> To educate and train licensed premise employees on the procedures and requirements involved with receipt of materials.
<b>Initial Training:</b> 1-2 hours

**Principles of Receipt of Material**

The process of receipt of material or receiving raw materials is not as simple as just taking the raw materials into the licensed premise. There are regulations, guidelines and procedures to follow when receiving raw materials or other inventory into the cultivation facility licensed premise.

Upon receiving any raw materials, inventory or other items used in operations said items will be placed in a quarantine storage area within the receiving area of the licensed premise. Employees will need to quarantine any materials received to be used to produce marijuana. These items will include but not be limited to:

- Medical marijuana seeds
- Medical marijuana cutting/clones
- Medical marijuana plants
- Soil/potting mix
- Fertilizers
- Pesticides, insecticides and fungicides
- Growing containers

**Receipt of Materials**—upon receiving materials into the licensed premise, registered employees and/or licensed premise employees will need to document the receipt of materials on the *Receipt of Materials* log sheet.

*Example of Receipt of Materials Log Sheet can be seen below:*

<b>Receipt of Materials</b>							
<u>Date of Receipt:</u>	<u>Receiving Employee #1:</u>	<u>Receiving Employee #2:</u>	<u>Product/Strain/Attribute ID #:</u>	<u>Quantity Received:</u>	<u>Received From:</u>	<u>Materials Placed in Quarantine:</u>	<u>Materials Pass Visual Inspection:</u>
						YES NO	YES NO
<i>Describe why Materials did not pass visual inspection:</i>				<i>Corrective action to be taken:</i>			
<u>Materials Pass Visual Inspection after Corrective Action:</u>		<i>Describe why Materials did not pass visual inspection after corrective action:</i>		<i>Next corrective action to be taken:</i>			
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>If materials passed visual inspection, and are determined to be acceptable for use as intended, said materials may be released from the quarantine areas and used as intended.</i>							
<u>Date of Release of Materials:</u>	<u>Employee(s)/Supervisor Releasing Materials:</u>		<u>Product/Strain/Attribute ID # of Released Material(s):</u>		<u>Quantity Released:</u>		
<u>Record of Receipt of Materials Made in Perpetual Inventory Control System (POS)?</u>		<u>Required POS Records:</u> <i>date of receipt, quantity of material, types/variety of material date of release</i>		<u>Employee Making POS Record Entry:</u>		<u>Employee Witnessing POS Record Entry:</u>	
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>Notes/Comments:</i>							



**Quarantine Storage Area**—the quarantine storage area will be within the licensed premise and clearly identified on the facility floor plan diagram. The quarantine area will be classified as a “dirty” zone within the cultivation facility. Materials will be held within the quarantine area where they will be segregated from the rest of the cultivation licensed premise and/or “clean” areas of the facility.

**Inspection**—after received inventory items/materials are placed in quarantine, the items will need to be inspected to ensure there are no defects or contamination. All received items/materials will remain in the quarantined area until said material pass inspection and is determined to be acceptable for use as intended.

- Registered employees will be required to inspect all materials for visible defects and contamination
- Inspecting materials for contamination is essential for the facilities clean protocols and IPM measures
  - If a contamination is identified proper cleaning and/or segregation procedures will be implemented.
    - Cleaning and sanitizing the contamination: if the contamination is deemed reasonable to clean and sanitize you will need to clean and sanitize all surface areas of the material if possible. This should be done using a cleaning/sterilizing agent such as bleach.
    - If cleaning and sanitizing is not an option, the materials will be segregated within the quarantine area until they are properly destroyed and disposed of.
    - If contaminated with pests, insects or disease; immediately segregate the material while trying to identify the contamination.
      - Refer to the *IPM SOP* for proper identification and treatment of material (plants)
  - Once the materials are properly cleaned and sanitized and believed to be free from contamination they will need to be inspected a second time.
    - Materials will need to pass this second inspection prior to being released for their intended use.

**Release**—upon the received materials passing inspection and being determined to be acceptable for use as intended, the materials will be released from the quarantine receiving/storage area. At this time the materials can be used within the licensed premise for their intended use.

- Release materials if they pass initial inspection
- Release materials once they are cleaned and sanitized and pass secondary inspection

**Documentation and Record**—upon the materials being released from quarantine and determined to be acceptable for use as intended BPH registered employees and/or licensed premise employees will be required to log the materials into the inventory control system.

- Document and record new materials released from quarantine in the inventory control system (POS system)
- Ensure record is accurate with physical inventory on hand
- Ensure the *Receipt of Material* log sheet is filled out properly and completed



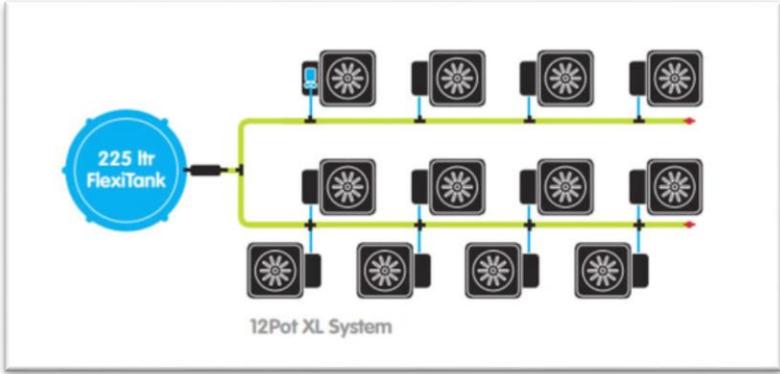
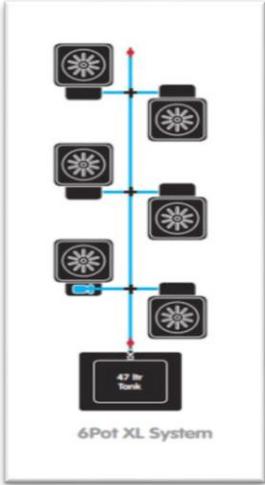
<b>Standard Operating Procedure:</b> Growing Containers—AutoPots Automated Watering System(s)
<b>Purpose:</b> To understand the set-up and operation of AutoPots automated watering system
<b>Scope:</b> To understand how to properly assemble and trouble shoot AutoPot systems. <i>AutoPot Set-Up Instructions can be found at:</i> <a href="http://www.autopot.co.uk/autopot-1pot-xl-system?download=92">http://www.autopot.co.uk/autopot-1pot-xl-system?download=92</a>
<b>Initial Training:</b> 2-4 hours

### The Principles of AutoPot Automated Watering System(s)

ACC utilizes AutoPot automated watering systems as the container and watering system for marijuana plants. The AutoPot watering system is a gravity-fed system utilizing a large main reservoir supplying water and/or nutrients to the marijuana plants in their own, individual AutoPot container. The individual AutoPot containers will vary depending on the plants growth stage. During the vegetative growth stage marijuana plants will be housed in 1 gallon pot/container and/or a 2.2 gallon AutoPot; and during the flowering growth stage marijuana plants will be transplanted into a 6.6 gallon AutoPot.



*AutoPot Systems are scalable to meet cultivation demand requirements*



**AutoPot Set-Up:**

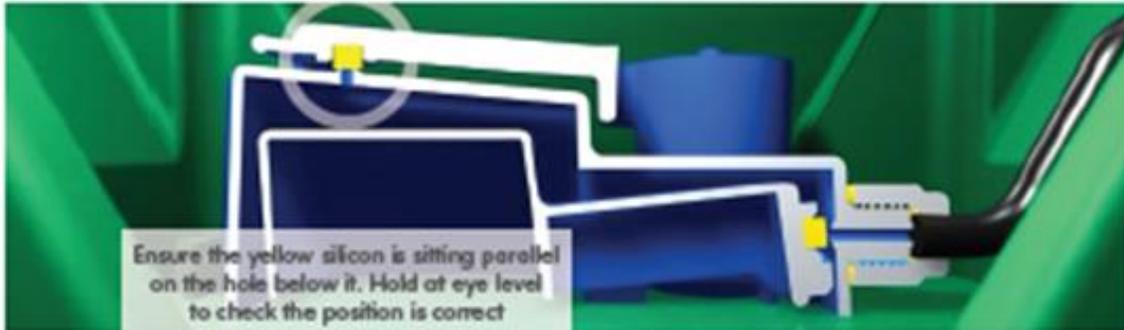
1. The AutoPot system should be used with Reverse Osmosis water or de-chlorinated water and this water can be stored in any size reservoir.
2. The reservoir should have a pressurized line (*coming from the RO system if applicable*), attached to a float valve that regulates the water level based on the usage of water by the plants. This design and install should be set up by a licensed plumber or an Autopot representative
3. Located near the bottom of the reservoir, there is a connector that is installed, again by a licensed plumber or Autopot representative that will attached to the main line that feeds the AutoPots.
4. Follow set-up instructions found in the AutoPot manual with the addition of adding two inches (2”) of perlite at step 1.5

*AutoPot set up instructions that can be found at <http://www.autopot.co.uk/autopot-1pot-xl-system?download=92> can be seen below:*



# AQUAvalve™

## Simple care guidelines



### Ensuring that the AQUAvalve floods and drains correctly

- 1** Making sure your AQUAvalve floods and drains correctly is simply achieved and only takes a few seconds.
- 2** Hold the AQUAvalve at eye level so that you can see the yellow silicon fitted to the top float resting on the hole below it
- 3** The yellow silicon must create a tight seal when touching the hole.
- 4** If it looks like it is not sitting parallel on the hole below, simply lift the top float and apply pressure to one side of the yellow silicon, drop the float and hold at eye level again. Repeat the procedure if necessary.

### Care and maintenance

- 1** At the end of your growing season, clean the AQUAvalve using warm soapy water. Using an old tooth brush will help.  
  
The AQUAvalve is easily disassembled. The top float will slide all the way across and the bottom float is unclipped from its pivoting position. The circular discs fitted to the top float can also be removed by using pliers to grip the raised point.  
  
At this point it is advisable to remove the yellow silicones to avoid them being lost.
- 2** It is also handy to have a paper clip or pipe cleaner to hand so that you can push it through the AQUAvalve nozzle, this will remove any lime scale build up that may have occurred during the growing season.  
  
Blowing through the AQUAvalve nozzle will also help to remove any build up. Do not under any circumstances use a drill & drill bit to clear the AQUAvalve nozzle.  
  
This will potentially damage the AQUAvalve beyond repair.



## Your 1Pot XL module set-up guidelines



Allow your  
**plants**  
to establish  
before turning your  
system ON.

Trays & Pots  
available in  
black



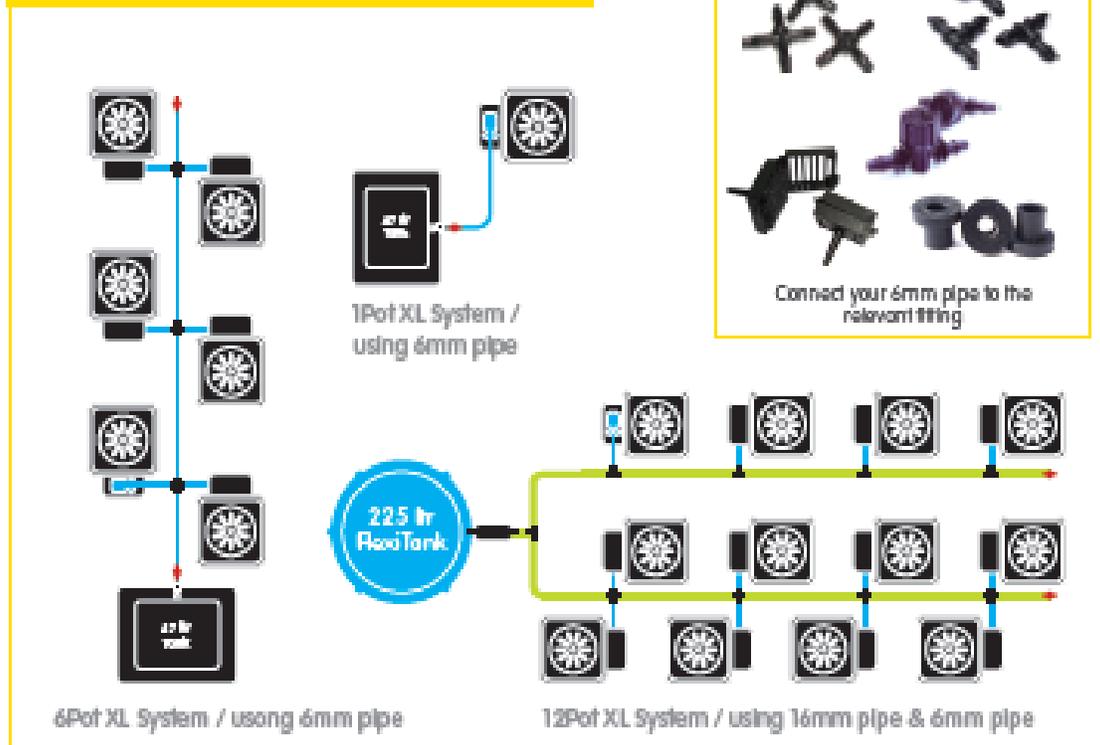
mail@autopot.co.uk | www.autopot.co.uk | +44 (0)844 8581520

### 1Pot XL module contents

- 1x 1Pot XL tray & lid
- 1x 25ltr pot
- 1x AQUAvalve
- 1x 1.0 metres of 6mm pipe
- 1x root control disc
- 1x 6mm tee connector
- 1x 16/6mm tee connector

### Plan views and options

### Suggested layouts

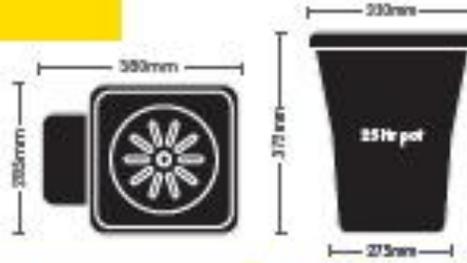


### Advice

- Pot up your plants, water through, then allow your plants to establish in the pots for a period of 7 to 10 days before turning your system on. This will encourage a stronger and healthier root system.
- Always raise your tank to a minimum of 150mm above the highest AQUAvalve and re-fill the tank when there is approximately a 1/3 of the solution left - NEVER ALLOW THE TANK TO RUN EMPTY.
- For best results, we recommend mineral fertilisers. Do not use organic fertilisers, as they have a tendency to block small pipe work.
- Clean all substrate from the bottom and sides of the pots before plating in each tray. This will ensure your system is clean from the start.
- Always use free draining substrates, for example: soil/perlite, coco/perlite, soil/day pebbles, coco/day pebbles, rockwool/day pebbles.

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### 1Pot XL dimensions



### 1Pot XL setup instructions

- 

**1** Place circular root control disc gold face down in the pot.
- 

**2** Fill pot with medium and pot up plants.  
Water through pot and allow to drain outside the tray.
- 

**3** Remove collar.  
Push 6mm pipe through collar and attach to AQUAvalve nozzle.  
Rescrew collar - **DONT** overturn... when you feel it grip **STOP**.
- 

**4** Connect AQUAvalve so 'half moon' is on T section in the tray.
- 

**5** Position tray so it is level.
- 

**6** Cut 6mm/16mm pipe to appropriate length
- 

**7** According to the size of your system connect your 6mm/16mm pipe to relevant fitting or tank...
- 

**8** Place pot in the tray, make sure it is **CLEAN!**  
Place lid over valve onto tray.

Using your front instruction sheet, repeat the module set up instructions for the number of trays.

**Allow your plants to establish for 7-10 days before turning system on**

**Advice**

If you require any guidance email - [mail@autopot.co.uk](mailto:mail@autopot.co.uk)



Quality Control

<b>Standard Operating Procedure: Quality Control</b>
<b>Purpose:</b> To describe the quality control
<b>Scope:</b> To train registered employees on quality control measures to be utilized within the cultivation operations
<b>Initial Training:</b> TBD

Quality control measures will primarily be in the form of adherence to the written standard operating procedures to ensure quality and consistency of products produced within the facility. BPH will utilize the established and proven SOP's for all cultivation operations. BPH will use standard operating procedures (SOP's) to promote good growing and handling practices including:

- All aspects of the:
  - Irrigation, propagation, cultivation, fertilization;
  - Harvesting, drying, curing;
  - Rework or reprocessing;
  - Packaging, labeling, and handling of medical marijuana products, byproduct; and
  - Waste products, and the control thereof, to promote good growing and handling practices.

BPH will require that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical marijuana has received the training, education, or experience necessary to perform assigned functions; and will also require that all registered employees practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

BPH will require grower agents to follow the protocol for Receipt of Material including:

- BPH shall quarantine received material that will be used to produce marijuana and/or manufactured marijuana products
- BPH shall inspect materials for defects and contamination.
- Material may not be released from quarantine by a BPH until the material:
  - Passes inspection; and
  - Is determined to be acceptable for use as intended.



<b>Standard Operating Procedure:</b> Growing Media and Nutrients, Supplements and Growth Additives
<b>Purpose:</b> To describe the growing media and nutrients, supplements and growth additives used
<b>Scope:</b> To train licensed premise employees on the type of growing media and nutrients, supplements and growth additives to be utilized within the cultivation operations
<b>Initial Training:</b> 1 hour

**Principles of Growing Media**

SoHum Living Soil (SoHum) is fully amended biodynamic potting mix which simplifies the growing process while maximizing yields and producing a consistent quality product. SoHum is a growing medium that is biodynamic, a soil developed to optimize the marijuana plants’ maximum genetic potential. In marijuana cultivation, the term “biodynamic” applies to the understanding that soil directly impacts plant development and emphasizes a natural approach to growing that focuses on the micro life in the soil.



The SoHum medium is a fully amended potting mix that contains none of the artificial components found in other soils and requires no chemical additives to spur growth. The potting mix is perfectly balanced with the proper mixture of nutrients and fertilizers promoting strong terpenoid and flavonoid development to enhance the medicinal benefits of the marijuana. SoHum is a fully amended biodynamic potting medium having nutritional amendments of a type and formulation required for optimal marijuana plant growth.

The potting mix consists of coconut coir, perlite, worm castings, biochar, 0-15-1 bat guano, 12-11-2 bat guano, greensand, lime, glacial rockdust, azomite, alfalfa meal, kelp meal, langbeinite, fossilized, bone meal, feather meal, rock phosphate, neem seed meal and crab meal.

**The Benefits of SoHum Living Soil:**

- Compared with traditional soil and fertilizer growing programs, SoHum potting mix offers a number of advantages:
  - Consistent high grade quality
  - Improved plant immunity to disease
  - Reduced operator error
  - No need for expensive nutrient or additives

SoHum has been specifically formulated for optimal marijuana plant health and growth and can be used as a stand-alone nutrient/fertilizer regime for marijuana plants, eliminating the need for additional nutrients, fertilizers, additives, supplements, growth regulators or boosters.

**Soil Storage**—SoHum Living Soil has living microbes within the potting mix which require certain storage requirements.

- Potting mix should be stored on the pallets that they arrive on in the storage area.
- The soil storage area should be climate controlled between 68F-78F optimally but can withstand temperatures between 58F-88F.

- Pallets should be used and rotated according to date of arrival; using a First-In-First-Out (FIFO) inventory rotation system.
- For optimal bio-security, bags should be sanitized by wiping them down with a cleaning solution prior to transporting them to the transplant area.

**Nutrients, Supplements and Growth Additives**

There should be no need for additional nutrients, supplements or growth additives required when utilizing SoHum Living Soils. The potting mix contains all nutritional requirements for the entire lifecycle of the plant.

If a situation arises where nutritional deficiencies are identified, the use of natural, protein-chelated liquid nutrients and fertilizers is recommended. If using additional nutrients, supplements and/or growth additives follow manufacturer recommendations for mixing ratios and directions for use.

Upon using additional nutrients, supplements and/or growth additives outside of SoHum Living Soil, BPH registered employees will be required to document said application on the *Nutrients, Supplement and/or Growth Additive* log sheet. This log will need to be maintained with the Production Center cultivation records. Registered employees will place each monthly log in the appropriate folder within the cultivation operations file cabinet.

The documentation will detail which nutrients, supplements and/or growth additives were applied as well as the dosage rates and amounts applied to medical marijuana plants being cultivated.

<b><u>Nutrients, Supplements and/or Growth Additives</u></b>					
<b><u>Date:</u></b>	<b><u>Employee:</u></b>	<b><u>Grow Room:</u></b>	<b><u>Plant Attribute # and Batch #</u></b>	<b><u>Lifecycle Stage:</u></b>	<b><u>Week:</u></b>
				<input checked="" type="checkbox"/> Vegetative <input type="checkbox"/> Flowering	
<b>Nutritional Deficiency Identified?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>What is the nutritional deficiency (reason for application)?</b>	<b>Nutrient, Supplement and/or Growth Additive Applied:</b>		<b>Amount Applied:</b>	<b>Applied By:</b>
Note/Comments:					



Plant Tagging

**Standard Operating Procedure: Plant Tagging**

**Purpose:** To explain the principles and concepts of plant tagging

**Scope:** To educate and train registered employees and licensed premise employees on plant tagging for inventory control

**State of Hawaii Regulations**

The State of Hawaii requires that as soon as practical, each plant to be tagged with materials that are indelible and tamper-evident. Indelible is defined as something that is not able to be removed, and tamper-evident means that if the tag is removed or tampered with it will be visibly noticeable.

**Medical Marijuana Plant Tag Requirements:**

- Indelible
- Tamper-evident
- Temperature resistant
- Moisture resistant

Medical marijuana plant tags to be utilized by BPH will be indelible and tamper-evident. The tags will also be water and temperature resistant to ensure tags will not be destroyed during cultivation operations. Tags will be secured to medical marijuana plants using tamper-evident zip-ties. Plants tags should be made of plastic of a variation that will meet all regulatory requirements. *\*Medical marijuana plants are to be tagged once they are planted in a growing contained of 1-gallon or larger. This will ensure the marijuana plant will be large enough to support the plant tag.*

**Tagging**—after each marijuana clone/cutting is received into the licensed premise, created through propagation/cloning or sprouted from seed, the employee will record required plant information within the perpetual inventory control system, create, assign and securely attach a new plant tag to the plant’s container or to the plant itself.

- All transplants and harvests are to be recorded into inventory control system the day of transplant and/or harvest.
  - One employee will enter the record into the inventory control system with another employee witnessing the record; double check data inputs to insure there are no mistakes.
- Keep a hard copy on the licensed premise of every change that occurs pertaining to medical marijuana plant cultivation in the facility.

For every medical marijuana plant in the licensed premise BPH will:

- create a unique identifier for each plant (*attribute #*)
- assign each plant to a batch (*production batch #*)
- enter information regarding the plant (*attribute # and batch #*) into the inventory control system (*POS system*)
- create a tag with the unique identifier and batch number
  - enter information regarding the plant tag (*plant tag #*) into the inventory control system (*POS system*)
- securely attach the tag to a plant container or plant.

**Example of Marijuana Plant Tag:**





Mother Plants

<b>Standard Operating Procedure: Mother Plants</b>
<b>Purpose:</b> Demonstrate the correct technique used to maintain a mother plant as a marijuana genetic/strain bank.
<b>Scope:</b> Explains the principles of mother plants and how to maintain said plants.
<b>Plant Environment:</b> 75-85 <sup>o</sup> Fahrenheit; ~30-50% humidity
<b>Plant Light/Photo Cycle:</b> Minimum for 18 hours of continuous light and up to 24 hours of continuous light.
<b>Initial Training:</b> 4-6 hours

### **Principles of Mother Plants**

A “mother” plant is a female marijuana plant that is held in reserve in the vegetative state in which cutting or clones are taken from the mother plant to create, identical female marijuana plant. The idea behind keeping “mother” plants is to ensure marijuana genetics and strains are maintained for future crop production.

Any female marijuana plant can be turned into a mother plant to preserve marijuana genetics and strains. Mothers can be grown from seed or clone. Mother plants should be selected only if they are disease and pest free.

In order to maintain a mother plant you will need to maintain the proper vegetative growth light cycle of a minimum of 18 hours of lights on with 6 hours of lights off or 24 hours of continuous lights on.

Mother plants should be given minimal nutrients as you are not trying to grow the plant for vigorous growth but rather as a “genetics bank”; in this scenario the mother plant should be given enough nutrients to maintain healthy growth but you are not preparing the plant for the flowering growth stage.

### **ACC Recommendations for Mother Plants:**

1. Mothers should be held as mother plants for a maximum of six (6) months
2. Maintain mothers under 24-hours of continuous lights on
3. Keep mother plants “clean” through pruning
  - a. Maintain mother plant branch growth; plants will become bushy and thick with vegetation
  - b. Proper pruning and “thinning” out of the plant will ensure proper airflow and reduce the risk of pests and/or disease
4. Adhere to IPM protocols (*IPM SOP is discussed later*)
5. When a mother plant has reached the end of its lifecycle (6 months) the plant will be cloned from to take the final round of cuttings/clones
  - a. Upon taking the final cuttings from the mother plant, the plant will be killed off and discarded
    - i. Follow the marijuana waste disposal SOP (*SOP discussed later*)



Propagation and Cloning

<b>Standard Operating Procedure: Propagation and Cloning</b>
<b>Purpose:</b> Demonstrate the correct technique used to propagate (clone) a new plant and to facilitate new root development in cuttings.
<b>Scope:</b> Covers the propagation and cloning process within the cultivation facility. Approximately a 5-14 day process.
<b>Plant Environment:</b> 75-85 <sup>o</sup> Fahrenheit; ~50-80% humidity
<b>Plant Light/Photo Cycle:</b> Minimum for 18 hours of continuous light and up to 24 hours of continuous light.
<b>Initial Training:</b> 4-8 hours

### Documentation Log Sheets Required

#### 1) Propagation Log

#### Equipment/Tools Required

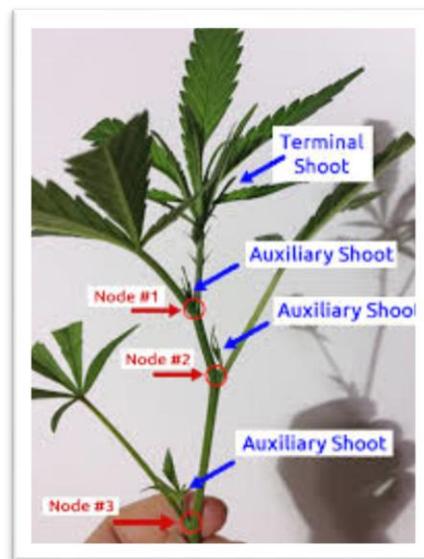
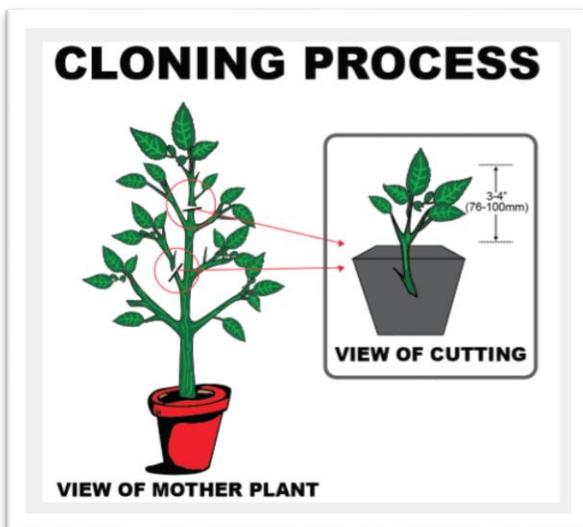
- Scissors, scalpel, razor blade
- Rooting hormone/stimulant
- Humidity dome
- Root cubes
- Plant tags

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### <WEEK 1>

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The cultivation process will begin in week one with the propagation/cloning of medical marijuana plants. Propagation/cloning is the process of producing a genetically identical plant. Every strand of DNA in a clone is exactly like the plant from which it was propagated; propagation/cloning allows for identical genetic reproduction ensuring marijuana genetics and strains can be cultivated infinitely.



Cannabis Cutting



### The Principles of Cloning a Plant

- 1) It is imperative to clone from a healthy mother plant; this is key to achieving quick root development during the cloning process. The stem of the area you select to cut should appear green with no signs of deficiency. A healthy clone will produce roots within 7-14 days.
- 2) Cuttings should be taken from a healthy mother plant and from an area of said mother plant that appears to have new growth and have at least 3 node sites (*see picture of marijuana cutting shown above*).

*Example of a healthy mother plant(s):*



- 3) The vegetation of the mother plant should show little to no sign of deficiency. Signs of nitrogen deficiency (yellowing) within the mother plant indicate a clone becoming phosphorous, calcium, and magnesium deficiency during the cloning process.
- 4) Mother plants must be examined for any contaminants to assure a clean clone, as clone environments are ideal for pest and fungus proliferate.

### Documentation Log Sheets Required

- 1) Propagation Log Sheet
- 2) Daily Environment Documentation

### Supplies/Tools Required

- 1) 5-gallon Bucket
- 2) Rooting Stimulant
- 3) Small cup
- 4) Scissors (clean/sharp)
- 5) Razor blade (new)
- 6) Large Cup
- 7) Root Cubes
- 8) Clone Dome
- 9) Clone tray

### Preparation

- 1) Fill 5-gallon bucket with 3 gallons of filtered water.
- 2) Adjust the water to 5.8 pH.
- 3) Pour some of the adjusted water over the pre-soaked Root Cube trays
- 4) Soak Root Cube (medium) in solution for 5 minutes *\*See below (if applicable; if root cubes are not pre-soaked with nutrients).*



**Selecting Samples (Mother Plants)**

1) Select the branches that allow for ideal clone, leaf and stem structure.

**1. Mother Plant**

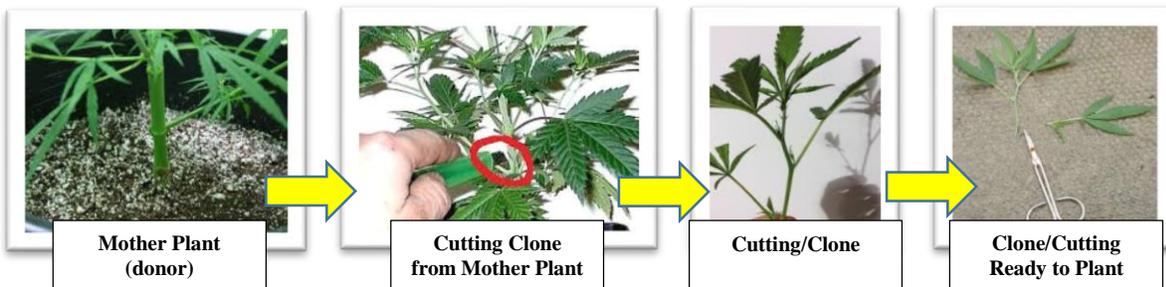
**2. Clone (cutting) to Take**

**3. Mother Plant after Cutting**

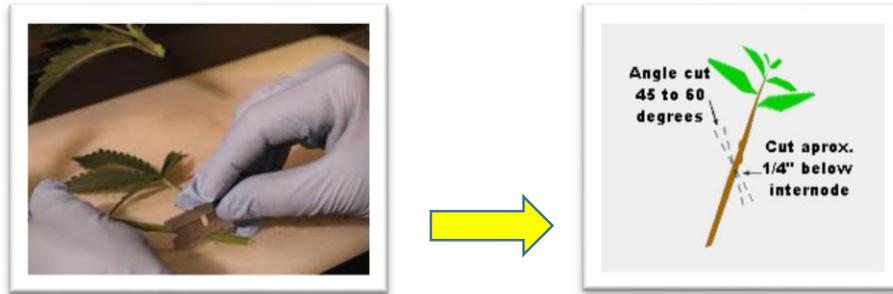


- 2) The samples should be 6-12 inches long.
- 3) 1” inch above the last node make a perpendicular (flat) laceration with a pair of scissors. Making the cut 1” above the node induces minimal stress and lowers risk of the Mother plant acquiring disease.
- 4) Trim all nodes except the 3-5 closest to the tip of the clone.
- 5) Form a loose fist with your hands to cup the leaves of the clone upward. Cut the tip of each major leaf off in a single motion.
- 6) Put the branch into a cup of water.
- 7) Repeat until you have finished taking samples of selected strain.
- 8) Only cut clones from one mother plant at a time.
- 9) Clean scissors with 91% rubbing alcohol between taking samples from each mother plant.

**Cutting Clones**



- Using a clean razor or scissors for each mother, make a laceration or cut segmenting the stem at a 45°-60° angle.



- Cut each branch to be 5-8 inches long.
- Make three (3) delicate length-wise lacerations to the exterior plant tissue immediately above the base of the cutting to increase the exposed surface area of the cutting.
- Dip the finalized portion of the clone into the rooting stimulant/hormone. Submerge the base of the cuttings stem 0.5" to 1" inches into the rooting solution/hormone.



- Firmly bracing the stem insert the sample into the rooter cube or into the clone hydroponic machine. Avoid bending or breaking the stalk while forcing the clone into a secure position.



- Place 30-50 clones into each humidity dome or into the hydroponic cloning machine.

**Examples of Humidity Domes:**



**Examples of Hydroponic Clone Machines:**



- 7) Keep the domes covered while taking each clone to maintain required humidity levels; this is not required for the hydroponic clone machines.
- 8) Place the clones into their position in each humidity dome or clone machine and put the humidity dome/clone machine under the T-5 light on the clone rack or in the clone room/area.



- 9) Record and document all clones taken and all relative information required and document on the propagation log sheet.
- 10) Store equipment and clean work area

**Clone Moisture Regulation**

- 1) During this process the employee must analyze the moisture levels of all clones in each humidity dome and/or hydroponic/aeroponic cloning machines.
  - a. As the employee encounters clones that appear to be dry, they will be watered with a cloning nutrient solution or 5.8 pH water solution.
- 2) If a humidity dome/plant is determined to need to be watered said plant or humidity dome will be watered with a cloning nutrient solution or 5.8 pH water
  - a. Let water sit in the humidity dome for approximately 3-5 minutes to allow the root cubes to absorb the water and/or cloning nutrient solution
  - b. After 3-5 minutes pour remaining/excess water out of humidity dome.



- 3) Repeat individually for each humidity dome that needs water.
- 4) Do not spray plants with water directly or leave standing/stagnant water in the humidity domes/clone trays
  - a. This will help prevent disease such as powdery mildew
- 5) Store equipment and clean work area.

**Clones with Health Root Development (ready for transplant and vegetative growth stage)**

- 1) Allow the clone root system 5-14 days to develop before transplanting into a larger, vegetative Autopot and/or pot/container.



- **Tagging**
  - After each marijuana clone/cutting is transplanted the employee will record:
    - The number of plants.
    - The number of each tag used for every plant.
    - The new location each plant.
    - The date of transplant.
  - Once the data is captured an employee will place the tags selected for that plant into each pot.
  - All transplants are to be recorded into POS software day of transplant.
    - Double check data inputs to insure there are no mistakes.
  - Keep a hard copy of every change that occurs in the facility.
    - Plant moves, transplants, harvests, and waste will be the most frequent and important data inputs.
      - Place plant on rack to be transported to new location.
        - Recordkeeping/Documentation required:
          - Record:
            - New location
            - Date of transplant
          - All changes are to be recorded in POS tracking software day of activity(s).

***Example of Marijuana Plant Tag:***





Example of the Propagation Log sheet:

<b><u>Propagation Log</u></b>					
<u>Date:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Plant ID#/Strain that Clone was Taken From:</u>	<u>Quantity of Cuttings Taken:</u>	<u>POS Record Made/Notes:</u>
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO

-----<WEEK 2>-----

After two (2) weeks in the propagation/cloning growth stages the medical marijuana plants will transition into the vegetative growth stage. Prior to transferring plants into the vegetative growth stage, registered employees will perform a preventative Integrated Pest Management (IPM) measure by spraying and/or dunking/dipping the plants in an insecticide and/or fungicide. The various IPM steps and processes are the next SOP discussed followed by the vegetative growth.



Integrated Pest Management (IPM)

<b>Standard Operating Procedure:</b> Integrated Pest Management (IPM)
<b>Purpose:</b> To ensure that cultivation facility employees are properly trained in the identification of pest and diseases, preventative maintenance measures, eradication techniques, and documentation of all relevant information for IPM.
<b>Scope:</b> Procedures covering preventative maintenance and IPM activities within the cultivation facility.
<b>Initial Training:</b> 4-8 hours

**The Principles of Integrated Pest Management (IPM)**

IPM takes advantage of all appropriate pest management options including, but not limited to, the use of pesticides. In contrast, organic food crop cultivation applies many of the same concepts as IPM but limits the use of pesticides to those that are produced from natural sources, as opposed to synthetic chemicals.

IPM is not a single pest control method but, rather, a series of pest management evaluations, decisions, and controls. When practicing IPM, growers who are aware of the potential for pest infestation *utilize a four-tiered approach*:

- 1) **Set Action Thresholds**—before taking any pest control action, IPM first sets an action threshold, which is where you determine the level of pest and/or disease infestation that are acceptable and levels of infestation requiring control measures.
- 2) **Monitor and Identify Pests**—this is the stage in where pests and/or disease should be identified. IPM programs work to monitor for pests and identify them accurately, so that appropriate control decisions can be made in conjunction with action thresholds. Proper identification of pests and disease is of utmost importance in order to select the proper action and control measures to implement.

<b><u>Pest and Disease Identification Documentation</u></b>		
Date of 1st Sign of Infestation:	Type of Issue: <input type="checkbox"/> Pest/Insect Infestation <input type="checkbox"/> Mold/Fungal Infestation <input type="checkbox"/> Bacterial Infestation <input type="checkbox"/> Other	
Name of Pest or Disease (if known):	Zone/Room of Infestation:	
Corrective Action to be Taken:		
Notes:		

- 3) **Prevention**—as a first line of pest control, IPM programs work to manage the crop or cultivation area to prevent pests from becoming a threat. Preventative measures are practiced prior to entering a cultivation facility and through proper ‘clean’ protocols, preventative plant measures such as disease-fighting and disease-preventing nutrients and organic compost teas, and proper/optimal growing environments (*temperature, humidity, CO2 level, etc.*).
- 4) **Control**—once monitoring, identification, and action thresholds indicate that pest control is required, and preventive methods are no longer effective, the IPM program then evaluates the proper control method both for effectiveness and risk. Control measures will include the use of organic compost teas to help fight pest and/or disease. Predatory insects can also be used as a control measure to fight invasive insects. As a last



resort, control measures will include the use of approved insecticides, fungicides and other chemicals. Any control measure utilized will be approved for use of crops intended for human consumption. Upon the need for control employees will begin a process of disease/pest eradication by using select insecticides, fungicides or other measures. Employees will utilize three (3) different pesticides and three (3) different fungicides to properly combat the disease(s)/pest(s). These measures will be applied to the marijuana plants on a 3-day rotation to effectively combat the intrusion.

### **Documentation Log Sheets Required**

- 2) Pest and Disease Identification Documentation
- 3) Pesticide/Fungicide Application Log Sheet

### **Equipment/Tools Required**

- Personal Protective Equipment
  - a. Eye Protection
  - b. Tyvek protective coveralls
  - c. Respirator
  - d. Rubber gloves
- Tools
  - a. Atomizer/Sprayer
  - b. Scissors
  - c. Sticky Traps

### **Pesticides, Fungicides and Herbicides**

ACC limits the use of pesticides, fungicides and herbicides to a minimum. Producing medicinal grade medicine that is free of unwanted contaminants is at the core of ACC's mission. Especially when the products are being concentrated into oil forms further increasing the potential harmful effects of contaminants. The cultivation methodology to be implemented by ACC will utilize organic cultivation techniques in a biodynamic super soil medium. A biodynamic soil will have an active ecosystem of beneficial bacteria, these beneficial bacteria not only improve the expression of the plants genetic potential but also improve the plants natural immunity reducing the need for reliance on pesticides. ACC will only utilize organic pesticide, fungicides and herbicides that are approved for use on crops for human consumption and are not harmful to humans, animals or the environment.

### **Potential Pesticides, Fungicides, Herbicides or Other Chemicals:**

1. Actinovate
2. Azamax
3. Organocide
4. BotaniguardES
5. Pyganic
6. GreenCure
7. Green Clean
8. Neem Oil
9. Compost Teas
10. ProKureV
11. Clorox Bleach
12. Hydrogen Peroxide
13. Isopropyl Alcohol

### **Fungicides:**

- 1) **Actinovate**—beneficial bacterium *Streptomyces lydicus*, the product is OMRI listed and is sprayed as a preventative measure, or as a combative measure. It is applied on both root pests, as well as molds and mildews on the foliage.
- 2) **GreenCure**— Green cure is a fungicide comprised of potassium bicarbonate and is OMRI listed. Green cure raises the pH of the leaf surface to a level where mildew cannot survive



- 3) **Organocide**—organocide if a fungicide.

#### **Pesticides:**

- 1) **Azamax** — the active ingredient in Azamax is Azadirachtin. The product is OMRI listed, and is used as a broad spectrum pesticide, it is applied as a foliar as well as a root drench.
- 2) **BotaniguardES**— Organic product; the active ingredient in BotaniguardES is Beauveria bassiana. This beneficial bacteria acts as a growth inhibitor to soft bodied insects.
- 3) **Pyganic**— the active ingredient in Pyganic is Pyrethrin. This is an organic pesticide derived from the chrysanthemum flower. The product is OMRI listed.

#### **Preventative Maintenance:**

- 1) **Neem Oil**— Neem oil is used as a broad range preventative measure. The oil mechanically prevents mildew by protecting foliar surfaces, and also disrupts insect respiration by clogging an insects spiracles, which intake and exhale air. The product is OMRI Listed.
- 2) **Green Clean**— Organic- Green clean is a broad range preventative, a combination of plant based oils, as well an organic emulsifier. Used to disrupt the respiration in molds and mildews
- 3) **Compost Teas**— Organic - fungal dominant compost tea is used to non-chemically prevent powdery mildew, Compost teas also prevent root borne diseases by combating them with an array of microbes. Compost teas also strengthen a plants natural resistance to disease.

#### **Cleaning and Sanitation:**

1. **ProKureV**— Oxidizing agent, general cleaning, room sterilizing
2. **Hydrogen Peroxide**— Oxidizing agent, general cleaning and sterilizing
3. **Isopropyl Alcohol**— general cleaning and sterilization
4. **Clorox Bleach**— general cleaning and sterilization

All four of these are used to sterilize equipment between uses, or between cultivation cycles when cleaning empty cultivation rooms.

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### **<Preventative Measures>**

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Preventing the introduction of insects, molds, mildews, bacteria, and diseases in general is a top priority of the cultivation facility. Preventative measures and procedures will be implemented and utilized within the cultivation facility. All employees working within the facility must adhere to all IPM procedures and preventative measure and procedures.

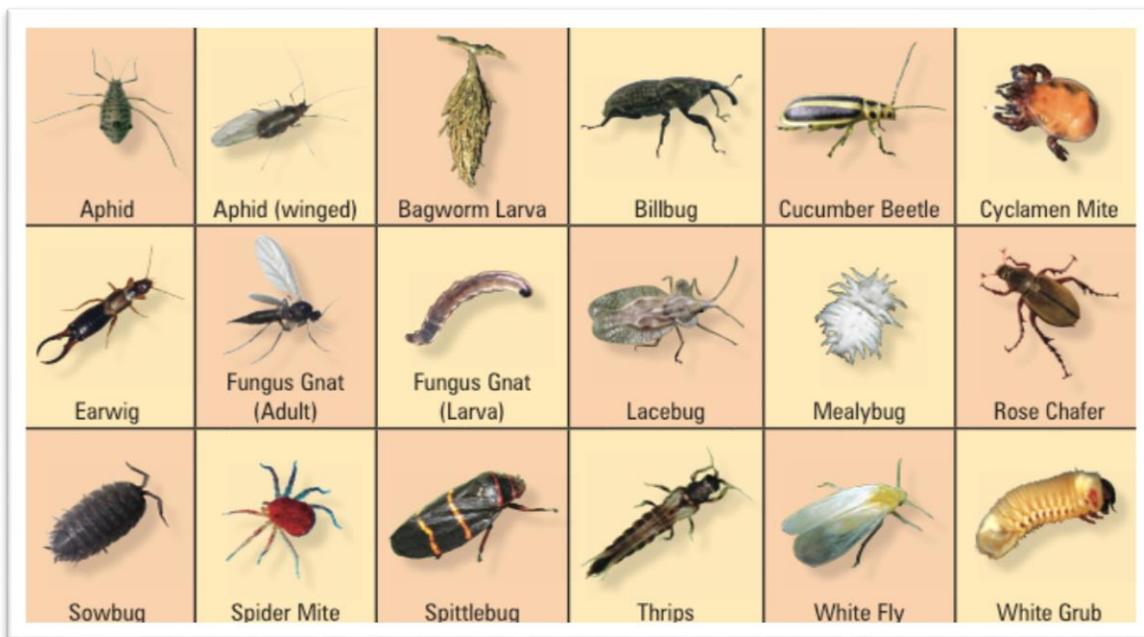
**Facility Entrance**—need to refer to and follow the Facility Entry Protocol SOP which explains the preventative procedures in place for entering the cultivation facility.

- **Cultivation Room(s)/Area(s)**—explains the preventative measures and procedures to follow prior to entering/while working within cultivation areas
  - Before entering the cultivation area all entry protocols for decontamination must be completed.
  - Once decontaminated the employee is to enter the facility through the air shower.
    - Air Shower: Enclosure that removes contaminates via air movement, pressure, and filtration.
  - Cultivation Rooms
    - At the entrance to each room a footbath will be required to decontaminate shoes. This will prevent employees from becoming a vector for spreading contaminates between rooms.
    - Gloves are required to be worn upon entry of each cultivation room.
    - Gloves are to be removed before exiting each cultivation area.
    - DO NOT use the same pair of gloves to manicure plants in two different rooms.
    - Gardeners will be trained in IPM to insure contaminates are located early in development.
  - **Cultivation Room Outbreak Protocol**—explains the procedures to follow once a problem or pest/disease arises.
    - After a room is labeled contaminated it must be kept isolated.

- Footbaths will be placed on both sides of the door.
- Lab coats will be worn in these isolated zones and are always removed before exiting the contamination zone.
- It is critical that the necessary precaution is taken to eliminate the spread of an outbreak.
  - Strict managerial protocol will be necessary during these times.
  - No employee shall enter this room without a Head Grower.
- **Cultivation Room Waste Disposal**—explains the procedures to follow within the cultivation rooms for waste disposal (*random trash and unwanted plant material*)
  - Each room will be equipped with two garbage cans.
    - One can for trash and another can specifically for plant material only.
      - Never mix plant waste with trash.
    - Plant Waste
      - Under state law plant waste must be weighed and recorded before going to the proper disposal unit.
      - A log will be kept at each door to record kilograms of manicure waste.

**<Identifying Pests and Disease(s)>**

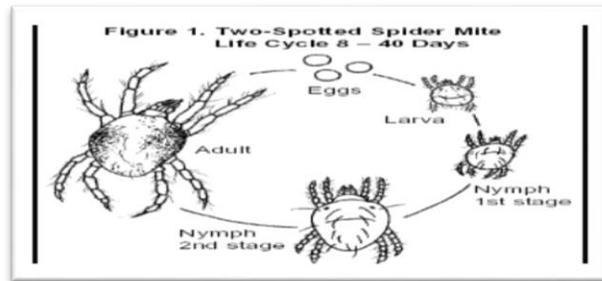
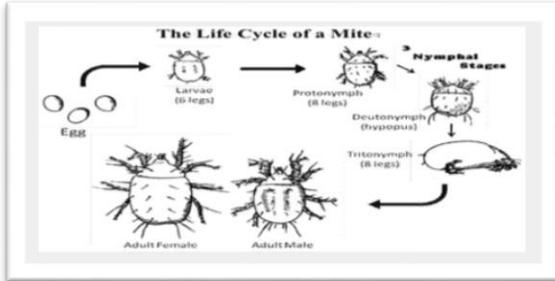
Marijuana plants can be susceptible to a multitude of different pests and insects. Highlighted within this IPM SOP will be the most common pests and insects found within a commercial cultivation facility.

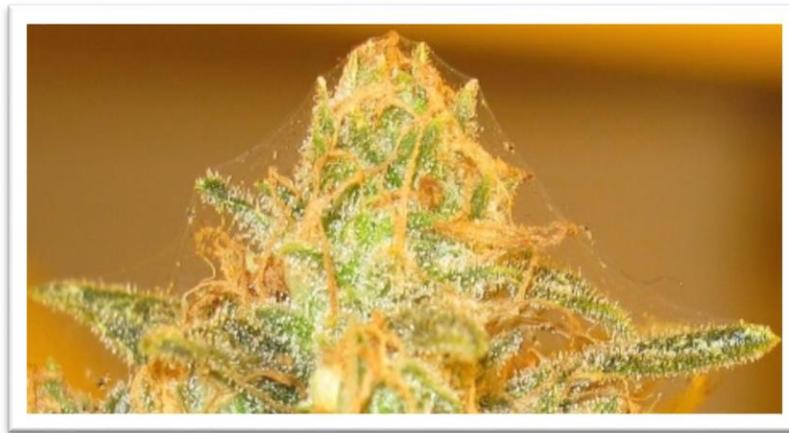


**Spider Mites**—generally live on the undersides of leaves of plants, where they may spin protective silk webs, and they can cause damage by puncturing the plant cells to feed. Spider mites are known to feed on several hundred species of plants, including the marijuana plant. Hot, dry conditions are often associated with population build-up of spider mites. Under optimal conditions (approximately 80 °F or 27 °C), the two-spotted spider mite can hatch in as little as 3 days, and become sexually mature in as little as 5 days. One female can lay up to 20 eggs per day and can live for 2 to 4 weeks, laying hundreds of eggs. This accelerated reproductive rate allows spider mite populations to adapt quickly to resist pesticides, so chemical control methods can become somewhat ineffectual when the same pesticide is used over a prolonged period.

**Action Threshold:** When multiple stages of the insect’s life cycle is identified.

**Monitoring and Identifying:** Keeping an eye out for each stage of the life cycle is key to monitoring plants for mites. There are 4 stages in a mites' life: egg, larvae, nymph, and adult. Eggs are laid on the underside of the leaf and take 3 days to hatch. Larvae and nymphs live in localized areas on the undersides of the leaves and avoid being exposed. Adult mites are mobile and move to areas of the plant where they can reproduce most efficiently. Looking at the bottom side of leaves will expose the egg, larvae, and nymph.





**Prevention:** The consequence of using broad-spectrum chemical pesticide is that the chemicals can be toxic to non-target beneficial or endangered species. The modern concept of biological pest control has been developed primarily by entomologists and in practice is taken to mean the use of living natural enemies to control pest species.

**Control:** In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

**Azamax** (follow manufacture recommendations for mix ratios):

- Fill 5-gallon bucket with 2 gallons of water.
- Add an emulsifier or wetting agent
- Mix 30 mL of Azamax per gallon of water.
- Apply as a foliar spray with pump sprayer and/or atomizer.

**Pyganic** (follow manufacture recommendations for mix ratios):

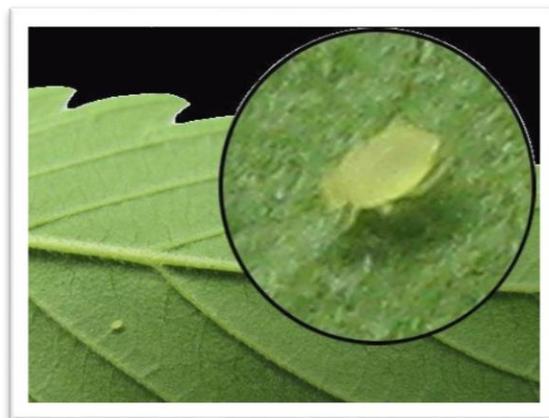
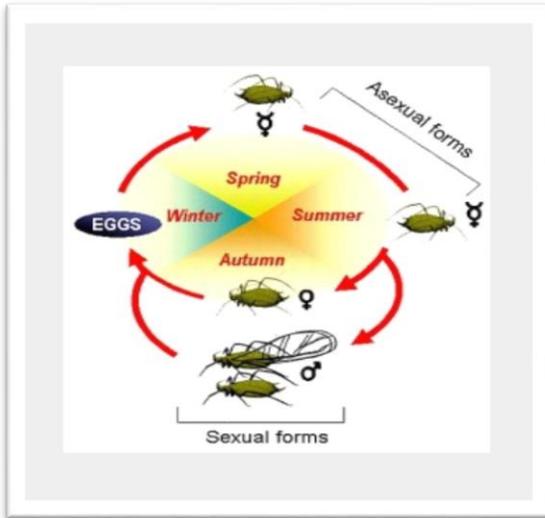
- Fill 5-gallon bucket with 2 gallons of water
- Add an emulsifier or wetting agent
- Mix 30mL of Pyganic per gallon of water
- Apply as a foliar spray with fogger

**<Aphids>**

**Aphids**—are small sap-sucking insects, and members of the superfamily Aphidoidea. Aphids are among the most destructive insect pests on cultivated plants in temperate regions.

**Action Threshold:** When multiple stage of the insect’s life cycle are identified.

**Monitoring and Identifying:** Aphids are visible to the human eye. These insects live together in localized colonies. An Aphids infestation will be obvious to the rudimentary gardener after the insect matures to its adult state. Early signs of an aphid infestation are visible when the tips of the oldest leaves begin to curl under. This is caused when the larvae begin to feed on the tips of roots.



**Control:** In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

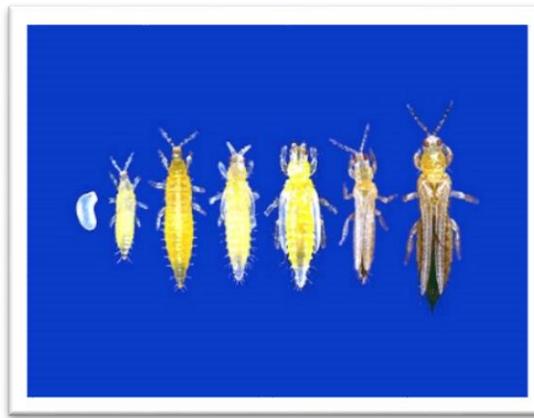
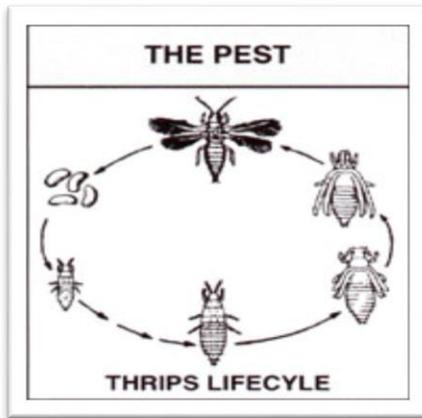
- **Aphid**
  - Spray Azamax at a rate of 30ml/g or use as soil drench
  - Place yellow sticky traps at the base of each plant.
    - Tie the sticky trap to the stalk where the aphids cannot crawl past the trap.
    - Replace sticky trap on each plant weekly for 4 weeks in all infested cultivation areas.

**<Thrips>**

**Thrips**—are tiny, slender insects with fringed wings. Thrips species feed on a large variety of plants and animals by puncturing them and sucking up the contents. A large number of thrips species are considered pests, because they feed on plants with commercial value such as the marijuana plant.

**Action Threshold:** When multiple stage of the insect’s life cycle are diagnosed.

**Monitoring and Identifying:** Daily inspection of the canopy allow the gardener to identify Thrips at the first visible plant indication of an infestation. Thrip larvae feed on the vegetative growth of the plant. Thrips damage the leaf structure leaving behind white scars called “color break,” which is pale or dark discoloring of leaf tissue that was killed.



**Control:** Thrips are typically an easier pest to mitigate, and 1-2 applications is all that is necessary. Apply Azamax and/or Monterey Garden Spray. In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

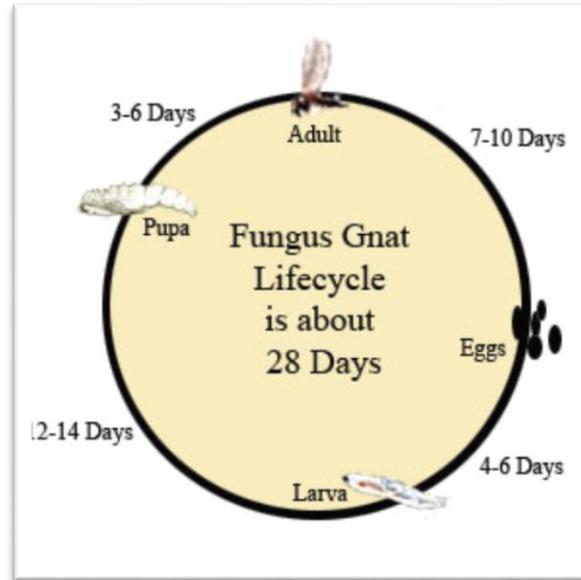
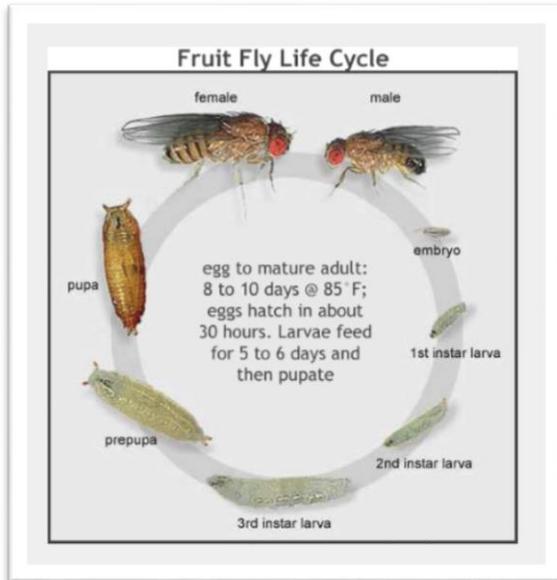
- Mix 30mL/gallon Azamax
- Apply as foliar spray to the canopy of all plants.
- Place yellow sticky traps at the base of each plant.
  - Tie the sticky trap to the stalk where the aphids cannot crawl past the trap.
  - Replace sticky trap on each plant weekly for 4 weeks in all infested cultivation areas.

**<Fungus Gnats>**

**Fungus Gnats**— are small, dark, short-lived flies. The larvae feed on plant roots and fungi, helping in the decomposition of organic matter. The adults are 2–5 mm long can carry diseases such as pythium on their feet.

**Action Threshold:** When multiple stage of the insect’s life cycle are identified.

**Monitoring and Identifying:** Fungus gnat infestations are obvious when the insect has matured to the adult stage. These pest are air born. They will be seen flying around the canopy, lights, and soil.



**Prevention:** Healthy organic soil will produce an array of micro life. Nematodes are predatory roundworms which feed on the larval stage of the fungus gnat. Applying organic cultivation methods will result in a diverse spectrum of natural predators which limit fungus gnat reproduction.

**Control:** In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

- **Fungus Gnat Larvae**
  - Mix 3mL/gallon H2O2 (hydrogen peroxide) in your reservoir.



- Saturate the soil mass completely.
- **Adult Fungus Gnat**
  - Place yellow sticky traps at the base of each plant.
    - Tie the sticky trap to the stalk where the aphids cannot crawl past the trap.
    - Replace sticky trap on each plant weekly for 4 weeks in all infested cultivation areas.

-----<Disease(s); Mold, Mildew and Bacteria>-----

Marijuana plants can be susceptible to a multitude of different diseases. Disease can range from a wide variety of different molds, mildews and bacteria. Highlighted within this IPM SOP will be the most common diseases found within a commercial cultivation facility.

-----<Powdery Mildew>-----

**Powdery Mildew**—is a fungal disease that affects a wide range of plants. Powdery mildew is caused by many different species of fungi. It is one of the easier diseases to spot, as its symptoms are quite distinctive. Infected plants display white powdery spots on the leaves and stems. The lower leaves are the most affected, but the mildew can appear on any above ground part of the plant. As the disease progresses, the spots get larger and denser as large numbers of asexual spores are formed, and the mildew may spread up and down the length of the plant. Powdery mildew grows well in environments with high humidity and moderate temperatures.

**Action Threshold:** First sign of infection.

**Monitoring and Identifying:** Daily inspections of the canopy allow a gardener to identify mildew at its earliest stages. Powdery Mildew begins to grow in the crevices of the leaf and stem. Identifying PM in these areas will keep a gardener ahead of the growth curve.



**Prevention:** Ultra-violet scrubbers will kill spores circulating through the air and will prevent spreading contaminants between rooms and plants.



**Control:** Chemical controls can be applied to prevent mildew from spreading across the vegetation. In the occurrence of an outbreak chemical fungicides will be used to prevent spreading contaminants between rooms. Fungicides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

- Powdery Mildew in Veg
  - Mix 30ml/gallon Green Cure.
  - Apply as foliar spray to the canopy of all plants.
    - The active ingredient changes the PH of the surface of the leaves not allowing mold spores to grow.
    - Continue spraying every 30 days or once visible again.
- Powdery Mildew in Flower
  - Mix 10mL/gallon Actinovate fungicide.
  - Apply as foliar spray to the canopy of all plants once first sign of PM.

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### <Pythium>

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**Pythium**— Commonly referred to as root rot is a fungal disease. To avoid root rot, it is best to only water plants when the soil becomes dry, and to put the plant in a well-drained pot. A plant with root rot will not normally survive, but can often be propagated so it will not be lost completely. Plants with root rot should be removed and destroyed.



**Action Threshold:** At first sign of the parasitic relationship.

**Monitoring and Identifying:** Pythium is a common development of plants that are over-watered. Monitoring the moisture of the soil will help identify an infection. A plant's leaves will droop when it is over saturated with moisture. Stagnant water left in a hydroponic system heightens risk of Pythium colonization.

**Prevention:** Do not allow stagnant water to evaporate anywhere in the cultivation environment.

**Control:** Kill and remove the plant.

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### <Botrytis>

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**Botrytis (Grey Mold/Bud Rot)** — is commonly known as grey mold or bud rot. Bud rot is the result of consistently wet or humid conditions, and typically results in the loss of the affected flowers.



**Action Threshold:** After first sign of the mold developing.

**Monitoring and Identifying:** When the humidity in a cultivation facility exceeds 50% the plants are at risk of developing Botrytis. Botrytis grows on the inside of the flower where the dense cluster of calyxes supplies adequate moisture and nutrient to the mold. Physically separating the calyxes of each large cola by hand will expose Botrytis for diagnosis.

**Prevention:** Maintain homeostasis of the atmosphere in the cultivation environment. Make sure there is adequate air circulation over the plant canopy.

**Control:** Maintain humidity at or below 45%.

### **Quarantine of Marijuana Plants**

The first step to quarantining a cultivation room is to stop any risk of immediate spread. The room the pest is found in must be immediately closed, and no registered employees may enter or exit. The registered employees in the affected room upon discovery must first line up by the entrance remove gloves, replace gloves, and put on a full body chemical suit with foot covers. The registered employees are then allowed to exit the room while stepping in the footbath, and head to the air shower. After the air shower has cycled, if time allows, registered employees will take a second shower, and change into clean scrubs. These registered employees may now finish the entry protocol, and reenter the “clean” area of the facility.



The contaminated room is now under quarantine protocol, which creates a barrier where the risk of spread can be reduced. During this time, the minimum number of registered employees necessary to complete tasks will enter the room. These registered employees will undergo separate entry protocols designated to the contaminated room. A station of necessary equipment will be placed next to the contaminated room for easy access to body suits, gloves, hairnets, and sterilizing equipment such as hydrogen peroxide. Prior to entry to the contaminated room, registered employees will put on a full body suit, hair net, clean gloves, and shoe covers. During the time in the room, this covering clothing is designed to keep and pests on the suit, and away from the grower agent's hair, and scrubs. When exiting the room, employees will line up by the door to complete the exit protocol. Employees will remove all garments except scrubs, and shoes. The grower agent will place the contaminated clothing into a trash bag for immediate disposal. Upon exiting the room, employees will exit through the air shower, and repeat the entry protocol, to complete work on the rest of the facility. This room will remain on quarantine protocol for 1-week post finding zero sign of pests on daily inspections. It is imperative to inspect each room closely in order assure the quarantine protocol can be halted.



Chemical Treatment

<b>Standard Operating Procedure:</b> Chemical Treatment of Plants
<b>Purpose:</b> To explain how to properly treat a plant with chemicals ( <i>pesticide, insecticide, fungicide, etc.</i> ) and the different methods of treatment.
<b>Scope:</b> To train employees on proper treatment of plants and different methods of treatment. <i>*Refer to IPM SOP and manufacturer directions for chemical usage rates, frequency and amounts.</i>
<b>Training:</b> 4-6 hours

### **The Principles of Chemical Treatment of Plants**

If a pest and/or disease issue is identified within the marijuana crop being cultivated, IPM protocol dictates for a physical chemical application of required pesticides, insecticide, fungicides or other chemicals to eradicate the identified issue.

Facility employees will need to refer to the IPM SOP to determine which pesticide, fungicide, insecticide or other chemical is required to spray on the marijuana crop to rid the infestation/issue. Refer to the instructions on the identified chemical for proper mix/dosage rates.

All pesticide treatment applicators and applications will follow State and federal pesticide requirements for any pesticide applied.

Pesticide applicators/registered employees will undergo required courses and testing to obtain a Private Applicators Certificate, as well as recertification every 3 years, becoming Registered Employees by the State of Hawaii. Applicant's Consultant will complete requirements for Reciprocity. All pesticides applied will be approved by the FDA's National Organic Program, and will be approved on the National List of allowed and prohibited pesticides and OMRI approved.

### **Chemical Treatment of Plants through Dipping/Dunking**

The principle behind dipping/dunking marijuana plants as a chemical application is through dipping/dunking you ensure that the entire surface area of the plant has been treated with the desired chemical. (*When spraying plants with desired chemicals, it is not always ensured that every surface area of the plant has been treated*)

#### **How to Dip/Dunk a Plant:**

1. Get a decent sized container to fill with the desired chemical and water (*follow manufacturer recommended mix rate/dosage instruction*)
  - a. The size of container needed will be determined by the size of plants intended to be dipped/dunked
  - b. Typically a 5-gallon bucket should suffice as you should only dip/dunk smaller plants. However if the need does arise to dip/dunk a larger plant, a plastic trash bin can be utilized to dip/dunk larger plants.
2. Once the container is properly mixed with the desired chemical at the proper rate the plants can be dipped/dunked in the solution
  - a. Ensure that prior to dipping/dunking a plant that you have a hold of the plant medium as you do not want the medium (*dirt, coco, etc.*) to fall into the chemical solution
3. Once the plant has been dipped/dunked, do NOT place it directly under HID lighting as this could result in the plant burning and other negative effects
  - a. Wait until the plant appears to be 75% to 90% dry before placing it back under HID or grow lighting

### **Chemical Treatment of Plants with a Sprayer** (*pump sprayer, automated sprayer or atomizer*)

- Fill the pump sprayer or atomizer sprayer with the proper dilution of the required chemical according to manufacture recommendations.



- Spray applications on marijuana plants should be done while the HID/LED lights are OFF.
  - If the lights are left on, and the plants sprayed/treated it may cause plant burning and damage.
- Spray plants with a gentle action trying not to cause damage to plant stalks, branches and/or leaves.
- Ensure to adequately spray all undersides of plant leaves as this is where a majority of pests live.
- Allow plants to dry completely prior to placing the plants back underneath HID/LED lighting and prior to turning the lights back on.

***Example of Pump Sprayer(s):***



***Examples of Atomizer Sprayer(s):***



**Chemical Treatment of Plants through Root Drench**

Sometimes there is a need to perform a soil/root drench on the plants to eliminate a disease and/or pest. This is done through mixing the desired chemical with the proper mix rates/dosage rates that the manufacturer suggests, once the desired chemical is properly mix at the correct rates the mixture is then evenly poured into the plants container containing the medium (*soil, coco, etc.*).

Pour the mixed chemical all over the plants base and medium as if you were hand watering the plant.

**Documentation**—after an employee of the licensed premise applies any pesticide, insecticide, fungicide or other chemical application to marijuana plants they will be required to document the application on the ***Pesticide/Fungicide Application Documentation*** log sheet.

***Example of Pesticide/Fungicide Application Documentation:***



American Cannabis Company  
growing the next frontier



### Pesticide/Fungicide Application Documentation

<u>Date/Time Applied</u>	<u>Employee/Signature/License #</u>	<u>EPA Registration #</u>	<u>Name of Pesticide</u>	<u>RFID Tag #/Batch # or Room Applied To</u>	<u>Amount Applied</u>



Transplanting

<b>Standard Operating Procedure:</b> Transplanting Marijuana Plants
<b>Purpose:</b> To explain how to properly transplant marijuana plants into a larger container.
<b>Scope:</b> To train employees how to properly transplant, tag and record/document transplanting activities.
<b>Initial Training:</b> 4-6 hours

### **The Principles of Transplanting Plants**

Transplanting is the process of staging plant into a larger sized container. Typically transplanting will be done 2-3 times during the plants lifecycle 1) from a clone into a 1 gallon container, 2) from a 1 gallon container into a 2-7 gallon container and 3) from a 2-7 gallon container into the final container of 7-15 gallons.

- **Pre-Transplant**
  - Rooms receiving transplants should be cleaned and ready for cultivation.
  - Water valves on mainlines of plumbing that feed vegetative plants are turned off to allow plants (12-24 hours) to adjust to proper moisture content for transplant.
  
- **Transplant**
  - Remove plants of strains being transplanted from container/AutoPot system onto transport racks.
    - Transport each strain as a group in order to keep our tagging organized.
  - Move plants to transplanting area.
  - Prepare new container/AutoPot for transplant.
    - Copper Screen (*only if using AutoPots*):
      - First, a mesh copper screen will be placed into the bottom of each pot with the copper facing away from the root zone (copper down)
        - Double check your work to be sure the correct equipment is installed
    - Perlite:
      - Second, 2" of Perlite will be placed on the bottom of each pot to insure the root zone is adequately aerated.
  - Fill container/AutoPot with adequate soil/medium to support a 1 gallon sized root zone.
  - Remove the plant from the pot following these steps:
    - Carefully press the sides of the 1 gallon pot inward to loosen the root mass.
    - Place hand on top of soil with stalk between fingers
    - Spread fingers apart to support the inverted root mass
    - Carefully flip plant over with plant between fingers
    - Pull pot upward away from roots
    - Balancing the root mass
    - Aerate dense clusters of roots by gently loosening the growing medium/plant root structure
  - Slowly rotate plant upright and place gently into new container/AutoPot.
  - Fill in empty space with soil/medium.
    - Tamp pot on table/ floor to evenly compact soil/medium
  - Water until soil is thoroughly saturated
  - Place tag into soil/medium; or around plant base or on a branch
  
- **Tagging**
  - After each plant is transplanted the employee will record:
    - The number of plants.
    - The number of each tag used for every plant.
    - The new location each plant.



- The date of transplant.
- Once the data is captured an employee will need to ensure that the plant tag/unique ID tag remains with the plant throughout the plants entire lifecycle.
- All transplants are to be recorded into POS software day of transplant.
  - Double check data inputs to insure there are no mistakes.
- Keep a hard copy of every change that occurs in the facility.
  - Plant moves, transplants, harvests, and waste will be the most frequent and important data inputs.
    - Place plant on rack to be transported to new location.
      - Recordkeeping/Documentation required:
        - Record:
          - New location
          - Date of transplant
  - All changes are to be recorded in POS tracking software day of activity(s).

**Example of Marijuana Plant Tag:**



**Example of Transplant Log Sheet:**

<b><u>Transplant Log</u></b>									
<u>Date:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Plant ID# and Batch #:</u>	<u>Plant Lifecycle Stage:</u>	<u>Original Container Size:</u>	<u>New Container Size:</u>	<u>POS Record Made:</u>		
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	



Vegetative Growth Stage

<b>Standard Operating Procedure: Vegetative Growth Stages</b>
<b>Purpose:</b> Demonstrate to proper methods and techniques for healthy marijuana cultivation. Including light cycles, feeding schedules, plant care and maintenance, Integrated Pest Management (IPM), etc.
<b>Scope:</b> These procedures cover marijuana cultivation procedures, methods and techniques in the vegetative and flowering growth stages within the cultivation facility.
<b>Plant Environment:</b> 75-85 <sup>0</sup> Fahrenheit; Humidity ~30-50%
<b>Plant Light/Photoperiod: Vegetative Cycle:</b> Minimum of 18 hours of light ( <i>18 hours lights on; 6 hours light off</i> ) and up to 24 hours of continuous light.
<b>Initial Training:</b> 8-16 hours

### **Documentation Log Sheets Required**

- 1) Daily Environment Documentation
- 2) Daily Plant Monitoring Log Sheet
- 3) Weekly Plant Monitoring Log Sheet
- 4) Daily Products Transfer/Wholesale Log Sheet
- 5) Marijuana Waste Log Sheet

### **Supplies/Tools Required**

- 1) Scissors
- 2) Measuring cups
- 3) Sunglasses
- 4) Personal Protective Equipment (PPE)
  - a. Protective eye gear
  - b. Respirators
  - c. Tyvek protective coveralls
  - d. Etc.
- 5) Watering hoses
- 6) Meters
  - a. TDS pen
  - b. pH Meter
  - c. Light Meter
- 7) Plant Ties
- 8) Trash can(s)

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### **<WEEK 3>**

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Week 3 is the first week of the vegetative growth stage. The purpose of the vegetative growth stage is to prepare the plant for the flowering growth stage. The vegetative stage is very important stage in the marijuana life cycle, a healthy vegetative plant will become a healthy flowering plant producing optimal medicine.

*Examples of Marijuana Plants in the Vegetative Growth Stage (can be seen below):*



**Transplanting**—process of staging plant into larger sized containers during vegetative growth stage.

- Prepare the 1-2 gallon pot to be filled with soil/medium.
- Fill pot to proper height with SoHum soil/medium.
- Lightly press clone into soil/medium.
- Pack the soil around the clone with fingertips.
- Thoroughly water in clone with ½ gallon of filter water.
- Plant 1 strain at a time.
  - This prevents mislabeling of genetics.
- Place each clone/container on rack system to be moved into its vegetative room.

**Foliar Feeding**—the foliar application of plant nutrients is the fastest, most effective method for treating deficiencies. Directly applying the appropriate solution provides nearly immediate results, and can have easily noticeable effects on yield and overall plant health. Foliar sprays can be used to supplement deficient nutrients, introduce beneficial organisms, and also add certain supplements, which, add to flavor and potency. Compost tea foliar applications should be not be applied after the 5<sup>th</sup> week of the flowering cycle.

### Step 1: Foliar Tea

- Fill tea brewer with de-chlorinated, or RO water, and begin aerating.
- In a large tea bag, combine the ingredients below.

### Step 2: Preparing Solution

- For foliar application tea will be diluted with water at a ratio of 1:5
- Pour tea through a 70 micron filter or filter floss to remove sediment
- Dilute tea and fill sprayer as close to spraying time as possible

→ *ALL measurements per 5 gallons*

#### **Foliar Tea:**

- 1 Cups Worm castings
- 1 Cups Humisoil
- 1/2 Cup Alfalfa Meal

#### **Directly in Water:**

- 2 Tbsp. Powdered Molasses
- 2 Tbsp. Liquid Kelp
- 1 tsp Glacial Rock Dust
- Aerate tea for 24 hours

### Step 3: Application

- Approximately 1-2 hours before lights turn on, or immediately after lights turn off, prepare to spray solution
- During application, wear a respirator
- Using pump sprayer or atomizer to apply tea solution to foliage, making sure to coat the underside and top of all leaf surfaces and stems



#### Step 4: Clean Brewer and sprayer

- Immediately after application wash sprayer and rinse with hydrogen peroxide solution
- Clean brewer immediately after brewing is complete. An unsterile brewer can cause breakouts of non-beneficial microbes

\*Note: If compost tea is already being brewed in the facility it can be used for foliar application as long as it does not contain large amounts of guanos.

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### <WEEK 4>

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During the 4<sup>th</sup> week, plants will transition into rapid growth. The root structures will take hold of the soil mass maximizing the plants water absorption. Expect increase water consumption and prepare plants for transplant into large pots by pruning undergrowth. Train plants at the end of this week.

**\*\* NEVER prune a plant prior to taking cuttings/clones from the plant. The material to be pruned from the plant can be used as cuttings to create clones for the future cultivation. \*\***

**Pruning Marijuana Plants**—Pruning marijuana plants is imperative to ensure high yields, as well as a fundamental part of integrated pest management. Without proper pruning, plants will allocate energy to lower-level, light deprived flowers. This will deprive your high yielding canopy, causing light airy flowers. Keeping the plant undergrowth clean of unhealthy and overcrowded branches allows greater airflow and decreases available habitats for pests, molds, and mildews.

Marijuana strains vary greatly in their growth habits creating very different Anatomical Plant Analysis (APA). A strain's APA is defined by its growth characteristics such as, transition period growth, node spacing, flowering period, and flower morphology. These characteristics differ between every strain, and must be documented to create a standardized pruning technique for each one. Transition period growth is particularly important when developing a strain specific pruning procedure. This transition growth is defined by the increased vertical growth during the first stage of the flowering period, followed by increased lateral flower production.

Sativa dominant strains will typically have a longer period of transition growth, and some will still grow vertically into the 4<sup>th</sup> week of the flowering period. These strains with longer transition growth periods will require increased pruning, some sativa strains may need the bottom half of branches to be removed. This increased pruning will also decrease the node spacing during the growth period and form tighter, denser flowers. Indica strains will have a much shorter transition growth period, and will require less pruning. This shorter transition growth period must be taken into consideration in order to ensure maximum yields. In general indica dominant strains should be pruned only 1/3 from the base of the plant, and only very light deprived bud sites should be removed. These strains should also be switched to the flowering period later than sativa strains to ensure maximum yields.

#### Step 1: Preparation

- 1) Clean scissors with isopropyl alcohol
- 2) Assess plants APA's to identify plants requiring pruning

#### Step 2: Pruning Marijuana Plants

- 1) Starting at the lowest point of the plant; begin removing branches on the bottom third of the plant (*keep in mind strains APA and pruning procedure*)
- 2) After bottom third of the plant is clear, remove any undergrown branches and bud sites in the center/core of the plant
- 3) Removing weak bud sites, but not removing the entire branch will cause the plant to concentrate energy into the terminal bud on the branch and increase yields
- 4) Be sure to note what strain you are pruning, and if it is properly pruned according to its APA and designated pruning procedure

#### Step 3: Post-Pruning

- 1) Move plants to designated location



- 2) Clean work area ensuring no plant material remains, and area is free of debris

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<WEEK 5>

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The goal of week 5 is to transplant, relocate, and monitor the growth of plants approaching the flowering cycle. Maintaining the health of plants at this stage will allow for maximum node development during the first 3 weeks of flower.

**Transplant: Vegetative to Flower (1-7 gallon)**

- **Pre-Transplant**
  - Rooms receiving transplants should be cleaned and ready for cultivation.
  - Water valves on mainlines of plumbing that feed vegetative plants are turned off to allow plants (12-24 hours) to adjust to proper moisture content for transplant.
- **Transplant**
  - Remove plants of strains being transplanted from container/AutoPot system onto transport racks.
    - Transport each strain as a group in order to keep our tagging organized.
  - Move plants to transplanting area.
  - Prepare new container/AutoPot for transplant.
    - Copper Screen (*only if using AutoPots*):
      - First, a mesh copper screen will be placed into the bottom of each pot with the copper facing away from the root zone (copper down)
        - Double check your work to be sure the correct equipment is installed
    - Perlite:
      - Second, 2" of Perlite will be placed on the bottom of each pot to insure the root zone is adequately aerated.
  - Fill container/AutoPot with adequate soil/medium to support a 1 gallon sized root zone.
  - Remove the plant from the pot following these steps:
    - Carefully press the sides of the 1 gallon pot inward to loosen the root mass.
    - Place hand on top of soil with stalk between fingers
    - Spread fingers apart to support the inverted root mass
    - Carefully flip plant over with plant between fingers
    - Pull pot upward away from roots
    - Balancing the root mass
    - Aerate dense clusters of roots by gentle massaging
  - Slowly rotate plant upright and place gently into new container/AutoPot.
  - Fill in empty space with soil/medium.
    - Tamp pot on table/ floor to evenly compact soil/medium
  - Water until soil is thoroughly saturated
  - Place tag into soil/medium; or around plant base or on a branch
  - Place plant on rack to be transported to new location.
    - Recordkeeping/Documentation required:
      - Record:
        - New location
        - Date of transplant
      - All changes are to be recorded in POS tracking software day of activity(s).

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<WEEK 6>

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Monitoring the plants closely for pests will prevent outbreaks later in the flower cycle. Treat for any visible signs of target species.

- Adhere to IPM protocol; final vegetative spray treatment prior to transitioning into flowering growth stage
- After week six, the medical marijuana plants will be transitioned into the flowering growth stage where the plants' photo cycle will be altered causing them to begin producing flowers. The flowering growth stage is the next SOP discussed.



Flowering Growth Stage

<b>Standard Operating Procedure: Flowering Growth Stage</b>
<b>Purpose:</b> Demonstrate proper methods and techniques for healthy marijuana cultivation, including light cycles, feeding schedules, plant care and maintenance, Integrated Pest Management (IPM), etc.
<b>Scope:</b> These procedures cover marijuana cultivation procedures, methods and techniques in the flowering growth stages within the cultivation facility.
<b>Plant Environment:</b> ~72-78 <sup>0</sup> Fahrenheit; Humidity ~30-50%
<b>Plant Light/Photoperiod: Flowering Cycle:</b> 12 hours of lights on and 12 hours lights off. <i>(must be 12 hours of uninterrupted darkness)</i>
<b>Training:</b> 8 hours

### Documentation Log Sheets Required

- 1) Daily Environment Documentation
- 2) Daily Plant Monitoring Log Sheet
- 3) Weekly Plant Monitoring Log Sheet
- 4) Daily Products Transfer/Wholesale Log Sheet
- 5) Marijuana Waste Log Sheet

### Equipment/Tools Required

- 1) Scissors
- 2) Measuring cups
- 3) Sunglasses
- 4) Personal Protective Equipment (PPE)
  - a. Protective eye gear
  - b. Respirators
  - c. Tyvek protective coveralls
  - d. Etc.
- 5) Watering Pumps, Hoses, Watering Can, etc.
- 6) Meters
  - a. TDS pen
  - b. pH Meter
  - c. Light Meter
- 7) Trellis Netting/plant stakes
- 8) Plant Ties
- 9) Trash can(s)

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### <WEEK 7>

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The 7<sup>th</sup> week is the first week of the flowering growth stage. The flowering growth stage is where your marijuana plants will start to form flowers. This is the stage of the plants life when the majority of weight is gained and oil production occurs. The marijuana plants should be prepared for the flowering growth stage by supporting the plants stock and/or branches through trellising, staking, pruning, and defoliating any excessive canopy.

*Examples of Marijuana Plants in Flowering Growth Stage (can be seen below):*



*Early Flowering Stage*



*Mid Flowering Stage*



*Late Flowering Stage*

**Pruning/Defoliating**—Remove unwanted plant growth. A majority of the required pruning/defoliating will have already occurred during the vegetative stage; so during this time of pruning/defoliating you should only remove new plant growth and foliage that has regrown in previously pruned areas. Pruning/defoliating will allow light to penetrate the plant canopy and result in optimal plant growth and production.

**Trellis Netting**—the use of trellis netting for marijuana cultivation plays several roles in plant health. The main goal in trellising is to provide support for the plant when flower/bud weight increases later in the flowering stage. Providing this support also allows the plant to dedicate energy to flower production, rather than expending energy supporting heavy flowers. Besides physical support, trellising also improves airflow under the canopy, which is an integral aspect of integrated pest management.

→Trellis netting should occur within the first 5-7 days of the flowering cycle.

### Step 1: Plant Preparation

- Plants should be previously pruned according to pruning procedures
- Plants should be in final position for completion of round.

### Step 2: Hanging Trellis

- In open areas, spread trellis to full extension
- Starting furthest from entry point, attach one short side of trellis to wall, or trellis support
- Stretch the remaining trellis over the canopy, laying ovetop of the plants
- Pull the trellis tight, and attach to wall or trellis support
- The trellis should be uniformly tight, 2”-4” below the top of canopy

### Step 3: Adjusting Plant Canopy

- Situate branches evenly in the canopy, concentrating on preventing crowding in any one area
- The tallest branches protruding more than 6” above the canopy should be woven underneath the trellis, or tied to trellis with a plant tie.
- After the Branches are evenly distributed, check underneath the trellis for hanging branches to either be pushed upward into trellis or be removed if they will not reach the canopy.
- All strains have different growth habits, and require different trellising techniques. Sativa strains will require more attention to create adequate support. Indica dominant strains will require little to no time organizing the canopy. Pay close attention to each of your strain’s habits and adjust the canopy accordingly.



#### Step 4: Clean Up

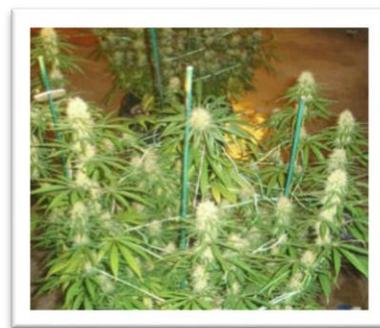
- Clean any remaining plant matter, and trash from the area
- Discard all plant matter into the designated waste bin and discard all trash in the designated trash bin

**Staking/supporting**—The plants will begin producing flowers and gain mass as they approach harvest. Some of the plants stalks and/or branches may need additional support from plant stakes (*bamboo stakes can be seen below*).

- Add support stakes to branches needing support to prevent branches from lying on one another or breaking/snapping.



OR



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#### <WEEK 8-18>

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Over the course of the next several weeks the plant will complete its genetic drive to produce the flowers. The plants will begin to show characteristics of their APA. Pruning, trellising and staking/supporting plants according to this analysis will increase yields and mitigate pest outbreaks. Over the course of weeks 8 through 18 the main objective will be to monitor the marijuana plants, cultivation facility and equipment.

It will be imperative to be aware of all environments and equipment within the facility to be able to locate and identify any potential problems or unforeseen circumstances. Being proactive during the flowering cycle will reduce the risk of equipment malfunction or failure which could have detrimental effects on the plants being cultivated.

Monitor the canopy of each room daily for:

- Pest(s)
- Fungus/disease
- Plant sex; signs of plant hermaphroditism



Performing the proper checks and balances over the next few weeks will determine the quality of the manufactured product. Maintaining ideal growing environments to achieve the plants maximum genetic potential is our goal. Employees must maintain a log of temperature, humidity, and CO2 concentration in the environment of each cultivation area. Records should be maintained daily upon entry of each room.

At this stage in the growth cycle, if there are no visible indications of stress induced on the plants and pests have yet to be identified, the room will require less attention and only inspections are necessary. Check all reservoirs daily to insure plants are receiving adequate hydration.

#### **Determining if Plants are ready for Harvest**

Harvest will occur between the 16<sup>th</sup> and 18<sup>th</sup> week depending on the marijuana strain. Sativa and hybrid genetic lineages should be allowed the full 70 day flowering cycle to reach maturity (*approximately 10 to 14 weeks of flowering growth stage*). Indica strain's flowering growth stage time lengths vary depending on lineage, but most will be harvested around day 60 (*approximately 8 to 10 weeks of flowering growth stage*). \*Refer to ***Harvesting Marijuana*** SOP.

- Monitor the calyxes and the maturity of the trichomes to understand when a strain has reached maturity and is ready to be harvested.
  - Use a microscope to observe the marijuana plants trichomes to determine if the plant is ready to be harvested
    - If a plant is ready to be harvested, the trichomes should appear milky white in color
      - If trichomes are clear, or see-through in color the plant is not ready to be harvested and should be allowed to continue growing in order to reach maturity.
      - If the trichomes appear to be a dark amber or reddish color, the plant may have been allowed to grow too long and over-mature. This will degrade the medicinal properties and benefits of the marijuana.



<b>Standard Operating Procedure:</b> Weights and Measurements and Scale Calibration
<b>Purpose:</b> To explain how to use certified scales for weights and measurements
<b>Scope:</b> To train registered employees on proper use of NTEP certified scales to be used for weights and measures as well as scale calibration/certification
<b>Initial Training:</b> 1 hour

**Types of Scales to be used**

BPH will utilize NTEP-certified scales for the weighing of all medical marijuana, medical marijuana products, medical marijuana waste and all green waste.

**NTEP Certification**— The National Conference on Weights and Measures issues an NTEP Certificate of Conformance following successful completion of an evaluation of a device. It indicates that the device(s) described in the Certificate is/are capable of meeting applicable requirements of the *NIST Handbook 44*.\* <http://www.ncwm.net/ntep/faqs#WhatIsNTEPcertificate>

**Scale Use**

All medical marijuana harvested at BPH’s licensed premise will be weighed and packaged using NTEP-certified scales certified for legal trade and that have been calibrated and certified ISO/IEC 17025 accredited by a Hawaii calibration service supplier.

**Scale Calibration and Frequency**

BPH will ensure that all scales and balances are calibrated by an accredited calibration service supplier. The frequency of having BPH scales calibrated will be on a six (6) month basis. This routine calibration will be documented on the Scale Calibration Log sheet and maintain on the licensed premise.

*Example of the Scale Calibration Log Sheet:*

<b><u>Scale Calibration</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Scale Serial #/ID #:</u>	<u>Calibration Service Supplier:</u>	<u>Scale Calibrated</u>	<u>Notes/Comment:</u>
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
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Harvesting Marijuana

### Standard Operating Procedure: Harvesting Marijuana

**Purpose:** To explain the steps and procedures involved with harvesting marijuana, including: cutting, weighing, processing, trimming, drying, and curing.

**Scope:** Covers the post-cultivation harvest process within the cultivation facility.

**Initial Training:** 8-16 hours

#### Documentation Log Sheets Required

- 1) Harvested Marijuana Log Sheet
- 2) Marijuana Waste Log Sheet

#### Equipment/Tools Required

- 1) Heavy-Duty Sheers
- 2) Certified Scales (hanging scale for wet weight and table scale for trimmed flower/bud and sugar leaf)
- 3) Scissors
- 4) Plant labels/tags
- 5) Drying Racks
- 6) Containers/Jars
- 7) Soil Disposal Carts

#### Principles of Harvesting Marijuana

The harvesting of marijuana is the final process with the plant lifecycle. The harvesting process is when all cultivation activities have come to an end and the marijuana plants flowers are fully ripened and ready to be harvested. The harvest and post-harvest process involves four (4) major steps; 1) harvesting the marijuana plants, 2) trimming the marijuana plants, 3) drying the marijuana and 4) curing the marijuana.

- **Harvesting**
  - Cutting the marijuana plants stock at the point where the stock meets the soil or growing medium. Record the **Plants Attribute #** or **Unique ID #** and strain information on the **Harvested Marijuana Log Sheet**.
  - Once marijuana plant is cut, the plant must be weighed as a whole. This is typically called the marijuana plant **‘Wet Weight’**. Record this weight on the **Harvested Marijuana Log Sheet**.
  - All soil root balls from harvested plants will be placed into the soil disposal cart



Cut the Plant at Base





Weigh Entire Wet Plant



Documentation

Once the marijuana plant(s) have been chopped and weighed on an NTEP-certified hanging scale, record the wet weight of the plant(s) on the *Harvested Marijuana Log Sheet*.

<b><u>Harvested Marijuana</u></b>						
<b><u>Date:</u></b>	<b><u>Plant Attribute # and Batch#:</u></b>	<b><u>Plant Strain:</u></b>	<b><u>Wet Weight:</u></b>	<b><u>Waste Weight:</u></b>	<b><u>Trim Weight:</u></b>	<b><u>Bud Weight:</u></b>





Processing Operations

<b>Standard Operating Procedure:</b> Processing Operations
<b>Purpose:</b> To explain post-harvest activities, procedures and protocols. Including: trimming, processing, weighing, packaging and labeling.
<b>Scope:</b> Covers the processing activities within the cultivation facility.
<b>Initial Training:</b> 8-16 hours

### What is Included in the Post-Extraction Operations

- 1) Trimming marijuana plants
- 2) Weighing, packaging and labeling finished marijuana medicine
- 3) Marijuana waste disposal

### Documentation Log Sheets Required

- 1) Finished Marijuana Medicine Log Sheet
- 2) Marijuana Waste Disposal Log Sheet

### Equipment/Tools Required

- 1) Nitrile gloves
- 2) Certified Table Scale
- 3) Packaging Materials
- 4) Labeling Materials

### Principles of Processing Operations

Processing operations will consist of the processing/trimming, drying and curing of medical marijuana. Also included in the processing operations if the packaging and labeling of medical marijuana.

- 1) **Processing/trimming** – The marijuana plant will be broken down by removing the larger fan leaves, and hung on drying racks preparing for packaging. Registered employees will be required to wear nitrile gloves during all processing and/or trimming procedures.
  - This is where the marijuana plant will be broken down from the whole plant form into individual branches and grades. This will typically create 3 different ‘grades’ of marijuana from the same plant:
    - **Flower(s)/bud(s)**—this is the portion of the marijuana plants and typically referred to as the ‘kola buds’. This medicine has received all of the optimal growing conditions throughout the plants entire lifecycle (proper light conditions and distribution, optimal CO2 levels, etc.).
    - **Sugar Leaf/trim**—this is typically the lower levels of the plant where the HID lighting cannot fully penetrate resulting in ‘larfy/leafy’ marijuana buds and the sugar leaves that have been trimmed off the plants and flowers. This material is typically used in infused products manufacturing and extraction operations.
    - **Waste**—this is comprised of all the material that will not be used from the plant. This material must be weighed and recorded on the *Harvested Marijuana Log Sheet*. Marijuana waste is typically comprised of:
      - Stalks and stems
      - Fan leaves
      - Roots
      - Other unusable material
  - Make sure that all required information is recorded and transferred with any and all marijuana plant materials. Required information to be transferred with marijuana material:



- Plant strain/name
- Harvest/process date
- Plant Attribute # and Batch #

**Trimming**—this is when the processed marijuana will be trimmed. This process involves trimming all of the leafy material away from the flowers/buds. The trimmed leaf material (sugar leaf) is still usable and typically used in Infused Products Manufacturing or for marijuana extraction. All registered employees are required to “glove-up” prior to commencing any trimming operations. Registered employees will be required to wear and change gloves often throughout the day.

- Trim the leafy material of marijuana flowers; properly weigh the trimmed flowers (buds) as well as weigh all the trim (sugar leaf) and record the weights on the *Harvested Marijuana Log Sheet*. Weights to be recorded (*ensure recording to proper Plant Attribute # or Unique ID #*):
  - Flower/bud weight
  - Trim/sugar leaf weight

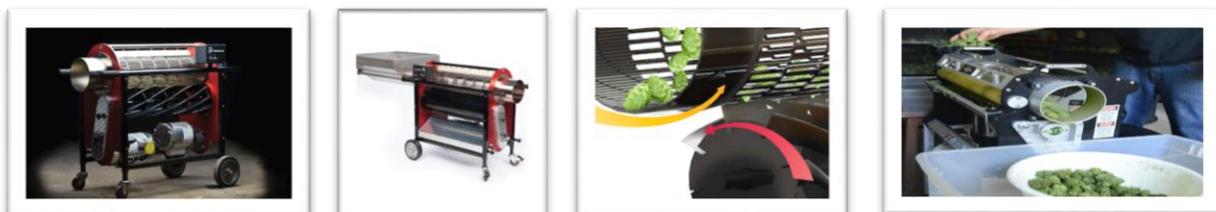


- Once the marijuana material is trimmed it is ready for drying.
- Trimming can be done by using traditional hand-trimming methods or the use of new automated trimming machines such as the TRIMINATOR.
  - If using a trim machine (*ACC recommends the TRIMINATOR*) please refer to the *Trim Machine Operation SOP*.

**Example of Traditional Hand Trimming:**



**Example of a Trim Machine:**





- 2) **Drying**—this is when the marijuana plants will be dried. The drying process is a somewhat delicate process as you do not want to over dry the flowers, but leaving too much moisture in the flowers could result in mold and bud rot.
- Plants will be hung upside down using metal S hooks on a mobile wire shelf
  - Make sure to properly label each plant on the drying racks (ensure all required information is recorded and follows material through drying process to ensure records are not lost.)
    - Required information:
      - Plant Attribute # and Batch #
      - Plant Strain
      - Date flowers (buds) were placed on rack



**Examples of Drying Racks:**



- 3) **Curing**—the curing process begins once the plants have been properly dried.
- Plants can be cured in multiple ways
  - Plants can be cured in place (*within the drying room*) by adjusting the room’s humidity to an equal level as the interior of the flowers. This allows the cannabinoids to fully gain their respective medicinal properties. This process can take 1-2 weeks, depending on desired cannabinoid and terpene values.
  - Plant material (*typically only the plant flowers/buds*) can be placed in a container (*typically a glass jar*) for an extended period of time. During this curing method, the containers will need to be opened periodically to allow air circulation (*this processes is commonly referred to as “burping” the container*).
  - Upon completion of curing, the product will be weighed, tracked, and sent to the vault for storage until extraction.
  - Make sure to properly labels all curing containers with all required information:
    - Plant Attribute # and Batch #
    - Plant Strain
    - Date flowers (buds) were placed in curing container

**Example of Curing in Glass Jars:**



4) **Weighing and Packaging Medical Marijuana**—is the process of accurately weighing the medical marijuana to be put into packages for distribution. Packaging regulations and requirements may vary, so it is essential to reference the state and local laws and regulations pertaining to packaging requirements for medical marijuana business. Use of NTEP certified scales for the weighing of all marijuana products is mandatory.

- All BPH packing will be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
- Packaging must be opaque so that the product cannot be seen from outside the packaging;
- The packaging must be constructed to protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.
- Packages must not contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; providing that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
- Marijuana will be carefully weighed and packaged at the production center. All products will be packaged, recorded into the inventory system, and labeled per Hawai‘i regulations.



- Upon marijuana being weighed and packaged registered employees are required to document the marijuana weight associated to the product with a unique attribute number and batch number. This documentation must be done with two registered employees, one employee to make the record in the inventory control system and a second to witness the record.
- Ensure inventory control system is updated to show the packaged marijuana weights and specifications.

**Examples of Child-Resistant Packaging:**



5) **Labeling**—all packages of medical marijuana will require a label to be conspicuously placed on the package.



- Labels must be made of weather resistant and tamper-evident material
  - As a redundancy, registered employees will be required to recheck each package for a label prior to shipping and package containing medical marijuana from the Licensed Premise.
  - **Hawaii specific labeling requirements:**
    - Labels must use black lettering only on a white background with no pictures or graphics
    - Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
      - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
      - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
    - The dispensary licensee’s license number and the name of the production center where the marijuana in the product was produced;
    - The batch number and date of packaging;
    - A computer tracking inventory identification number barcode generated by tracking software;
    - Date of harvest or manufacture and a “use by date”;
    - Instructions for use;
    - The phrases “For medical use only” and “Not for resale or transfer to another person”;
    - The following warnings:
      - “This product may be unlawful outside of the State of Hawai‘i and is unlawful to possess or use under federal law”;
      - “This product has intoxicating effects and may be habit forming”;
      - “Smoking is hazardous to your health”;
      - “There may be health risks associated with consumption of this product”;
      - “This product is not recommended for use by women who are pregnant or breast feeding”;
      - “Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug”;
      - “When eaten or swallowed, the effects of this drug may be delayed by two or more hours”
    - A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
    - The name of the laboratory that performed the testing
- 6) **Secure, Segregated Storage**—Upon medical marijuana being packaged, BPH registered employees will be required to hold the marijuana in secure, segregated storage until released for distribution
- The secure, segregated storage will be within the production center vault(s).

**Standard Operating Procedure: Inventory Reconciliation Procedure**

**Purpose:** To explain the purpose and processes involved with inventory reconciliation.



**Scope:** Covers the steps involved with inventory reconciliation.

**Initial Training:** 4-6 hours

### **The Principles of Inventory Reconciliation**

It is recommended to perform physical inventory on weekly or monthly basis. At minimum, a monthly inventory reconciliation is to be performed at each facility. This is where every product within the facility will be physically counted, documented and then reconciled (*compared*) against the inventory recorded in the POS system or computer inventory system.

The physical inventory on-hand that is counted should be identical to the inventory that is recorded within the POS system. If there are deviations in these numbers then action must be taken to determine the shortage(s).

- 1) Count **ALL** on-hand inventory at the facility
  - Marijuana plants
    - Mother plants
    - Clones
    - Vegetative plants
    - Flowering plants
    - Hanging/drying plants and material
  - Finished marijuana
    - Flower/bud (*packaged and ready for transport*)
    - Trim/sugar leaf (*packaged and ready for transfer*)
- 2) Document all counted on-hand inventories on the appropriate ***Cultivation Inventory—Marijuana Plants*** (*daily, weekly, or monthly*) log sheet.
- 3) Reconcile counted on-hand inventories against on-hand inventories in the POS system
  - Document discrepancies on the appropriate ***Cultivation Inventory—Marijuana Plants*** and the ***Cultivation POS Inventory Reconciliation*** and ***Product Loss Log Sheet*** between the counted on-hand inventory and POS inventory.
  - Investigate all discrepancies
- 4) Inventory Discrepancies—discrepancies between the inventory stock and the inventory within the inventory control system (*outside of normal weight loss due to moisture loss and handling*)
  - Investigate all discrepancies within one (1) business day
    - Perform inventory audit and reconciliation
    - Review transactions within the inventory control system
    - Review security surveillance footage
  - Report theft or diversion to the Department AND local Police within one business day
    - Contact the Department and local Police in multiple fashions as a redundancy
      1. Contact directly through phone conversation
      2. Contact electronically through email, fax or other electronic means
  - Within 30 days
    - the inventory discrepancy investigation must be conducted and completed
    - the standard operating procedures amended (*if needed*)
    - send an investigation report and audit to the Department

***Example of Cultivation Inventory—Marijuana Plants log sheet:***



### Cultivation Inventory--Marijuana Plants

<u>Date:</u>	<u>Employee:</u>	<u>Grow Room:</u>	<u>Plant ID/Strain:</u>	<u>Quantity:</u>	<u>Lifecycle Stage:</u>

Example of Cultivation POS Inventory log sheet:

<u>Cultivation POS Inventory Reconciliation</u>							
<u>Date:</u>	<u>Product Name:</u>	<u>Product Attribute #/Unique ID #:</u>	<u>Quantity On Hand:</u>	<u>Quantity in POS System:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Notes:</u>

Example of Product Loss log sheet:

<u>Product Loss Log Sheet</u>				
<u>Date:</u>	<u>Product Name/Category</u>	<u>Product Attribute # or Unique ID #</u>	<u>Total Quantity Loss:</u>	<u>Product Loss Valuation:</u>
				\$
<u>Reporting Employee:</u>	<u>Manager/Supervisor:</u>	<u>Product Loss Due To:</u>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<u>Internal Investigation:</u>	<u>Required Authorities Notified:</u>	<u>Authorities Notified (list all):</u>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<u>Note/Comments:</u>				



Trim Machine Operation

**Standard Operating Procedure: Trim Machine Operation**

**Purpose:** To understand how to properly operate the TRIMINATOR trim machine.

**Scope:** To train employees on the proper handling, use and maintenance of the TRIMINATOR. TRIMINATOR user manual can be found online at: <http://thetriminator.com/wet-marijuana-trimmer-machine/>

**Initial Training:** 2-4 hours

**The Principles of the Trim Machine Operation and Maintenance**

Any automated trimming machine being utilized should be used with caution as the machine can cause harm and bodily damage if not used properly. It is recommended to read the user manual and manufacturer instruction prior to use of any automated trim machine.

ACC recommends the use of the TRIMINATOR automated trimming machine for marijuana operations. More information on the TRIMINATOR can be found at the website: <http://thetriminator.com/wet-marijuana-trimmer-machine/>



TRIMINATOR user manual can be found at:

<https://drive.google.com/a/americanmarijuanaconsulting.com/file/d/0B236JzITJeCVaVo1SG5IN1Vna05YU1ZMY3AyR283cGdfUW5J/view>

*TRIMINATOR Spec Sheet can be seen below:*



# TRIMINATOR

## AUTOMATIC CLEANING SYSTEM

eliminates cleaning stops and maximizes production

## COMMERCIAL SIZE

the industry's highest capacity drum allows you to trim up to 2.5X faster

## LOCKING WHEELS

keep the machine in place no matter the slope



## NO BED-KNIFE

no hassles with our bed-knife free design

## WASH DOWN COVER

makes cleaning easy

## TECHNOLOGY

### RESIN REPEL SELF-CLEANING SYSTEM



**WHY** it keeps you trimming long after others have stopped to clean.

**HOW** our patented Resin Repel system uses atomized water to inhibit resin build up, allowing you to trim massive harvests non-stop.

### TRIM LOGIC TECHNOLOGY



**WHY** it cuts closer for hand-trimmed quality results.

**HOW** by eliminating the bed-knife and pushing the cutting blades within .0025" you get a closer trim every time.

## SPECIFICATIONS

### MACHINE

**HEIGHT:** 39 in  
**WIDTH:** 18.5 in  
**LENGTH:** 45 in  
**WEIGHT:** 235 lbs  
**AC VOLTAGE:** 120 V  
**MAX AMPS:** 18 Amps  
**SHIPPING WEIGHT:** 353 lbs

### VACUUM

**HEIGHT:** 92 in (w filter)  
**WIDTH:** 29 in  
**LENGTH:** 37 in  
**WEIGHT:** 140 lbs  
**CFM:** 1300 CFM  
**AC VOLTAGE:** 120 V  
**MAX AMPS:** 16 Amps

**APPLICATION**  
WET TRIM

**WARRANTY**  
2 YEAR

THETRIMATOR.COM



530.265.4277



INFO@THETRIMATOR.COM



MADE IN USA



Laboratory Testing

<b>Standard Operating Procedure:</b> Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana and manufactured marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Cultivation Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

### Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

### State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)
  - Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.



- If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the ***Marijuana Waste SOP*** upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

**Preparation of Medical Marijuana Samples to be Tested**

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Flower/bud—ensure adequate quantity from batch for sampling (~7-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# FLW001 → Create new ‘Sample Package’: FLWT101
- Fill out all required documentation/log sheets
  - ***Samples for Laboratory Testing***
  - ***Marijuana Product Shipping Manifest***

<b><u>Marijuana Samples for Laboratory Testing</u></b>					
Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:





- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow ***Transferring/Transporting SOP***

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show medical marijuana potency, cannabinoid profiles, terpene profiles, and contaminants (if any present). The testing laboratory will provide BPH test results from each batch and lot tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meet all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**— there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm$  90-100% of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating

It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.



- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<b><u>Marijuana Batch Samples for Laboratory Testing</u></b>						
Date Sample Prepared:	Grower Agent #1:	Grower Agent #2:	Product Attribute ID #, Batch# and Strain/Variety	Sample Quantity/Weight:	Test Sample ID # (NEW) :	Receiving Laboratory:
Date Sample Shipped:	Sample Pass Testing		Certificate of Analysis Provided w/ Supporting Data?	If sample failed testing, will batch be reprocessed or destroyed?		Licensed Processor to Send Batch to:
	<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed		
Batch Potency	Batch Purity	Batch expiration date data/support:			Notes/Details:	
Date of 6-month interval test:	Sample Pass Testing	Certificate of Analysis Provided w/ Supporting Data?	Batch Potency	Batch Purity	Batch expiration date data/support:	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
Notes/Comments:						

**Release for Distribution**

All batches of marijuana are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH’s registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.

- This process will be completed by two (2) registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

**Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.



Shipping Marijuana Products, Transferring/Transporting

**Standard Operating Procedure: Shipping, Transferring/Transporting Marijuana Products,**

**Purpose:** To explain the steps required to be followed to ship marijuana and manufactured marijuana products to BPH retail dispensary locations.

**Scope:** Covers the training required and procedures for registered employees covering the shipping/transporting of marijuana and manufactured marijuana products.

**Initial Training:** 2-4 hours

**The Principles of the Shipping Procedure, Transferring/Transporting**

The marijuana and manufactured marijuana products will be transported by no less than two registered employees to BPH retail dispensary locations.

**The Transportation Process:**

- 1) New Inventory Order
- 2) Fulfillment
- 3) Create Manifest/Trip Plan
- 4) Transportation
- 5) Delivery
- 6) Post-Delivery

**1) New Inventory Order**

- 1) Fill out *Marijuana Products Transportation (Outgoing)* log sheet
- 2) Create a new invoice for inventory order
  - a. Date that order is placed
  - b. Products and quantities ordered
  - c. Prices of products
  - d. Estimated delivery date and time

**2) Fulfillment**

- 1) Collect products needed for inventory order
- 2) Take ordered/collected products out of the inventory control system
- 3) Package the order of products into a container that is constructed on tamper-evident, opaque material
  - a. The use of tamper-evident cardboard boxes, hard plastic opaque cases that can be locked with tamper-evident seals or locks, or a similar shipping package that will meet Hawaii requirements
  - b. Seal said tamper-evident package with tamper-evident tape.
  - c. If transporting multiple packages to the same dispensary, the packages will need to be shipped within one large opaque tamper-evident container.
- 4) **Repackaging**—if necessary, registered employees may have to repackage the delivery items into a container that is constructed of tamper-evident opaque materials and sealed with tamper-evident tape
  - a. This will typically only happen if the original packaging is defective or gets destroyed.
  - b. Medical marijuana will need to be repackaged if not originally packaged in an opaque container.
  - c. Repackaging may be required if multiple packages are identified as being shipped to the same recipient
    - i. If this is the case, then the packages will need to be repackaged into one large opaque tamper-evident container and sealed with tamper-evident tape
      1. Ensure package is sealed with tamper-evident tape; seal all entry/access points
- 5) Complete the *Marijuana Products Daily Transfer/Shipping* log sheet
  - a. Example of *Marijuana Products Daily Transfer/Shipping* log sheet can be seen below:



### Marijuana Products Daily Transfer

<u>Date:</u>	<u>Employee Preparing Transfer:</u>	<u>Marijuana Product Name/Batch ID #/Strain:</u>	<u>Quantity Shipped:</u>	<u>Receiving Retail Dispensary Location:</u>	<u>Receiving Employee:</u>

- 6) Create new record within the inventory control system for the products being transported—registered employees will need to create a record of the products prior to transportation any marijuana products.
  - a. Information required on record:
    - i. Date and time of the sealing of the package for shipment
    - ii. Name a signature of the registered grower agent who prepared and sealed the package
    - iii. Name and address of BPH
    - iv. Transfer identification number
    - v. A description of the package being transported including the weight of each item
    - vi. The name and address of the party receiving the shipment

### 3) Manifest/Trip Plan Creation—See *Marijuana Product Transfer Manifest SOP*

Prior to the transportation of any marijuana products or marijuana-infused products a facility agent will generate a manifest/trip plan including at a minimum:

- 1) The name of the agents who will be transporting;
- 2) The automobile license plate, make and model;
- 3) The date, start time of the trip and estimated delivery time;
- 4) A description including the exact amount, type and batch of any marijuana products and marijuana-infused products being transported; and
- 5) The intended route of transportation.

Facility management shall maintain a copy of the manifest/trip plan document at the location of departure, record the manifest/trip plan with any needed authorities, and the transporting employees will maintain a copy of the manifest/trip plan during the transportation.

### 4) Transportation

This section covers how to transport the product to the other BPH facilities. All applicable state and local laws/regulations pertaining to transportation of medical marijuana products will need to be strictly adhered to by all organization team members. All transportation/shipping to be done in-house by BPH registered employees and/or transportation agents. BPH does not intend to use a secure transportation company unless deemed absolutely necessary.

**Transportation Vehicle Requirements**—all agents responsible for transporting medical marijuana must:

- 1) Use of an unmarked, unidentifiable vehicle
  - a. Vehicle should not have any BPH markings, logos or identifiers on the vehicle
  - b. Vehicle should not raise awareness that it may be transporting medical marijuana and/or medical marijuana products of any kind



- 2) Ensure the vehicle has current, valid registration from the State
  - a. Registration paperwork should be located in vehicle glovebox
  - b. Vehicle license plate should have current, valid registration sticker
- 3) Ensure the vehicle has current valid proof of insurance
  - a. Proof of insurance paperwork should be located in the glovebox
- 4) Ensure the vehicle has a current safety check
  - a. Safety check paperwork should be located in the glovebox

**Transportation Agent Requirements**—all agents responsible for transporting medical marijuana must:

- 1) There will be at minimum two registered employees and/or transportation agents for every product shipment. Each transportation agent will play a separate and vital role.
  - o One transportation agent will be required to drive the transportation vehicle and to remain with the transportation vehicle at all times.
  - o The second transportation agent is to remain with the medical marijuana product be transported at all times and to ensure that the product is secure at all times during transport.
- 2) Wearing appropriate work attire
  - o Work attire for BPH transportation agents will be plain with no company logos, brands or identification.
  - o BPH transportation agents should not appear to indicate ownership or possession of marijuana.
    - Plain polo shirt
    - Plain khakis/jean pants
    - Plain dress/tennis shoes
  - Failure to arrive to a scheduled shift with proper attire will result in not being able to make transports, incident noted in personal file and possible disciplinary action.
- 3) Possess a current and valid State-issued marijuana industry worker identification;
- 4) Possess a current and valid State-issued driver's license;
- 5) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or marijuana-infused products pursuant to regulation, all transporting agents shall:

- 1) Carry a copy of the manifest/trip plan with him or her for the duration of the trip;
- 2) Wear their agent card and/or have Commission approved identification readily available;
- 3) Use a vehicle without any medical marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or marijuana-infused products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation as well as a back-up emergency cell phone; and
- 5) Ensure that the medical marijuana is not at all visible to the public.

**5) Delivery**

- 1) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the shipping manifest/trip plan
- 2) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

**6) Post-Delivery**



**Post-Delivery Protocol**—after transporting marijuana products or marijuana-infused products, pursuant to the regulations the employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.

**Documentation of Delivery**—both the transporting dispensing facility and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Division agents for review upon request.

**Deviations from Transportation Plan**—the transporting agent shall immediately report all diversion due to loss or theft of marijuana or marijuana-infused products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the state licensing authorities as required per state regulations. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



<b>Standard Operating Procedure:</b> Marijuana Product Transfer Manifest
<b>Purpose:</b> To explain the requirements for the marijuana products transfer manifest
<b>Scope:</b> To educate and train registered employees on the creation and use of the marijuana products transfer manifest
<b>Initial Training:</b> 1-2 hours

**Principles of the Electronic Manifest**

The transfer manifest will be required for each and every delivery of marijuana product from BPH’s production center. Registered employees will be required to complete the physical marijuana product transfer manifest form.

Prior to transporting or shipping a package containing marijuana and/or manufactured marijuana products, BPH will require registered employees to complete the marijuana product transfer manifest process. Registered employees will need to complete the manifest form and scan/email a copy of the manifest to the retail dispensary location recipient. Registered employees and/or transportation agents will also maintain two (2) physical copies of the manifest form to keep and have present during any transporting of marijuana products. Upon delivery of the marijuana products, the shipping registered employee will provide a physical copy of the manifest for the recipient to maintain.

**Requirements**

All transportation of products are required to use a manifest for chain of custody procedures and to ensure safe transport of marijuana products and that no theft or diversion is occurring during transport. BPH will utilize a manifest to record the chain of custody for the transportation of products containing marijuana. The manifest will include a chain of custody that records:

- The name and cell phone number of the registered employees in the vehicle;
- The transfer identification number;
- The weight and description of each individual package that is part of the shipment, and the total number of individual packages;
- The name of the registered employee that prepared the transfer;
- The name and address of the receiving licensee; and
- Any handling or storage instructions.

**Chain of Custody—Transport** with packages containing marijuana will need to be tracked and recorded throughout the shipping process within the inventory control system. The chain of custody for all shipments containing medical marijuana must be accurately documented within the manifest and inventory control system.

The inventory control system will contain, at a minimum, the following entries as a chain of custody, in the order listed:

- An entry by the registered employee who has prepared the delivery, including the date and time of preparation;
- An entry by a shipping licensee’s registered employee, of the date and time of the placement of the shipment into the marijuana product transport vehicle;
- An entry by licensee’s registered employee receiving the delivery including the date and time of the acceptance; and
- If any other person had custody or control of the delivery, that person’s identity, the circumstances, duration, and disposition.

A manifest **MUST** be created for **EACH** delivery of products containing medical marijuana.



BPH will require registered employees to complete a **Marijuana Product Transfer Manifest Form** prior to transporting or shipping any marijuana and/or manufactured marijuana products. Refer to the **Transfer Marijuana Products Transferring/Transportation SOP** for transportation requirements. **Marijuana Product Transfer Manifest Form can be seen below:**

		<b>Marijuana Product Transfer Manifest</b>		<b>Transfer Identification #:</b>	<i>Test results included for ALL products being shipped?</i> <input type="checkbox"/> YES <input type="checkbox"/> NO
<i>*This form must be completed prior to the shipping of any marijuana or manufactured marijuana products. This Record for Transfer must be present along with the Transportation/Trip Manifest Form with ALL shipments of marijuana and/or manufactured marijuana products from the Licensed Premise.</i>					
Date Package/Shipment Sealed:		Time Package/Shipment Sealed:		License # of Originating Entity:	
Name of Registered Employee who prepared and sealed the package:					
Signature of Registered Employee who prepared and sealed the package:					
Name of Originating Entity: Blue Planet Healing LLC					
Address of Originating Entity:				Phone #:	
				Email:	
<i>*If you are delivering more than fifteen (15) products to one stop, use a second form to list the additional product(s).</i>					
<input type="checkbox"/> Check Here if multiple pages are used <i>List the total number of pages in the Manifest here</i> _____					
<b>Receiving Retail Dispensary Location Information</b>		<b>Marijuana/Product(s) within the Shipment</b>	<b>Quantity/Weight</b>	<b>Attribute #/Product ID #</b>	
Stop Number on Route:		1)			
Name of Receiving Party:		2)	Blue Planet Healing LLC		
License # of Retail Dispensary Location:		3)			
Address of Receiving Retail Dispensary Location:		4)			
		5)			
Phone # of Receiving Dispensary:		6)			
Date and Approximate Time of Departure:		7)			
Date and Approximate Time of Arrival:		8)			
Route to be Traveled:		9)			
		10)			
		11)			
		12)			
		13)			
		14)			
		15)			
Additional Description: <i>(add description/details about the marijuana products and/or manufactured marijuana product(s))</i>					
<b>PRODUCT REJECTION (if only a portion of the shipment is rejected, circle that portion above.)</b>					
Name of Person Receiving or Rejecting Product(s):				Date:	
<i>I confirm that the contents of this shipment match the weight records above, and I agree to the custody of those portions of this shipment NOT circled above. Those portions that ARE circled above were returned to the individual delivering this shipment.</i>					
Signature:			Signature of Individual Taking Receipt of Rejected Portion of this Shipment:		
Name of Person Transporting Product(s):			Signature of Person Transporting Product(s):		
Make, Model, License Plate #:				Date of Signature:	



**Standard Operating Procedure: Customer Complaints and Returns**

**Purpose:** To explain the steps involved for handling customer complaints and product returns.

**Scope:** Covers the steps involved to handle customer complaints and product returns appropriately.

**Documentation Log Sheets Required**

- 1) Customer Complaint Form
- 2) Returned Marijuana Products Log Sheet
- 3) Returned Marijuana Products Waste

**The Principles of Handling Customer Complaints and Product Returns**

It is important to have proper procedures in place for the handling of customer complaints and/or product returns. By having these initiatives in place you can ensure the most satisfied customer base possible. Below are best practice steps to take when confronted with a customer complaint and/or product return.

**State of Hawaii Requirements**

- In the event a complaint is associated with a serious adverse event, BPH will require registered employees to:
  - Promptly report the complaint to the Commission
  - Report the complaint to any licensed processor or licensed dispensaries that may have received a shipment containing medical marijuana from the batch determined to cause the complaint
- As required by State of Hawaii regulations, in the event a complaint associated with a serious adverse event, BPH will be required to promptly report the complaint to, (1) the Commission, (2) either the licensed grower from which the medical marijuana originated, or the licensed processor from which the medical marijuana concentrate originated, (3) the certifying physician caring for the qualifying patient.
  - As a licensed grower operation, BPH’s registered employees will be limited to report to the Commission in the event a complaint is associated with a serious adverse event.
    - Within 24-hours registered employees must report the complaint to the Commission

**Recalling of Medical Marijuana**—if a batch or lot of medical marijuana is determined through testing to fail to meet specification, BPH will do the following:

- Order a recall of all products derived from or included in the batch
- Notify all dispensaries and/or processors who may have obtained medical marijuana products from such a batch or lot of the recall
  - Using the inventory control system and/or physical documentation log sheets/records to identify all licensed processors and/or licensed dispensaries that may have received a distribution containing medical marijuana from the production batch or lot
  - After identifying the licensed processors and/or dispensaries, registered employees will be required to directly notify said companies.
- Offer and pay reimbursement for any returned medical marijuana
  - Offer to replace the medical marijuana product free of charge or offer full monetary reimbursement to the licensed processors and/or licensed dispensaries.

**Handling Customer Complaints**—when a customer wishes to make a formal complaint, follow the following procedures:

- Have customer wishing to form a complaint to complete the *Customer Complaint Form*



- File complaint within the customer complaint folder located within a limited-access area within the Licensed Premise
- Notify management of the formal complaint
- Notify the Department of the formal complaint

	<b>Customer Complaint Form</b>	
	<b>Date:</b>	<b>Location:</b>
	<b>Customer Name:</b>	
	<b>Employee Documenting Complaint:</b>	<b>Supervisor on Duty:</b>
	<b>Description of Complaint:</b>	
	<b>Corrective Action to be Taken:</b>	
	<b>Customer Comments:</b>	
	<b>Customer Signature:</b>	<b>Date:</b>
	<b>Employee Signature:</b>	<b>Date:</b>

In the event of a formal complaint regarding the quality or safety of medical marijuana is received, BPH will require registered employees to review and investigate the complaint within 24-hours to determine:

- If the complaint is substantive or reports a serious adverse event
- Determine the batch number of the marijuana—this can be accomplished using the records and documentation maintained throughout the cultivation process to determine if there were any deviations in production
  - If the complaint is substantive or reports a case of a serious adverse event, registered employees will determine the batch number of the marijuana
  - Registered employees will be required to investigate the record and circumstances of the production of the batch and lot to determine:
    - If there was a deviation from the standard operating procedure in the production of the medical marijuana by reviewing production logs, records and documentation
      - Test retention samples of the batch and lot to an independent testing laboratory.
        - Send retention samples from batch and lot in question to licensed testing laboratory for testing
          - If testing reveals that the batch or lot fails to meet specifications, follow steps for recall below in following SOP
          - Notify any and all patients, caregivers and dispensaries who may have obtained medical marijuana products from such a batch or lot of the recall
            - Use the inventory control system and physical records to determine who may have



- received a batch of medical marijuana from the recalled batch
- Upon identifying retail dispensary locations that have received marijuana from the batch in recall, registered employees will need to notify the licensed dispensary directly with two means:
  - Via phone call, AND
  - Via email

**Investigation of Complaint**—BPH will require registered employees to investigate all complaints regarding the quality or safety of medal marijuana. Registered employees will be required to review records and documentation from the cultivation operations to determine if there was any deviation from production.

- Review all cultivation records and documentation log sheets
  - Try to determine if there were any deviation in production
  - If the is a deviation in production, see **Standard Operating Procedures SOP**
  - Determine the batch number and/or lot number of the medical marijuana
    - Reviewing records and documentation for substantive changes in production
- Meet with complainant to understand the serious adverse event (*if applicable*)
  - Meeting with the complainant registered employees may be able to identify the medical marijuana batch associated with the complaint
- Order a recall of the medical marijuana batch if necessary; follow **Product Recall SOP**

**Handling Customer Returns** – When a customer wishes to return a product, perform the following procedure:

- Acquire the product needing to be returned and begin the process of completing the Returned Marijuana Products Log Sheet
- Ask for the reason as to why the product is being returned and record this information.
- Log the product as being returned into the electronic inventory tracking system
- Offer and pay reimbursement for the medical marijuana products tracking system.
- Ensure that the Returned Marijuana Products Log Sheet is completed and filed.

*Example of a Returned Marijuana Products Log Sheet:*

<b><u>Returned Marijuana Products Log Sheet</u></b>					
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Patient/Caregiver Returning Cannabis Product:</u>	<u>Marijuana Product Returned (Name/Attribute#):</u>	<u>Quantity/Weight:</u>	<u>Reason for Product Return</u>

*Example of a Returned Marijuana Waste Log Sheet:*

<b><u>Returned Marijuana Waste Log Sheet</u></b>						
<u>Date:</u>	<u>Registered Employee:</u>	<u>Qualified Patient/Caregiver:</u>	<u>Marijuana Product to Dispose:</u>	<u>Waste Weight:</u>	<u>Mixed With:</u>	<u>Total Weight to Dispose:</u>



Product Recall

<b>Standard Operating Procedure:</b> Product Recall
<b>Purpose:</b> To ensure that all required steps and procedures are take when there is a need to recall a marijuana product.
<b>Scope:</b> Procedures covering voluntary and involuntary product recalls.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required Within the Cultivation Facility**

- 1) Product Recall Log

**Principles of Product Recall**

Manufacturers, importers, distributors and retailers of consumer goods are liable for the products they provide to consumers and face the potential of product recalls for potentially dangerous or hazardous products. The same is true for the marijuana businesses as manufacturers and retailers of consumer medical marijuana products, for the facility may need to conduct a product recall in the future. For most consumer products the recall process is handled and regulated by the Consumer Product Safety Commission (CPSC), and for all intents and purposes the marijuana business recall plan will follow the guidelines of the CPSC.

The Consumer Product Safety Commission (CPSC) has compiled resources to assist companies that manufacture, import, distribute, retail, or otherwise sell consumer products. CPSC has developed a Recall Handbook that can be utilized in case a product recall needs to be ordered. The Recall Handbook details how to recognize potentially hazardous consumer products as soon as possible. The book explains how to develop and implement a “corrective action plan” (called a CAP) to address the hazards; it explains CPSC’s Fast Track Program. The Recall Handbook also discusses how to communicate recall information to consumers and how to monitor product recalls. The Consumer Product Safety Commission’s Recall Handbook will be a valuable tool utilized by the company if the need for a product recall ever arises.

The Recall Handbook should be referenced to determine exact protocol for recall and the requirements from the Consumer Product Safety Commission. The Recall Handbook can be obtained online from <http://www.cpsc.gov/PageFiles/106141/8002.pdf>.

**When to Recall Medical Marijuana Products**

As a manufacturer, distributor, and/or retailer of consumer products, the cultivation facility has a legal obligation to immediately report the following types of information:

- 1) A defective product that could create a substantial risk of injury to consumers;
- 2) A product that creates an unreasonable risk of serious injury or death;
- 3) Marijuana or manufactured marijuana is determined to contain a contaminate of some kind
- 4) Marijuana or manufactured marijuana batch did not successfully pass required testing but was released for distribution

Failure to fully and immediately report this information may lead to substantial civil or criminal penalties. Consumer Product Safety Commission’s staff advice is “when in doubt, report.” BPH will ensure communication with the required state and local authorities within 24 hours of becoming aware of the need for a product recall. BPH will then proceed to the recalling protocol and how to recall the product.

**How to Recall Medical Marijuana Products**

The facility will develop a recall plan following guidance from the Recall Handbook provided by the CPSC. Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory

management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by state regulations will ensure a streamlined recall process if ever necessary.

### **Corrective Action Plan (CAP)**

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and steps needed to be taken by the facility once a product recall is required.

#### **Step One: Industry Notification**

If a marijuana or manufactured marijuana product is believed to need a recall, BPH will contact all retail dispensary locations to notify them of the situation and the need for product recall. BPH will also contact required state and local authorities within 24 hours of obtaining reportable information. As the cultivator and/or manufacturer of the product needing to be recalled, BPH will need to contact the end users of the recalled product; contacting qualified patients will prove to be difficult, but will be possible through the utilization of the inventory control and POS systems. At this stage of the recall, retail dispensary locations will need to ensure that they have a proper recall process in place to contact qualified patients that were dispensed the product being recalled.

#### **Step Two: Public Notification**

The cultivation facility or dispensing establishment will post notifications about the product recall on its website as well as make partnering cultivation centers and dispensing organizations aware of the product recall. The actual recalling processes will be handled by both the cultivation center and the dispensing organizations.

As the dispensing organization issuing a recall notice, it will be important to reach the end users or the recalled product. The facility will post notification about the recall on Facility websites and social media as well as post written notices of the recall on location for patients and customers to view. The recall notice will include all pertinent information regarding the product being recalled, contact information and other information relating to the recall. Information will include but not be limited to:

- 1) Product name and unique attribute number
- 2) Product batch number
- 3) Dispensing date range of recalled product
- 4) Retail dispensary locations

Once the recall notification has been issued to all applicable dispensing organizations and medical marijuana patients, the facility will wait to receive recalled products from dispensing organizations and/or licensed medical marijuana patients and caregivers. Once recalled products have been received, the facility will properly dispose of all recalled products. The disposal of these products should conform to the state regulations for waste disposal.

#### **Step Three: Procurement**

BPH issuing a product recall to qualified patients and primary caregivers will need to be ready to obtain and secure recalled products from qualified patients. Patients should be able to bring in the products being recalled to the retail dispensary location. It will be at BPH's discretion whether to issue a refund, replace the recalled product at no cost, or to take other measures.

- Upon receiving recalled marijuana and/or manufactured marijuana products, registered employees will document the return of the recalled marijuana product
- After documentation, registered employees will securely store the recalled marijuana product in segregated storage until disposal
  - Recalled medical marijuana must be securely stored until properly destroyed and disposed of.



### Step Four: Documentation and Record Retention

BPH will maintain all documentation all records regarding any and all product recalls issued. Registered employees will be required to fill out the required **Product Recall Log Sheet**.

<b><u>Product Recall Documentation Log Sheet</u></b>				
<u>Date:</u>	<u>Product Name</u>	<u>Product Attribute # or Unique ID #</u>	<u>Quantity to be Recalled</u>	<u>Supervisor</u>
List Potential Patient/Caregivers to Notify:				
Regulatory Agencies Notified: <input type="checkbox"/> MMCC <input type="checkbox"/> FDA <input type="checkbox"/> CSPA <input type="checkbox"/> Other				
<u>Date:</u>	<u>Quantity Collected:</u>	<u>Collected From (Patient/Caregiver):</u>	<u>Accepting Employee:</u>	<u>Notes/Details</u>

### Step Five: Disposal

The facility will ensure that any and all recalled marijuana products are disposed of according to all state and local regulations. The facility will follow marijuana waste disposal and destruction procedures outlined within these SOP's for proper disposal of recalled medical marijuana.

- Recalled material must not be destroyed or disposed of until authorized by the Commission.
  - Recalled medical marijuana will need to be stored and segregated until the disposal of recalled material is authorized by the Commission.
    - Stored recalled material in the quarantined secure storage area of the Licensed Premise.
- Once receipt of notification from the Commission that the disposal of recalled medical marijuana is authorized, registered employees will dispose of the medical marijuana according to the **Marijuana Waste Disposal SOP**.
  - Registered employees must dispose of medical marijuana within 24-hours of Commission authorization.



<b>Standard Operating Procedure:</b> Marijuana Waste Destruction and Disposal
<b>Purpose:</b> To explain required and proper disposal processes for marijuana waste.
<b>Scope:</b> Covers marijuana waste grinding, mixing and disposal measures within the retail dispensing facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Marijuana Waste Disposal Log

**Equipment/Tools Required**

- 1) Wood chipper/plant grinder
- 2) Mixing material (material to mix marijuana waste with at 50/50 ratio)
- 3) Trash bags
- 4) Dumpster/trash compactor

**Requirements of Marijuana Waste Disposal**

All marijuana waste, byproducts, undesired materials, green waste and returned/recalled marijuana will be destroyed by rendering the waste unrecognizable, unusable and unrecoverable.

BPH will require registered employees to weigh, document, record and destroy all marijuana waste according to the written standard operating procedures. All marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated will be destroyed and disposed of according to the written SOP.

**Secure, Segregated Storage**—all medical marijuana waste will be stored in secure, segregated storage on the Licensed Premise until receipt of authorization from the Commission of destroy and dispose of the medical marijuana waste.

- The secure, segregated storage will promote good growing and handling practices.

**Marijuana Waste Disposal**—all medical marijuana waste, byproducts and undesired products will be destroyed and disposed of according to all applicable state and local regulations. Facility management will ensure proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state regulations. Record all required information on the *Marijuana Waste Log Sheet*.

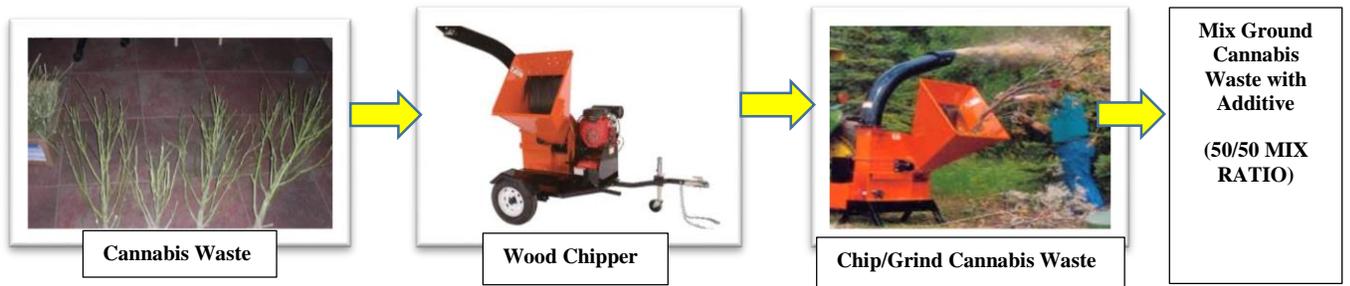
**Disposal**—Disposal of any marijuana product waste must be rendered unrecognizable, unusable and unrecoverable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.

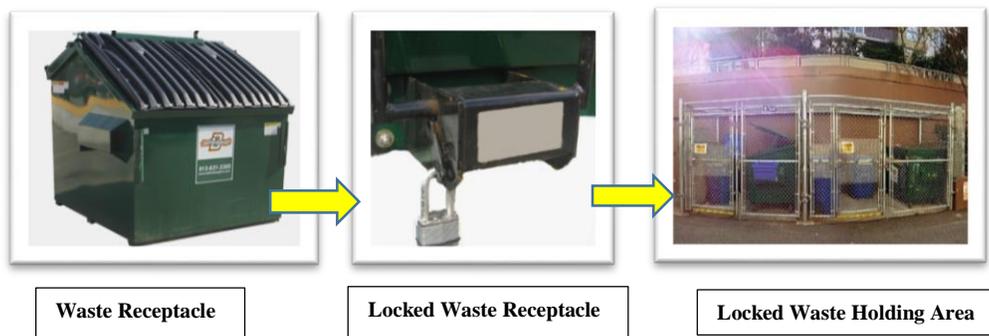


Cannabis Stalks (waste)

**Grinding Marijuana Waste (Stalks, Stems, Leaves and Other Material)**



**\*\*BPH shall not dispose of marijuana product waste in an unsecured waste receptacle not in possession and control of the licensed premise. It is recommended to have a lock on the physical dumpster as well as the area where the dumpster is maintained.**



*Example of Marijuana Waste Documentation Log Sheet (see below):*





<b>Standard Operating Procedure:</b> Facility Cleaning and Sanitation
<b>Purpose:</b> To explain required and proper cleaning and sanitation practices.
<b>Scope:</b> Covers cleaning and sanitation measures within the cultivation facility.
<b>Initial Training:</b> 4-6 hours

**What is the Purpose of Cleaning and Sanitation?**

Proper cleaning and sanitation practices are essential within the cultivation facility. A clean and sanitary cultivation facility will reduce the risk of pests, insects and diseases. The marijuana plants can only be as clean as the room in which they are cultivated. The goal is to produce the safest medicinal marijuana within a clean and sanitary facility.

**Documentation Log Sheets Required**

- 1) Cleaning and Sanitation Log Sheet

**Equipment/Tools Required**

- 1) Personal Protective Equipment (PPE)
- 2) Broom and Dust Pan
- 3) Mop and Mop Bucket
- 4) Bleach
- 5) Cleaning Towels
- 6) Paper Towels

**Principles of Cleaning and Sanitation**

To prevent the accumulation of marijuana oils, resins, plant material, and any remaining pests, strict cleaning procedures must be followed. Cleaning and sterilizing surfaces will aid in pest management, as well as lowering overall microbial levels in processing areas, and on product. Cultivation areas will undergo thorough cleaning in between the harvest stages, and plants reentering the room. Once all plants are harvested, all non-permanent growing equipment will be removed, including pots, plant carts, scissors, etc. Registered employees will thoroughly vacuum all surfaces to remove dust, loose debris, and any plant material. The entire room will then be systematically misted with a chlorine dioxide solution. This chlorine dioxide solution will begin to break down and sterilize any organic material so it may be easily wiped off in the next step. This spray will also enter small spaces not easily reached by manual cleaning. Fans will remain running during this spraying operation to ensure mist is moved around the room thoroughly. Employees will then wipe all surfaces down with the same chlorine dioxide solution. These two steps combined will assure all surfaces are clean and sterile.

During daily operation tools, which come in contact with marijuana, will be soaked in isopropyl alcohol. Transport carts, worktables, and other cultivation furniture will undergo weekly cleaning and sterilizing. After growing medium is disposed, plant containers will be washed and sterilized using a powered washing machine. Pots will be sterilized using a hydrogen peroxide solution, and dried before use.

Due to the nature of marijuana products, cleaning surfaces in processing areas is crucial. Build up caused by marijuana can be very difficult to remove when left for long periods of time. For general removal of resins, a disposable cloth is coated with 91% isopropyl alcohol, and used to wipe all surfaces free of material. For heavily soiled areas use a metal scraper to remove resins. Marijuana trimming machines require daily cleaning to maintain performance, and sterility. Machines will be disassembled, and separated depending on cleaning method. Metal parts are cleaned using isopropyl alcohol; all other parts will be cleaned and sterilized using a steam cleaner.

Drying trays will be sterilized in between each use; wiping trays with isopropyl alcohol will do this. Drying trays will be thoroughly cleaned monthly by first soaking them in hot water to loosen and material, then wiping trays down with isopropyl alcohol. Curing containers will be cleaned and sterilized between uses by wiping down all surfaces with isopropyl alcohol. Drying racks will also be wiped with isopropyl alcohol in between uses.

All areas of the facility, which will contain any marijuana product, or equipment, will have Puradigm air & surface sterilizing technology installed. This system uses advanced oxidation, and multi-cluster ionization technology to instantly kill bacteria, mold, mildew, and other microbes. General maintenance is required on these systems including changing bulbs, changing filters, and general cleaning. This maintenance is done according to the manufacturers recommendations.

After each drying period is complete, drying rooms will be vacuumed to remove dust and plant debris. All surfaces in the room will be wiped with hydrogen peroxide or bleach solutions. The processing, drying, curing, and packaging rooms will be cleaned thoroughly after each harvest. All floors are first vacuumed to be free of dust and plant debris. All surfaces are wiped clean and sterilized using either hydrogen peroxide or bleach solution. This step will assure no microbial cross contamination between harvests.

Apart from clean entry protocols practiced by agents, incoming soil and equipment must also be sterilized. Incoming pallets of soil will be kept in a quarantine room containing Puradigm sterilizing technology. Once the allotted time of air sterilization occurs, the pallets will be moved into a clean room air shower. In the air shower, ions will be dispersed to remove static electricity from plastic bags. Compressed air is blasted at the contents of the air shower, and the air is removed, and filtered.

Major cleaning and sanitation should be done within the cultivation facility when specified by the ***Cleaning and Sanitation Schedule***. Vegetative/flowering rooms should be thoroughly cleaned after the zone/room is completely emptied of all plants. This will be done when moving vegetative plants from the vegetative zone/room into the flowering zone/room or once a flowering room's plants are completely harvested and the room is emptied.

#### **General Daily Cleaning at the Facility:**

- **Cultivation Room(s)**
  - All cultivation rooms should be swept daily
    - Mother room
    - Propagation/clone room
    - Vegetative room(s)
    - Flowering room(s)
  - All trash and plant waste material should be collected and removed from cultivation rooms
  - Foot bath should be checked/changed daily (*if applicable*)
- **General Area(s)**
  - All hallways and accesses will be swept and mopped daily
  - All trash and debris should be collected and removed from the facility general areas on a daily basis
  - The bathrooms should be kept clean and maintained by each employee on a daily basis
  - Parking lot area should be maintained on a regular basis; free of trash and debris
- **Entry (*man trap*)**
  - The "man trap" area should be thoroughly cleaned and sanitized on a daily basis
    - Sweep floor
    - Sanitize floor, walls, door handles
  - Sanitizing footbath solution will be changed every other day

#### **Specific Cleaning at the Facility:**

- **Harvested Cultivation Room(s):**
  - Beginning at the top of the room, dust, and wipe down all surfaces with a 5% bleach solution
    - Be sure to wipe all surfaces thoroughly
  - Sweep and vacuum (*wet/dry shop vac*) all floors
  - Mop all floors with a 5% bleach solution and allow to dry



- Check to assure all surfaces have been sterilized
- Once a zone/room has been properly cleaned and sanitized, employees are required to properly document the activities on the *Cleaning and Sanitation Documentation Log*.

*Example of Cleaning and Sanitation Documentation log sheet:*

<b><u>Cleaning and Sanitation Documentation</u></b>					
Date:	Zone/Room Cleaned:	Cleaning Agent(s) Used:	Reason for Cleaning:	Notes/Comments:	Cleaned By (initial) :





Equipment Operation

<b>Standard Operating Procedure:</b> Equipment Operation
<b>Purpose:</b> To identify the various equipment to be utilized within the facility
<b>Scope:</b> To identify the equipment to be utilized, and where employees can obtain copies of the manufacturer
<b>Initial Training:</b> 4-8 hours

### **The Principles of Equipment Operation**

For all 3<sup>rd</sup> party equipment being utilized within the facility it is recommended to refer to the manufacturer instructions and user manuals for proper operation, set-up, maintenance, cleaning or any other equipment information. Manufacturer instructions and user manuals should have been provided as a hard copy with all original equipment. If the original user manual has been lost or misplaced, refer to the manufacturer company website or contact them directly for a replacement manual.

Some manufacturing companies offer user manuals and instructions as an electronic version which can be obtained online from the company website.

Below are some of the specific equipment utilized by ACC along with the company website where user manuals and/or manufacturer instructions and suggests can be obtained.

#### **1) AutoPots**

- a. Website: <http://autopot-usa.com/products/1pot-xl/product/56-1pot-xl-module-only>
- b. User Guide: [file:///C:/Users/Sam/Downloads/003\\_2015\\_1POT\\_MODULE\\_XL\\_SETUP\\_A5\\_BTT%20v2%20\(1\).pdf](file:///C:/Users/Sam/Downloads/003_2015_1POT_MODULE_XL_SETUP_A5_BTT%20v2%20(1).pdf)

#### **2) Heliospectra LED Lighting**

- a. Spec Sheet: [https://cdn.shopify.com/s/files/1/0621/8261/files/Product\\_Leaflet\\_-\\_LX601.pdf?8354](https://cdn.shopify.com/s/files/1/0621/8261/files/Product_Leaflet_-_LX601.pdf?8354)
- b. User Guide: [http://www.heliospectra.com/sites/default/files/lx60\\_user\\_guide.pdf](http://www.heliospectra.com/sites/default/files/lx60_user_guide.pdf)

#### **3) Lightstick T5 Fluorescent Lighting**

- a. Website: <http://www.brewtek.ca/en/fluorescent-lighting/t5-fixtures/lightstick-t5-4-4-tube-9440>
- b. User Guide: [http://sunlightsupply.s3.amazonaws.com/documents/product/960300\\_Instructions.pdf](http://sunlightsupply.s3.amazonaws.com/documents/product/960300_Instructions.pdf)

#### **4) TRIMINATOR**

- a. Website: <http://thetriminator.com/wet-marijuana-trimmer-machine/>
- b. User Guide: <https://drive.google.com/a/americanmarijuanaconsulting.com/file/d/0B236JzITJeCVaVo1SG5IN1Vna05YU1ZMY3AyR283cGdfUW5J/view>

#### **5) Roto-Scrub Pot washer**

- a. User Guide: [http://www.dillonfloral.com/pdfs/Roto\\_Scrub\\_documentation\\_032108.pdf](http://www.dillonfloral.com/pdfs/Roto_Scrub_documentation_032108.pdf)

#### **6) Patriot Electric Wood Chipper**

- a. Website: <http://www.patriot-products-inc.com/P/31/WoodChipperLeafShredder15hpElectricInternational>
- b. User Guide: <http://www.patriot-products-inc.com/Content/files/eleccsvmanual.pdf>

#### **7) RO system**

- a. Website: <http://purewatersolutions.com/>

#### **8) Environmental Controller**

- a. Website: <http://www.agrowtek.com/>



- b. User Guide: [http://agrowtek.com/doc/GrowControl\\_GC-Pro.pdf](http://agrowtek.com/doc/GrowControl_GC-Pro.pdf)
- 9) **Emergency eye wash**
  - a. Website: <http://www.globalindustrial.com/p/safety/first-aid/eyewash-stations/portable-eye-wash-station-16-gallon-capacity>
- 10) **Air Locks/Shower**
  - a. Website: <http://www.terrauniversal.com/cleanroom-passthroughs/clean-room-air-showers.php>
  - b. User Guide: [http://www.terrauniversal.com/uploads/tech\\_resources/air\\_shower\\_installation\\_manual\\_20141217\\_with\\_appended\\_docs\\_121714115355.pdf](http://www.terrauniversal.com/uploads/tech_resources/air_shower_installation_manual_20141217_with_appended_docs_121714115355.pdf)
- 11) **26 Quart High Performance Blender**
  - a. Website: <http://www.webstaurantstore.com/26-quart-high-performance-vertical-tilting-blender-110v-220v/915LAR25.html>
  - b. User Guide: [http://www.webstaurantstore.com/documents/pdf/omcan\\_blendr\\_operating\\_manual.pdf](http://www.webstaurantstore.com/documents/pdf/omcan_blendr_operating_manual.pdf)
- 12) **Digital Scale**
  - a. Website: [http://www.coleparmer.com/Product/A\\_D\\_FX\\_2000iN\\_NTEP\\_Tploading\\_Balance\\_2200\\_g\\_x\\_0.1g/EW-11115-82](http://www.coleparmer.com/Product/A_D_FX_2000iN_NTEP_Tploading_Balance_2200_g_x_0.1g/EW-11115-82)
- 13) **Hanging Digital Scale**
  - a. Website: [http://www.americanweigh.com/product\\_info.php?cPath=46&products\\_id=1230](http://www.americanweigh.com/product_info.php?cPath=46&products_id=1230)



Equipment Maintenance, Cleaning and Sanitation

**Standard Operating Procedure: Equipment Maintenance, Cleaning and Sanitation**

**Purpose:** To explain facility equipment maintenance, cleaning and sanitation

**Scope:** To educate and train licensed premise employees on requirements and procedures pertaining to facility equipment maintenance and the proper cleaning and sanitation of facility equipment.

**Initial Training:** 2-4 hours

**Principles of Equipment Maintenance, Cleaning and Sanitation**

Equipment utilized within the cultivation operations at the licensed premise will need to be routinely maintenance, cleaned and sanitized. There are multiple reasons for this routine maintenance, cleaning and sanitation including operator safety. Regular maintenance should be done in order to keep the equipment operating and functioning properly, this reduce the risk of an operator getting injured while operating the equipment. The maintenance procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Equipment will need to be cleaned and sanitized after equipment comes into contact with medical marijuana it will need to be properly cleaned and sanitized. The cleaning and sanitation procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Licensed premise employees performing the maintenance and/or cleaning and sanitation will be required to document the maintenance and/or cleaning and sanitation within the *Equipment Maintenance, Cleaning and Sanitation Log Sheet*.

*Example of BPH's Equipment Maintenance, Cleaning and Sanitation Log Sheet:*

<b><u>Equipment Maintenance, Cleaning and Sanitation</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Equipment Name/Model #:</u>	<u>Date of Last Maintenance</u>	<u>Date of Last Cleaning &amp; Sanitation</u>	<u>Notes/Comments</u>





Facility Exit Protocol

<b>Standard Operating Procedure:</b> Facility Exit Protocol
<b>Purpose:</b> To explain how employees should exit the production center.
<b>Scope:</b> Covers the steps involved for properly exiting the production center.
<b>Initial Training:</b> 1-2 hours

When an employee has finished their work shift, they will exit the “clean” area of the cultivation facility in the same way they enter, however the process for exiting will be done in reverse.

**How to Exit the Production Center:**

1. Exit the clean area through the Air-Lock Chamber
2. Enter the locker room
3. Change out of provided work wear attire/uniform
  - a. Scrubs
  - b. Hair nets
  - c. Hats
  - d. Garden shoes
4. Place used work wear in the proper laundry bin
5. Change back into street clothes
6. Exit the locker room
7. Exit the facility through the man trap.
  - a. Arm the security alarm system to *AWAY (if applicable)*

Emergency Protocol

<b>Standard Operating Procedure:</b> Emergency Protocol
<b>Purpose:</b> To describe all steps and protocols to be followed by employees should an emergency occur within the facility.



**Scope:** Procedures covering emergency situations occurring within the facility.

**Initial Training:** 2-4 hours

### **Documentation Log Sheets Required**

- 1) Emergency Situation Documentation Sheet

### **Equipment/Tools Required**

- 1) Panic Alarm/Button
- 2) Fire Extinguisher
- 3) Chemical Spill Kit
- 4) Emergency eye wash station(s)
- 5) First Aid Kit
- 6) Emergency defibrillator

### **The Principles of Emergency Protocols**

A facility emergency management plan is designed to educate and train facility employees on the actions and procedures to follow in the event of an emergency. In the case of an emergency, facility employees will need to respond quickly and think strategically in order to successfully manage the emergency situation. Having a good understanding of the facility emergency management plan will enable employees to better adapt to and handle emergencies.

The most important thing to remember during an emergency situation is to try to stay calm, if the emergency situation is out of your control and you need assistance, contact emergency services immediately if possible.



**Burglary:** Burglary is legally defined as the criminal offense of breaking and entering a building illegally for the purpose of committing a crime. Burglaries generally will occur at the Licensed Premise after operating hours and while there are no registered employees present. Typically burglaries occur during the night and are not discovered until the next day during normal operating hours.

- If upon entering the Licensed Premise and a registered employees notice something is afoul and upon investigation a burglary was determined to have occurred in the previous night, then registered employees will be required to document the incident and notify all required authorities.
  - Registered employees will be required to report the incident of burglary to:
    - The Commission
    - Local medical marijuana authority (*if applicable*)
    - Local police



**Robbery or Theft:** Robbery is legally defined as the taking of money or goods in the possession of another, from his or her person or immediate presences, y force or intimidation. The number one rule registered employees will need to follow when/if dealing with a robbery is to comply with all robber demands

- If you are being robbed at gunpoint or if you feel as if your life is in danger, comply with all requests from perpetrator/suspect. Give them whatever they ask for.
- Try to signal for help using the personal security panic buttons provided, by activating one of multiple, strategically placed panic alarm buttons, or through the panic button/police services button located on the alarm panel.
- Contact law enforcement as soon as possible
- Notify any required State or local authorities immediately (within 24 hours)
  - Local police services
  - The Commission
- Comply with all applicable laws and regulations
- Document the situation in the *Emergency Situation Documentation* log sheet



Alarm Panel



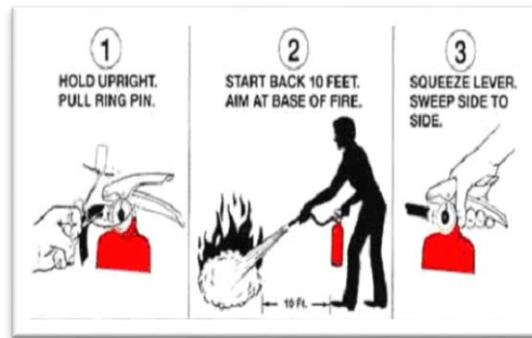
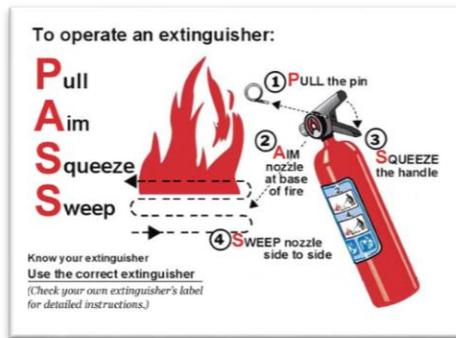
Panic Alarms/Buttons



**Fire Emergency:**

- If a small isolated fire is present, try to exhaust the fire with one of the fire extinguishers on site
- In case of a fire emergency, first leave the facility; once clear of the facility dial 911 and/or local fire authority for Fire Emergency Services or push the symbol on the alarm panel for fire emergency upon exiting the facility
- Document the situation in the *Emergency Situation Documentation* log sheet

**Fire Emergency Cont.**



**Chemical Emergency:**

- Dangerous Substance/Chemical Exposure:
  - If an employee accidentally has their eyes exposed to toxic, poisonous or dangerous substances or chemicals; said employee will need to locate the installed emergency eye wash station(s) to properly flush and clean their eyes. Notify emergency medical services for further assistance
- Chemical Spill:



- Try to use a chemical spill kit for smaller incidents of chemical spill
- If a chemical spill is large or you do not know how to handle the situation; get the facility manager to handle the situation and/or contact proper emergency services
  - Posted near or included with the chemical spill kit should be an emergency contact information sheet displaying which emergency services should be contacted.
    - For the BPH and the State of Hawaii this will include but not be limited to:
      - Environmental Protection Agency (EPA)
        - For emergencies and other sudden threats to public health, such as:
          - oil and/or chemical spills,
          - radiation emergencies, and
          - biological discharges,
            - call the National Response Center at 1-800-424-8802.
          - For **pesticide poisoning**, call 911 if the person is unconscious, has trouble breathing, or has convulsions. Otherwise, call **Poison Control at 1-800-222-1222**.
- Document the situation in the *Emergency Situation Documentation* log sheet



### Medical Emergency:

- If it is a minor medical situation such as a small cut, scrape or minor burn; retrieve the first aid kit on site and treat wound with items found in the first aid kit
- If the situation appears to be a severe medical situation such as someone suffering from a heart attack, retrieve the emergency defibrillator and follow the instructions provided; notify 911 or local medical emergency services for further assistance
- If the medical situation is an emergency; contact medical emergency services immediately. This can be done through activating the medical response button found on the alarm panel, or by calling 911 for medical emergency services
- If a serious injury occurs while an employee is working, such as a slip and fall resulting in possible broken bones or a cut requiring stitches, BPH facility management will need to complete a worker compensation insurance claim form prior to the employee seeking medical assistance. This procedure does not take long, but the form will need to be completed in order for the injured employee to have a workers compensation medical claim.
- Document the situation in the *Emergency Situation Documentation* log sheet



**Other Emergencies:**

- Contact 911 if it is a current emergency. Contact your local police and/or State regulatory authorities for break-ins or burglaries that may have occurred when the facility operations were closed
- Contact any required State or local authority in cases of theft, break-ins or burglaries
- Document the situation in the *Emergency Situation Documentation* log sheet



**Example of Emergency Situation Documentation Log Sheet:**

<u><b>Emergency Situation Documentation</b></u>		
Date:	Reporting Employee:	Manger on Duty:
Type of Emergency: <input type="checkbox"/> Robbery of Theft <input type="checkbox"/> Fire Emergency <input type="checkbox"/> Chemical Spill <input type="checkbox"/> Medical Emergency <input checked="" type="checkbox"/> Other Emergency		
Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO		Which Authorities:
Description of the Incident:		





Loss of Personnel

**Standard Operating Procedure: Loss of Personnel**

**Purpose:** To describe all steps and protocols to be followed prior to or after the loss of personnel.

**Scope:** Procedures covering loss of personnel situations occurring within the facility.

The following will cover procedures to follow when terminating a key employee as well as when a key employee decides to leave the organization on their own accord.

**Job Termination**—if the need arises to terminate the position of a key personnel there will be some basic steps and procedures to follow within operations.

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e. employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel
4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e. mutual separation and key personnel is always welcome back at BPH facilities under visitor status, employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was previously filled by key personnel. Key personnel positions will need to be filled as soon as possible by ownership and/or management without sacrificing quality of applicant pool. Some basic steps should be followed to find and place a suitable replacement for the vacant position.

1. Review resumes and applications from qualified applicants
2. Call said qualified applicants to conduct an informal, initial phone interview
  - a. If you get a good response from applicant, schedule an in-person interview
3. Conduct in-person interviews with qualified applicants
4. Review interviewed applicants
  - a. Select applicant who is most qualified for the vacant position
5. Contact said applicant and offer the vacant position
6. If applicant accepts the job offer, proceed with normal hiring procedure and required paperwork



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# STANDARD OPERATING PROCEDURES

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*State Of Hawai'i Production Center—Manufacturing Operations*





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**-----STATE REGULATORY COMPLIANCE DISCLOSURE-----**

*Medical marijuana facilities operate in a highly regulated industry, as such adherence to all applicable state and local laws pertaining to the cultivation, production, manufacturing, possessing and dispensing of marijuana and/or marijuana-infused products within the facility is of utmost importance. State and local laws and regulations will vary among states; it is recommended to read and have good understanding of the state and local laws and regulations in which you operate. Having a good understanding of the state and local laws is the first step in being educated on how to operate within regulations, the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within a regulated market.*

**-----CONFIDENTIALITY DISCLOSURE-----**

“Confidential Information and Intellectual Properties” means and includes any tangible or intangible information or material that is confidential or proprietary to Consultant that Client may obtain knowledge of through, or as a result of, its relationship with Consultant. Such information shall be deemed Consultant’s Confidential Information and Intellectual Properties whether or not owned or developed by Consultant. Confidential Information and Intellectual Properties shall also include, but is not limited to, any inventions, processes, designs, formulae, trade secrets, Standard Operating Procedures, know-how, confidential information, trademarks, copyrights, service marks, domain names, computer software, data and documentation, and all similar intellectual property.

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**DEFINITION**

Manufacturing Infused Product (“MIP”)—refers to the production center where manufacturing activities and operations occur. Also can refer to manufactured marijuana products.



Employee Qualifications

<b>Standard Operating Procedure:</b> Employee Qualifications
<b>Purpose:</b> To determine the qualifications possessed by registered employees
<b>Scope:</b> To evaluate prospective and current registered employee qualifications
<b>Initial Training:</b> TBD

BPH’s employment qualifications and requirements are detailed within the Employee Handbook which is a separate, additional document that can be viewed upon request.

**JOB DESCRIPTIONS/QUALIFICATIONS:**

A detailed Job Description will be developed for each employment position within the production facility. The following is a list of the initial anticipated employment positions:

- General Manager
- Extraction Manager
- Extraction Techs
- Production Manager
- Production Techs
- Quality Control
- Sanitation Associates
- Logistics Tech

**Duties, Authority, Responsibilities and Qualifications of Personnel:**

It is Company policy to employ individuals who are qualified to properly perform their assigned job responsibilities. These employee qualifications in compliance with applicable State regulations shall be documented in the job description and may consist of age restrictions, formal education, work experience, criminal history background checks, in-house training or combination thereof. Each job description summary will include a list of duties, authority, responsibilities and qualifications of personnel which will be used to determine employee qualifications for hiring and training purposes.

The Job descriptions will also include a list of the standard operating procedures that position is required to know.

**FACILITY EMPLOYMENT POLICIES:**

The following are general employment qualifications and training policies for the facility:

- 1) Documentation of each employee's formal education (degrees completed, courses taken, etc.) shall be kept on file.
- 2) Where appropriate, a summary of previous work experience (i.e. a resume) shall be adequate documentation to demonstrate an employee's qualifications to perform or supervise facility operations.
- 3) Supervision of Personnel: Given the sensitive nature of the industry it is vital that employees are adequately supervised at all times and in compliance with security protocols (see security plan guide). The Job Descriptions for each position includes identification of the reporting supervisor. The extraction and production manager will be onsite and is responsible for the overall supervision of all employees.
- 4) Adherence to Confidentiality Requirements: Each Employee and/or agent of the Company will be trained in and required to adhere to the Company’s confidentiality requirements. Each employee will be required to sign a Non-disclosure Agreement, as well as a Confidentiality Statement representing their covenant with the Company.



5) Periodic Performance Evaluations and Disciplinary Actions: Performance evaluations will occur bi-annually. The performance evaluations will be written and maintained in the employee's personnel file. This information will be used to determine compensation and pay increases as well as disciplinary actions and grounds for dismissal.

6) A written record documenting the completed individual training procedures shall be signed by the participants and trainer during each training session.

7) All company employees will attend in-house training conducted by qualified individuals in HACCP, current Good Manufacturing Procedures (cGMPs), and general sanitary practices and in the specific Standard Operating Procedures (SOPs) which pertain to their assigned work responsibilities. Such training shall be performed on an ongoing basis to assure the employee is familiar with these procedures and practices. Additionally each employee will supplement their training with review of relevant video educational materials for example:

**HACCP Video:**

Part 1 - [https://www.youtube.com/watch?v=7nbjd\\_TnU8o](https://www.youtube.com/watch?v=7nbjd_TnU8o)

Part 2 - [https://www.youtube.com/watch?v=gRJ7q\\_2Vkrc](https://www.youtube.com/watch?v=gRJ7q_2Vkrc)

**Principles of GMP**

<https://www.youtube.com/watch?v=JHkGgFUuZwE>

8) The General Manager/Quality Assurance Manager shall exercise oversight of the organizations practices and procedures and who have documented training and experience in quality assurance and quality procedures.

9) All registered employees will be twenty-one (21) years of age or older.

10) All staff members who could potentially come in contact with or handle medical marijuana or medical marijuana products will not include anyone who has been convicted of any felony of sale or possession of drugs, narcotics or controlled substances in accordance with the requirements of section thirty-three hundred sixty-four of the public health law.

11) All staff members who could potentially come in contact with or handle medical marijuana or medical marijuana products will not include anyone who has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding.

12) All staff members who could potentially come in contact with or handle medical marijuana or medical marijuana products shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by the Department.

13) Personnel engaged in the manufacture, processing, packing or holding of medical marijuana products shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand and arm coverings, shall be worn as necessary to protect products from contamination.

14) Any person shown at any time to have an apparent illness or open lesions that may adversely affect the safety or quality of a product shall be excluded from direct contact with components, product containers, closures, in-process materials and finished products. All personnel shall be instructed to inform their supervisor of any health conditions that may have an adverse effect on a product. All personnel shall practice good sanitation and health habits.

15) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, holding or shipment of each product. Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as a limited-access area. Records shall be maintained identifying those areas individuals are authorized to enter.

16) Consultants advising on the manufacture, processing, packing, holding or shipment of medical marijuana products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained with the name, address, and qualifications of any consultants and the type of service they provide.



## **FACILITY TRAINING PLAN:**

The training program for all manufacturing employees will include but is not limited to the following areas of focus:

1. Training on Commission Statutes and Rules and Other State and Local Laws and Regulations
2. Training on Company Standard Operating Procedures.
3. Training on Detection and Prevention of Diversion of Cannabis
4. Training on Security and the Company's Security System
5. Training on Hazards and Safety and Emergency Procedures such as a Medical Emergency, Fire, Chemical Spill, Security and a Threatening Event.
6. Training on Inventory Control and Record Keeping
7. Annual training to update and reinforce knowledge in above areas

All employees will attend in-house training conducted by qualified individuals in Current Good Manufacturing Practices (cGMP), general sanitary practices, and in the specific Standard Operating Procedures (SOPs) that pertain to their assigned work responsibilities. Such training will be performed on an ongoing basis to ensure the employee is familiar with these procedures and practices. A written record documenting the completed individual training procedures will be signed by the participants and trainer during each training session. Each SOP will include a section for signature of the employee to indicate they have completed training in the performance of the procedure.

The Department of Human Resources, in coordination with unit directors, is responsible for the development and execution of employee training. The Human Resources department will work in coordination with Quality Control and the Compliance Department to develop the curriculum for the Company's training system. Human resources and department heads are responsible to the Compliance Department who has the ultimate oversight responsibility for training requirements, and for auditing department training records.

The company shall develop a detailed training manual for the education of processor agents employed at the facility. In addition to the Company's training manual, additional training materials will be made available such as video presentations, industry guides, and GMP publications and other literature. These will be maintained within the facility in a library of information at all times available to the staff.

The company shall additionally make its training materials and attendance records available at all times, onsite, at our Production Facility for inspection by the Commission or its authorized representative.

The TRAINING MANUAL may include the following areas of focus:

1. A new-hire orientation training section - All new employees will go through an orientation training before starting their employment. The training manual will include an orientation section containing a review of all company policies, such as drug-free workplace rules and confidentiality requirements. This phase of training will also include an orientation to the SOP system and how to use it on the job.
2. Laws and Regulations: This section of the training manual will include critical laws and regulations the Company and employees are subject to. Certain of these laws and regulations will also be incorporated into the company's SOPs.
3. SOP training curriculum -The training manual will include a comprehensive copy of the Company's SOPs. The primary training curriculum for processor agents for the performance of their duties will be the SOPs themselves. The SOPs will have an administrative section which will include a signature line for employees and managers to indicate proficiency. This documentation will go into the employee's files to be available for audit and for inspection by the commission.
4. Detection and prevention of diversion - This section of the training manual will be created with the assistance of our professional security consultant. They will also develop the security plan for the company and will perform training sessions for the employees.
5. Processor Facility Security - This section of the training manual will be created with the assistance of our professional security consultant. They will also develop the security plan for the company and will perform training sessions for the employees.
6. Safety and emergencies - This section of the manual will be created with the assistance of our security consultants, processor consultants and local fire and safety agencies. All employees will be trained on emergency situations and periodic drills will be performed to ensure preparedness.

7. Inventory Control - The training manual will include a section that provides an overview of inventory control. The inventory control system is a third party software system which will have a comprehensive user manual. This user manual will be retained onsite and will be available for inspection at all times by the commission.

Consultants advising or training on the manufacture, processing, packing, holding or shipment of medical marijuana products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained with the name, address, and qualifications of any consultants and the type of service they provide.

#### **DOCUMENTATION**

Attendance at formal training classes will be mandatory and documented. Additionally, specific training on SOPs, including applicable laws and regulations, will be signed off by both the employee and a supervisor. This documentation will be retained in the employee's personnel file so that it can be audited by the compliance division. Human resource files and training documentation will be maintained in hard copy and an electronic environment for ease of interaction, retention, and inspection by the commission. Employment contracts will specify attendance at training classes, and in the event the employee does not complete the required training in the specified time, this would be grounds restricting their hours until the training is completed and ultimately dismissal.



<b>Standard Operating Procedure:</b> Standard Operating Procedures
<b>Purpose:</b> To explain the standard operating procedures needed to be adhered to within the Licensed Premise
<b>Scope:</b> To cover the education and training required pertaining to the standard operating procedures utilized within the Licensed Premise.
<b>Initial Training:</b> TBD

**Definitions**

**Standard Operating Procedure (SOP)**—a set of step-by-step instructions to achieve a predictable, standardized, desired result often within the context of a longer overall process. At its simplest, an SOP is a repeated application of unchanged processes and procedures and its documentation. These SOP’s are to be followed as directed and not deviated for the cultivation of marijuana within any Blue Planet Healing LLC (BPH) registered production centers.

**Material Change**—a material change is defined as a major deviation from the standard procedure, or changing the procedure or methodology drastically enough to notice a change. The material change is important enough to notice or to have an effect on the standard operating procedure.

**Principles of Standard Operating Procedures**

The cultivation of marijuana can be difficult for the rudimentary gardener. American Marijuana Company’s (ACC) Standard Operating Procedures (SOP’s) insure consistent production of high quality medical marijuana. BPH will utilize said SOP’s for all marijuana cultivation methodologies and operations. Understanding and abiding by the following SOP’s is mandatory for all registered employees working within BPH’s registered dispensary facilities.

The standard operating procedures must be practiced and utilized to cultivate each plant and to produce each batch of marijuana. The strict adherence to the written SOP’s will aid in BPH’s quality control program and measures. The written SOP’s have been developed within a regulated marijuana industry with the purpose of creating systems and procedures that result in a consistent and reproducible marijuana product. The cultivation process is broken down into each week of the plant’s lifecycle. Apply the following SOP instructions to the lifecycle of each plant in the facility. Do not deviate from exact instruction within these standard operating procedures.

- Failure to practice and utilize BPH’s written standard operating procedures is grounds for disciplinary action and possible job termination.

Written standard operating procedures will be utilized for all cultivation activities and operations, for the cultivation of all marijuana plants to ensure consistency of the batch with the variety and for accuracy of the day-to-day production. The written standard operating procedures will ensure consistency of batch and accuracy of day-to-day production if utilized properly and not deviated from.

- Registered employees will be required to record and maintain documentation log sheets and forms to record the cultivation process
  - Required documentation and record keeping is highlighted throughout the SOP’s and indicates which documentation log sheets and records are to be taken and maintained.
    - Registered employees will need to pay careful attention to each standard operating procedure to ensure proper documentation and record keeping
      - The documentation should demonstrate consistency of batch with the medical marijuana variety being cultivated
      - The documentation should also demonstrate the accuracy of the day-to-day production within the Licensed Premise.
- Any major deviation from the standard operating procedure defined as a material change that could impact the quality of batch must be documented, recorded and maintained on the Licensed Premise
  - Registered employees are required to document any major deviation in production of a batch from the standard operating procedure



### Deviation/Material Change to Standard Operating Procedures

Upon recognizing the need for or making a material change to a standard operating procedure, registered employees will be required to document the material change within the *Material Change to SOP's* log sheet and update the current SOP to reflect the material change.

<b><u>Deviation/Material Change to SOP's</u></b>		
<b>Date:</b>	<b>Registered Employee:</b>	<b>Deviation in Production:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Reason for the deviation</b> ( <i>identify and describe in detail the deviation from the SOP</i> ):		
<b>SOP requiring material change:</b>		
<b>Material Change made to the SOP</b> ( <i>please describe in detail</i> ):		
<b>SOP Updated?</b> <input type="checkbox"/> YES	<b>Date Updated:</b>	<b>Update By:</b>
<b>Manager/Supervisor Awareness and Approval:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Manager/Supervisor Signature:</b>	
<b>Sample of production batch with deviation sent to independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Sample of production batch with deviation determined to meet specifications for the variety by BPH and the independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>Medical Cannabis Batch Released for Distribution?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Additional Notes/Comments:</b>	
<i>After documentation of a material change to a standard operating procedure, registered employees will be required to maintain the record of material change within a limit-access and secured area of the Licensed Premise.</i>		

### Deviations in Production—Independent Laboratory Testing

Per State of Hawai'i regulations, BPH will not release any batch of marijuana or manufactured marijuana products if there was any deviation in production from the batch from the standard operating procedure. All medical marijuana will need to be securely held and stored until:

- The sample from the batch of marijuana and/or manufactured marijuana product with any deviation in production is sent to an independent testing laboratory for testing
  - The marijuana will not be released for distribution until after an independent testing laboratory and BPH determines, as a result of testing, that the batch meets the specifications for the variety and the determination is recorded.
- Follow *Samples for Laboratory Testing* and the *Transferring/Transporting and Shipping Medical Marijuana* standard operating procedures for procedures and requirements pertaining to laboratory testing and transport.
  - Ensure to follow Sampled for Laboratory Testing
    - Fill out and record all required documentation log sheets
      - Fill out *Material Change Samples for Laboratory Testing* log sheet (*can be seen below*)



**Material Change Samples for Laboratory Testing**



<b>Date:</b>	<b>Employee:</b>	<b>Attribute ID #/Product Batch #/Strain:</b>	<b>Sample Quantity:</b>	<b>Sample Attribute ID # (NEW) :</b>	<b>Receiving Laboratory:</b>



State Regulatory Compliance

<b>Standard Operating Procedure:</b> State Regulatory Compliance Training
<b>Purpose:</b> To explain the regulatory compliance needed to be adhered to in the State of Hawai'i.
<b>Scope:</b> To cover the regulations enacted within Hawaii pertaining to legally operating a marijuana business.
<b>Initial Training:</b> training done on individual time

**Required Documents**

- 1) State Regulations
- 2) Local/City Regulations (*if applicable*)

**The Principles of State Regulatory Compliance Training**

BPH will require all registered employees to read and become familiar with the State and Local/City regulations that have been enacted pertaining to operating a legal, licensed marijuana business.

BPH will keep a physical, up-to-date copy of any and all laws and regulation in which you must operate under at every licensed facility. Every registered employee will receive a hard copy of the laws and regulation which they can read and become familiar with.

Key State Regulations Employees Should be Familiar With:

- Who can have access to the facility
  - Visitor process
- Packaging and labeling compliances and requirements
- Allowed purchase amounts (quantities and distribution timeframe)
- Hours of allowed operation
- Inventory tracking and required record keeping
- Security procedures and protocols
- Laboratory testing requirements
- Transportation of marijuana products
- Etc.

**State of Hawaii**

- <http://health.hawaii.gov/medicalmarijuana/>



Record Keeping and Documentation

<b>Standard Operating Procedure:</b> Record Keeping and Documentation
<b>Purpose:</b> To ensure that all required marijuana cultivation records and data are properly recorded and documented. Including zone/room environments, transplant logs, IPM applications, inventory, etc.
<b>Scope:</b> Procedures covering record keeping and documentation for activities within the cultivation Licensed Premise.
<b>Initial Training:</b> 4-8 hours

### **What is the Purpose of Record Keeping and Documentation?**

Marijuana cultivation facilities operate in a highly regulated industry, as such proper record keeping and documentation are essential within the cultivation facility. Having records of crop inputs such as growing media records and pesticide applications will aid during the cultivation process to ensure proper feedings occur and that plants are not treated with chemicals more than absolutely necessary.

### **Equipment/Tools Required**

- 1) Pen or pencil
- 2) Clipboard
- 3) Log Sheets

### **Principles of Record Keeping and Documentation**

Adherence to all applicable state and local laws pertaining to the cultivation of marijuana within the production center facility is of utmost importance. State and local laws and regulations will vary among states; having a good understanding of the state and local laws is the first step in being educated on the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within Hawai'i's regulated market.

Required records and documentation are noted throughout the written Standard Operating Procedures; BPH's registered employees will be required to make such records and documentation as part of their job responsibilities. Registered employees will be required to make two sets of all records and documentation; one set of records and documentation will be made within the BioTrackTHC™ inventory control system, and a second set of records and documentation will be made using physical log sheets and templates. The physical records and documentation will be maintained on at the production center within a limited access area. Failure to create and maintain records and documentation will be grounds for disciplinary action and/or job termination.

Record Keeping and documentation are noted within other SOP's where documentation is required. The SOP's will also reference which documentation records and log sheets are required to be filled out and maintained.

### **Manufacturing Operational Records:**

- Manufactured Marijuana Products—Inventory
- POS Inventory
- Inventory Reconciliation
- Daily Marijuana Products Transfer/Shipping Log
- Marijuana Waste Log
- Finished Marijuana Log
- Cleaning and Sanitation Log
- Product Recall Log
- Returned Marijuana Log
- Employee List
- Visitor Documentation Log
- Etc.

## **Secondary Records**

BPH will maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution. BPH will require registered employees to maintain secondary records on the Licensed Premise. The physical records and documentation log sheets will serve as secondary, back-up records and documentation that will be maintained independent of the inventory control system.

Per Hawaii regulations, records required to be maintained separate of the inventory control system:

- **Records of Each Distribution**
  - Records of distribution must include:
    - The name and address of the recipient retail dispensary location
    - The quantity delivered
    - The name, strength, batch number of the product

### **Requirements of Secondary Records:**

- Records must be maintained independent of the inventory control system
  - Physical records will be maintained within a file cabinet, separate from the inventory control system
- Records must be searchable
  - Records will be organized and filed alphabetically according to recipient name
- Records must be secure
  - Records will be maintained within the Licensed Premise, located within a limited-access area inside a manager office equipped with an independent security alarm system. The records will be held within a lockable filing cabinet inside the secure office.
- Records must be tamper-evident
  - The file cabinet where secondary records are to be maintained will have a secure, tamper-evident locking mechanism on it.

## **Records and Documents Storage Retention**

Unless otherwise specified, BPH will retain and maintain all records and duplicate sets of records for a minimum of six (6) years.

### **Duplicate Records and Off-Site Storage**

BPH will maintain duplicate sets of all records required by regulation. These duplicate copies of BPH records will be maintained at a secure, off-site location. This location will only be disclosed to personnel with proper security clearance. The off-site record storage will be secured with a security alarm and surveillance system to ensure access is limited to authorized personnel only. BPH will maintain duplicate copies of all records at a secure storage facility within Hawaii.

## **Reports**

BPH can generate a list of the products and their specifications that have been offered for distribution. These reports can to be provided to the Department upon request.

- Reports can be created through the BioTrackTHC™ inventory control system
  - Within the inventory control system, BPH will be able to generate a list of all the products along with their specifications that were offered for distribution
  - This list can be generated for all products offered within specific date ranges



General Security/Diversion Prevention Training

<b>Standard Operating Procedure:</b> General Security/Diversion Prevention Training
<b>Purpose:</b> To explain the general security and diversion prevention training needed to be adhered to.
<b>Scope:</b> To understand security and diversion prevention training requirements.
<b>Initial Training:</b> 4-8 hours

**Diversion and Trafficking Prevention Training**

Diversion and trafficking prevention will primarily be done using the various security alarm and surveillance equipment installed and utilized at BPH’s production facility. The various security alarm and surveillance equipment utilized is explained in more detail within the Security Plan which is a separate, additional document that can be viewed upon request. All BPH registered employees will be trained on all security equipment, measures and policies prior to commencing work within the production center.

BPH will utilize BioTrackTHC’s inventory control system and industry best practices and policies to reduce the risk of diversion and theft of marijuana products. All marijuana plants will be tagged, recorded and tracked through the inventory control system from seed-to-sale.

The use of professional security systems from Securitas that will be installed at all of organization facilities will also help to reduce the risk to diversion, loss, theft or unauthorized access.

If any marijuana or manufactured marijuana product loss or discrepancy noticed by a registered employee, management shall be made aware of the loss immediately. Inventory discrepancies should be easily noticeable with the use of the inventory control system. The diversion or product loss must be documented on the **Product Loss** log sheet which can be seen below.

<b><u>Product Loss Log Sheet</u></b>				
<b><u>Date:</u></b>	<b><u>Product Name/Category</u></b>	<b><u>Product Attribute # or Unique ID #</u></b>	<b><u>Total Quantity</u></b> <b><u>Loss:</u></b>	<b><u>Product Loss</u></b> <b><u>Valuation:</u></b>
				\$
<b><u>Reporting</u></b> <b><u>Employee:</u></b>	<b><u>Manager/Supervisor:</u></b>	<b><u>Product Loss Due To:</u></b>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<b><u>Internal</u></b> <b><u>Investigation:</u></b>	<b><u>Required Authorities</u></b> <b><u>Notified:</u></b>	<b><u>Authorities Notified (list all) :</u></b>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<b><u>Note/Comments:</u></b>				

### **Video Surveillance System.**

Securitas will design video surveillance systems at BPH's production center that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

### **Alarm System.**

Each production center operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

### **System Failure.**

In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

### **Other Security Measures.**

All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH- approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

### **Production Center Specific Security Measures.**

In addition to all the above mentioned and all other security measures required by HRS Chapter 329D and HAR Chapter 11-850, BPH will utilize a perimeter security fence around each PC that surrounds the entire premise sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any marijuana in any form as required by HAR §1185052 (1). In addition, BPH will secure all marijuana and manufactured marijuana products in a locked room, vault or container which is securely fixed to a wall or the floor to ensure product safety and to prevent theft.

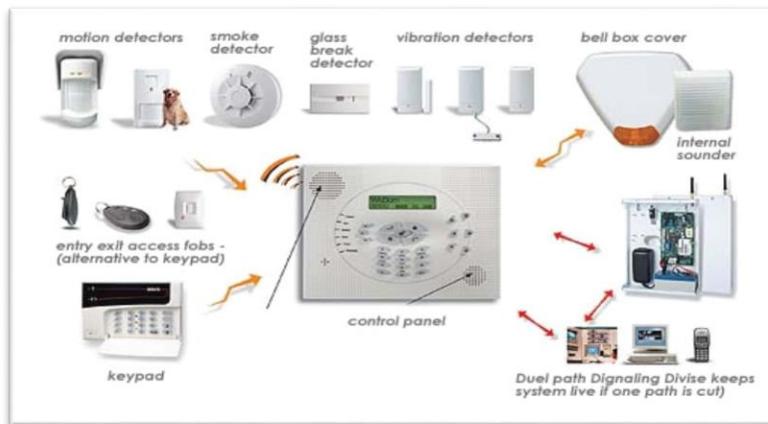
### **Transportation Security.**

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees. 3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH's tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be



packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

**Alarm Surveillance**—a primary alarm system will be installed at all BPH registered dispensary facilities by Securitas, a licensed alarm companies. An advanced security alarm system on all perimeter entry points, perimeter windows, and secured interior rooms. Motion detection equipment and camera equipment will be used to ensure the entire facility(s) is continuously safe from intrusion and product diversion.



**Video Surveillance**—an advanced video surveillance and recording system at all BPH facilities. All cameras will record in digital format and be maintained to meet the requirements outlined by State and local regulations. Video cameras will be maintained in each room and be used to identify any activity occurring within the room and be capable of recording and viewing in low light conditions. An onsite DVR and an additional offsite DVR will be utilized to store all footage; all video surveillance recording will be stored for a minimum of one year.



**Security Lighting**—security lighting around the entire perimeter of the production center to allow surveillance in low light conditions and deter potential intrusion.



**Motion Detector Alarms**—the professional security alarm system will utilize motion detectors that will detect intrusion and will automatically notify the proper authorities.



**Duress Alarms**—the security and alarm systems will utilize a duress alarm button on the alarm panels that can be pushed by employees in the case of an emergency. Different duress alarm buttons can be pushed to automatically notify the proper authority; police, fire or emergency services.



**On-Site Electronic Monitoring**—facility security rooms will have a large screen call-up monitor (at least 19”) and a video printer capable of immediately producing a clear still photo from all video cameras.



**Commercial Grade Door Locks**—commercial-grade, non- residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas. Key-card access door locks may also be utilized to further limit access at facilities.



**Safes and Product Storage**—Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana products and cash.



<b>Standard Operating Procedure:</b> Perpetual Inventory Control System
<b>Purpose:</b> To explain the principles and concepts of the perpetual inventory control system
<b>Scope:</b> To educate and train registered employees and licensed premise employees on the perpetual inventory control system
<b>Initial Training:</b> TBD

**Principles of the Perpetual Inventory Control System**

BPH will utilize a perpetual inventory system from a regulated marijuana industry-specific inventory system provider, BioTrackTHC™. This inventory control system has been developed specifically for the regulated marijuana industry and has been customized to include all marijuana business operational needs. The systems have been designed to be user friendly, the ability to be mobile, and with inventory control capabilities to track every medical marijuana plant and product from seed to sale.

The inventory control system will be designed to have the ability to promptly identify a discrepancy in stocks of marijuana plants and products. BPH administrators of the system will be notified of a substantial reduction in an inventory stock level and be prompted to investigate the inventory levels to insure no theft, diversion or discrepancies occurred. Administrators and users can run inventory reports from the inventory control system to check inventory stock levels that have been recorded in the inventory control system against a physical inventory audit to further determine inventory discrepancies.

**Inventory Control /POS System**—the tracking of all medical marijuana products from seed to sale will be done through inventory management through the use of template log sheets, computer systems, Secure Information Systems (SIS) and selected Point-of-Sale systems (POS). All medical marijuana plants and products are to be tagged, recorded and tracked through the inventory control system. Failure to do so can result in disciplinary action and/or job termination.



*\*Inventory control system and/or Point-of-Sale (POS) system training will be provided by an expert or consultant from the inventory control system supplier, BioTrackTHC™. This 3<sup>rd</sup> party training will be required for all BPH registered employees prior to working within the production center.*

Registered employees will be required to utilize the inventory control system to identify, record, monitor and track all medical marijuana plants and products from the time the medical marijuana is propagated from seed or cutting to the time it is delivered to a licensed dispensary, licensed processor or a qualifying patient or caregiver. The standard operating procedures detail multiple situations when plant tagging, monitoring and recording activities are required by registered employees within the production center.



Marijuana plants will be given a unique attribute number, assigned to a production batch which and recorded in the inventory control system. The plant will then be given a new and unique plant tag with the plants identification and specifications and be recorded in the inventory control system, the tag will remain with the plant throughout the plants lifecycle enabling the plant to be identified and tracked.

The inventory control system intended to be utilized within BPH's production center will in the event of a serious adverse event have the ability to track any marijuana plant or product back to the originating source, including the ability of tracking marijuana from a qualifying patient back to the source of the marijuana. The marijuana believed to have caused a serious adverse event should have a product label with product information and specifications such as the product name, unique attribute number, batch number and originating entity. With this information, the marijuana product will be able to be traced back to the originating source of the medical marijuana.



OSHA Compliance

<b>Standard Operating Procedure:</b> OSHA Compliance and Training
<b>Purpose:</b> To explain the principles and concepts of OSHA regulations.
<b>Scope:</b> To understand OSHA requirements to create a safe work environment.
<b>Initial Training:</b> 4-6 hours

### OSHA Training

Registered employees have the right to a safe workplace, and BPH intends to provide a safe work environment for all registered employees at all BPH facilities. The Occupational Safety and Health Act of 1970 (OSH Act) was passed into law as a preventative measure for workers from being killed or seriously harmed while at work. The law requires employers to provide employees with working conditions that are free from known dangers.

The OSH Act created the Occupational Safety and Health Administration (OSHA). This regulatory agency sets and enforces protective workplace safety and health standards. OSHA is also charged with providing information, training and assistance to workers and employers to educate and train individuals on workplace safety. Employees may file a complaint if they feel necessary which will result in OSHA to inspect the workplace if they feel OSHA standards are not being met or that there may be serious hazards or danger. More information on the Occupational Safety and Health Administration can be found online at the website: <https://www.osha.gov/>.

**OSHA's Mission**—With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

**OSHA Training**—The OSHA Outreach Training Program for General Industry provides training for workers and employers on the recognition, avoidance, abatement, and prevention of safety and health hazards and dangers in workplaces in general industry. This program also provides information regarding workers' rights, employer responsibilities, and how to file a complaint. Employees can attend a 10-hour or 30-hour class delivered by OSHA-authorized trainers. The 10-hour class is intended for entry level workers, while the 30-hour class is more appropriate for supervisors or workers with some safety responsibility. OSHA training helps to ensure that workers are more knowledgeable about workplace hazards, dangers and their rights.

Under the OSH Law, employers have a responsibility to provide a safe workplace free from known hazards or dangers. The OSHA website provides a short summary of employer responsibilities with which BPH will ensure compliance.

- Provide a workplace free from serious recognized hazards and comply with standards, rules and regulations issued under the OSH Act.
- Examine workplace conditions to make sure they conform to applicable OSHA standards.
- Make sure employees have and use safe tools and equipment and properly maintain this equipment.
- Use color codes, posters, labels or signs to warn employees of potential hazards.
- Establish or update operating procedures and communicate them so that employees follow safety and health requirements.
- Employers must provide safety training in a language and vocabulary workers can understand.
- Employers with hazardous chemicals in the workplace must develop and implement a written hazard communication program and train employees on the hazards they are exposed to and proper precautions (and a copy of safety data sheets must be readily available). See the OSHA page on Hazard Communication.
- Provide medical examinations and training when required by OSHA standards.
- Post, at a prominent location within the workplace, the OSHA poster (or the state-plan equivalent) informing employees of their rights and responsibilities.
- Report to the nearest OSHA office all work-related fatalities within 8 hours, and all work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours. Call our toll-free number: 1-800-321-OSHA (6742); TTY 1-877-889-5627. [Employers under federal OSHA's jurisdiction were required to



begin reporting by Jan. 1, 2015. Establishments in a state with a state-run OSHA program should contact their state plan for the implementation date].

- Keep records of work-related injuries and illnesses. (Note: Employers with 10 or fewer employees and employers in certain low-hazard industries are exempt from this requirement.)
- Provide employees, former employees and their representative's access to the Log of Work-Related Injuries and Illnesses (OSHA Form 300). On February 1, and for three months, covered employers must post the summary of the OSHA log of injuries and illnesses (OSHA Form 300A).
- Provide access to employee medical records and exposure records to employees or their authorized representatives.
- Provide to the OSHA compliance officer the names of authorized employee representatives who may be asked to accompany the compliance officer during an inspection.
- Not discriminate against employees who exercise their rights under the Act. See our "Whistleblower Protection" webpage.
- Post OSHA citations at or near the work area involved. Each citation must remain posted until the violation has been corrected, or for three working days, whichever is longer. Post abatement verification documents or tags.
- Correct cited violations by the deadline set in the OSHA citation and submit required abatement verification documentation.
- OSHA encourages all employers to adopt an Injury and Illness Prevention Program. Injury and Illness Prevention Programs, known by a variety of names, are universal interventions that can substantially reduce the number and severity of workplace injuries and alleviate the associated financial burdens on U.S. workplaces. Many states have requirements or voluntary guidelines for workplace Injury and Illness Prevention Programs. Also, numerous employers in the United States already manage safety using Injury and Illness Prevention Programs, and we believe that all employers can and should do the same. Most successful Injury and Illness Prevention Programs are based on a common set of key elements. These include: management leadership, worker participation, hazard identification, hazard prevention and control, education and training, and program evaluation and improvement. OSHA's Injury and Illness Prevention Programs topics page contains more information including examples of programs and systems that have reduced workplace injuries and illnesses.

### **Plan for OSHA Compliance**

Below details BPH's plan for compliance with OSHA will begin by ensuring that all organizational facilities are free from known hazards and/or dangers. Although OSHA is a federal organization and we are not currently held to OSHA standards, BPH feels it is best practices to be aware of OSHA guidelines and adhere to said guideline within our operations.

All registered employees will be provided basic training covering workplace safety pertaining to identifying and preventing potential hazards and or dangers such as trip hazards. This basic training will begin with training all new employees on policies and procedures. Proper and adequate training can help to reduce workplace accidents through educating and training employees on operations, policies and procedures. Employees will be given a tour of the facility property and areas in which the employee will have access to (limited or restricted). Other training to be included in BPH's plan for OSHA compliance will include:

- Training on SOP's
- Regulatory compliance training (laws and regulations pertaining to medical marijuana cultivation, processing or dispensing)
- Basic training on workplace safety
- Recognition of potential workplace hazards or dangers



<b>Standard Operating Procedure:</b> Employee Dress Code and Personal Hygiene
<b>Purpose:</b> To explain the employee dress code required.
<b>Scope:</b> Covers the dress code requirements for employees.
<b>Initial Training:</b> 30 minutes

### **Principles of Employee Dress Code**

The cultivation facility is considered a “clean” room type setting and as such employees of the cultivation facility will be required to change out of street clothes and into provided work wear to be worn during all scheduled work shifts. The work wear will consist of medical-type scrubs and garden shoes.

Employees are expected to arrive at facilities and enter the locker rooms immediately after entering the facility to shower and change into provided work wear. This will reduce the cultivation P areas from exposure to outside contaminants such as pests and diseases.

**Registered employees**—BPH registered employees working will be required to wear approved attire while working within the production center.

- Registered employees will be provided work attire to be worn while working within the Licensed Premise.
  - Work uniform such as scrubs
  - Closed-toe garden shoes such as Crocks
  - Hat (*optional*)

**Transportation Agents**— BPH registered employees working will be required to wear approved attire while on duty. Transportation agent work attire will differ from that of registered employees due to State regulations mandating transportation agents must not have any identifying logos or markings that could indicate ownership or possession of marijuana.

- Transportation agents will be required to wear un-identifying work attire
  - Plain jeans or khakis pants
  - Plain polo or button-up shirt
  - Closed-toe shoe

### **Personal Hygiene Policy**

This policy has been set forth in order to ensure that all employees are practicing good personal hygiene to ensure that are products are produced in safest and most sanitary means possible. The personal hygiene policy includes but is not limited to the following:

- A. Maintaining adequate personal hygiene
  - a. Arrive to work clean in appearance/clean clothes.
  - b. Showering every day is essential
  - c. Deodorant and a clean personal smell is required
- B. Men must be neatly groomed/shaven
  - a. Mustaches or beards allowed if maintained
  - b. We reserve the right to ask you to wear a beard cover if we deem it necessary
- C. Long hair must be constrained in a neat manner to avoid hair coming into contact with food items
  - a. A hat or hairnet is preferred
  - b. Jewelry of any kind is not permitted

- i. This includes earrings, rings, bracelets, watches, etc.
- D. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and
  - E. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

### **General Sanitary Requirements**

BPH will take all reasonable measures and precautions to ensure that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for medical marijuana products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.

BPH will have hand-washing facilities that are convenient and furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

That all registered employees working in direct contact with processing, preparation, weighing or repackaging of medical marijuana products shall conform to hygienic practices while on duty, including but not limited to:

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the processing, preparation, weighing or repackaging of medical marijuana products and at any other time when the hands may have become soiled or contaminated; and
- Refraining from having direct contact with preparation of medical marijuana products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical marijuana products.

Registered employees are required to ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical marijuana products are exposed. Registered employees are required to ensure that floors, walls, and ceilings are adequately cleaned and kept clean and kept in good repair.

That the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

Registered employees must ensure that all contact surfaces, including utensils and equipment used for the preparation of medical marijuana products shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used with medical marijuana and used in accordance with labeled instructions;

BPH requires all toxic cleaning compounds, sanitizing agents, solvents used in the production of medical marijuana and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of medical marijuana products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. That medical marijuana products that can support the rapid growth of undesirable microorganisms will be held in a manner that prevents the growth of these microorganisms; and the storage and transport of finished medical marijuana products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.



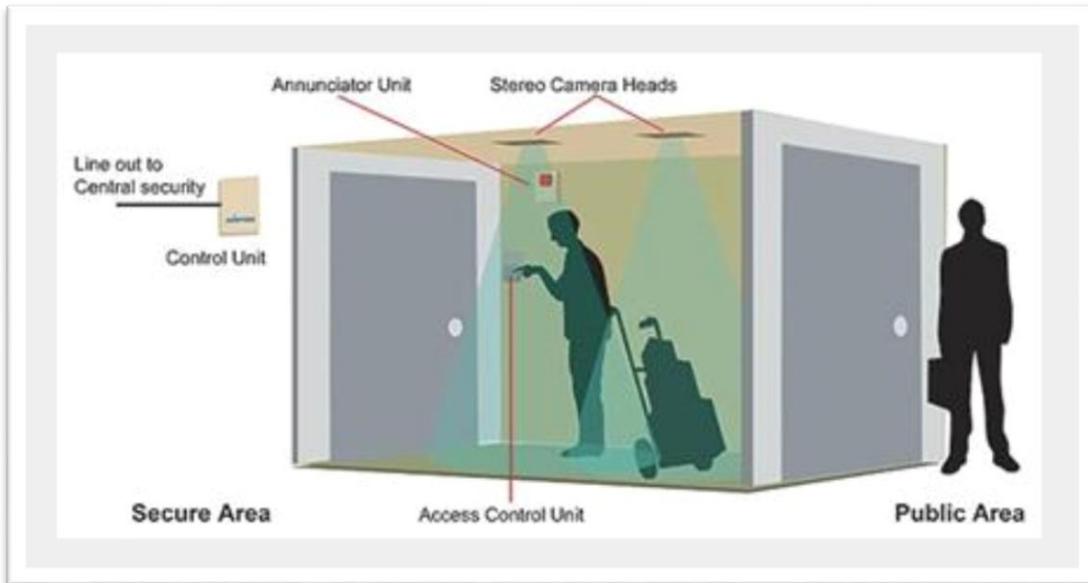
<b>Standard Operating Procedure:</b> Facility Entry Protocol and Good Handling Practices
<b>Purpose:</b> To explain how employees should enter the production center and procedures to follow to gain access to Limited Access Area(s).
<b>Scope:</b> Covers the steps involved for properly entering the production center as well as good handling practices
<b>Initial Training:</b> 2-4 hours

**Principles of Facility Entry Protocol**

The primary objective of having a specific facility entry protocol is to try to reduce the exposure and risk to outside contaminants from entering the facility. Containments can be anything from pests such as insects and diseases such as powdery mildew. It will be of utmost importance for employees to be mindful of where they have been immediately before arriving at the cultivation facility as this can determine the likelihood and types of contaminants possible.

Upon arriving at the cultivation facility, registered employees will enter the facility using their issued key/keycard or the like, enter the facility’s ‘entry vestibule’. This area is designed as a security measure against unwanted intruders. There will be a magnetic door that can only be opened by personnel with the proper security clearance. This door will be opened through the use of an access control unit.

***Example of a “Entry Vestibule”:***



Upon exiting the “Entry Vestibule” employees will head directly for the locker rooms where they will change out of all street clothes, take showers and change into provided work attire/uniform prior to entering the “clean” area of the cultivation facility.

**Locker Room Steps for Employees to Follow:**

1. Enter locker room
2. Remove **ALL** street clothes and place them in your locker
  - a. *ALL* clothes
    - i. Hats



- ii. Socks
    - iii. Shoes
  3. Take a shower
    - a. This is done as another preventative measure to ensure the production center is not exposed to any outside contaminants
  4. Change into provide work attire/uniform
    - a. Scrubs
    - b. Hair nets
    - c. Hat (optional)
    - d. Garden shoes

Upon successfully showering and changing into the provided work wear, employees will be ready to begin their work shift within the “clean” area of the production center.

Upon exiting the locker room, employees will go through an “air-lock” chamber to remove any remaining potential contaminants prior to entering the clean area. Upon exiting the Air-Lock chamber, the employee will be in the “clean” area of the production center.

***Example of an Air-Lock Chamber:***



**Good Handling Practices**

The indoor environment offers little help to registered employees in terms of biosecurity, so preventative maintenance and clean protocols are essential in operations. Plants are typically cultivated and arranged in close proximity and as such plants in close proximity to each other spread diseases, molds, mildews, and insects with ease in comparison to the natural growing conditions found outside. Due to this, very strict clean entry protocols, as well as quarantine, and biosecurity procedures are necessary.

The facility will be divided into a “clean zone” and a “dirty zone”.

- The clean zone represents any area where marijuana products will be whether in plant form, flower form, concentrate, or infused product.
  - All “clean zones” in the facility will require registered employees to follow the clean entry protocol to enter.
- The dirty zone represents any area where no marijuana product will ever be (excluding marijuana waiting destruction and disposal), including soil receiving, and administration offices.



Limited Access Areas

<b>Standard Operating Procedure:</b> Limited Access Areas
<b>Purpose:</b> To explain Limited Access Areas, who is allowed in these areas, and procedures to follow within the Limited Access Area.
<b>Scope:</b> Covers the steps involved in escorting visitors in limited access areas.
<b>Initial Training:</b> 1 hour

### The Principles of Limited Access Areas

A Limited Access Area is a building, room, or other contiguous area upon the Licensed Premises where medical marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee. Limited Access Areas are areas within the licensee's facility where only certain people will have the required permission to access.

Limited Access Areas may have people in them without the proper permission as long as the Visitor SOPs and state regulatory required protocols are followed. Registered employees will follow the *Visitor SOP*; with allowed visitors being escorted by a registered employee at all times while in the facility and Limited Access Areas.

Limited access areas should be limited to State licensed, facility employees only. If a visitor needs to access the limited access areas, registered employees will be required to follow the written *Visitor SOP*.





Visitors

<b>Standard Operating Procedure: Visitors</b>
<b>Purpose:</b> To explain the processes involved to accept/allow visitors into the retail dispensary.
<b>Scope:</b> Covers the required steps to follow to allow visitors into the facility.
<b>Initial Training:</b> 1 hour

**Requirements**

- 1) Visitor Log Sheet
- 2) Visitor pass

Pursuant to 329D-15 and 329D-16, unauthorized access to retail dispensing locations and/or a production center is a Class C felony. Due to the strict penalties for infractions, BPH will take steps to identify all potential subcontractors, maintenance workers, and any other individual identified as needing to visit one of BPH retail dispensing locations or our production center. Such steps will allow said individuals to submit proactively to fingerprint cards and background checks and be aware of the information submitted to the Department. In order to obtain Department approval, BPH also intends to identify secondary, back-up individuals who can be utilized as resources if the primary resource is unavailable; these secondary subcontractors and resources will also be required to submit fingerprint cards and authorize consent for background investigations to ensure the individual does not have any felony convictions or other offenses listed in §11-850-17.

**The Principles of Visitor Protocol**

BPH’s visitor protocol will follow industry best practices and current regulations. There will be situations that arise that will require someone to enter the registered dispensary facility premises who is not a State-licensed industry worker or not a State-registered patient or caregiver but they will need access to the facility. Common visitors typically will be support-type businesses such as HVAC, electric and plumbing, general contractors, etc.

All visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

Approved visitors will be required to provide a BPH registered employee with a current, valid government-issued identification. The registered employee will confirm the individual is on the BPH’s Department-approved list, make a photocopy of the visitor’s ID and maintain the photocopy with the visitor log book; visitors will be required to sign in and out with a registered employee and provide a written reason for the visit (e.g. maintenance work, HVAC, repairs, etc.). Upon completing these requirements, the registered employee will issue a ‘visitor badge’ for the visitor to wear and display while at any BPH registered dispensary facility. BPH will also require a registered employee to remain with the visitor for the duration of the visit to ensure the visitor does not interact with or handle any marijuana plant, material, product, or manufactured marijuana product.

- **Government-Issued ID**—all visitors must have a current and valid government-issued ID (passport, Driver’s License, military ID)
  - Ensure that the government-issued ID is current (check expiration date on ID)
- **Verification**—Verify the validity of the government-issued ID and that the visitor is on the current Department-approved list
- **Photocopy**— Make photocopy of visitor’s government-issued ID
  - Make a photocopy of visitor’s ID; Photocopy is to remain with *Visitor Log Sheet*

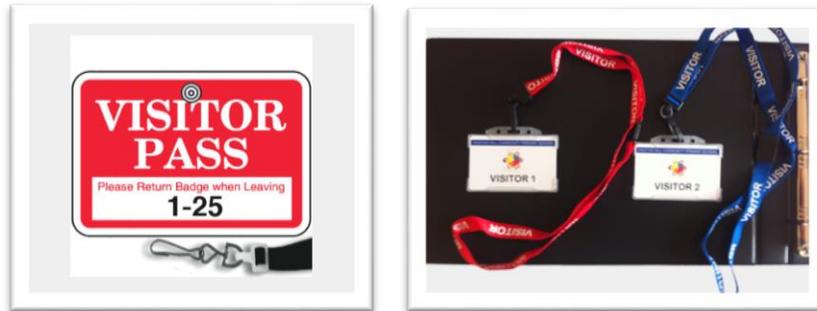


- **Access**—Allow or deny access to the facility
  - Allow entry to dispensary if the visitor has a valid government-issued ID.
  - Deny entry to the facility if the visitor does not have a valid government-issued ID.
- **Record/Documentation**—Have visitor fill out the *Visitor Log Sheet*
  - *Visitor Log Sheet* will document visitors name, company, date, time-in, time-out, signature, reason for the visit
  - Maintain photocopy of visitor ID with the *Visitor Log Sheet*
  - This record of visit must be retained and maintain on the licensed premise for a minimum of two (2) years.

**Visitor Access Process:**

- 1) Check visitors ID and credentials at the check-in station
  - a. Make photocopy of Visitor’s ID
- 2) Verify with management that visitors are expected and on the current Department-approved list
- 3) Fill out *Visitor Log Sheet*
- 4) Have said visitor sign-in and date the *Visitor Log Sheet*
- 5) Give visitor a ‘*Visitor Pass*’
- 6) When visitor is finished at the licensed premises:
  - a. Have visitor sign-out on *Visitor Log Sheet*
  - b. Collect the ‘*Visitor Pass*’ from said visitor

*Example of a Visitor Pass can be seen below:*



*Example of Visitor Sign-In Documentation Log Sheet:*

<u><b>Visitor Sign-In Documentation Log Sheet</b></u>							
<u>Date</u>	<u>Time In</u>	<u>Time Out</u>	<u>Visitor Name</u>	<u>Visitor's Company</u>	<u>Visitor Signature</u>	<u>Reason for Visit</u>	<u>Registered Employee Escort</u>



Receipt of Material

<b>Standard Operating Procedure: Receipt of Materials</b>
<b>Purpose:</b> Explain procedure and requirements for receiving raw materials
<b>Scope:</b> To educate and train licensed premise employees on the procedures and requirements involved with receipt of materials.
<b>Initial Training:</b> 1-2 hours

**Principles of Receipt of Material**

The process of receipt of material or receiving raw materials is not as simple as just taking the raw materials into the licensed premise. There are regulations, guidelines and procedures to follow when receiving raw materials or other inventory into the cultivation facility licensed premise.

Upon receiving any raw materials, inventory or other items used in operations said items will be placed in a quarantine storage area within the receiving area of the licensed premise. Employees will need to quarantine any materials received to be used to produce marijuana. These items will include but not be limited to:

- Medical marijuana seeds
- Medical marijuana cutting/clones
- Medical marijuana plants
- Soil
- Fertilizers
- Pesticides, insecticides and fungicides
- Growing containers

**Receipt of Materials**—upon receiving materials into the licensed premise, registered employees and/or licensed premise employees will need to document the receipt of materials on the *Receipt of Materials* log sheet.

*Example of Receipt of Materials Log Sheet can be seen below:*

<b>Receipt of Materials</b>							
<u>Date of Receipt:</u>	<u>Receiving Employee #1:</u>	<u>Receiving Employee #2:</u>	<u>Product/Strain/Attribute ID #:</u>	<u>Quantity Received:</u>	<u>Received From:</u>	<u>Materials Placed in Quarantine:</u>	<u>Materials Pass Visual Inspection:</u>
						YES NO	YES NO
<i>Describe why Materials did not pass visual inspection:</i>				<i>Corrective action to be taken:</i>			
<u>Materials Pass Visual Inspection after Corrective Action:</u>		<i>Describe why Materials did not pass visual inspection after corrective action:</i>		<i>Next corrective action to be taken:</i>			
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>If materials passed visual inspection, and are determined to be acceptable for use as intended, said materials may be released from the quarantine areas and used as intended.</i>							
<u>Date of Release of Materials:</u>	<u>Employee(s)/Supervisor Releasing Materials:</u>		<u>Product/Strain/Attribute ID # of Released Material(s):</u>		<u>Quantity Released:</u>		
<u>Record of Receipt of Materials Made in Perpetual Inventory Control System (POS)?</u>		<u>Required POS Records:</u> <i>date of receipt, quantity of material, types/variety of material date of release</i>		<u>Employee Making POS Record Entry:</u>		<u>Employee Witnessing POS Record Entry:</u>	
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>Notes/Comments:</i>							



**Quarantine Storage Area**—the quarantine storage area will be within the licensed premise and clearly identified on the facility floor plan diagram. The quarantine area will be classified as a “dirty” zone within the cultivation facility. Materials will be held within the quarantine area where they will be segregated from the rest of the cultivation licensed premise and/or “clean” areas of the facility.

**Inspection**—after received inventory items/materials are placed in quarantine, the items will need to be inspected to ensure there are no defects or contamination. All received items/materials will remain in the quarantined area until said material pass inspection and is determined to be acceptable for use as intended.

- Registered employees will be required to inspect all materials for visible defects and contamination
- Inspecting materials for contamination is essential for the facilities clean protocols and IPM measures
  - If a contamination is identified proper cleaning and/or segregation procedures will be implemented.
    - Cleaning and sanitizing the contamination: if the contamination is deemed reasonable to clean and sanitize you will need to clean and sanitize all surface areas of the material if possible. This should be done using a cleaning/sterilizing agent such as bleach.
    - If cleaning and sanitizing is not an option, the materials will be segregated within the quarantine area until they are properly destroyed and disposed of.
    - If contaminated with pests, insects or disease; immediately segregate the material while trying to identify the contamination.
      - Refer to the *IPM SOP* for proper identification and treatment of material (plants)
  - Once the materials are properly cleaned and sanitized and believed to be free from contamination they will need to be inspected a second time.
    - Materials will need to pass this second inspection prior to being released for their intended use.

**Release**—upon the received materials passing inspection and being determined to be acceptable for use as intended, the materials will be released from the quarantine receiving/storage area. At this time the materials can be used within the licensed premise for their intended use.

- Release materials if they pass initial inspection
- Release materials once they are cleaned and sanitized and pass secondary inspection

**Documentation and Record**—upon the materials being released from quarantine and determined to be acceptable for use as intended BPH registered employees and/or licensed premise employees will be required to log the materials into the inventory control system.

- Document and record new materials released from quarantine in the inventory control system (POS system)
- Ensure record is accurate with physical inventory on hand
- Ensure the *Receipt of Material* log sheet is filled out properly and completed



Quality Control

<b>Standard Operating Procedure: Quality Control</b>
<b>Purpose:</b> To describe the quality control
<b>Scope:</b> To train registered employees on quality control measures to be utilized within the cultivation operations
<b>Initial Training:</b> TBD

Quality control measures will primarily be in the form of adherence to the written standard operating procedures to ensure quality and consistency of products produced within the facility. BPH will utilize the established and proven SOP's for all cultivation operations. BPH will use standard operating procedures (SOP's) to promote good growing and handling practices including:

- All aspects of the:
  - Irrigation, propagation, cultivation, fertilization;
  - Harvesting, drying, curing;
  - Rework or reprocessing;
  - Packaging, labeling, and handling of medical marijuana products, byproduct; and
  - Waste products, and the control thereof, to promote good growing and handling practices.

BPH will require that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical marijuana has received the training, education, or experience necessary to perform assigned functions; and will also require that all registered employees practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

BPH will require grower agents to follow the protocol for Receipt of Material including:

- BPH shall quarantine received material that will be used to produce marijuana and/or manufactured marijuana products
- BPH shall inspect materials for defects and contamination.
- Material may not be released from quarantine by a BPH until the material:
  - Passes inspection; and
  - Is determined to be acceptable for use as intended.

**UNM QUALITY ASSURANCE PLAN**

Possible contamination will be tracked through the use of a Hazard Analysis Critical Control Point (HACCP) Plan. Critical control points will be identified, monitored and preventative procedures recorded throughout the production of marijuana products. The shelf stability of all products will be confirmed. Process controls for water activity, pH levels, and proper packaging will be utilized.

**Corrective Action**

Corrective actions are detailed within the CCP Hazard Analysis Chart. If contamination is discovered after a Production Lot has shipped then the Product Recall Plan will be used.

**Shelf Stability Testing**

Shelf stability testing will be conducted on site. Shelf stability is the time that a product will retain throughout its period of storage and use, the same properties and characteristics that is possessed at the time of its packaging. Forms will be tested and approved before production for patients begins.

Shelf stability testing will cover the four areas of concern:

1. **Chemical:** The product retains its chemical integrity and potency, within specified limits.
2. **Physical:** The original physical properties, including appearance, palatability, odor, and wholesomeness are retained.



3. **Microbiological:** Resistance to microbial growth and product safety is retained according to specified requirements overall bacterial growth is maintained within acceptable levels.
4. **Toxicological:** No significant increase in toxicity occurs.

### **Control by Water Activity, pH, Chemicals, and Packaging**

Water activity and pH will be directly controlled in all products produced within the Production Area. A combination of controls, rather than relying on only one will be utilized. Inhibitors to growth of microbiological contaminants will be added to the marijuana product in the form of food safe additives or substances such as citric acid, if needed. In addition, adjustments to the atmosphere of the packaged product using special packaging techniques will be implemented during packaging, if needed. This is because a one-control system carried to the extreme, can be harsh, making food unacceptable to consumers. The use of multiple controls is called the 'Hurdle Concept'. Microbiological controls using pH, water activity, inhibitors, and atmosphere will be described in this section.

### **pH CONTROL**

Every microorganism has a minimum, optimum, and maximum pH for growth. Yeasts and molds can grow at low pH, but 4.6 is generally considered the level that will prevent the growth and toxin production for pathogens. Some pathogens, in particular *E. coli* 0157:H7, can survive acidic conditions for extended periods of time, even if their growth is inhibited. pH is considered primarily a means of growth inhibition and not a method for destruction of existing pathogens. However, at low pH values many microorganisms will be destroyed if held at that pH for significant time. A pH 4.6 is used as a divider between high-acid and low-acid foods. Some products that are naturally low-acid are processed in a way that makes them a high-acid products. This is called acidification.

### **Measuring pH**

The pH meter will be a two electrode. One is the reference electrode and one is the measuring electrode. When not in use, the electrodes are stored submerged in distilled water or other solutions as recommended by the manufacturer. The instrument must be checked each day of use with two different buffer solutions -- one on either side of the expected equilibrium pH. After calibration, the electrodes should be rinsed off with distilled water and then they can be used for testing. The operation and calibration of the pH meter must follow the meter manufacturer's instructions.

### **Thermometer Calibration**

1. Fill a 2-quart measure with ice.
2. Add water to within 1 inch of top of container.
3. Stir mixture well.
4. Let sit for one minute.
5. Place thermometer in container so that the sensing area of stem or probe is completely submerged over the dimple.
6. Keep the thermometer from touching sides or bottom of container.
7. Let thermometer stay in ice water for 30 seconds or until the dial stops moving.
8. Place the calibration tool on the hex adjusting nut and rotate until the dial reads 32 °F, while in ice water.
9. Some digital stemmed thermometers (thermistors) and thermocouples have a reset button that should be pushed.
10. Repeat process with each thermometer.

### **pH METER CALIBRATION PROCEDURE AND ANALYSIS:**

1. The pH meter is calibrated at least once on the day of use as outlined in section
2. The standard buffers used are pH 4.0, pH 7.0, and pH 10.0. A small amount is dispensed into a smaller container for calibration. Per manufacturers recommendations the standard pH buffers should be used for calibration only one time and disposed after calibration has been finalized.
3. If the final pH of the reagent or medium falls between a pH of 7.0 and 10.0, use the pH 7.0 and 10.0 calibration buffer solutions for the two point calibration.
4. If the final pH of the reagent or medium falls between a pH of 4.0 and 7.0, use the pH 4.0 and 7.0 calibration buffer solutions for the two point calibration.

### **WATER ACTIVITY CONTROL**

Like pH, every microorganism has a minimum, optimum, and maximum water activity for growth. Yeasts and molds can grow at a low water activity, however 0.85 is considered the safe cutoff level for pathogen growth. A water activity

of 0.85 is based on the minimum water activity needed for *S. aureus* toxin production. Products above a water activity of 0.85 will utilize acidification as the barrier to control the growth of pathogens. Products with water activities between 0.60 and 0.85 are classified as intermediate moisture foods. These do not require refrigeration to control pathogens, but have a limited shelf-life because of spoilage, primarily by yeast and mold. For the most part, products with a water activity below 0.60 have an extended shelf-life, even without refrigeration.

**PACKAGING**

Reduced oxygen packaging is used to prevent the growth of microorganisms in order to extend the shelf-life of the product and keep the integrity of the product intact. Packaging is different from the other methods of control. Although packaging is sometimes used to control microbiological growth, it is limited to the control of spoilage microorganisms. Packaging serves two functions:

1. it prevents contamination of the food or
2. it extends the effectiveness of food preservation methods

**QUALITY ASSURANCE: Marijuana Product CCP Hazard Analysis Chart**

Issued:

Reviewed:

Next Review:

CCP	Hazard & Source/ Cause	Critical Limit	Monitoring Procedure	Corrective Actions	Record Keeping	Verification
CCP1 – Marijuana Product is moved to Climate Controlled Secure Storage. Marijuana Product is moved	<b>Microbiological Hazards</b> -Microbiological growth due to breakdown of refrigeration unit.	Temperature of Ingredients must be stored at consistent temperature.	<b>Who:</b> Production Manager <b>What:</b> monitor temperature of Climate Controlled Secure Storage <b>How Often:</b> Twice daily using calibrated thermometer.	Properly discard of Marijuana Product if temperature variance is greater than 20 degrees Fahrenheit	Refrigeration Log Calibration Log	Production Manager reviews and signs off on Refrigeration and Calibration Logs
CCP2 - Proper sanitation of all packaging	<b>Physical Hazards</b> -Physical contamination from operator -Foreign body/broken glass/dust contamination from source of origin and/or storage environment <b>Chemical Hazards</b> -Chemical contamination from high ppm of sanitizer.	Any foreign objects present.  50 -200 ppm sanitizer concentration	<b>Who:</b> Production Manager or Sanitation Manager <b>What:</b> Properly inspects bottles and caps for physical hazards. Follows sanitation SOP and use testing strips for ppm accuracy <b>How Often:</b> As Needed	Discard any broken bottles and foreign objects.  Use ppm test strips to for proper sanitizer mixture.	Sanitation Log	Sanitation Manager logs ppm test strip readings in Sanitation Log. Daily sign off by Production Manager.
CCP3 - Use Filling Equipment to fill all packaging.	<b>Physical Hazards</b> -Physical contamination from operator -Foreign body/dust contamination from production environment.  <b>Microbiological Hazard</b>	Any foreign objects present.  Temperature must be consistent and ph of products in filler must be <4.6ph	<b>Who:</b> Production Manager <b>What:</b> Follow SOP and Hygiene Guidelines. Take ph and monitor temperature. <b>How Often:</b> Every Production Batch	re- test for proper pH level after adding citric acid or food safe equivalent. Minimum pH level required is 4.6 or <.	-Staff hygiene policy/program in place with all site staff trained and records of training maintained and retained on personnel files. -Controlled by proper sanitation of production environment.	Production Manager logs all ph and temperature readings into Production Log. Calibration of Thermometers and ph tester entered into Calibration Log.



	-Microbiological growth due to improper pH levels before filling. -Microbiological growth due to improper temperature monitoring.				-Proper pH levels are monitored with a properly calibrated pH meter, calibrated with proper pH 4 and pH 7 buffers. -Staff pH policy/training in place with all site staff trained and records of training retained in personnel records. -The critical limit is established at 4.0 or below by the appropriate manufacturer's recommendation. -Staff awareness/training programs in place with records of training retained and filed.	
CCP4 – Marijuana Product is moved to Climate Controlled Secure Storage. Marijuana Product is moved	<b>Microbiological Hazards</b> -Microbiological growth due to breakdown of refrigeration unit.	Temperature of Ingredients must be stored at consistent temperature.	<b>Who:</b> Production Manager <b>What:</b> monitor temperature of Climate Controlled Secure Storage <b>How Often:</b> Twice daily using calibrated thermometer.	Properly discard of Marijuana Product if temperature variance is greater than 20 degrees Fahrenheit	Refrigeration Log Calibration Log	Production Manager reviews and signs off on Refrigeration and Calibration Logs

VALIDATION:

Name:

Name:

Position:

Position:

Date:

Date:



<b>Standard Operating Procedure:</b> Weights and Measurements and Scale Calibration
<b>Purpose:</b> To explain how to use certified scales for weights and measurements
<b>Scope:</b> To train registered employees on proper use of NTEP certified scales to be used for weights and measures as well as scale calibration/certification
<b>Initial Training:</b> 1 hour

**Types of Scales to be used**

BPH will utilize NTEP-certified scales for the weighing of all medical marijuana, medical marijuana products, medical marijuana waste and all green waste.

**NTEP Certification**— The National Conference on Weights and Measures issues an NTEP Certificate of Conformance following successful completion of an evaluation of a device. It indicates that the device(s) described in the Certificate is/are capable of meeting applicable requirements of the *NIST Handbook 44*.\* <http://www.ncwm.net/ntep/faqs#WhatIsNTEPcertificate>

**Scale Use**

All medical marijuana harvested at BPH’s licensed premise will be weighed and packaged using NTEP-certified scales certified for legal trade and that have been calibrated and certified ISO/IEC 17025 accredited by a Hawaii calibration service supplier.

**Scale Calibration and Frequency**

BPH will ensure that all scales and balances are calibrated by an accredited calibration service supplier. The frequency of having BPH scales calibrated will be on a six (6) month basis. This routine calibration will be documented on the Scale Calibration Log sheet and maintain on the licensed premise.

*Example of the Scale Calibration Log Sheet:*

<b><u>Scale Calibration</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Scale Serial #/ID #:</u>	<u>Calibration Service Supplier:</u>	<u>Scale Calibrated</u>	<u>Notes/Comment:</u>
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
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				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	





## **Equivalent Weights for Manufactured Marijuana Products**

### **Assessment of the pre-mixed total weight (in ounces or grams) of usable marijuana contained within in an extract, oil, or infused product.**

The pre-mixed total weight of usable marijuana contained in an extract, oil or infused product is determined by the amount of marijuana plant material used to make the marijuana extract or oil. To determine the amount of usable marijuana in an infused product the additional step of determining the amount of extract or oil used to make an infused product is necessary.

Equivalency of marijuana flower or trim to extract, oil or infused product can vary due to several variables;

1. The tetrahydrocannabinol (THC) content of the marijuana flower or trim.
2. The THC content of the extract or oil produced from marijuana flower or trim.
3. The amount of THC infused into the infused product.

The average tetrahydrocannabinol (THCa) percentage of medical marijuana flower ranges from 15 - 19%. THCa is the form of THC found within the marijuana plant material. THCa is the non-psychoactive bio-synthetic precursor to THC. THCa must be decarboxylated to become bioavailable to the human body and is done so in the production of some extracts an oil and with all infused product production. During decarboxylation the THCa loses carbon and oxygen molecules, and about 12.3 percent of its weight. This must be taken into account when determining the usable weight of marijuana found in extract, oil, or infused products.

Extraction efficiency for CO2 Sub/Supercritical Extract and Oil average from an average between 60% - 80%. This range provides an estimated average total of 70% of the total THC milligrams available within the plant will be extracted. The oil or extract is then lab tested to determine the exact amount of active cannabinoids in the product. These lab results are then used to determine how much in weight or volume of the extract or oil is to be used in the infused product formulation. Infused products are measured in activated milligrams of THC. No more than 10 milligrams THC per dose. No more than 100 total THC milligrams per package.

Projected extracted milligrams of THC per gram of plant material based on average extraction efficiencies of yield and THC percentage:

1. Beginning plant material THC % is 15%.
2. Extraction efficiency is 70%.
3. Infused Product is to contain 10 milligrams of active THC

Example: of 1 gram of medical marijuana = 1000mg Total Weight

- A. The medical marijuana is 15% THC the total available THC milligrams within that one gram is 150 milligrams. (1000mg X 15% = 150mg)
- B. The CO2 Extraction efficiency is equal to 70% total amount of THC milligrams extracted 105 mg THC per gram of plant material.
- C. 105 mg of THC will produce 10.5 units of 10 mg THC infused products.
- D. 1/10 gram would be the pre mixed total weight of usable marijuana contained within the infused product.



Manufacturing Operations

<b>Standard Operating Procedure:</b> Manufacturing Operations
<b>Purpose:</b> To explain post-harvest activities, procedures and protocols. Including: manufacturing, processing, weighing, packaging and labeling.
<b>Scope:</b> Covers the manufacturing activities within the cultivation facility.
<b>Initial Training:</b> TBD

-----**UNM EXTRACTION AND PRODUCTION GENERAL OPERATIONS**-----

**Overview**

The extraction and production area of the production center will manage and produce the extraction of cannabinoids from the leaves and flowers of the female marijuana plant and the production of these extractions into medical marijuana products. The extraction and production area shall meet or exceed requirements set forth by the State of Hawaii. All extraction, packaging and labeling of medical marijuana products will comply with all state and local laws. All local and state fire, safety and building codes will be followed and internal manufacturing systems will be approved before operation.

The medical marijuana product extraction and production area will be physically separated from the other areas within the manufacturing facility and shall be considered a Limited Access Area. Only employees designated to work within the area will be permitted access. The extraction and production area will have designated areas for: Production, Packaging and Labeling, Climate Controlled Storage (walk-in coolers, reach-in coolers and freezers), Secured Storage and Toxic and/or Flammable Materials Storage. The area for the extraction and production of medical marijuana products will have mechanical ventilation of sufficient capacity as necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke and fumes.

The extraction and production area will have independent exhaust vents respectively in addition to the facility HVAC system. Equipment and surfaces used throughout the areas of extraction, manufacturing, processing and packaging of medical marijuana products will be constructed of NSF certified stainless steel. All equipment and utensils used will be lab grade or of commercial kitchen standards and meet or exceed State of Hawaii requirements. The extraction and production areas will be open and free as to provide ample space for preparation and sanitation.

**Extraction**

Marijuana concentrate is extracted from raw, cured marijuana by the use of:

- CO2 Sub/Super-Critical Extraction provides pure, solvent-free extracts by utilizing carbon dioxide. CO2 is a green alternative to solvent-based extraction techniques. The properties of a supercritical fluid can be altered by varying the pressure and temperature, allowing selective extraction. The low viscosity of supercritical carbon dioxide allows it to penetrate into the material more easily while its diffusivity allows for faster extractions. CO<sub>2</sub> is an environmentally friendly solvent that leaves no residue. Known as the “Entourage Effect” these “Whole Plant Extractions” are known to be more effective medicinally by four unique qualities:
  - Ability to affect multiple targets within the body
  - Ability to improve the absorption of active ingredients
  - Ability to overcome bacterial defense mechanisms
  - Ability to minimize adverse side effects.

CO2 extractions will be performed in a professional-grade, closed- loop extraction system, rated to minimum 900 pounds per square inch.

All solvents will be stored in secure and approved flammable materials storage containers. All MSDS sheets will be displayed along with emergency procedures to provide proper response to an accident involving a solvent.

Employees will be trained by the industry's best practices and company extraction Standard Operating Procedures (SOPs). Marijuana flower and trim is cured in the Cultivation Area of the Manufacturing Facility. After the curing process, cured flower and trim will be delivered securely to the Extraction Area of the Manufacturing Facility and prepared for the extraction process. Marijuana from the cultivation area will be delivered securely to the extraction area when properly cured and ready to be extracted. The chain of custody of the marijuana plant material from cultivation to extraction will be documented within the Seed-to-Sale Inventory Tracking Software. The extraction staff will properly and securely store the marijuana leaves and flowers until the cannabinoids are processed and extracted. Marijuana extract shall be assigned a lot number immediately upon creation. Extraction employees will be trained in the best practices of all emergency procedures.

The extraction area ventilation system will be spark-resistant and separate from the main manufacturing HVAC system. All employees working in the Extraction and Production Area will be trained in Standard Operating Procedures, Good Manufacturing Practices and Emergency Procedures.

## **CHEMICAL HANDLING**

### **Material Safety Sheets:**

Safety data sheets (SDS), material safety data sheets (MSDS), and product safety data sheets (PSDS) are an important component of product stewardship and occupational safety and health. They are intended to provide workers and emergency personnel with procedures for handling or working with that substance in a safe manner, and include information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment, and spill-handling procedures.

Our standard operating procedures will include reference to relevant safety data sheets applicable to that specific process documented in the SOP. In addition, the Company will maintain a comprehensive database of all safety data sheets in hard copy and electronic scanned copies on site. The Company will ensure the SDSs are readily accessible to employees for all hazardous chemicals in their workplace. We will also designate a person responsible for obtaining and maintaining the SDSs and contacting the manufacturer to obtain one.

Employees will be trained with regard to the use of safety data sheets as part of the orientation process as well as the specific training provided by their supervisor in the performance of their duties. OSHA has published a "brief" describing the "Hazard Communication Standard: Safety Data Sheets". Section 7 of this brief covers the Handling and Storage of chemicals and outlines the type of information that will be included in the SDS for a chemical. This brief will be provided to all employees in the training process to provide guidance to help workers who handle hazardous chemicals to become familiar with the format and to understand the contents of the SDSs. It will also be included in relevant SOPs as a clickable link.

### **OSHA Protocols for handling and storage of chemicals:**

The safety of our employees and the public is our foremost business consideration. The prevention of accidents and injuries takes precedence over expedience. In the conduct of our business, every attempt will be made to prevent accidents from occurring. The Company's safety SOPs address both OSHA regulations and good laboratory practice. Key laboratory personnel will be required to participate in OSHA Certification in Health and Safety educational classes. All employees will be fully trained in the safe and efficient use of chemicals, tools, and machinery.

There are several key safety precautions necessary for extraction operations:

The room must be well ventilated and separate from all other processes. The area will have a CO2 monitor as a safety precaution designed to sound when the level of CO2 in the room nears an unsafe level. Equipment safety features must be maintained so that in the event of a leak, pressure will no longer be maintained by the system and the pump will shut off.

Standards will be established, documented and followed for chemical receiving, tracking, storage, and disposal. The General Manager and department supervisors will implement and maintain the PPE program. The program will be compliant with OSHA and EPA standards and address:

1. Hazards present;
2. Selection, maintenance, and use of PPE;
3. Training; and
4. Monitoring.

Personnel will be required to wear protective clothing, chemical resistant gloves and goggles when handling hazardous chemicals.

For each of the chemicals we are using in our production process we will determine the appropriate OSHA protocols. OSHA has defined specific protocols for handling and storage of chemicals in their CFR regulations. These are included in OSHA CFR 29, Standard number 1910, subpart H. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

All employees will be appropriately trained on spill response. Every employee is responsible for participating in spill response activities. A fully stocked spill kit will be maintained in the processing and laboratory facilities.

Our batch processing for extraction generally uses CO<sub>2</sub>, though other chemicals may be used for processing and sanitation. Hence we will adopt, CFR 29 H 1910.101 which concerns the general requirement for Compressed Gases. This will apply to our use of CO<sub>2</sub> in extraction during the chemical processing stage of production. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

Another example is CFR 29 H 1910.106 which concerns the requirements for Flammable liquids. This OSHA protocol will also be applicable to certain of our processes for production, such as those processes which use ethanol, and for sanitation where flammable liquids or aerosols are used. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

#### **MANUFACTURING PROCESS VALIDATION**

GMP defines Validation as: “Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting predetermined specifications and quality attributes.”

These production runs will be of limited units, produced under routine conditions and the number of production runs and observations made will be sufficient to allow for the normal extent of variation and trends to be established and provide sufficient data for evaluation. This will include at a minimum, 10 batches of any new concentrate, product or process. A state of control will be maintained with the use of procedures for monitoring and control systems for process performance and product quality. The facility will utilize an ISO9001 ‘Process Approach’ Quality-Management System to analyze hazards and place managerial controls on each process.

Before any batch or lot is commercially-distributed, we will have gained a high-degree of assurance that processes will consistently produce products meeting attributes of identity, strength, quality, purity, and potency. Additionally, FDA211.180 (e) states the quality standards of each product will be evaluated “annually” to determine the need for changes in product specifications, manufacturing or control procedures.

The FDA describes process-validation in three stages:

- (1) Process Design: The commercial-manufacturing process is defined during this stage.
- (2) Process Qualification: The process design is evaluated to determine if the process is capable of reproducible, commercial manufacturing.
- (3) Continued Process Verification: Ongoing assurance is gained during routine production that processes remains in a state of control.

The following are examples of circumstances requiring validation:

1. Major site changes
2. Major changes to equipment
3. Major Changes in Composition and Components:
  - a. addition of a new product
  - b. addition of a new dietary ingredient to a formulation;
  - c. changes to excipient concentration that are likely to have detectable impact on formulation quality and performance.
4. Major Process Changes: Changes to the type of process used in the manufacturing of the product, such as change from wet granulation to direct compression of dry product.
5. Major Changes to Specification: usually as a result of a formulation change;
6. When an adverse event is experienced where a process has failed to provide the desired result, such as contamination, and the process must be re-evaluated.

### **VALIDATION MASTER PLAN:**

The Company will create an SOP to document our master plan and standard protocols for validation, summarized as follows:

1. Establish predetermined specifications that define a successful validation result.
2. Determine appropriate resources and assign responsibilities for the project.
3. Define equipment and instruments to be used.
4. Define ingredients and chemicals to be used.
5. Establish review team.
6. Establish time-line and number of production runs included in the test.
7. Determine number of units or volume of production in each run.
8. Define test protocols (number of units in each lot to be “sampled”, sampling methods, testing protocols and laboratories).
9. Documents used:
  - a. Validation plan
  - b. Validation report
  - c. Discrepancy forms
  - d. SOPs
  - e. System-change request forms
  - f. Test results
10. Perform validation on a minimum of 10 lots produced according to a single manufacturing order during the same cycle of manufacture.
11. Acceptance. All documentation obtained and filed in the established Validation Filing System.

### **VARIATION**

During Production of validation Lots employees will identify sources of variation affecting process performance and product quality for improvement to reduce or control variation. Scrutiny of intra-batch and inter-batch variation is part of a comprehensive process-verification program under 21CFR§211.180(e). Control Procedures shall be established to monitor the output and validate performance of manufacturing processes that may be responsible for variability in the characteristics of in-process material and the drug product.

Sources of Variation include:

Employees -Employees will be trained to analyze parameters and attributes identified in the control strategy to verify continued operation within a state of control. Employees will provide feedback on product quality from both internal and external sources (e.g., complaints, product rejections, non-conformances, recalls, deviations, audits and regulatory inspections). Employees will be provided proper tools to perform their duties and receive ongoing education and training. Supervisors will perform Direct Observation of SOPs during Process-Validation runs.

Raw Materials - Strict SOPs of sourcing raw ingredients will be followed. Specifications of quality for suppliers have been developed to limit the variability of raw materials and packaging. We have the advantage of purchasing raw material from suppliers with existing strategic partnerships with our consultants. All suppliers have proven cGMP and tested product. Product received into the facility will be inspected upon arrival, recorded, refused or received, and stored in accordance with FDA cGMP Sec.211.80, 211.82 and 211.86. These controls are a foundation of the validation process by limiting the variable of compromised or inconsistent packaging and raw-materials entering the facility. We will source our marijuana from our own vertically-integrated cultivation facility located contiguous to our processing operation. In addition to a lab-testing facility we will utilize in-house testing at critical control points (including: raw marijuana, marijuana concentrate, marijuana infused final product) throughout the production facility to control intrinsic variables.

Equipment - Equipment used in production will be used for its intended use and will be of “appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.” (FDA cGMP Sec211.63) All equipment will be regularly maintained and documented. (FDA cGMP Sec211.67) Employees will be properly trained and certified on equipment.

Measurement Systems -Acceptance criteria for sampling and testing conducted by the quality control unit shall be adequate to assure the batches meet each appropriate specification and appropriate quality control criteria as a condition for their approval and release.

SOP– SOPs are discussed in detail in other sections of the application and will document every movement and method in the process.

Environment -Managerial control measures will be implemented in all phases of the operation. Controls of critical control-points will be supported with proper documentation in accordance to FDA cGMP Sec.211.100. Data collection of the production process is ongoing with direct-observation documentation of all critical control-points throughout receiving, extraction, production, storage, sample collection, and lab testing. Documentation provides a record that appropriate corrective actions were taken when critical limits were not met due to internal or external variables.

The validation process will allow us to:

1. Understand the sources of variation
2. Detect the presence and degree of variation
3. Understand the impact of variation on the process and ultimately on product attributes
4. Control variation in a manner commensurate with the risk it represents to the process
5. Judge whether we have gained sufficient understanding to provide a high degree of assurance in our manufacturing process to justify commercial distribution.

#### **DOCUMENTATION**

All Validation Protocols, final Validation Reports and associated testing results required by this procedure shall be retained for at least five years after distribution of the product manufactured, processed or packaged utilizing that that process or equipment.

### **-----Blue Planet Healing Manufactured Marijuana Product Descriptions-----**

#### **1. Medical Marijuana Sublingual Tincture**

Medical Marijuana Sublingual Tinctures are administered sublingually by the use of a measured dropper. Sublingual tinctures shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The droppers have measurement demarcations as to provide safe and easy dosing levels. Sublingual Tinctures offer patients the ability to ‘micro-dose’ cannabinoids in measurements of 2-3 mg of active cannabinoids. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana Sublingual Tinctures will be labeled and packaged in ASTM certified child resistant re-sealable dropper caps that will maintain the child resistant effectiveness for multiple openings.

#### **2. Medical Marijuana Infused Sublingual Tablet**

Medical Marijuana Infused Sublingual Tablets are designed to dissolve slowly in a patient’s mouth making an effective sublingual administered product. Each individual Sublingual Tablet shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. The product will be lab tested for accurate active cannabinoid profile. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana infused sublingual tablets will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **3. CO2 Medical Marijuana Concentrate**

A concentrated extract of cannabinoids, including but not limited to THC, CBD, and CBN created using a Closed-Loop Sub/Supercritical CO2 Extraction. CO2 is a non-polar solvent, which is efficient at extracting the Cannabinoids, Terpenes, and Flavonoids from Medical Marijuana plant matter. This concentrated form of Medical Marijuana can have up to a 90% concentration of cannabinoids. The product will be lab tested for accurate active cannabinoid profile.



Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **4. Medical Marijuana Infused Lotion**

Medical Marijuana Infused Lotion products are an oil based lotion to be applied directly to the skin, not meant for oral consumption. Infused Lotions shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Marijuana infused lotions will be packaged in squeeze tubes with an ASTM certified child resistant re-sealable cap that will maintain the child resistant effectiveness for multiple opening.

#### **5. Medical Marijuana Infused Salve**

The Medical Marijuana Infused Salve is an ointment, not meant for oral consumption, to promote the healing of the skin and muscles. The Salve provides gentle relief for abrasions, sores, dry, cracked or chapped skin. Infused Salves shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The unique formulation of active cannabinoids and all natural soothing and plant based pain relief provides convenient and fast acting relief for patients. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **6. Medical Marijuana Infused Serum**

The Medical Marijuana Infused Serum, not meant for oral consumption, is a water based formulation of active cannabinoids, antioxidants, all natural ingredients to provide patient relief. It is a fast absorbing active ingredients that penetrate the skin faster than lotions or gels. Serums are super-efficient delivery methods as small amounts are absorbed into the skin quickly and deeply. Infused Serums shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **7. Medical Marijuana Infused Gel**

The Medical Marijuana Infused Gel, not meant for oral consumption, is a Aloe based gentle moisturizer, with a proprietary formulation of herbs, essential oils and active cannabinoids. The Gel provides fast and long lasting muscle relief for patients. Infused Gels shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **8. Medical Marijuana Infused Capsule**

Medical Marijuana Infused Capsules are a blend of active cannabinoids and all natural ingredients within a gelatin capsule. The gelatin capsule dissolves in the stomach of the patient releasing the cannabinoids and ingredients. Each individual Capsule shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. Medical Marijuana Capsules will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **-UNM MANUFACTURING PRODUCTION STANDARD OPERATING PROCEDURES-**

#### **PRODUCTION OF SALVE**

#### **PRODUCT DESCRIPTION**

1oz Medical Marijuana Infused Salve

#### **POLICY**

To prepare and package Topical salve in child resistant packaging. All production will be documented.

#### **RESPONSIBILITY**

Production Manager or their designee.

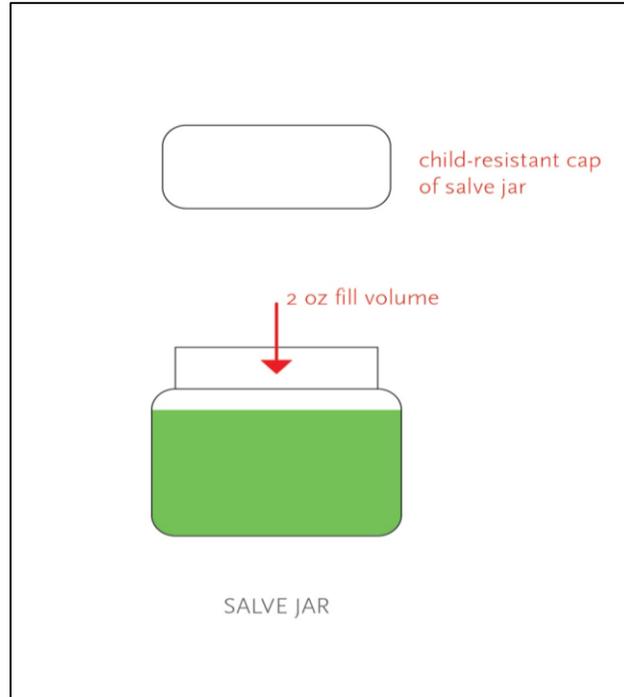
#### **RECORDS**



Production Log  
Inventory Tracking Software

**PROCEDURE**

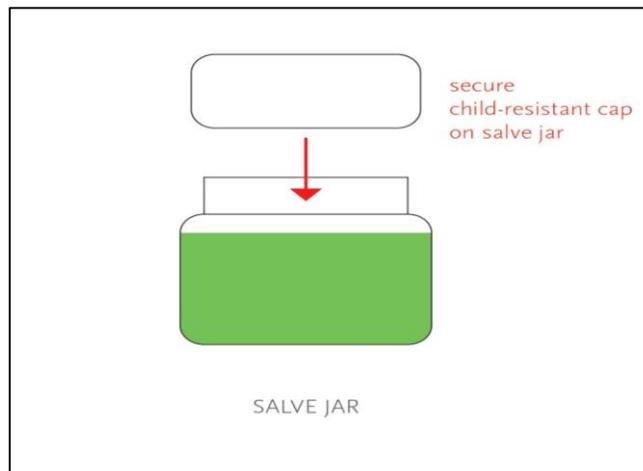
1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers, caps or droppers. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers, caps or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\#)\text{mg/THC} = (\#) \text{ total mg needed}$
  - o **divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.
  - o  $(\#) \text{ total mg needed}/(\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Fill Topical salves to the 1 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



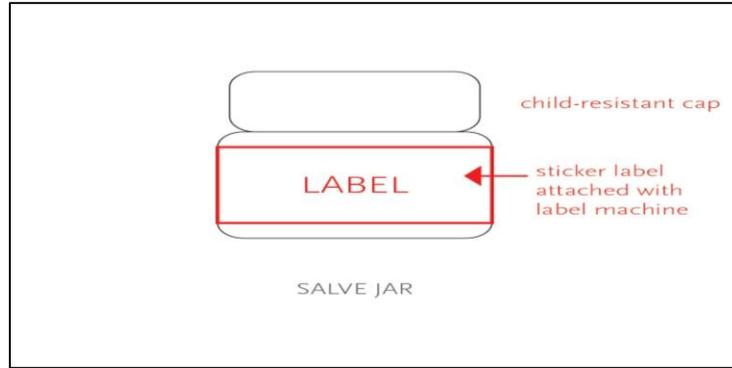
13. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.

14.

Apply the child resistant cap to the jar. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

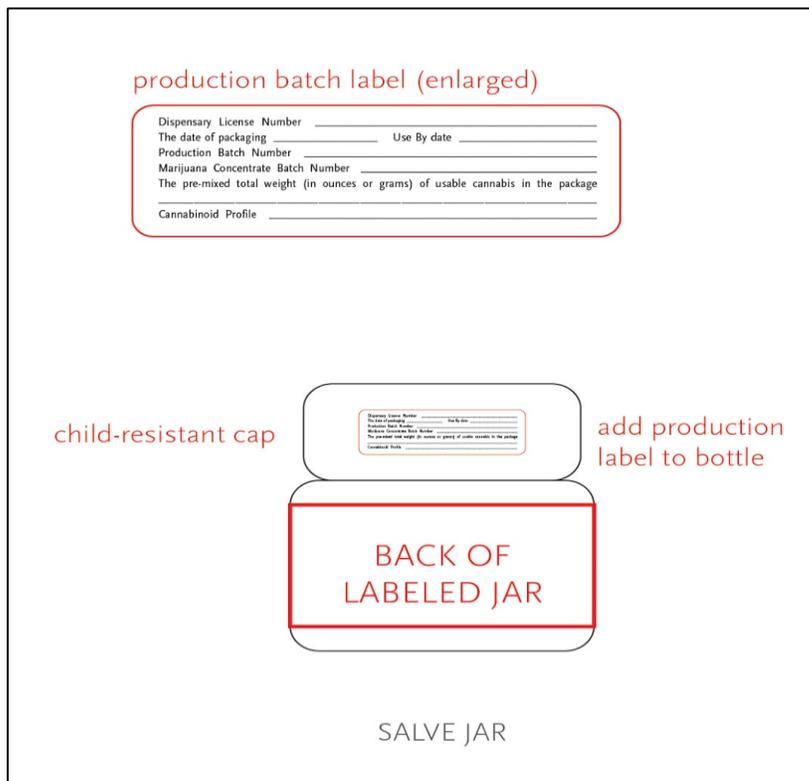


15. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Salve package properly so that front of label is centered on front of the package.



16. Apply the Production Batch Sticker which will contain the following information:

- Dispensary License Number
- The date of packaging and “use by” date
- Production Batch Number
- Marijuana Concentrate Batch Number
- The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
- A list of cannabinoid content by weight.



17. Final Quality Control Inspection of product includes:

- proper label applied correctly
- proper production batch label applied correctly
- dropper cap is applied correctly
- package is clean and dry



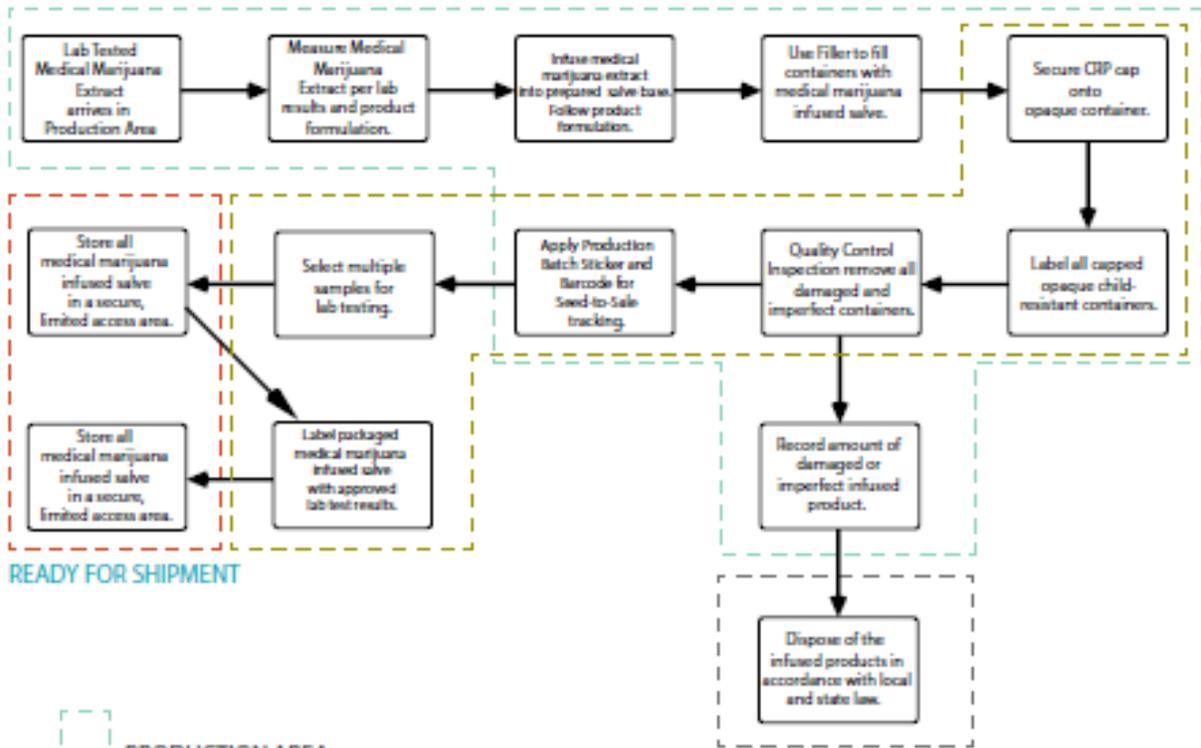
18. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
19. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
20. Complete the Production Form and enter information into Inventory Tracking Software.
21. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
22. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
23. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Salve can be seen below:*



## MEDICAL MARIJUANA INFUSED SALVE PROCESS FLOW DIAGRAM

BEGIN PROCESS →



READY FOR SHIPMENT

- PRODUCTION AREA
- PACKAGING AREA
- STORAGE AREA
- DISPOSAL

## PRODUCTION OF INFUSED TOPICAL SERUM

### PRODUCT DESCRIPTION

1oz Medical Marijuana Infused Topical Serum

### POLICY

To prepare and package Topical Serum in child resistant packaging. All production will be documented.

### RESPONSIBILITY

Production Manager or their designee.

### RECORDS

Production Log

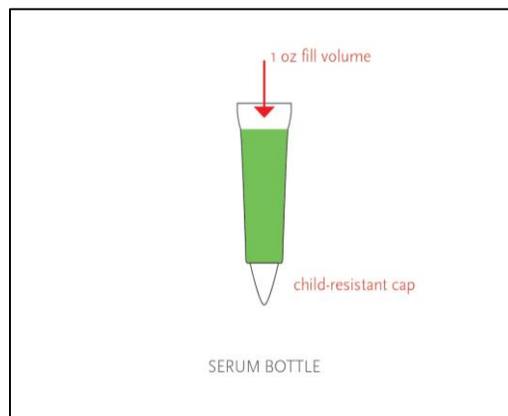
Inventory Tracking Software

### PROCEDURE

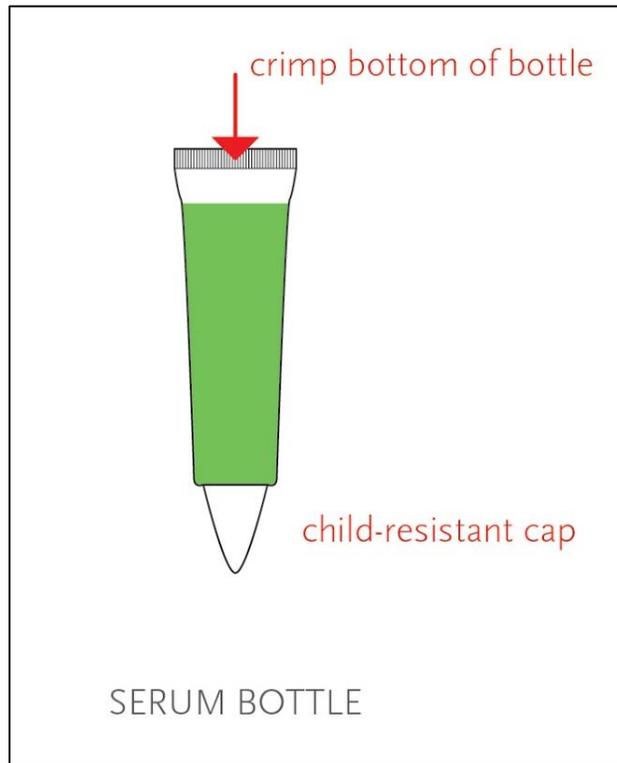
1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' Fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$



- **divide the total mg needed by the mg of THC per gram of the concentrate.**
  - **(#) total mg needed/(#) mg THC per gram = grams of concentrate to use in production**
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
  11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
  12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
  13. Fill Topical Serums to the 1 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



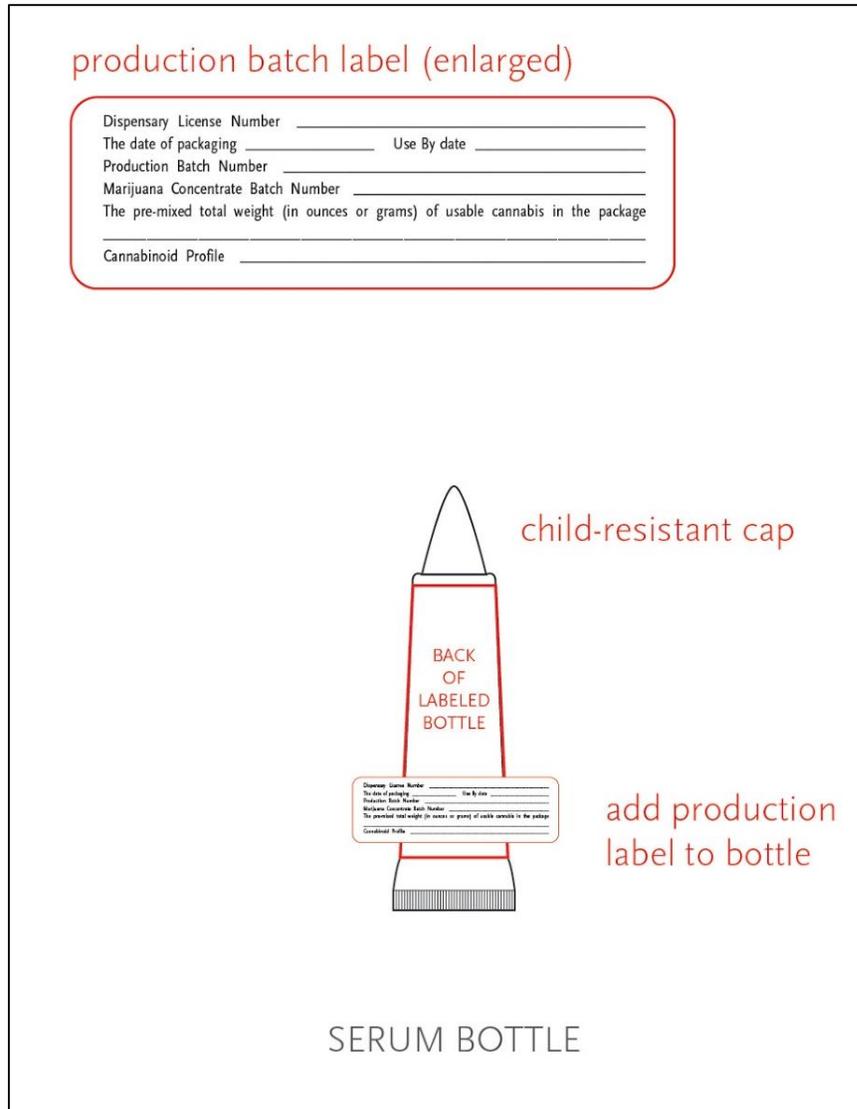
14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Serum package properly so that front of label is centered on front of the package.



17. Apply the Production Batch Sticker which will contain the following information:
1. Dispensary License Number
  2. The date of packaging and "use by" date
  3. Production Batch Number
  4. Marijuana Concentrate Batch Number
  5. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  6. A list of cannabinoid content by weight.



18. Final Quality Control Inspection of product includes:
  1. proper label applied correctly
  2. proper production batch label applied correctly
  3. dropper cap is applied correctly
  4. package is clean and dry
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
21. Complete the Production Form and enter information into Inventory Tracking Software.
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the

consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
24. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
25. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Serum can be seen below:*

## **PRODUCTION OF TOPICAL GEL**

### **PRODUCT DESCRIPTION:**

3oz Medical Marijuana Infused Gel

### **POLICY:**

To prepare and package Topical Gel in child resistant packaging. All production will be documented.

### **RESPONSIBILITY**

Production Manager or their designee.

### **RECORDS**

Production Log

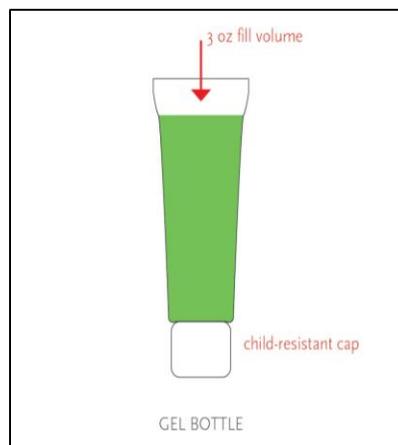
Inventory Tracking Software

### **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.



5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\# \text{ mg/THC}) = (\#) \text{ total mg needed}$
  - o **divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.
  - o  $(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
13. Fill Topical Gels from the open tube side with the child resistant cap facing down. Fill to the 3oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.





14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube closed. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

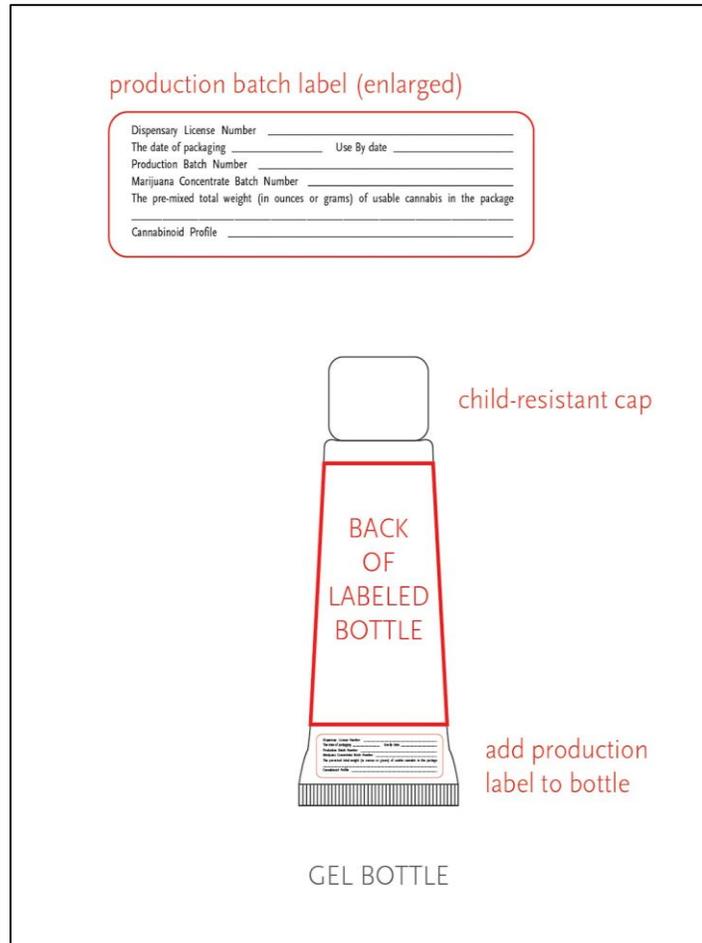


16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Gel package properly so that front of label is centered on front of the package.



17. Apply the Production Batch Sticker which will contain the following information:

1. Dispensary License Number
2. The date of packaging and "use by" date
3. Production Batch Number
4. Marijuana Concentrate Batch Number
5. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
6. A list of cannabinoid content by weight.



18. Final Quality Control Inspection of product includes:
  1. proper label applied correctly
  2. proper production batch label applied correctly
  3. dropper cap is applied correctly
  4. package is clean and dry
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, Reason for disposal, and Quantity of the marijuana product to be disposed of.
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
21. Complete the Production Form and enter information into Inventory Tracking Software.
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

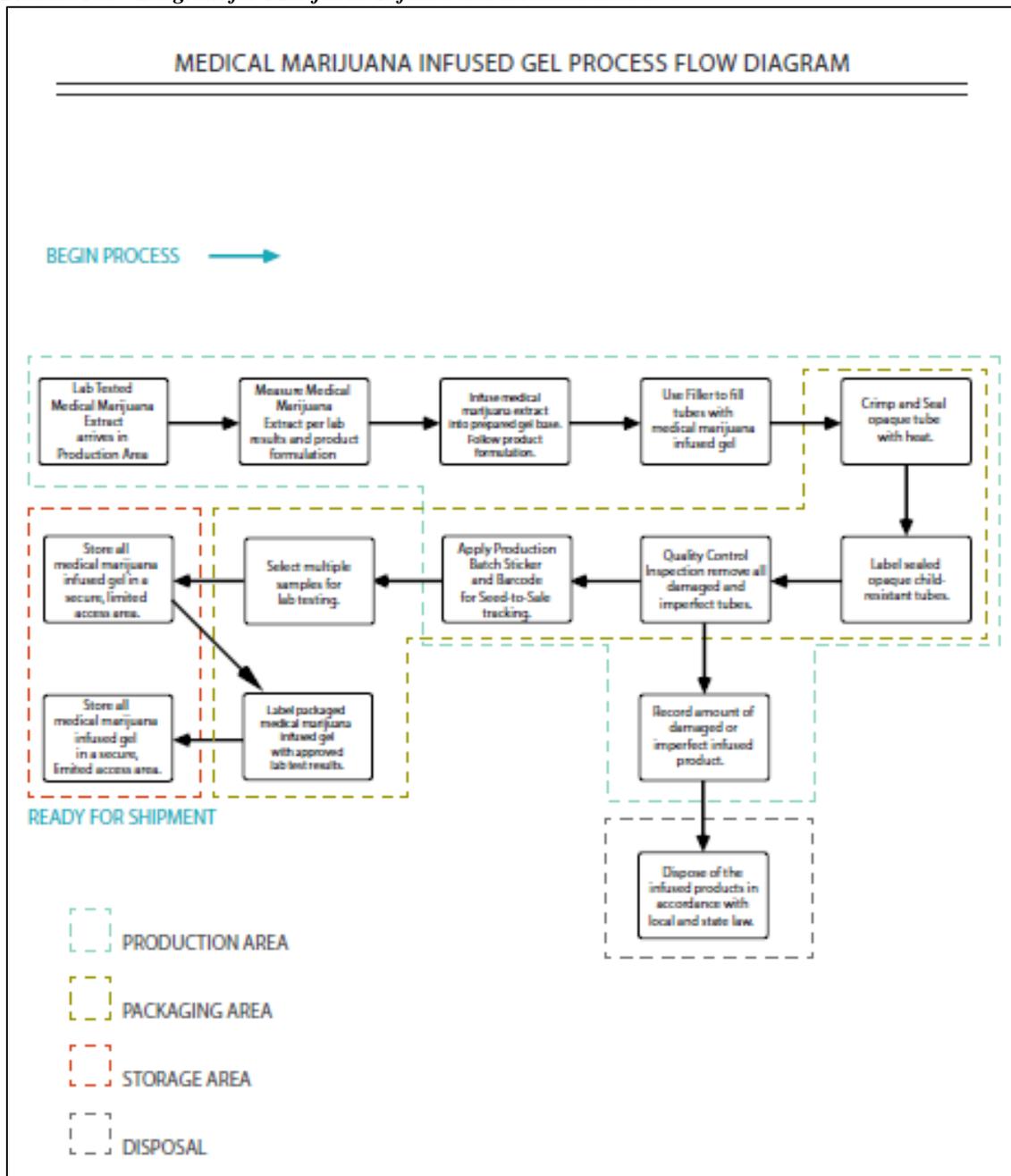


23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.

Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.

24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Gel can be seen below:*



## PRODUCTION OF SUBLINGUAL MARIJUANA TINCTURES

### PRODUCT DESCRIPTION

2oz Sublingual Medical Marijuana Tincture. 2ml Dropper for Metered Dosing.

### POLICY

To prepare and package sublingual marijuana tinctures in child resistant packaging. All production will be documented.

### RESPONSIBILITY

Production Manager or their designee.

### RECORDS

Production Log  
Inventory Tracking Software

### PROCEDURE

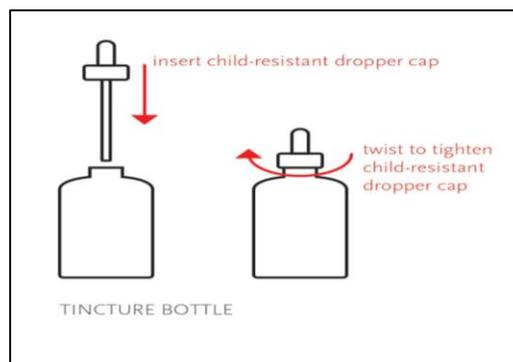
1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all containers and droppers. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers, caps or droppers. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - a. **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - b.  $(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$



- c. **divide the total mg needed by the mg of THC per gram** of the concentrate.
  - d.  $(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
  11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
  12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
  13. Fill Tinctures to the 2 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.

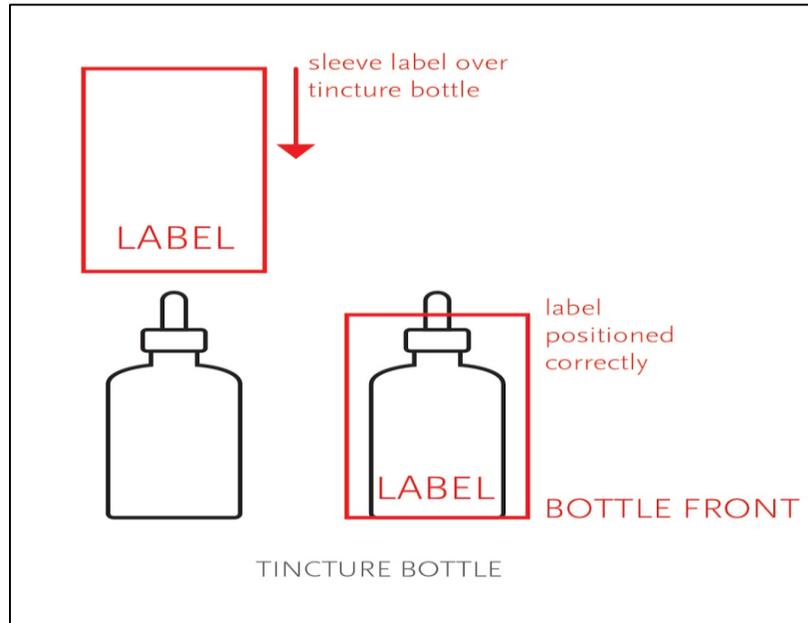


14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Secure and seal child resistant dropper cap. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.





16. Turn power on to the Heat Shrink Tunnel. Set speed control to '3' and Heat control to 180F. For tincture labeling close top 4 heat tunnel vents, leaving only the bottle 2 vents open. Allow 15 minutes for Heat Tunnel to reach temperature. If applicable turn on exhaust fan to remove hot air from production area.
1. Label with tamper evident, opaque shrink-wrap label. Perform and document Direct Observation Quality Control that labels contain all required information. "Sleeve" the bottled product. -- Place shrink wrap label onto every filled and capped tincture bottle by sliding the label over the container and positioning the label properly so that front of label is centered on front of bottle.



2. Run Sleeved product through the heat tunnel. Carefully place each unit onto the conveyor belt so that the Tincture bottle stays upright. Bottle placement should be so that the front of the bottle faces the left side of the Heat Tunnel. As tincture bottles exit the Heat Tunnel each unit should be Quality Control inspected for tearing, wrinkling, stretching, or improper label placement. Adjust Heat Tunnel controls if necessary. Next, Label products with Production Batch Label.

Apply the Production Batch Sticker which will contain the following information:

- a. Dispensary License Number
- b. The date of packaging and "use by" date
- c. Production Batch Number
- d. Marijuana Concentrate Batch Number
- e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
- f. A list of cannabinoid content by weight.



Final Quality Control Inspection of product includes:

- proper label applied correctly
- proper production batch label applied correctly
- dropper cap is applied correctly
- package is clean and dry

Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.

Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.

Complete the Production Form and enter information into Inventory Tracking Software.

Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab

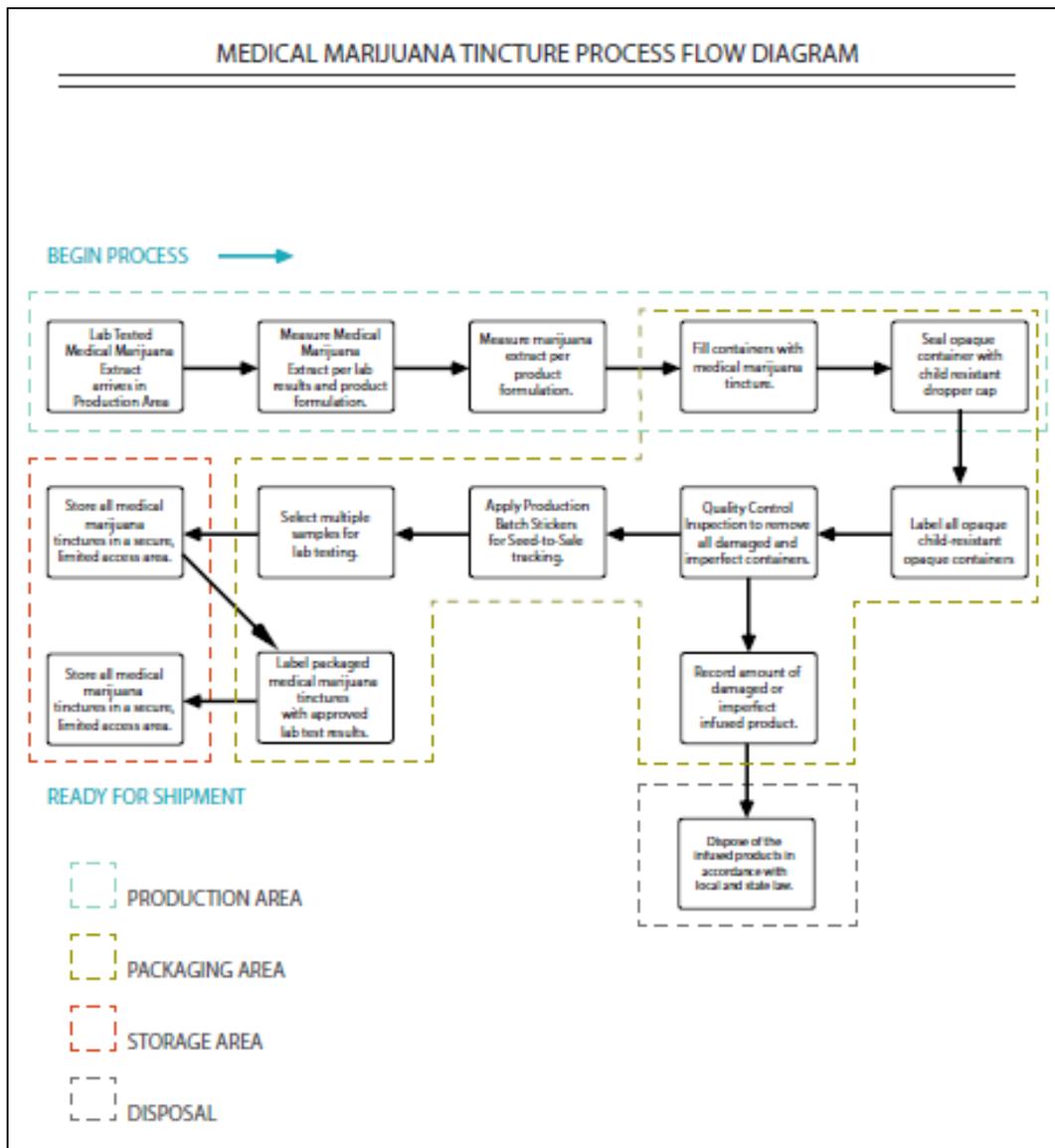
facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

Move all final marijuana products to a secure storage area within the Production Area to await lab test results.

Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.

Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Tincture can be seen below:*



**PRODUCTION OF MARIJUANA SUBLINGUAL TABLET**

**PRODUCT DESCRIPTION**

Medical Marijuana Sublingual Tablet

**POLICY**

To prepare and package marijuana concentrate into accurately dosed sublingual Tablets.

**RESPONSIBILITY**

Production Manager or their designee.

**RECORDS**

Production Log

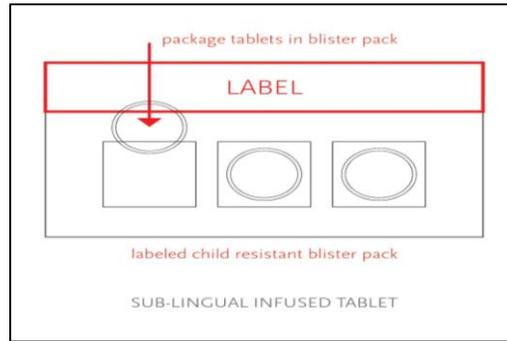
Seed-to-Sale Inventory Tracking System

**PROCEDURE**

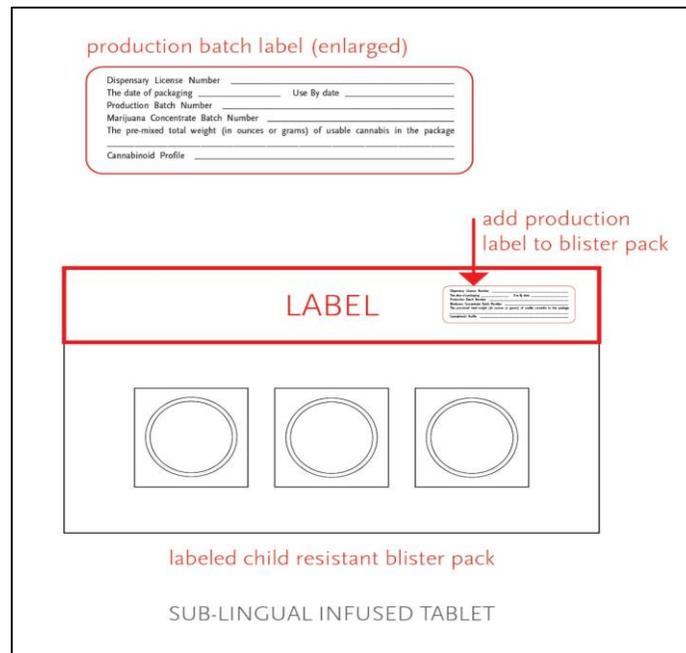
1. Before daily processing begins, sanitize work surface with 50 - 200 ppm sanitizer solution.
2. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level.
3. Wipe all work surfaces with bleach solution, allow to air dry
4. Ensure that all utensils are cleaned and sanitized.
5. Have a container with sanitizer on the table at all times.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form by assigning a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name. The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form Inventory Tracking Software Inventory Tracking software will be used to track all medical marijuana products.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a State certified testing lab ensure consistent and metered medical marijuana products.
9. Use a NTEP approved scale to measure an accurate amount of marijuana extract per medical marijuana product formulation.
10. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Use the assembled and sanitized equipment to form the tablets. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of medical marijuana product. Quality Control Direct Observation of the tablets to provide a safe and consistent medical marijuana product.



13. Operate the packaging equipment to package tablets in child resistant packaging. The packaging provides a consistent and recognizable child resistant packaging to provide safety for the patient.



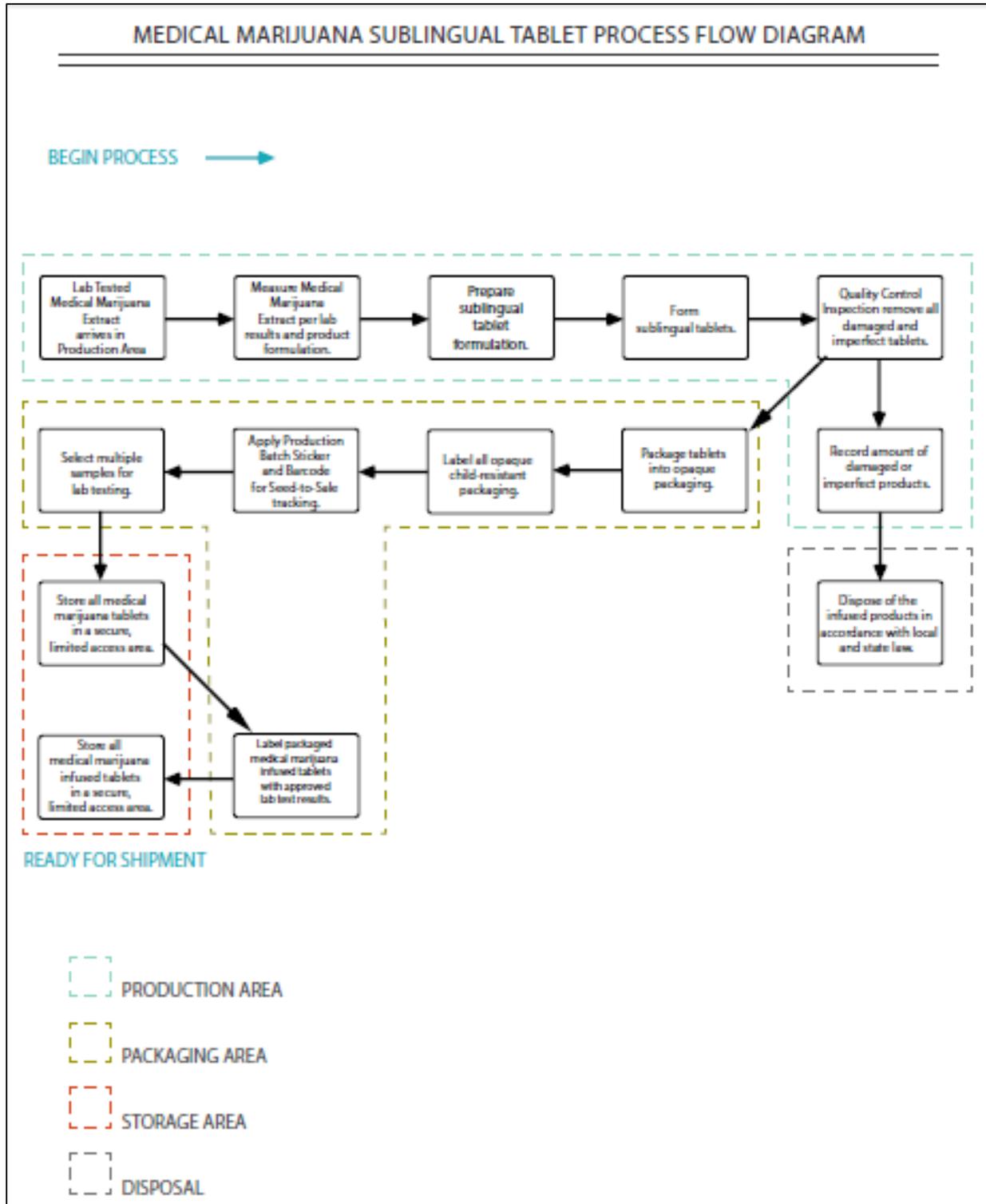
14. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information.



15. Final Quality Control Inspection of product.
16. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
17. Once documented render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
18. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch.
19. Enter Batch Number, quantity produced, date of production, and marijuana extract Batch information into Inventory Tracking Software.

20. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
21. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
22. Upon receiving approved test results for the marijuana product Production Batch, apply Production Batch Sticker to the final product. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
23. Apply the Production Batch Sticker which will contain the following information:
  - a. Dispensary License Number
  - b. The date of packaging and “use by” date
  - c. Production Batch Number
  - d. Marijuana Concentrate Batch Number
  - e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - f. A list of cannabinoid content by weight.
24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

***The Process Flow Diagram for Marijuana Infused Sublingual Tablet can be seen below:***



### PRODUCTION OF INFUSED TOPICAL LOTION

#### PRODUCT DESCRIPTION

6oz Medical Marijuana Infused Lotion

#### POLICY

To prepare and package Infused Topical Lotion in child resistant packaging. All production will be documented.

## RESPONSIBILITY

Production Manager or their designee.

## RECORDS

Production Log  
Inventory Tracking Software

## PROCEDURE

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.

**multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run

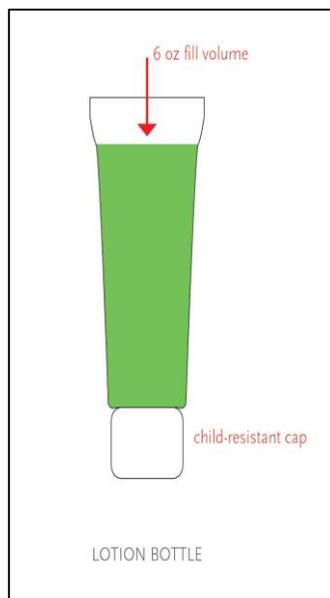
$(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$

**divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.



(#) total mg needed/(#) mg THC per gram =  
grams of concentrate to use in production

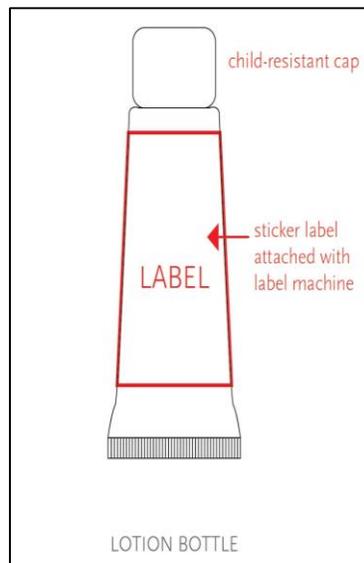
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
13. Fill Topical Lotions to the 6oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Lotion package properly so that front of label is centered on front of the package.



18. Apply the Production Batch Sticker which will contain the following information:
- Dispensary License Number
  - The date of packaging and "use by" date
  - Production Batch Number
  - Marijuana Concentrate Batch Number
  - The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - A list of cannabinoid content by weight.

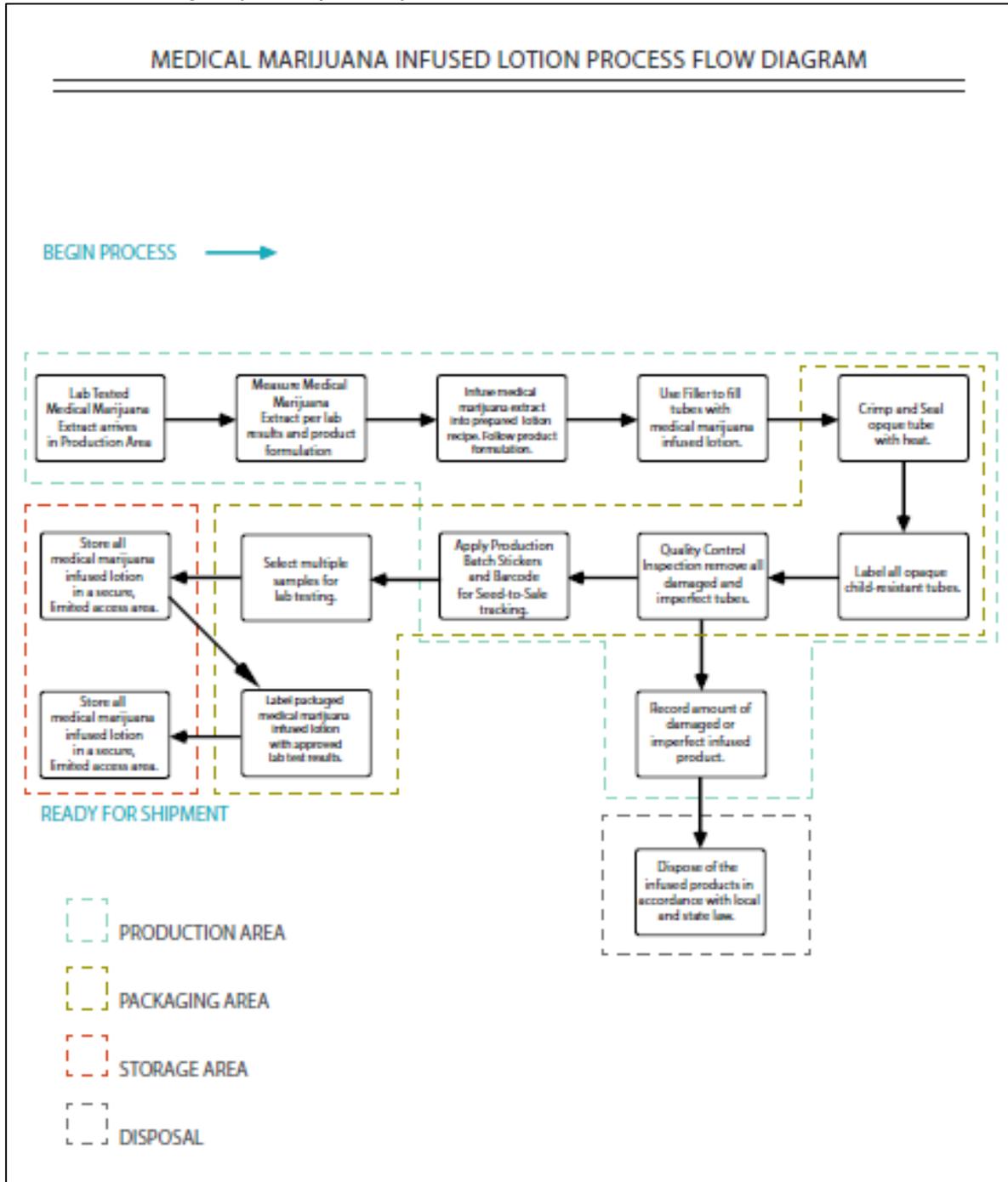


19. Final Quality Control Inspection of product includes:
  - a. proper label applied correctly
  - b. proper production batch label applied correctly
  - c. dropper cap is applied correctly
  - d. package is clean and dry
20. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
21. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
22. Complete the Production Form and enter information into Inventory Tracking Software.
23. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
24. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
25. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.



26. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

The Process Flow Diagram for Marijuana Infused Lotion can be seen below:



**PRODUCTION OF MARIJUANA CAPSULE**

**PRODUCT DESCRIPTION**

Medical Marijuana Infused Capsule

## **POLICY**

To prepare and package marijuana concentrate into consistent and metered capsules.

## **RESPONSIBILITY**

Production Manager or their designee.

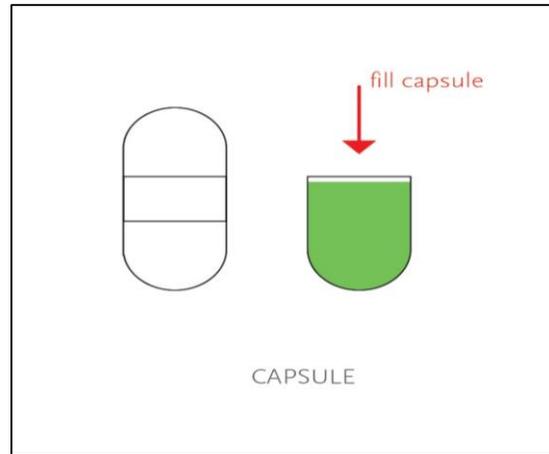
## **RECORDS**

Production Log

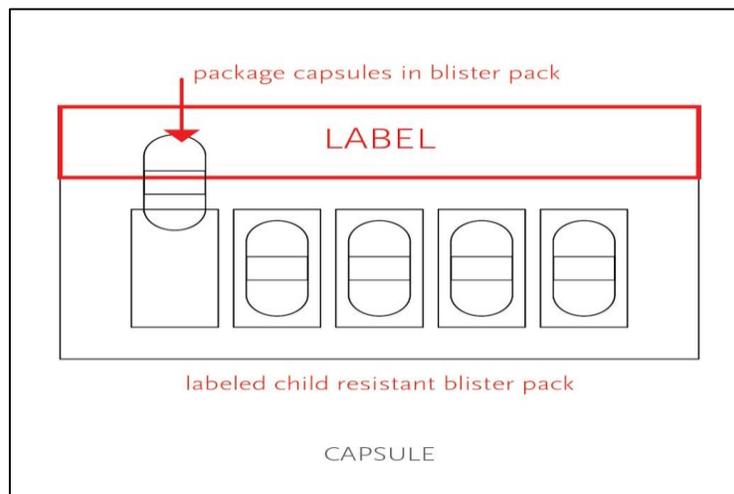
Seed-to-Sale Inventory Tracking System

## **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50 - 200 ppm sanitizer solution.
2. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level.
3. Wipe all work surfaces with bleach solution, allow to air dry.
4. Ensure that all utensils are cleaned and sanitized.
5. Have a container with sanitizer on the table at all times.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form by assigning a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name. The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form Inventory Tracking Software Inventory Tracking software will be used to track all medical marijuana products.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a State certified testing lab ensure consistent and metered medical marijuana products.
9. Use a NTEP approved scale to measure an accurate amount of marijuana extract per medical marijuana product formulation.
10. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Using the assembled and sanitized packaging equipment to fill and seal Capsules. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product. Quality Control Direct Observation of the filled and sealed containers will document proper quantity amounts and sealing of each container to provide a safe and consistent marijuana product.



13. Operate the packaging equipment to package and label capsules in child resistant packaging. The packaging provides a consistent and recognizable child resistant packaging to provide safety for the patient.



14. Final Quality Control Inspection of product.

15. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, Reason for disposal, and Quantity of the marijuana product to be disposed of.

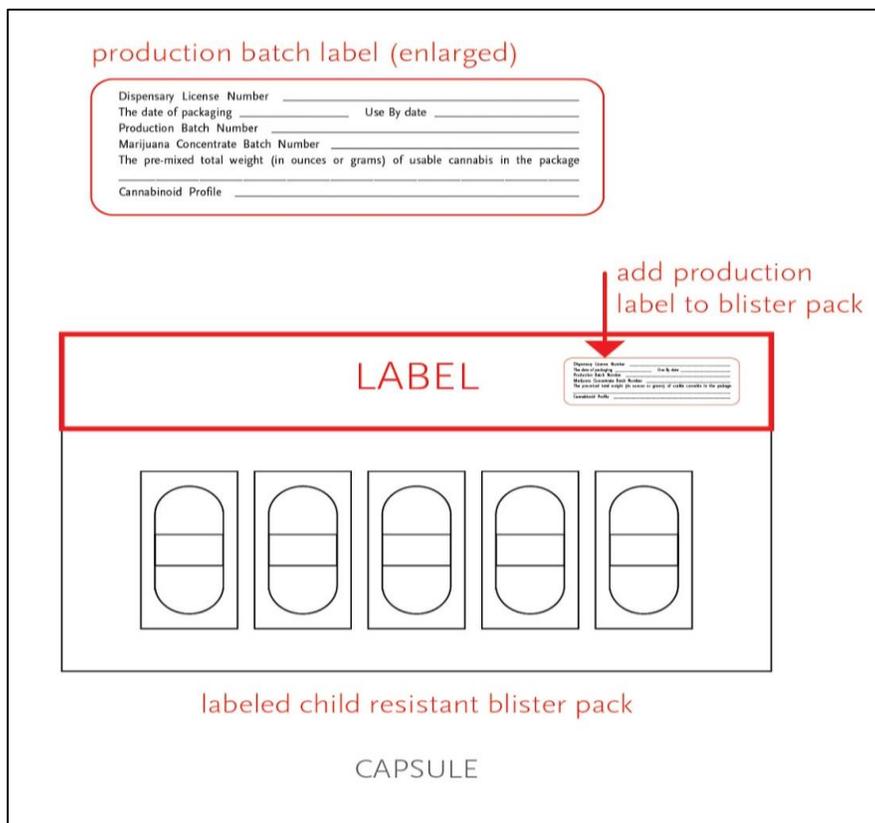
16. Once documented render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.

17. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch.

18. Enter Batch Number, quantity produced, date of production, and marijuana extract Batch information into Inventory Tracking Software.

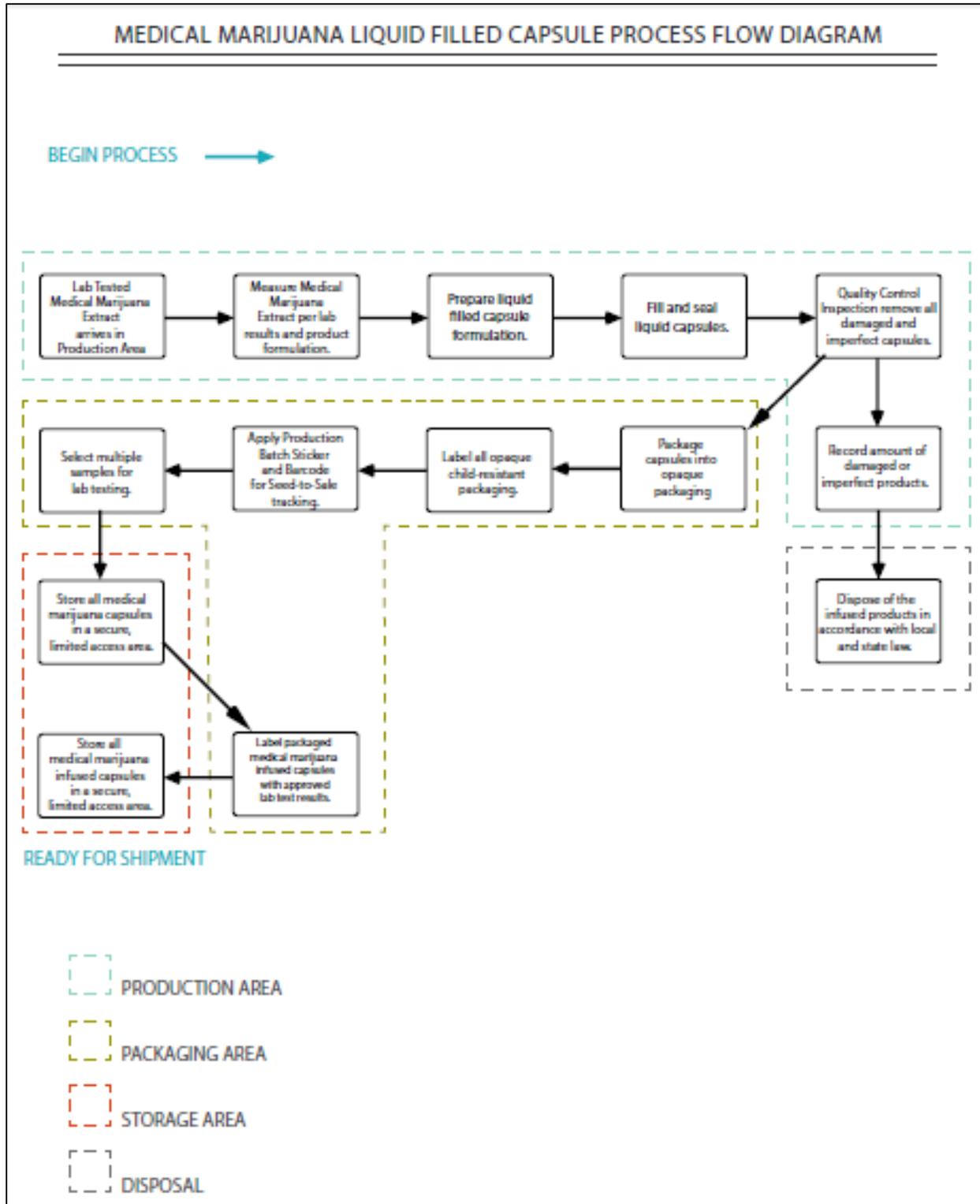


19. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
20. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
21. Upon receiving approved test results for the marijuana product Production Batch, apply Production Batch Sticker to the final product. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
22. Apply the Production Batch Sticker which will contain the following information:
  - a. Dispensary License Number
  - b. The date of packaging and “use by” date
  - c. Production Batch Number
  - d. Marijuana Concentrate Batch Number
  - e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - f. A list of cannabinoid content by weight.



23. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Liquid Filled Capsule can be seen below:*





-----**CLOSED LOOP SUB AND SUPERCRITICAL CO<sub>2</sub>**-----

**EXTRACTION**

**PRODUCT DESCRIPTION**

A concentrated extract of cannabinoids including but not limited to THC, THCA, THCV, CBD, CBDA, CBDV, CBN, CBG, and CBC derived from the leaves and flowers of the female marijuana plant.

**EXTRACTION METHOD**

CO<sub>2</sub> has a polarity that is compatible for the solubilization of lipophilic compounds such as lipids and essential oils. The low polarity index makes SFE CO<sub>2</sub> highly advantageous during medical marijuana extraction. Closed-Loop Sub/Supercritical CO<sub>2</sub> and Co-Solvent Introduction. CO<sub>2</sub> is a non-polar solvent. We utilize the latest Subcritical (17 MPa / 2500 PSI and below) and Supercritical (above 17 MPa/ 2500 PSI) Fluid Extraction (**SFE**) technologies and combine them with our own proprietary processes, formulas and equipment. SFE allows the processing of our medical grade marijuana at low temperatures limiting thermal degradation while preserving the most vital medicinal components of the plant.

**POLICY**

To follow all company standard operating procedures and sanitation protocols while manufacturing marijuana extract in compliance with Hawaii State and local law.

**RESPONSIBILITY**

Lab Manager or their designee.

**RECORDS**

Seed-to-Sale Inventory Tracking Software

**EQUIPMENT**

- 1) One extraction vessel 5000 mL in size.
- 2) Two separators each 1500 ML in size.
- 3) Temperature range maintained between 40 and 50 °C.
- 4) Pressures are created to subject the marijuana flowers to either a subcritical extraction process or a supercritical extraction process.

Pressure variance applied to each process:

- subcritical extraction process pressures: (17 MPa\* and below)
- supercritical extraction process pressures: (above 17 MPa to 69 MPa)

\* MPa: 1 megapascal (MPa) = 145.037738 pound-force/square inch (PSI)

**Our Sub/Supercritical Extraction Process is illustrated in 8 procedures:**

2. Penetration of matrix (marijuana plant matter).
3. SCF solubilizes the solutes inside the pores.
3. Intra-particle (or internal) diffusion of the solutes takes place until the external surface is fully saturated with solvent.
4. External (or film) diffusion of the solutes from solid-fluid interface to the SCF bulk.
5. Precipitation of target solutes in the trapping system by changing the pressure and/or temperature of the fluid.
6. Apply proprietary formulas that vary time intervals and solvent quantities to control and output the anticipated extraction grade and type.



7. Apply proprietary extract refinement processes to complete the end product output.
8. Based on the final extract output selected, Co-solvents are sometimes introduced at different phases of the extraction process.

**(8a) CO-SOLVENT Introduction:**

Co-solvents are introduced at different time phases of the extraction process based on the desired final product. Primary intervals are 25%, 50%, and 75% time interval to completion of the extraction process.

Additional Extraction Runs, Matrix Disposal and further Solvent Reclaim:

Due to our closed-loop extraction equipment, all solvents are reclaimed for re-use or disposed per State of Hawaii solvent removal procedures. Due to the primary extraction process achieving a greater than 90% efficiency very little extract potential resides within the marijuana plant matter. The remaining extract potential of the marijuana is subjected to a primary ethanol solvent rinse to capture all remaining marijuana extract. The exhausted post extract marijuana plant matter is then classified as “unusable” and packaged for safe removal and disposal from the lab.

A) Subcritical extraction process (17 MPa and below)

Time Interval to completion of process is related to the percentage (%) of co-solvent introduced of total solvent in system at a temperature range: 40- 50 °C.

- 25% / 10%
- 50% / 5%
- 75% / 2%

B) Supercritical extraction process (above 17 MPa to 69 MPa)

Time Interval to completion of process is related to the percentage (%) of co-solvent introduced of total solvent in system at a temperature range: 40- 50 °C

- 25% / 10%
- 50% / 5%
- 75% / 2%

**Extraction Process Yield:**

Yields utilizing our proprietary CO<sub>2</sub> and co-solvent methods are expected to be greater than **90+%**.

The remaining extract potential of the marijuana is subjected to a primary food-grade ethanol solvent rinse to capture all remaining marijuana extract from the plant matter.

The extraction equipment schematic is illustrated in **Diagram Two:**

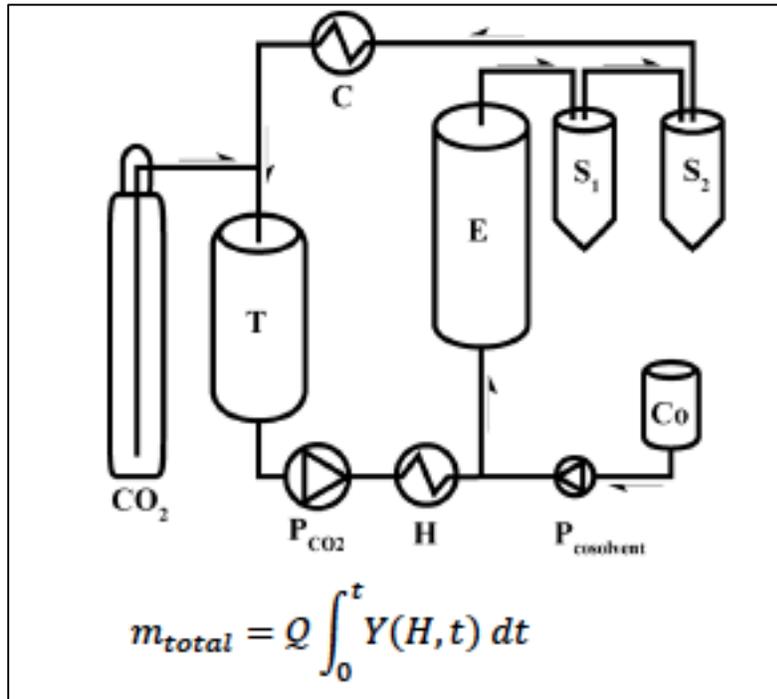
First, the liquid carbon dioxide is pumped through a heat exchanger to reach the system at supercritical state. Next, the SC CO<sub>2</sub> is uniformly pumped into the extractor where the dry and ground plant material forms a fixed bed of solid matrix. The extraction can be performed in static (with no follow-through) or dynamic (with follow-through) mode or in a mixed approach. During extraction, the supercritical solvent passes through the plant matrix bed and dissolves the soluble compounds. The mixture solvent-plant solutes are separated in flash tanks (cyclonic and gravimetric separators) usually changing drastically the solvent power of CO<sub>2</sub> by depressurization or temperature change or both. Then, CO<sub>2</sub> is cooled at liquid state and compressed to return to the extractor.



American Cannabis Company  
growing the next frontier



Raw Diagram of the supercritical fluid extraction process:



Legend Descriptor for Supercritical Extraction machine:

- (T): Storage Tank
- (PCO2): CO<sub>2</sub> Pump
- (H): Heat exchanger
- (Co): Solvent Pump
- (E): Extraction vessel
- (S1-S2): Separation cells
- (C): Condenser

The versatility of SC CO<sub>2</sub> as extraction technology utilizes the solvent's efficiency through the simple change of pressure and temperature. The range of variation of SC CO<sub>2</sub> density is relatively wide, from 0.2 g cm<sup>-3</sup> at 8 MPa and 40 °C to 1.0 g cm<sup>-3</sup> at 69 MPa and 50 °C. Furthermore, the increase of temperature leads to reduction of density of supercritical fluids but, on the other hand, the increase of temperature affects the volatility of target compounds. For volatile marijuana oil extraction through SC CO<sub>2</sub>, small changes in temperature cause significant changes in solubility with a non-linear relationship. The operative pressure is one of the primary parameters we utilize to influence the fluid density and therefore the solvent power of supercritical fluid and co-solvent. We also utilize the effects of temperature depends on the nature of plant material and has to be determined case by case.

For the analysis of solubility of target compounds and for the design of extraction process, four parameters are extremely helpful in the understanding of solute behavior in supercritical fluids. The miscibility or threshold pressure, that is the pressure at which the solute starts to be transferred into the supercritical fluid; the pressure of maximum solubility of solute; the fractionation pressure range, that is the pressure region between the miscibility and maximum solubility pressures and; the physical properties of the solute, particularly its melting point. The determination of the last two parameters allows us to define the best conditions for solubility and selectivity, because these compounds diffuse better above their melting points and an operative pressure between miscibility and maximum solubility increases the selectivity of extraction.

By closely monitoring, utilizing and adjusting the pressure and temperature during extraction, the global yield of the marijuana plant matter is determined and maintained. Global yield refers to a single target compound or to the global

mixture of compounds. This parameter is closely related to the solubility of the solute in the supercritical fluid. Moreover, the solubility of target compounds can be determined also from the slope of the linear portion of the extraction curve in the stage of constant-extraction rate period (CER).

Beyond the extraction parameters related to the engineering aspects such as pressure, temperature and flow rate, other factors related to the nature of plant material can influence the SFE. The particle size, shape, surface area, porosity, and moisture level of extractable solutes are variables that depend on the nature of the matrix or pretreatment of the plant material. As a rule, the smaller the particle size of the marijuana plant material, the more exposed surface for SC CO<sub>2</sub> penetration and solute heat transfer. However, the excessive grinding of the material might produce an extraction bed extremely thick and the SC CO<sub>2</sub> could find fast tracks inside the extractor (fluid channeling effect), thus reducing the contact with the plant material. This is closely monitored during our extraction phase to negate this occurring since it reduces the overall efficiency of the extraction process.

Moreover, the moisture content of the solid material influences not only the extraction quality and yield but also the fluid dynamics of the solvent. Water can act as co-solvent by interacting with the supercritical solvent and by changing the overall polarity of the fluid. However, extracted water can increase the formation of ice blockages. Therefore, drying the raw material is recommended in order to have a water content of around 4–14%.

Co-solvents act through two hypothetical mechanisms: solute-co-solvent interaction, and matrix swelling which facilitates the contact of the solutes with the solvent. The co-solvents do not have absolute mechanism of action; their effects are related to the type of co-solvent, plant material and target compounds. Studies about the effects of co-solvents at constant pressure and temperature evaluated the extraction efficiency of different modifiers at increasing percentages for volatile marijuana oil extractions. The addition of ethanol decreases the number of extracted terpenes with respect to pure SC CO<sub>2</sub> but increases the overall “whole plant” being extracted given the polarity of stated co-solvent.

We use co-solvents, especially at high percentages to change the critical parameters of the solvent mixture. Our co-solvent is food grade ethanol added in a percentage that varies from 1% to 15%

#### **4) ADVANCEMENT OF SFE EXTRACTION TECHNOLOGY:**

SFE is a technology that allows extraction of a wide range of diverse compounds. Our focus on utilizing, refining and expanding its use insures the best possible medical grade marijuana extracts available in the market.

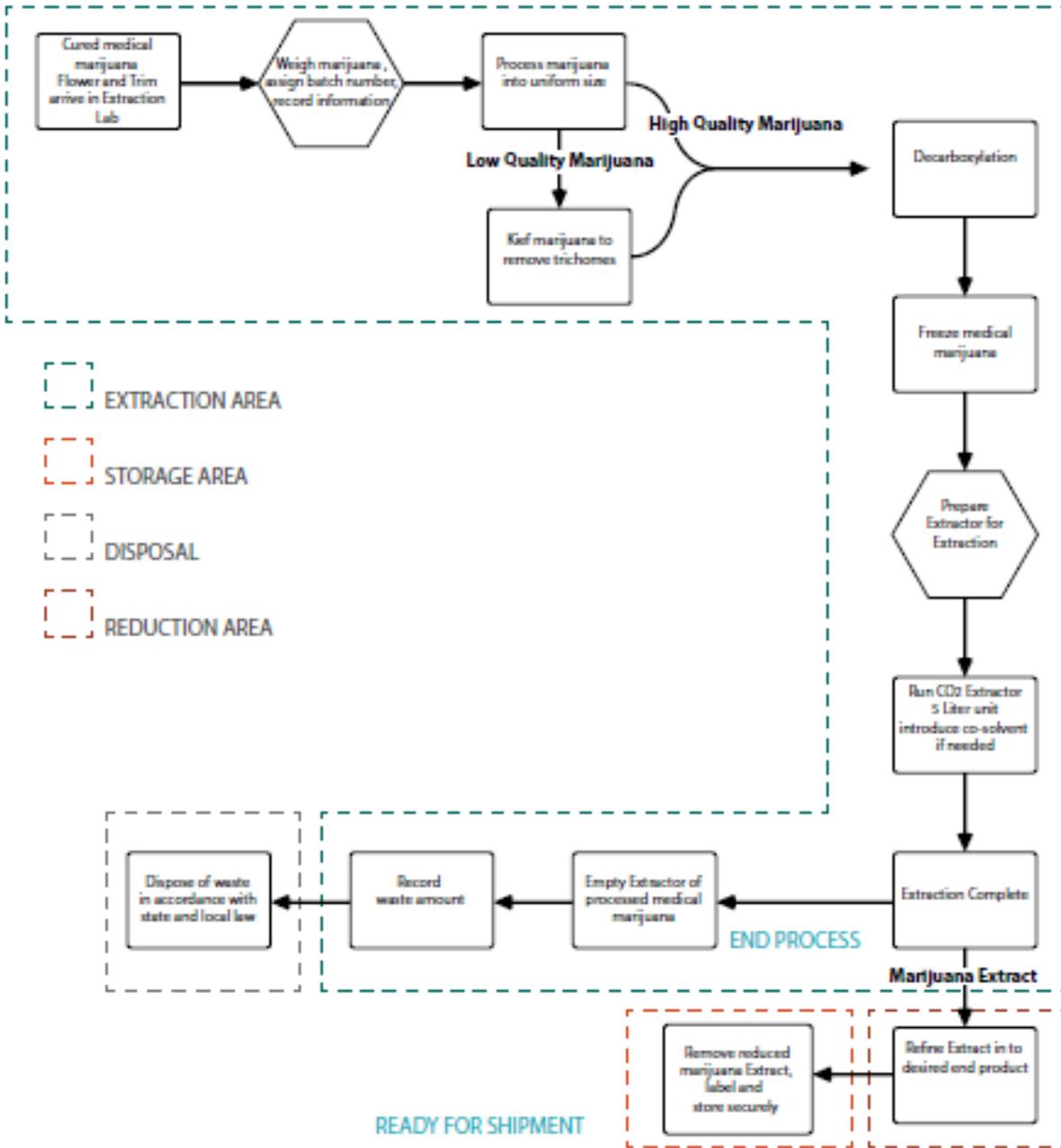
By focusing our efforts on natural solvents such as CO<sub>2</sub> and food grade ethanol we will continue to provide the most environmentally friendly, medically centered medicinal-grade marijuana extracts to patients. With our focus on “whole plant” extracts we continue to advance the accepted medical focus on the entourage effect, namely that the sum of the plant together offers far more medicinal benefits than a strict isolation and assimilation of any one component of the marijuana plant. Additionally, since SFE adds a new dimension to the pharmaceutical and nutraceutical medicine advancement, its potential technologically and economy provides new, sustainable, and safe marijuana extract based medicine to patients.

*The Process Flow Diagram for Marijuana CO<sub>2</sub> Oil can be seen below:*



### CO2 SUB/SUPERCRITICAL EXTRACTION FOR PRODUCTS AND CONCENTRATES (SOLVENT AND CO-SOLVENT) PROCESS FLOW DIAGRAM

BEGIN PROCESS →





---

## -----PACKAGING OF CO<sub>2</sub> OIL-----

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### **PRODUCT DESCRIPTION**

CO<sub>2</sub> Oil packaged in child resistant containers

### **POLICY**

To prepare and package CO<sub>2</sub> Oil packaged in child resistant containers. All production will be documented.

### **RESPONSIBILITY**

Production Manager or their designee.

### **RECORDS**

Production Log

Inventory Tracking Software

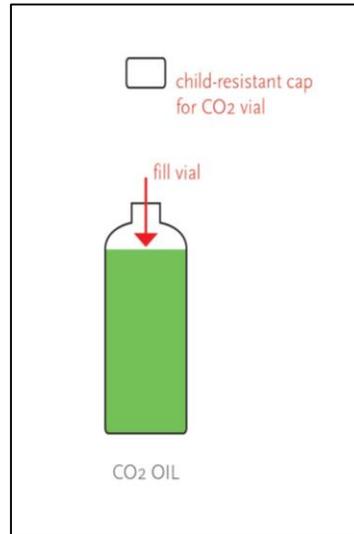
### **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all containers and droppers. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers and caps. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve CO<sub>2</sub> Oil from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Date and Product Name.
8. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
9. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
10. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the packaging of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to



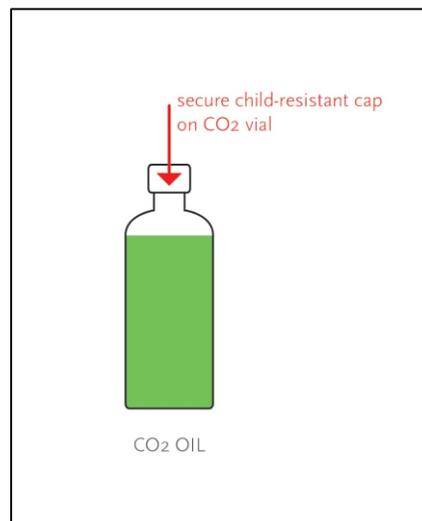
ensure safe and consistent medical marijuana products.

11. Fill CO2 oil vial using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



12. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.

13. Secure and seal child resistant cap. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

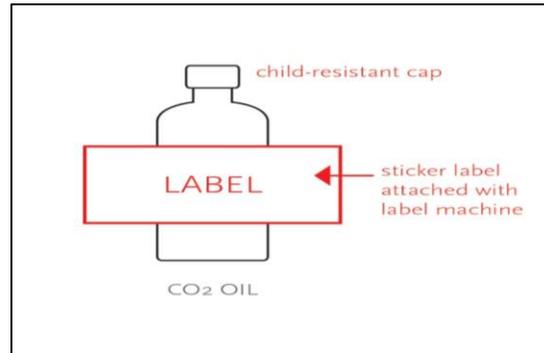


14. Turn power on to the Heat Shrink Tunnel. Set speed control to '3' and Heat control to 180F. For CO2 oil vial labeling close top 4 heat tunnel vents, leaving only the bottle 2 vents open. Allow 15 minutes for Heat Tunnel to reach temperature. If applicable turn on exhaust fan to remove hot air from production area.

15. Label with tamper evident, opaque shrink-wrap label. Perform and document Direct Observation Quality Control that labels contain all required information. "Sleeve" the bottled product. -- Place shrink wrap label onto

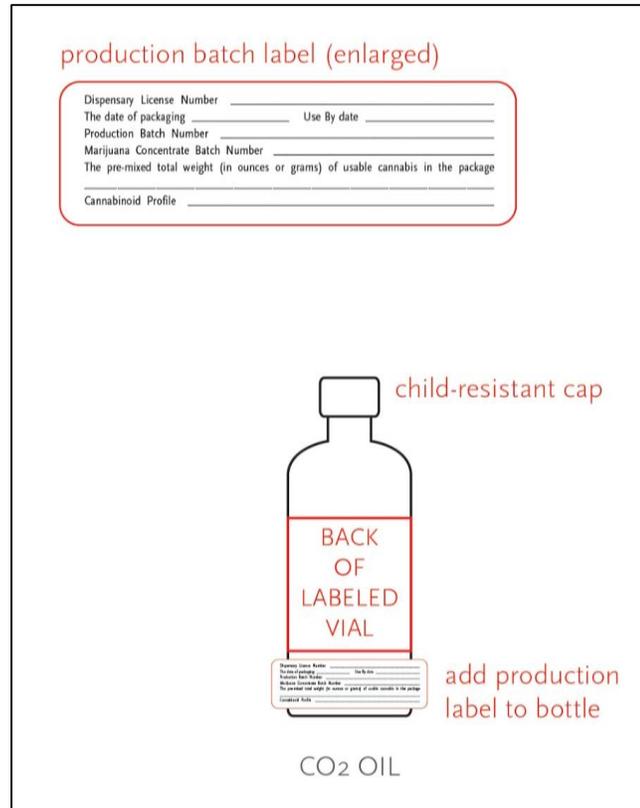


every filled and capped CO<sub>2</sub> oil vial by sliding the label over the container and positioning the label properly so that front of label is centered on front of bottle.



16. Run Sleeved product through the heat tunnel. Carefully place each unit onto the conveyor belt so that the CO<sub>2</sub> oil vial stays upright. Bottle placement should be so that the front of the bottle faces the left side of the Heat Tunnel. As CO<sub>2</sub> oil vial exit the Heat Tunnel each unit should be Quality Control inspected for tearing, wrinkling, stretching, or improper label placement. Adjust Heat Tunnel controls if necessary. Next. Label products with Production Batch Label.

17. Apply the Production Batch Sticker which will contain the following information:
- Dispensary License Number
  - The date of packaging and “use by” date
  - Production Batch Number
  - Marijuana Concentrate Batch Number
  - The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - A list of cannabinoid content by weight.



18. Final Quality Control Inspection of product includes:
  - a. proper label applied correctly
  - b. proper production batch label applied correctly
  - c. dropper cap is applied correctly
  - d. package is clean and dry
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for Disposal, and Quantity of the marijuana product to be disposed of.
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
21. Complete the Production Form and enter information into Inventory Tracking Software.
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
24. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and

consistent.

25. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

**-----PACKAGING AND LABELING MANUFACTURED MARIJUANA PRODUCTS-----**

**Weighing and Packaging Medical Marijuana**—is the process of accurately weighing the medical marijuana to be put into packages for distribution. Packaging regulations and requirements may vary, so it is essential to reference the state and local laws and regulations pertaining to packaging requirements for medical marijuana business. Use of NTEP certified scales for the weighing of all marijuana products is mandatory.

- All BPH packing will be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
- Packaging must be opaque so that the product cannot be seen from outside the packaging;
- The packaging must be constructed to protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.
- Packages must not contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; providing that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
- Marijuana will be carefully weighed and packaged at the production center. All products will be packaged, recorded into the inventory system, and labeled per Hawai'i regulations.



- Upon marijuana being weighed and packaged registered employees are required to document the marijuana weight associated to the product with a unique attribute number and batch number. This documentation must be done with two registered employees, one employee to make the record in the inventory control system and a second to witness the record.
- Ensure inventory control system is updated to show the packaged marijuana weights and specifications.

It is important for qualifying, registered patients' to understand the importance of packaging and labeling medical marijuana products. Proper packaging and labeling will achieve two primary objectives; 1) the medical marijuana product will be properly labeled to identify who the product is intended for, dosage rates and instruction and other important information pertaining to the patient or the medical marijuana derivative products, and 2) proper child-resistant packaging will help to ensure children cannot easily access the medical marijuana derivative product(s).

**Examples of Child-Resistant Packaging:**





Child Resistant Packaging to be used for pill-form edibles (*capsules*)



Child Resistant Packaging to be used for oils (*for sublingual administration*)



Metered Dosage Packaging to be used for oils (*vaporization administration*)



Tamper-Evident Packaging to be used for pill-form edibles (*capsules*)



Tamper-Evident Packaging to be used for oils (*for sublingual administration*)



Tamper-Evident Packaging to be used for oils (*for vaporization*)



**Labeling**—all packages of medical marijuana will require a label to be conspicuously placed on the package.

- Labels must be made of weather resistant and tamper-evident material
- As a redundancy, registered employees will be required to recheck each package for a label prior to shipping and package containing medical marijuana from the Licensed Premise.
- **Hawaii specific labeling requirements:**
  - Labels must use black lettering only on a white background with no pictures or graphics
  - Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
    - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
    - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
  - The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
  - The batch number and date of packaging;
  - A computer tracking inventory identification number barcode generated by tracking software;
  - Date of harvest or manufacture and a "use by date";
  - Instructions for use;
  - The phrases "For medical use only" and "Not for resale or transfer to another person";
  - The following warnings:
    - "This product may be unlawful outside of the State of Hawai'i and id unlawful to possess or use under federal law";
    - "This product has intoxicating effects and may be habit forming";



- “Smoking is hazardous to your health”;
  - “There may be health risks associated with consumption of this product”;
  - “This product is not recommended for use by women who are pregnant or breast feeding”;
  - “Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug”;
  - “When eaten or swallowed, the effects of this drug may be delayed by two or more hours”
- A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
  - The name of the laboratory that performed the testing

**Examples of manufactured marijuana product labels:**

**SAMPLE PRODUCT LABEL: LOTION**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**SAMPLE PRODUCT LABEL: SALVE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**SAMPLE PRODUCT LABEL: SERUM**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**SAMPLE PRODUCT LABEL: GEL**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.



**SAMPLE PRODUCT LABEL: CAPSULE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**CAPSULE**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, use or other directions to use. Includes any cautions, warnings and/or other instructions that are necessary to ensure safe and effective use of the product.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: TABLET**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**TABLET**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, use or other directions to use. Includes any cautions, warnings and/or other instructions that are necessary to ensure safe and effective use of the product.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: TINCTURE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**TINCTURE**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, use or other directions to use. Includes any cautions, warnings and/or other instructions that are necessary to ensure safe and effective use of the product.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: CO<sub>2</sub> OIL**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**CO<sub>2</sub> OIL**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, use or other directions to use. Includes any cautions, warnings and/or other instructions that are necessary to ensure safe and effective use of the product.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

- 1) **Secure, Segregated Storage**—Upon manufactured marijuana products being packaged, BPH registered employees will be required to hold the marijuana in secure, segregated storage until released for distribution
  - o The secure, segregated storage will be within the production center vault(s).



<b>Standard Operating Procedure:</b> Inventory Reconciliation Procedure
<b>Purpose:</b> To explain the purpose and processes involved with inventory reconciliation.
<b>Scope:</b> Covers the steps involved with inventory reconciliation.
<b>Initial Training:</b> 4-6 hours

### **The Principles of Inventory Reconciliation**

It is recommended to perform physical inventory on weekly or monthly basis. At minimum, a monthly inventory reconciliation is to be performed the production center. This is where every product within the facility will be physically counted, documented and then reconciled (*compared*) against the inventory recorded in the POS system or computer inventory system.

The physical inventory on-hand that is counted should be identical to the inventory that is recorded within the POS system. If there are deviations in these numbers then action must be taken to determine the shortage(s).

- 1) Count **ALL** on-hand inventory at the facility
  - Marijuana raw material
    - Marijuana trim leaf
    - Marijuana flower
  - Finished manufactured marijuana products
- 2) Document all counted on-hand inventories on the appropriate ***Marijuana Products Inventory*** log sheet.
- 3) Reconcile counted on-hand inventories against on-hand inventories in the POS system
  - Document discrepancies on the appropriate ***Marijuana Products Inventory*** and the ***POS Inventory Reconciliation*** and ***Product Loss Log Sheet*** between the counted on-hand inventory and POS inventory.
  - Investigate all discrepancies
- 4) Inventory Discrepancies—discrepancies between the inventory stock and the inventory within the inventory control system (*outside of normal weight loss due to moisture loss and handling*)
  - Investigate all discrepancies within one (1) business day
    - Perform inventory audit and reconciliation
    - Review transactions within the inventory control system
    - Review security surveillance footage
  - Report theft or diversion to the Department AND local Police within one business day
    - Contact the Department and local Police in multiple fashions as a redundancy
      1. Contact directly through phone conversation
      2. Contact electronically through email, fax or other electronic means
  - Within 30 days
    - the inventory discrepancy investigation must be conducted and completed
    - the standard operating procedures amended (*if needed*)
    - send an investigation report and audit to the Department

***Example of Manufactured Marijuana Products Inventory log sheet:***



<b><u>Manufactured Marijuana Products Inventory</u></b>						
<u>Date:</u>	<u>Raw Material Product Batch #/Plant ID #/Strain:</u>	<u>Raw Material Quantity:</u>	<u>Manufactured Marijuana Product Batch #:</u>	<u>Quantity</u>	<u>Employee 1:</u>	<u>Employee 2:</u>

Example of POS Inventory log sheet:

<b><u>Manufactured Products POS Inventory Reconciliation</u></b>							
<u>Date:</u>	<u>Product Name:</u>	<u>Product Batch #/Unique ID #:</u>	<u>Quantity On Hand:</u>	<u>Quantity in POS System:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Notes:</u>

Example of Product Loss log sheet:

<b><u>Product Loss Log Sheet</u></b>				
<u>Date:</u>	<u>Product Name/Category</u>	<u>Product Attribute # or Unique ID #</u>	<u>Total Quantity Loss:</u>	<u>Product Loss Valuation:</u>
				\$
<u>Reporting Employee:</u>	<u>Manager/Supervisor:</u>	<u>Product Loss Due To:</u>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<u>Internal Investigation:</u>	<u>Required Authorities Notified:</u>	<u>Authorities Notified (list all) :</u>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<u>Note/Comments:</u>				



Laboratory Testing

<b>Standard Operating Procedure:</b> Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana and manufactured marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

### **Documentation Log Sheets Required**

- 1) Cultivation Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

### **Equipment/Tools Required**

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

### **POLICY**

To submit medical marijuana for lab testing.

### **RESPONSIBILITY**

Production Manager, Extraction Manager or their designee.

### **RECORDS**

BioTrackTHC™ Seed-to-Sale Inventory Tracking System and physical documentation log sheets

### **PROCEDURES**

Any medical marijuana sample is tested at the lab for the required cannabinoid profile, contaminants, any pesticide/herbicide/fungicide used during production of the medical marijuana product, and any growth regulator used during production of the medical marijuana product. Test results will be transmitted directly from the Testing Lab to the Extraction Manager. The Extraction Manager will assign the test results to the extraction batch number and document results in inventory tracking software. The accurate cannabinoid profile information will be utilized in the production formulations and standard operating procedures for medical marijuana product production to ensure safe, secure, accurate and consistent cannabinoid dosing and labeling

#### **1. Post-Harvest:**

- a. The first phase of quality control consists of visually inspecting the leaves and flowers of harvested and cured marijuana. Upon approved inspection, samples of the leaves and flowers will be sent to a lab to test for potency and contaminants. A medical marijuana “leaves and flowers sample collection” SOP will be followed. Lab test results will be used:
  - i. to compare against post extraction results
  - ii. to ensure the cultivated and cured marijuana plants are of consistent quality and THC/CBD concentrations
  - iii. to create concentrates of consistent quality.
- b. Uniform and homogenous leaves and flowers samples will be placed within sealed, child-resistant containers. One sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the



sample to the testing lab. Remaining samples will be kept securely stored for future testing as required.

## 2. Post Processing:

- a. The second phase of quality control will test the extract produced from the leaves and flowers of the marijuana plant. A sample from each lot of extract will be tested to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. A uniform and homogenous sample will be placed within a sealed, child-resistant container. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab.

## 3. Finished Product:

- a. A number of samples, which accurately represent the production lot of the final medical marijuana product, will be selected for lab testing. Cannabinoid profile and contaminant testing will be performed to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. “Final medical marijuana product samples” will be submitted to the testing lab facility, sealed, packaged and labeled exactly as they will be delivered to a patient obtaining the product at a dispensing facility.
- c. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab. All final medical marijuana products will be kept secured in a limited access area until approved test results are received. No final medical marijuana product will be shipped to a dispensing facility until approved lab test results are received and the final marijuana product is labeled with test results.

## Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

## State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)



- Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.
  - If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the *Marijuana Waste SOP* upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

### **Preparation of Medical Marijuana Samples to be Tested**

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Manufactured marijuana products—ensure adequate quantity from batch for sampling (~2-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# MIP001 → Create new ‘Sample Package’: MIPT101
- Fill out all required documentation/log sheets
  - *Samples for Laboratory Testing*
  - *Marijuana Product Shipping Manifest*



<u>Marijuana Samples for Laboratory Testing</u>					
Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:

- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow *Shipping, Transferring/Transporting SOP*

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show marijuana product potency, cannabinoid profiles, terpene profiles, contaminants (if any present). The testing laboratory will provide BPH test results from each batch tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meets all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**— there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm$  90-100% of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating



It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.

- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<b><u>Marijuana Batch Samples for Laboratory Testing</u></b>						
<b>Date Sample Prepared:</b>	<b>Grower Agent #1:</b>	<b>Grower Agent #2:</b>	<b>Product Attribute ID #, Batch# and Strain/Variety</b>	<b>Sample Quantity/Weight:</b>	<b>Test Sample ID # (NEW):</b>	<b>Receiving Laboratory:</b>
<b>Date Sample Shipped:</b>	<b>Sample Pass Testing</b>	<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>If sample failed testing, will batch be reprocessed or destroyed?</b>		<b>Licensed Processor to Send Batch to:</b>	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed			
<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>			<b>Notes/Details:</b>	
<b>Date of 6-month interval test:</b>	<b>Sample Pass Testing</b>	<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
<b>Notes/Comments:</b>						

**Release for Distribution**

All batches of marijuana products are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH’s registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.



- This process will be completed by two (2) registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

**Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.



Transferring/Transporting Marijuana Products Transferring/Transporting

**Standard Operating Procedure: Transferring/Transporting Marijuana Products**

**Purpose:** To explain the steps required to be followed to transport marijuana and manufactured marijuana products to BPH retail dispensary locations.

**Scope:** Covers the training required and procedures for registered employees covering the transferring/transporting of marijuana and manufactured marijuana products.

**Initial Training:** 2-4 hours

**The Principles of the Transferring/Transporting Procedure**

transport

**The Shipping Process:**

- 1) New Transfer/Transport Order
- 2) Fulfillment
- 3) Create Manifest/Trip Plan
- 4) Transportation
- 5) Delivery
- 6) Post-Delivery

**1) New Shipping Order**

- 1) Fill out *Marijuana Products Shipment (Outgoing)* log sheet
- 2) Create a new invoice for transport order
  - a. Date that order is placed
  - b. Products and quantities ordered
  - c. Prices of products
  - d. Estimated delivery date

**2) Fulfillment**

- 1) Collect products needed for transfer/transport order
- 2) Take ordered/collected products out of the inventory control system
- 3) Package the order of products into a container that is constructed on tamper-evident, opaque material
  - a. The use of tamper-evident cardboard boxes, hard plastic opaque cases that can be locked with tamper-evident seals or locks, or a similar shipping package that will meet Hawaii requirements
  - b. Seal said tamper-evident package with tamper-evident tape.
  - c. If shipping multiple packages to the same recipient, the packages will need to be shipped within one large opaque tamper-evident container.
- 4) **Repackaging**—if necessary, registered employees may have to repackage the shipment into a container that is constructed of tamper-evident opaque materials and sealed with tamper-evident tape
  - a. This will typically only happen if the original packaging is defective or gets destroyed.
  - b. Medical marijuana will need to be repackaged if not originally packaged in an opaque container.
  - c. Repackaging may be required if multiple packages are identified as being shipped to the same recipient
    - i. If this is the case, then the packages will need to be repackaged into one large opaque tamper-evident container and sealed with tamper-evident tape
      1. Ensure package is sealed with tamper-evident tape; seal all entry/access points
- 5) Complete the *Marijuana Products Daily Transfer/Transport* log sheet
  - a. Example of *Marijuana Products Daily Transfer/Transport* log sheet can be seen below:



### Manufactured Marijuana Products Daily Transfer

<u>Date:</u>	<u>Employee Preparing Transfer:</u>	<u>Manufactured Marijuana Product Name/Batch ID #/Strain:</u>	<u>Quantity Transported:</u>	<u>Receiving Retail Dispensary Location:</u>	<u>Receiving Employee:</u>

- 6) Create new record within the inventory control system for the products being shipped—registered employees will need to create a record of the products prior to shipping any marijuana products.
  - a. Information required on record:
    - i. Date and time of the sealing of the package for shipment
    - ii. Name a signature of the registered grower agent who prepared and sealed the package
    - iii. Name and address of BPH
    - iv. Shipment identification number
    - v. A description of the package being shipped including the weight of each item
    - vi. The name and address of the party receiving the shipment

### 3) Manifest/Trip Plan Creation—See *Marijuana Product Shipping Manifest SOP*

Prior to the transportation of any marijuana products or marijuana-infused products a facility agent will generate a manifest/trip plan including at a minimum:

- 1) The name of the agent(s) who will be transporting;
- 2) The automobile license plate, make and model;
- 3) The date, start time of the trip and estimated delivery time;
- 4) A description including the exact amount, type and batch of any marijuana products and marijuana-infused products being transported; and
- 5) The intended route of transportation.

Facility management shall maintain a copy of the manifest/trip plan document at the location of departure, record the manifest/trip plan with any needed authorities, and the transporting employees will maintain a copy of the manifest/trip plan during the transportation.

### 4) Transportation/Shipping

This section covers how to transport the wholesale order to the purchasing organization/facility. All applicable state and local laws/regulations pertaining to transportation of medical marijuana products will need to be strictly adhered to by all organization team members. All transportation/shipping to be done in-house by BPH registered employees and/or transportation agents. BPH does not intend to use a secure transportation company unless deemed absolutely necessary.

**Transportation Vehicle Requirements**—all agents responsible for transporting medical marijuana must:

- 1) Use of an unmarked, unidentifiable vehicle
  - a. Vehicle should not have any BPH markings, logos or identifiers on the vehicle
  - b. Vehicle should not raise awareness that it may be transporting medical marijuana and/or medical marijuana products of any kind



- 2) Ensure the vehicle has current, valid registration from the State
  - a. Registration paperwork should be located in vehicle glovebox
  - b. Vehicle license plate should have current, valid registration sticker
- 3) Ensure the vehicle has current valid proof of insurance
  - a. Proof of insurance paperwork should be located in the glovebox

**Transportation Agent Requirements**—all agents responsible for transporting medical marijuana must:

- 1) There will be at minimum two registered employees and/or transportation agents for every product shipment. Each transportation agent will play a separate and vital role.
  - One transportation agent will be required to drive the transportation vehicle and to remain with the transportation vehicle at all times.
  - The second transportation agent is to remain with the medical marijuana product be shipped at all times and to ensure that the product is secure at all times during transport.
- 2) Wearing appropriate work attire
  - Work attire for BPH transportation agents will be plain with no company logos, brands or identification.
  - BPH transportation agents should not appear to indicate ownership or possession of marijuana.
    - Plain polo shirt
    - Plain khakis/jean pants
    - Plain dress/tennis shoes
      - Failure to arrive to a scheduled shift with proper attire will result in not being able to make transports, incident noted in personal file and possible disciplinary action.
- 3) Possess a current and valid State-issued marijuana industry worker license;
- 4) Possess a current and valid State-issued driver's license;
- 5) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or marijuana-infused products pursuant to regulation, all transporting agents shall:

- 1) Carry a copy of the manifest/trip plan with him or her for the duration of the trip;
- 2) Wear their agent card and/or have Commission approved identification readily available;
- 3) Use a vehicle without any medical marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or marijuana-infused products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation as well as a back-up emergency cell phone; and
- 5) Ensure that the medical marijuana is not at all visible to the public.

## **5) Delivery**

- 1) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the shipping manifest/trip plan
- 2) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

## **6) Post-Delivery**

**Post-Delivery Protocol**—after transporting marijuana products or marijuana-infused products, pursuant to the regulations the employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.



**Documentation of Delivery**—both the transporting dispensing facility and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Division agents for review upon request.

**Deviations from Transportation Plan**—the transporting agent shall immediately report all diversion due to loss or theft of marijuana or marijuana-infused products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the state licensing authorities as required per state regulations. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



<b>Standard Operating Procedure:</b> Marijuana Product Transport Manifest
<b>Purpose:</b> To explain the requirements for the marijuana products shipping manifest
<b>Scope:</b> To educate and train registered employees on the creation and use of the marijuana products shipping manifest
<b>Initial Training:</b> 1-2 hours

**Principles of the Electronic Manifest**

The shipping manifest will be required for each and every transfer/transport of marijuana product from BPH’s production center. Registered employees will be required to complete the physical marijuana product shipping manifest form.

Prior to transporting a package containing marijuana and/or manufactured marijuana products, BPH will require registered employees to complete the marijuana product shipping manifest process. Registered employees will need to complete the manifest form and scan/email a copy of the manifest to the retail dispensary location recipient. Registered employees and/or transportation agents will also maintain two (2) physical copies of the manifest form to keep and have present during any transporting of marijuana products. Upon delivery of the marijuana products, the shipping registered employee will provide a physical copy of the manifest for the recipient to maintain.

**Requirements**

All shipment are required to use a manifest for chain of custody procedures and to ensure safe transport of marijuana products and that no theft or diversion is occurring during transport. BPH will utilize a manifest to record the chain of custody for the shipment of products containing marijuana. The manifest will include a chain of custody that records:

- The name and address of the shipping licensee;
- The shipping licensee’s shipment identification number;
- The weight and description of each individual package that is part of the shipment, and the total number of individual packages;
- The name of the registered employee that prepared the shipment;
- The name and address of the receiving licensee; and
- Any handling or storage instructions.

**Chain of Custody**—shipments with packages containing marijuana will need to be tracked and recorded throughout the transport process within the inventory control system. The chain of custody for all transports containing medical marijuana must be accurately documented within the manifest and inventory control system.

The inventory control system will contain, at a minimum, the following entries as a chain of custody, in the order listed:

- An entry by the registered employee who has prepared the shipment, including the date and time of preparation;
- An entry by a shipping licensee’s registered employee, of the date and time of the placement of the shipment into the marijuana product transport vehicle;
- An entry by licensee’s registered employee receiving the shipment including the date and time of the acceptance; and
- If any other person had custody or control of the shipment, that person’s identity, the circumstances, duration, and disposition.



A manifest **MUST** be created for **EACH** shipment of products containing medical marijuana.

BPH will require registered employees to complete a ***Marijuana Product Transport Manifest Form*** prior to transporting or shipping any marijuana and/or manufactured marijuana products. Refer to the ***Transport/Transfer Marijuana Products SOP*** for transportation requirements. ***Marijuana Product Transport Manifest Form can be seen below:***

		<b><u>Marijuana Product Transport Manifest</u></b>		<b>Transfer Identification #:</b>		<i>Test results included for ALL products being shipped?</i> YES NO	
*This form must be completed prior to the shipping of any marijuana or manufactured marijuana products. This Record for Transfer must be present along with the Transportation/Trip Manifest Form with ALL shipments of marijuana and/or manufactured marijuana products from the Licensed Premise.							
Date Package/Shipment Sealed:		Time Package/Shipment Sealed:		License # of Originating Entity:			
Name of Registered Employee who prepared and sealed the package:							
Signature of Registered Employee who prepared and sealed the package:							
Name of Originating Entity: Blue Planet Healing LLC							
Address of Originating Entity:						Phone #:	
						Email:	
*If you are delivering more than fifteen (15) products to one stop, use a second form to list the additional product(s).							
<input type="checkbox"/> Check Here if multiple pages are used <span style="float: right;">List the total number of pages in the Manifest here _____.</span>							
Receiving Retail Dispensary Location Information			Marijuana/Product(s) within the Shipment	Quantity/Weight	Attribute #/Product ID #		
Stop Number on Route:			1)				
Name of Receiving Party:	Blue Planet Healing LLC		2)				
License # of Retail Dispensary Location:			3)				
Address of Receiving Retail Dispensary Location:			4)				
			5)				
Phone # of Receiving Dispensary:			6)				
Date and Approximate Time of Departure:			7)				
Date and Approximate Time of Arrival:			8)				
Route to be Traveled:			9)				
			10)				
			11)				
			12)				
			13)				
			14)				
			15)				
Additional Description: <i>(add description/details about the marijuana products and/or manufactured marijuana product(s))</i>							
<b>PRODUCT REJECTION</b> <i>(if only a portion of the shipment is rejected, circle that portion above.)</i>							
Name of Person Receiving or Rejecting Product(s):						Date:	
I confirm that the contents of this shipment match the weight records above, and I agree to the custody of those portions of this shipment <b>NOT</b> circled above. Those portions that <b>ARE</b> circled above were returned to the individual delivering this shipment.							
Signature:				Signature of Individual Taking Receipt of Rejected Portion of this Shipment:			
Name of Person Transporting Product(s):				Signature of Person Transporting Product(s):			
Make, Model, License Plate #:						Date of Signature:	



Customer Complaints and Returns

**Standard Operating Procedure: Customer Complaints and Returns**

**Purpose:** To explain the steps involved for handling customer complaints and product returns.

**Scope:** Covers the steps involved to handle customer complaints and product returns appropriately.

**Documentation Log Sheets Required**

- 1) Customer Complaint Form
- 2) Returned Marijuana Products Log Sheet
- 3) Returned Marijuana Products Waste

**The Principles of Handling Customer Complaints and Product Returns**

It is important to have proper procedures in place for the handling of customer complaints and/or product returns. By having these initiatives in place you can ensure the most satisfied customer base possible. Below are best practice steps to take when confronted with a customer complaint and/or product return.

**State of Hawaii Requirements**

- In the event a complaint is associated with a serious adverse event, BPH will require registered employees to:
  - Promptly report the complaint to the Commission
  - Report the complaint to any licensed processor or licensed dispensaries that may have received a shipment containing medical marijuana from the batch determined to cause the complaint
- As required by State of Hawaii regulations, in the event a complaint associated with a serious adverse event, BPH will be required to promptly report the complaint to, (1) the Commission, (2) either the licensed grower from which the medical marijuana originated, or the licensed processor from which the medical marijuana concentrate originated, (3) the certifying physician caring for the qualifying patient.
  - As a licensed grower operation, BPH's registered employees will be limited to report to the Commission in the event a complaint is associated with a serious adverse event.
    - Within 24-hours registered employees must report the complaint to the Commission

**Recalling of Medical Marijuana**—if a batch or lot of medical marijuana is determined through testing to fail to meet specification, BPH will do the following:

- Order a recall of all products derived from or included in the batch
- Notify all dispensaries and/or processors who may have obtained medical marijuana products from such a batch or lot of the recall
  - Using the inventory control system and/or physical documentation log sheets/records to identify all licensed processors and/or licensed dispensaries that may have received a distribution containing medical marijuana from the production batch or lot
  - After identifying the licensed processors and/or dispensaries, registered employees will be required to directly notify said companies.
- Offer and pay reimbursement for any returned medical marijuana
  - Offer to replace the medical marijuana product free of charge or offer full monetary reimbursement to the licensed processors and/or licensed dispensaries.

**Handling Customer Complaints**—when a customer wishes to make a formal complaint, follow the following procedures:

- Have customer wishing to form a complaint to complete the *Customer Complaint Form*
- File complaint within the customer complaint folder located within a limited-access area within the Licensed Premise
- Notify management of the formal complaint
- Notify the Department of the formal complaint

	<i>Customer Complaint Form</i>	
	<b>Date:</b>	<b>Location:</b>
	<b>Customer Name:</b>	
	<b>Employee Documenting Complaint:</b>	<b>Supervisor on Duty:</b>
	<b>Description of Complaint:</b>	
	<b>Corrective Action to be Taken:</b>	
<b>Customer Comments:</b>		
<b>Customer Signature:</b>	<b>Date:</b>	
<b>Employee Signature:</b>	<b>Date:</b>	

In the event of a formal complaint regarding the quality or safety of medical marijuana is received, BPH will require registered employees to review and investigate the complaint within 24-hours to determine:

- If the complaint is substantive or reports a serious adverse event
- Determine the batch number of the marijuana—this can be accomplished using the records and documentation maintained throughout the cultivation process to determine if there were any deviations in production
  - If the complaint is substantive or reports a case of a serious adverse event, registered employees will determine the batch number of the marijuana
  - Registered employees will be required to investigate the record and circumstances of the production of the batch and lot to determine:
    - If there was a deviation from the standard operating procedure in the production of the medical marijuana by reviewing production logs, records and documentation
      - Test retention samples of the batch and lot to an independent testing laboratory.
        - Send retention samples from batch and lot in question to licensed testing laboratory for testing
          - If testing reveals that the batch or lot fails to meet specifications, follow steps for recall below in following SOP
          - Notify any and all patients, caregivers and dispensaries who may have obtained medical



marijuana products from such a batch or lot of the recall

- Use the inventory control system and physical records to determine who may have received a batch of medical marijuana from the recalled batch
- Upon identifying retail dispensary locations that have received marijuana from the batch in recall, registered employees will need to notify the licensed dispensary directly with two means:
  - Via phone call, AND
  - Via email

**Investigation of Complaint**—BPH will require registered employees to investigate all complaints regarding the quality or safety of medical marijuana. Registered employees will be required to review records and documentation from the cultivation operations to determine if there was any deviation from production.

- Review all cultivation records and documentation log sheets
  - Try to determine if there were any deviation in production
  - If there is a deviation in production, see **Standard Operating Procedures SOP**
  - Determine the batch number and/or lot number of the medical marijuana
    - Reviewing records and documentation for substantive changes in production
- Meet with complainant to understand the serious adverse event (*if applicable*)
  - Meeting with the complainant registered employees may be able to identify the medical marijuana batch associated with the complaint
- Order a recall of the medical marijuana batch if necessary; follow **Product Recall SOP**

**Handling Customer Returns** – When a customer wishes to return a product, perform the following procedure:

- Acquire the product needing to be returned and begin the process of completing the Returned Marijuana Products Log Sheet
- Ask for the reason as to why the product is being returned and record this information.
- Log the product as being returned into the electronic inventory tracking system
- Offer and pay reimbursement for the medical marijuana products tracking system.
- Ensure that the Returned Marijuana Products Log Sheet is completed and filed.

*Example of a Returned Marijuana Products Log Sheet:*

<b><u>Returned Marijuana Products Log Sheet</u></b>					
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Patient/Caregiver Returning Cannabis Product:</u>	<u>Marijuana Product Returned (Name/Attribute#):</u>	<u>Quantity/Weight:</u>	<u>Reason for Product Return</u>



*Example of a Returned Marijuana Waste Log Sheet:*



### Returned Marijuana Waste Log Sheet

<u>Date:</u>	<u>Registered Employee:</u>	<u>Qualified Patient/Caregiver:</u>	<u>Marijuana Product to Dispose:</u>	<u>Waste Weight:</u>	<u>Mixed With:</u>	<u>Total Weight to Dispose:</u>

Product Recall

<b>Standard Operating Procedure:</b> Product Recall
<b>Purpose:</b> To ensure that all required steps and procedures are take when there is a need to recall a marijuana product.
<b>Scope:</b> Procedures covering voluntary and involuntary product recalls.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required Within the Cultivation Facility

- 1) Product Recall Log

#### Principles of Product Recall

Manufacturers, importers, distributors and retailers of consumer goods are liable for the products they provide to consumers and face the potential of product recalls for potentially dangerous or hazardous products. The same is true for the marijuana businesses as manufacturers and retailers of consumer medical marijuana products, for the facility may need to conduct a product recall in the future. For most consumer products the recall process is handled and regulated by the Consumer Product Safety Commission (CPSC), and for all intents and purposes the marijuana business recall plan will follow the guidelines of the CPSC.

The Consumer Product Safety Commission (CPSC) has compiled resources to assist companies that manufacture, import, distribute, retail, or otherwise sell consumer products. CPSC has developed a Recall Handbook that can be utilized in case a product recall needs to be ordered. The Recall Handbook details how to recognize potentially hazardous consumer products as soon as possible. The book explains how to develop and implement a “corrective action plan” (called a CAP) to address the hazards; it explains CPSC’s Fast Track Program. The Recall Handbook also discusses how to communicate recall information to consumers and how to monitor product recalls. The Consumer Product Safety Commission’s Recall Handbook will be a valuable tool utilized by the company if the need for a product recall ever arises.

The Recall Handbook should be referenced to determine exact protocol for recall and the requirements from the Consumer Product Safety Commission. The Recall Handbook can be obtained online from <http://www.cpsc.gov/PageFiles/106141/8002.pdf>.

#### **When to Recall Medical Marijuana Products**

As a manufacturer, distributor, and/or retailer of consumer products, the cultivation facility has a legal obligation to immediately report the following types of information:

- 1) A defective product that could create a substantial risk of injury to consumers;
- 2) A product that creates an unreasonable risk of serious injury or death;
- 3) Marijuana or manufactured marijuana is determined to contain a contaminate of some kind

- 4) Marijuana or manufactured marijuana batch did not successfully pass required testing but was released for distribution

Failure to fully and immediately report this information may lead to substantial civil or criminal penalties. Consumer Product Safety Commission's staff advice is "when in doubt, report." BPH will ensure communication with the required state and local authorities within 24 hours of becoming aware of the need for a product recall. BPH will then proceed to the recalling protocol and how to recall the product.

### **How to Recall Medical Marijuana Products**

The facility will develop a recall plan following guidance from the Recall Handbook provided by the CPSC. Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by state regulations will ensure a stream-lined recall process if ever necessary.

### **Corrective Action Plan (CAP)**

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and steps needed to be taken by the facility once a product recall is required.

### **Step One: Industry Notification**

If a marijuana or manufactured marijuana product is believed to need a recall, BPH will contact all retail dispensary locations to notify them of the situation and the need for product recall. BPH will also contact required state and local authorities within 24 hours of obtaining reportable information. As the cultivator and/or manufacturer of the product needing to be recalled, BPH will need to contact the end users of the recalled product; contacting qualified patients will prove to be difficult, but will be possible through the utilization of the inventory control and POS systems. At this stage of the recall, retail dispensary locations will need to ensure that they have a proper recall process in place to contact qualified patients that were dispensed the product being recalled.

### **Step Two: Public Notification**

The cultivation facility or dispensing establishment will post notifications about the product recall on its website as well as make partnering cultivation centers and dispensing organizations aware of the product recall. The actual recalling processes will be handled by both the cultivation center and the dispensing organizations.

As the dispensing organization issuing a recall notice, it will be important to reach the end users or the recalled product. The facility will post notification about the recall on Facility websites and social media as well as post written notices of the recall on location for patients and customers to view. The recall notice will include all pertinent information regarding the product being recalled, contact information and other information relating to the recall. Information will include but not be limited to:

- 1) Product name and unique attribute number
- 2) Product batch number
- 3) Dispensing date range of recalled product
- 4) Retail dispensary locations

Once the recall notification has been issued to all applicable dispensing organizations and medical marijuana patients, the facility will wait to receive recalled products from dispensing organizations and/or licensed medical marijuana patients and caregivers. Once recalled products have been received, the facility will properly dispose of all recalled products. The disposal of these products should conform to the state regulations for waste disposal.

### **Step Three: Procurement**

BPH issuing a product recall to qualified patients and primary caregivers will need to be ready to obtain and secure recalled products from qualified patients. Patients should be able to bring in the products being recalled to the retail dispensary location. It will be at BPH’s discretion whether to issue a refund, replace the recalled product at no cost, or to take other measures.

- Upon receiving recalled marijuana and/or manufactured marijuana products, registered employees will document the return of the recalled marijuana product
- After documentation, registered employees will securely store the recalled marijuana product in segregated storage until disposal
  - Recalled medical marijuana must be securely stored until properly destroyed and disposed of.

**Step Four: Documentation and Record Retention**

BPH will maintain all documentation all records regarding any and all product recalls issued. Registered employees will be required to fill out the required *Product Recall Log Sheet*.

<b><u>Product Recall Documentation Log Sheet</u></b>				
<u>Date:</u>	<u>Product Name</u>	<u>Product Attribute # or Unique ID #</u>	<u>Quantity to be Recalled</u>	<u>Supervisor</u>
List Potential Patient/Caregivers to Notify:				
Regulatory Agencies Notified: <input type="checkbox"/> MMCC <input type="checkbox"/> FDA <input type="checkbox"/> CSPA <input type="checkbox"/> Other				
<u>Date:</u>	<u>Quantity Collected:</u>	<u>Collected From (Patient/Caregiver):</u>	<u>Accepting Employee:</u>	<u>Notes/Details</u>

**Step Five: Disposal**

The facility will ensure that any and all recalled marijuana products are disposed of according to all state and local regulations. The facility will follow marijuana waste disposal and destruction procedures outlined within these SOP’s for proper disposal of recalled medical marijuana.

- Recalled material must not be destroyed or disposed of until authorized by the Commission.
  - Recalled medical marijuana will need to be stored and segregated until the disposal of recalled material is authorized by the Commission.
    - Stored recalled material in the quarantined secure storage area of the Licensed Premise.
- Once receipt of notification from the Commission that the disposal of recalled medical marijuana is authorized, registered employees will dispose of the medical marijuana according to the *Marijuana Waste Disposal SOP*.
  - Registered employees must dispose of medical marijuana within 24-hours of Commission authorization.



Marijuana Waste Destruction and Disposal

<b>Standard Operating Procedure:</b> Marijuana Waste Destruction and Disposal
<b>Purpose:</b> To explain required and proper disposal processes for marijuana waste.
<b>Scope:</b> Covers marijuana waste grinding, mixing and disposal measures within the retail dispensing facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Marijuana Waste Disposal Log

**Equipment/Tools Required**

- 1) Wood chipper/plant grinder
- 2) Mixing material (material to mix marijuana waste with at 50/50 ratio)
- 3) Trash bags
- 4) Dumpster/trash compactor

**Requirements of Marijuana Waste Disposal**

All marijuana waste, byproducts, undesired materials, green waste and returned/recalled marijuana will be destroyed by rendering the waste unrecognizable, unusable and unrecoverable.

BPH will require registered employees to weigh, document, record and destroy all marijuana waste according to the written standard operating procedures. All marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated will be destroyed and disposed of according to the written SOP.

**Secure, Segregated Storage**—all medical marijuana waste will be stored in secure, segregated storage on the Licensed Premise until receipt of authorization from the Commission of destroy and dispose of the medical marijuana waste.

- The secure, segregated storage will promote good growing and handling practices.

**Marijuana Waste Disposal**—all medical marijuana waste, byproducts and undesired products will be destroyed and disposed of according to all applicable state and local regulations. Facility management will ensure proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state regulations. Record all required information on the *Marijuana Waste Log Sheet*.

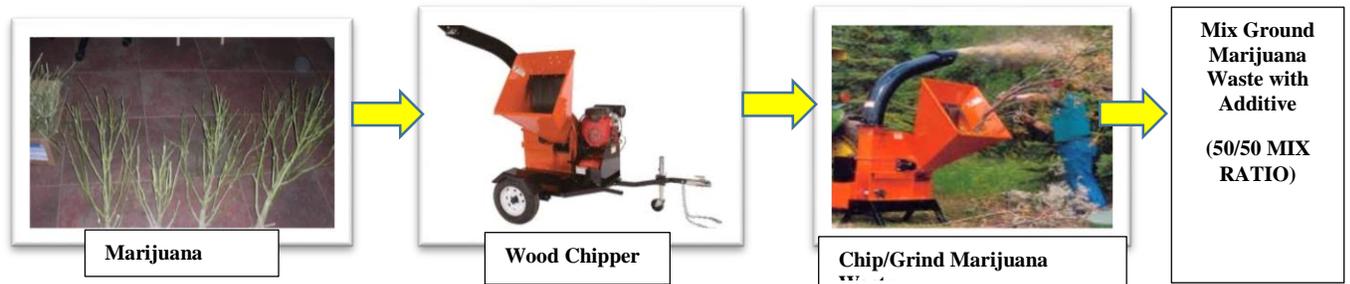
**Disposal**—Disposal of any marijuana product waste must be rendered unrecognizable, unusable and unrecoverable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:



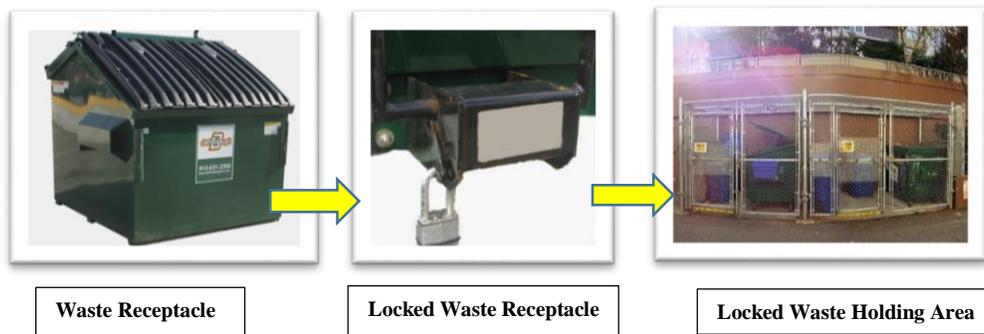
- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.



**Grinding Marijuana Waste (Stalks, Stems, Leaves and Other Material)**



**\*\*BPH shall not dispose of marijuana product waste in an unsecured waste receptacle not in possession and control of the licensed premise. It is recommended to have a lock on the physical dumpster as well as the area where the dumpster is maintained.**







Facility Cleaning and Sanitation

**Standard Operating Procedure: Facility Cleaning and Sanitation**

**Purpose:** To explain required and proper cleaning and sanitation practices.

**Scope:** Covers cleaning and sanitation measures within the cultivation facility.

**Initial Training:** 4-6 hours

**What is the Purpose of Cleaning and Sanitation?**

Proper cleaning and sanitation practices are essential within the cultivation facility. A clean and sanitary cultivation facility will reduce the risk of pests, insects and diseases. The marijuana plants can only be as clean as the room in which they are cultivated. The goal is to produce the safest medicinal marijuana within a clean and sanitary facility.

**Documentation Log Sheets Required**

- 1) Cleaning and Sanitation Log Sheet

**Equipment/Tools Required**

- 1) Personal Protective Equipment (PPE)
- 2) Broom and Dust Pan
- 3) Mop and Mop Bucket
- 4) Bleach
- 5) Cleaning Towels
- 6) Paper Towels

**Principles of Cleaning and Sanitation**

To prevent the accumulation of marijuana oils, resins, plant material, and any remaining pests, strict cleaning procedures must be followed. Cleaning and sterilizing surfaces will aid in pest management, as well as lowering overall microbial levels in processing areas, and on product. Cultivation areas will undergo thorough cleaning in between the harvest stages, and plants reentering the room. Once all plants are harvested, all non-permanent growing equipment will be removed, including pots, plant carts, scissors, etc. Registered employees will thoroughly vacuum all surfaces to remove dust, loose debris, and any plant material. The entire room will then be systematically misted with a chlorine dioxide solution. This chlorine dioxide solution will begin to break down and sterilize any organic material so it may be easily wiped off in the next step. This spray will also enter small spaces not easily reached by manual cleaning. Fans will remain running during this spraying operation to ensure mist is moved around the room thoroughly. Employees will then wipe all surfaces down with the same chlorine dioxide solution. These two steps combined will assure all surfaces are clean and sterile.

During daily operation tools, which come in contact with marijuana, will be soaked in isopropyl alcohol. Transport carts, worktables, and other cultivation furniture will undergo weekly cleaning and sterilizing. After growing medium

is disposed, plant containers will be washed and sterilized using a powered washing machine. Pots will be sterilized using a hydrogen peroxide solution, and dried before use.

Due to the nature of marijuana products, cleaning surfaces in processing areas is crucial. Build up caused by marijuana can be very difficult to remove when left for long periods of time. For general removal of resins, a disposable cloth is coated with 91% isopropyl alcohol, and used to wipe all surfaces free of material. For heavily soiled areas use a metal scraper to remove resins. Marijuana trimming machines require daily cleaning to maintain performance, and sterility. Machines will be disassembled, and separated depending on cleaning method. Metal parts are cleaned using isopropyl alcohol; all other parts will be cleaned and sterilized using a steam cleaner.

Drying trays will be sterilized in between each use; wiping trays with isopropyl alcohol will do this. Drying trays will be thoroughly cleaned monthly by first soaking them in hot water to loosen and material, then wiping trays down with isopropyl alcohol. Curing containers will be cleaned and sterilized between uses by wiping down all surfaces with isopropyl alcohol. Drying racks will also be wiped with isopropyl alcohol in between uses.

All areas of the facility, which will contain any marijuana product, or equipment, will have Puradigm air & surface sterilizing technology installed. This system uses advanced oxidation, and multi-cluster ionization technology to instantly kill bacteria, mold, mildew, and other microbes. General maintenance is required on these systems including changing bulbs, changing filters, and general cleaning. This maintenance is done according to the manufacturers recommendations.

After each drying period is complete, drying rooms will be vacuumed to remove dust and plant debris. All surfaces in the room will be wiped with hydrogen peroxide or bleach solutions. The processing, drying, curing, and packaging rooms will be cleaned thoroughly after each harvest. All floors are first vacuumed to be free of dust and plant debris. All surfaces are wiped clean and sterilized using either hydrogen peroxide or bleach solution. This step will assure no microbial cross contamination between harvests.

Apart from clean entry protocols practiced by agents, incoming soil and equipment must also be sterilized. Incoming pallets of soil will be kept in a quarantine room containing Puradigm sterilizing technology. Once the allotted time of air sterilization occurs, the pallets will be moved into a clean room air shower. In the air shower, ions will be dispersed to remove static electricity from plastic bags. Compressed air is blasted at the contents of the air shower, and the air is removed, and filtered.

Major cleaning and sanitation should be done within the cultivation facility when specified by the ***Cleaning and Sanitation Schedule***. Vegetative/flowering rooms should be thoroughly cleaned after the zone/room is completely emptied of all plants. This will be done when moving vegetative plants from the vegetative zone/room into the flowering zone/room or once a flowering room's plants are completely harvested and the room is emptied.

#### **General Daily Cleaning at the Facility:**

- **General Area(s)**
  - All hallways and accesses will be swept and mopped daily
  - All trash and debris should be collected and removed from the facility general areas on a daily basis
  - The bathrooms should be kept clean and maintained by each employee on a daily basis
  - Parking lot area should be maintained on a regular basis; free of trash and debris
- **Entry (*man trap*)**
  - The "man trap" area should be thoroughly cleaned and sanitized on a daily basis
    - Sweep floor
    - Sanitize floor, walls, door handles
  - Sanitizing footbath solution will be changed every other day

#### **Specific Cleaning at the Facility:**

- **Manufacturing Room(s):**
  - Beginning at the top of the room, dust, and wipe down all surfaces with a 5% bleach solution
    - Be sure to wipe all surfaces thoroughly
  - Sweep and vacuum (*wet/dry shop vac*) all floors



- Mop all floors with a 5% bleach solution and allow to dry
- Check to assure all surfaces have been sterilized
- Once a zone/room has been properly cleaned and sanitized, employees are required to properly document the activities on the *Cleaning and Sanitation Documentation Log*.

*Example of Cleaning and Sanitation Documentation log sheet:*

<u><b>Cleaning and Sanitation Documentation</b></u>					
<b>Date:</b>	<b>Zone/Room Cleaned:</b>	<b>Cleaning Agent(s) Used:</b>	<b>Reason for Cleaning:</b>	<b>Notes/Comments:</b>	<b>Cleaned By (initial) :</b>

**GENERAL PRINCIPLES OF SANITATION**

**PURPOSE/POLICY:**

The purpose of this policy is to define the general principles of sanitation throughout the marijuana product manufacturing area of the facility. All equipment will be maintained and sanitized in each operating unit at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality or purity of the medical marijuana product beyond its established specifications. Marijuana and marijuana products will be handled and held in a manner that prevents growth of pathogenic microorganism or formation of toxins. Major equipment will be assigned individual maintenance logs. Written programs will be established and followed for the maintenance of major equipment.

**ENVIRONMENTAL HEALTH (EHS) STATEMENT:**

“Any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have an infection, communicable disease (including but not limited to: diphtheria, measles, Salmonella enterica serotype Typhi infection, shigellosis), open or draining skin lesion, or any illness accompanied by diarrhea or vomiting, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, packaging components, in-process materials, marijuana, marijuana products, or contact surfaces, shall be excluded from working in any operations that may result in contamination until the health condition no longer exists. Employees are required to report any personal health condition that might compromise the cleanliness or quality of the medical marijuana the employee might handle.”

**SANITATION SYSTEMS:**

- ProKure-V
- Puradigm or AirOClean 420 air purification system

**RESPONSIBILITIES:**

- All Facility personnel must be aware of and have a proficient understanding of Company Sanitation policies and procedures:
- General Manager
- Extraction Manager
- Production Manager



- Extraction Tech
- Production Tech
- Sanitation Manager or his or her designee

## PROCEDURES:

1. The production facility will include an air purification system appropriate for the size of the room which will be checked daily to ensure it is functioning properly. This system will be employed to kill airborne molds and fungus. (Paradigm or AirOClean 420).
2. Before daily processing begins, evaluate that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for marijuana or marijuana product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.
3. All persons working in direct contact with preparation of marijuana or marijuana product shall conform to hygienic practices while on duty, including but not limited to:
  - a. Maintaining adequate personal cleanliness.
  - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Marijuana Product and at any other time hands/gloves may have become soiled or contaminated.
  - c. Wear company-issued, disinfected, outer-garments (scrubs) in a manner that protects against the contamination of components, packaging components, in-process materials, marijuana, marijuana-derived products, or any contact surface.
  - d. Remove all unsecured jewelry and other objects that might fall into components, marijuana products, equipment, or packaging, and removing hand jewelry that cannot be adequately cleaned during periods in which components, packaging components, in-process materials, or marijuana are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that effectively protects against contamination.
  - e. Maintain gloves of an impermeable material used in handling components, packaging components, in-process materials, and marijuana in an intact, clean, and sanitary condition.
  - f. Wear, where appropriate, hairnets, caps, beard covers, or other effective hair restraints.
  - g. Not eat food, chewing gum, drink beverages, or use tobacco products in areas where components, packaging components, in-process materials, marijuana products or any contact surfaces are exposed, or where contact surfaces are washed.
  - h. Take any other precautions necessary to protect against the contamination of components, packaging components, in-process materials, marijuana, marijuana-derived products, or contact surfaces with microorganisms, or other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
  - i. Take all precautions necessary to prevent unauthorized access to controlled access areas, and to maintain strict control of in-process materials marijuana and marijuana waste.
4. All persons working must ensure there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Marijuana or Marijuana Product.
5. All persons working must ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Marijuana or Marijuana Products are exposed.
6. All persons working must ensure that floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair.
7. All persons working must ensure that there is adequate safety-type lighting in all areas where Marijuana or Marijuana Products are processed or stored and where utensils or equipment are cleaned.



8. All persons working must ensure that the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming attractant, harborage, or breeding place for pests.
9. Bi-monthly room sanitation will be performed by fumigation (ie: fogging the room with ProKure-V).
10. Daily sanitation will also include spraying all production and extraction surfaces and equipment with ProKure-V).
11. All persons working must ensure that any buildings, fixtures, and other facilities are maintained in a sanitary condition.
12. All persons working must ensure that all contact surfaces, including utensils and equipment used for the preparation of Marijuana or Marijuana Product shall be cleaned and sanitized as frequently as necessary to protect against contamination.
  - a. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.
  - b. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Marijuana or Marijuana Product Manufacturing Facility and used in accordance with labeled instructions.
13. All persons working must ensure that toxic cleaning compounds, sanitizing agents, solvents used in the production of Marijuana Concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Marijuana, Marijuana Concentrate or Marijuana Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance.
14. All persons working must ensure that the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system.
15. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs.
16. Plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the facility and that shall properly convey sewage and liquid disposable waste from the Licensed Premises.
  - a. There shall be no cross-connections between the potable and wastewater lines.
17. All persons working must ensure that the Manufacturing Facility is providing its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair.
18. All persons working must ensure that all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Marijuana or Marijuana Product shall be conducted in accordance with adequate sanitation principles.
19. All persons working must ensure that Marijuana or Marijuana Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.
20. All persons working must ensure that storage and transport of finished Marijuana Product shall be under conditions that will protect against physical, chemical, and microbial contamination as well as against deterioration of any container.

#### **Corrective Action**

1. If, after visually inspecting all areas mentioned in the General Sanitary Requirements list, the supervisor finds areas that are not clean or in compliance, all procedures must be repeated until cleanliness is achieved.
2. Record corrective actions on Laboratory or Food Safety Checklist.



## **CLEANING AND SANITATION OF FILLER**

**RESPONSIBILITY:** Sanitation Supervisor or his or her designee

**FREQUENCY:** Sanitation to take place immediately before daily operations begin; 2. Filler to be rinsed with water only at each break (mid-morning, lunch, mid-afternoon); 3. Full cleaning and rinsing to take place after each work shift

**RECORDS:** *Production Kitchen Sanitation Checklist*

### **PROCEDURE:**

1. Before daily processing begins, sanitize filler and all filler parts with 65 p.p.m chlorine solution. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper p.p.m level. Pour bleach solution into filler. No rinse is necessary.
2. At mid-morning break, during lunch break, and during the mid-afternoon break, use yellow broom and black shovel to remove debris. Use black shovel to scoop debris into inedible waste container.
3. Use yellow mop bucket with mop to remove gross debris and sanitize floor, under filler and adjacent areas, with 200 ppm chlorine solution. Mix 3 gallons of water with 2 teaspoons full of unscented bleach in a 5 gallon bucket. Check the chlorine solution with tester strips to ensure proper ppm level. Pour bleach solution into mop bucket and use mop to remove gross debris and sanitize floor.
4. At the end of the shift, use yellow broom and black shovel to remove debris from floor. Use black shovel to scoop debris into inedible waste container.
5. Use yellow mop bucket with mop to remove gross debris and sanitize floor, under filler and adjacent areas, with 200 ppm chlorine solution. Mix 3 gallons of water with 2 teaspoons full of unscented bleach in a 5 gallon bucket. Check the chlorine solution with tester strips to ensure proper ppm level. Pour bleach solution into mop bucket and use mop to remove gross debris and sanitize floor.
6. Rinse filler and parts with water from a 5 gallon bucket full of hot water. Remove all filler parts and place into the wash compartment of the three compartment sink for proper cleaning, rinsing, and sanitizing. Mix 5 gallons of water with 2 tablespoons full of High Performance Double-Action Detergent. Pour detergent solution into the wash compartment of three compartment sink. Pour 5 gallons of hot water into the rinse compartment of the three compartment sink. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a 5 gallon bucket. Check the bleach solution with tester strip to ensure it is at the proper 65 ppm level for sanitizing. Pour bleach solution into the sanitize compartment of the three compartment sink.
7. Dip a green Scotch-Brite Heavy Duty pad into solution and scrub all filler parts. Place all filler parts into the rinse compartment of three compartment sink. Visually inspect all filler parts to ensure all soap has been removed. Place all filler parts into the sanitize compartment of three compartment sink. Let all filler parts sit in bleach solution for one minute. Remove all filler parts from solution and allow to air dry. No rinse is necessary. Visually inspect filler parts for cleanliness. Put away filler parts wearing freshly washed gloves.
8. Ask cleaning crew supervisor to inspect for cleanliness.

Complete *Production Kitchen Sanitation Checklist*



**Corrective Action:** If, after rinsing, visual inspection by cleaning crew supervisor finds areas that are not clean, cleaning procedures must be repeated until cleanliness is achieved. Record corrective actions on Production Kitchen Sanitation Checklist.

Equipment Maintenance, Cleaning and Sanitation

<b>Standard Operating Procedure:</b> Equipment Maintenance, Cleaning and Sanitation
<b>Purpose:</b> To explain facility equipment maintenance, cleaning and sanitation
<b>Scope:</b> To educate and train licensed premise employees on requirements and procedures pertaining to facility equipment maintenance and the proper cleaning and sanitation of facility equipment.
<b>Initial Training:</b> 2-4 hours

**Principles of Equipment Maintenance, Cleaning and Sanitation**

Equipment utilized within the cultivation operations at the licensed premise will need to be routinely maintenance, cleaned and sanitized. There are multiple reason for this routine maintenance, cleaning and sanitation including operator safety. Regular maintenance should be done in order to keep the equipment operating and functioning properly, this reduce the risk of an operator getting injured while operating the equipment. The maintenance procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Equipment will need to be cleaned and sanitized after equipment comes into contact with medical marijuana it will need to be properly cleaned and sanitized. The cleaning and sanitation procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Licensed premise employees performing the maintenance and/or cleaning and sanitation will be required to document the maintenance and/or cleaning and sanitation within the *Equipment Maintenance, Cleaning and Sanitation Log Sheet*.

*Example of BPH's Equipment Maintenance, Cleaning and Sanitation Log Sheet:*

<b><u>Equipment Maintenance, Cleaning and Sanitation</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Equipment Name/Model #:</u>	<u>Date of Last Maintenance</u>	<u>Date of Last Cleaning &amp; Sanitation</u>	<u>Notes/Comments</u>



Facility Exit Protocol

<b>Standard Operating Procedure:</b> Facility Exit Protocol
<b>Purpose:</b> To explain how employees should exit the cultivation/MIP facility.
<b>Scope:</b> Covers the steps involved for properly exiting the cultivation and/or MIP facility.
<b>Initial Training:</b> 1-2 hours

When an employee has finished their work shift, they will exit the “clean” area of the cultivation facility in the same way they enter, however the process for exiting will be done in reverse.

**How to Exit the Production Center:**

1. Exit the clean area through the Air-Lock Chamber
2. Enter the locker room
3. Change out of provided work wear attire/uniform
  - a. Scrubs
  - b. Hair nets
  - c. Hats
  - d. Garden shoes
4. Place used work wear in the proper laundry bin
5. Change back into street clothes
6. Exit the locker room
7. Exit the facility through the man trap.
  - a. Arm the security alarm system to *AWAY (if applicable)*



Emergency Protocol

<b>Standard Operating Procedure:</b> Emergency Protocol
<b>Purpose:</b> To describe all steps and protocols to be followed by employees should an emergency occur within the facility.
<b>Scope:</b> Procedures covering emergency situations occurring within the facility.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Emergency Situation Documentation Sheet

### Equipment/Tools Required

- 1) Panic Alarm/Button
- 2) Fire Extinguisher
- 3) Chemical Spill Kit
- 4) Emergency eye wash station(s)
- 5) First Aid Kit
- 6) Emergency defibrillator

### The Principles of Emergency Protocols

A facility emergency management plan is designed to educate and train facility employees on the actions and procedures to follow in the event of an emergency. In the case of an emergency, facility employees will need to respond quickly and think strategically in order to successfully manage the emergency situation. Having a good understanding of the facility emergency management plan will enable employees to better adapt to and handle emergencies.

The most important thing to remember during an emergency situation is to try to stay calm, if the emergency situation is out of your control and you need assistance, contact emergency services immediately if possible.





**Burglary:** Burglary is legally defined as the criminal offense of breaking and entering a building illegally for the purpose of committing a crime. Burglaries generally will occur at the Licensed Premise after operating hours and while there are no registered employees present. Typically burglaries occur during the night and are not discovered until the next day during normal operating hours.

- If upon entering the Licensed Premise and a registered employees notice something is afoul and upon investigation a burglary was determined to have occurred in the previous night, then registered employees will be required to document the incident and notify all required authorities.
  - Registered employees will be required to report the incident of burglary to:
    - The Commission
    - Local medical marijuana authority (*if applicable*)
    - Local police

**Robbery or Theft:** Robbery is legally defined as the taking of money or goods in the possession of another, from his or her person or immediate presences, y force or intimidation. The number one rule registered employees will need to follow when/if dealing with a robbery is to comply with all robber demands

- If you are being robbed at gunpoint or if you feel as if your life is in danger, comply with all requests from perpetrator/suspect. Give them whatever they ask for.
- Try to signal for help using the personal security panic buttons provided, by activating one of multiple, strategically placed panic alarm buttons, or through the panic button/police services button located on the alarm panel.
- Contact law enforcement as soon as possible
- Notify any required State or local authorities immediately (within 24 hours)
  - Local police services
  - The Commission
- Comply with all applicable laws and regulations
- Document the situation in the *Emergency Situation Documentation* log sheet



Alarm Panel



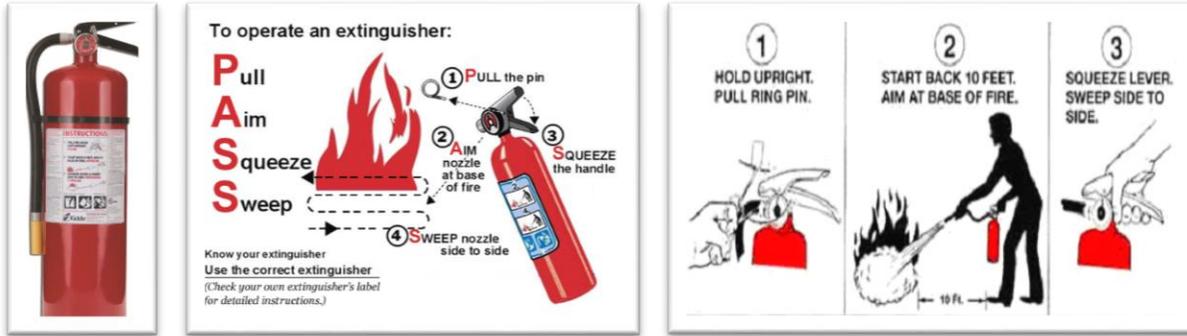
Panic Alarms/Buttons



**Fire Emergency:**

- If a small isolated fire is present, try to exhaust the fire with one of the fire extinguishers on site
- In case of a fire emergency, first leave the facility; once clear of the facility dial 911 and/or local fire authority for Fire Emergency Services or push the symbol on the alarm panel for fire emergency upon exiting the facility
- Document the situation in the *Emergency Situation Documentation* log sheet

*Fire Emergency Cont.*



**Chemical Emergency:**

- Dangerous Substance/Chemical Exposure:
  - If an employee accidentally has their eyes exposed to toxic, poisonous or dangerous substances or chemicals; said employee will need to locate the installed emergency eye wash station(s) to properly flush and clean their eyes. Notify emergency medical services for further assistance
  
- Chemical Spill:
  - Try to use a chemical spill kit for smaller incidents of chemical spill
  - If a chemical spill is large or you do not know how to handle the situation; get the facility manager to handle the situation and/or contact proper emergency services
    - Posted near or included with the chemical spill kit should be an emergency contact information sheet displaying which emergency services should be contacted.
      - For the BPH and the State of Hawaii this will include but not be limited to:
        - Environmental Protection Agency (EPA)
          - For emergencies and other sudden threats to public health, such as:
            - oil and/or chemical spills,
            - radiation emergencies, and
            - biological discharges,
              - call the National Response Center at 1-800-424-8802.
            - For **pesticide poisoning**, call 911 if the person is unconscious, has trouble breathing, or has convulsions. Otherwise, call **Poison Control at 1-800-222-1222.**
  
- Document the situation in the *Emergency Situation Documentation* log sheet



**Medical Emergency:**



- If it is a minor medical situation such as a small cut, scrape or minor burn; retrieve the first aid kit on site and treat wound with items found in the first aid kit
- If the situation appears to be a severe medical situation such as someone suffering from a heart attack, retrieve the emergency defibrillator and follow the instructions provided; notify 911 or local medical emergency services for further assistance
- If the medical situation is an emergency; contact medical emergency services immediately. This can be done through activating the medical response button found on the alarm panel, or by calling 911 for medical emergency services
- If a serious injury occurs while an employee is working, such as a slip and fall resulting in possible broken bones or a cut requiring stitches, SFN facility management will need to complete a worker compensation insurance claim form prior to the employee seeking medical assistance. This procedure does not take long, but the form will need to be completed in order for the injured employee to have a workers compensation medical claim.
- Document the situation in the *Emergency Situation Documentation* log sheet



**Other Emergencies:**

- Contact 911 if it is a current emergency. Contact your local police and/or State regulatory authorities for break-ins or burglaries that may have occurred when the facility operations were closed
- Contact any required State or local authority in cases of theft, break-ins or burglaries
- Document the situation in the *Emergency Situation Documentation* log sheet



*Example of Emergency Situation Documentation Log Sheet:*



<b><u>Emergency Situation Documentation</u></b>		
Date:	Reporting Employee:	Manger on Duty:
Type of Emergency: <input type="checkbox"/> Robbery of Theft <input type="checkbox"/> Fire Emergency <input type="checkbox"/> Chemical Spill <input type="checkbox"/> Medical Emergency <input type="checkbox"/> Other Emergency		
Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO		Which Authorities:
Description of the Incident:		

Loss of Personnel

<b>Standard Operating Procedure: Loss of Personnel</b>
<b>Purpose:</b> To describe all steps and protocols to be followed prior to or after the loss of personnel.
<b>Scope:</b> Procedures covering loss of personnel situations occurring within the facility.

The following will cover procedures to follow when terminating a key employee as well as when a key employee decides to leave the organization on their own accord.

**Job Termination**—if the need arises to terminate the position of a key personnel there will be some basic steps and procedures to follow within operations.

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e. employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel



4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e. mutual separation and key personnel is always welcome back at SFN facilities under visitor status, employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was previously filled by key personnel. Key personnel positions will need to be filled as soon as possible by ownership and/or management without sacrificing quality of applicant pool. Some basic steps should be followed to find and place a suitable replacement for the vacant position.

1. Review resumes and applications from qualified applicants
2. Call qualified applicants to conduct an informal, initial phone interview
  - a. If you get a good response from applicant, schedule an in-person interview
3. Conduct in-person interviews with qualified applicants
4. Review interviewed applicants
  - a. Select applicant who is most qualified for the vacant position
5. Contact said applicant and offer the vacant position
6. If applicant accepts the job offer, proceed with normal hiring procedure and required paperwork



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# STANDARD OPERATING PROCEDURES

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*State Of Hawaii Retail Dispensary Locations*





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**-----STATE REGULATORY COMPLIANCE DISCLOSURE-----**

*Medical marijuana facilities operate in a highly regulated industry, as such adherence to all applicable state and local laws pertaining to the dispensing of marijuana and/or manufactured marijuana products within the facility is of utmost importance. State and local laws and regulations will vary among states; it is recommended to read and have good understanding of the state and local laws and regulations in which you operate. Having a good understanding of the state and local laws is the first step in being educated on how to operate within regulations, the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within a regulated market.*

**-----CONFIDENTIALITY DISCLOSURE-----**

“Confidential Information and Intellectual Properties” means and includes any tangible or intangible information or material that is confidential or proprietary to Consultant that Client may obtain knowledge of through, or as a result of, its relationship with Consultant. Such information shall be deemed Consultant’s Confidential Information and Intellectual Properties whether or not owned or developed by Consultant. Confidential Information and Intellectual Properties shall also include, but is not limited to, any inventions, processes, designs, formulae, trade secrets, Standard Operating Procedures, know-how, confidential information, trademarks, copyrights, service marks, domain names, computer software, data and documentation, and all similar intellectual property.

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Client understands that all such Existing Consultant IP, including all Standard Operating Procedures shall remain the sole property of Consultant, and Client agrees that neither it, nor any of its officers, directors, employees, consultants, affiliates or anyone acting in concert with Client will: (i) acquire any ownership interest in any Existing Consultant IP; and (ii) will not, convey, sell, publicize, use, trade, distribute any Existing Consultant IP to any other person or business, or take or modify Existing Consultant IP in order to convey, sell or distribute to any other individual or business not a party to this Agreement, that results in competition with the consulting services offered by Consultant, or interferes with any existing or prospective business advantage Consultant may have. No other license to any Existing Consultant IP is granted or implied by this Agreement.



<b>Standard Operating Procedure:</b> Standard Operating Procedures
<b>Purpose:</b> To explain the standard operating procedures needed to be adhered to within the Licensed Premise
<b>Scope:</b> To cover the education and training required pertaining to the standard operating procedures utilized within the Licensed Premise.
<b>Initial Training:</b> TBD

**Definitions**

**Standard Operating Procedure (SOP)**—a set of step-by-step instructions to achieve a predictable, standardized, desired result often within the context of a longer overall process. At its simplest, an SOP is a repeated application of unchanged processes and procedures and its documentation. These SOPs are to be followed as directed and not deviated for the retail dispensing of marijuana within any Blue Planet Healing LLC (BPH) registered retail dispensary locations.

**Material Change**—a material change is defined as a major deviation from the standard procedure, or changing the procedure or methodology drastically enough to notice a change. The material change is important enough to notice or to have an effect on the standard operating procedure.

**Principles of Standard Operating Procedures**

American Cannabis Company’s (ACC) Standard Operating Procedures (SOPs) ensure consistent dispensing of high quality medical marijuana products. BPH will utilize said SOPs for all dispensing methodologies and operations. Understanding and abiding by the following SOPs is mandatory for all registered employees working within BPH’s registered dispensary facilities.

The standard operating procedures must be practiced and utilized to dispense each batch of marijuana and/or manufactured marijuana products. The strict adherence to the written SOPs will aid in BPH’s quality control, inventory control and state regulatory compliance. The written SOPs have been developed within a regulated marijuana industry with the purpose of creating systems and procedures that result in compliant operations. Apply the following SOP instructions to the daily retail dispensing activities within the facility. Do not deviate from exact instruction within these standard operating procedures.

- Failure to practice and utilize BPH’s written standard operating procedures is grounds for disciplinary action and possible job termination.
- Registered employees will be required to record and maintain documentation log sheets and forms to record the dispensing process
  - Required documentation and record keeping is highlighted throughout the SOPs and indicates which documentation log sheets and records are to be taken and maintained.
    - Registered employees will need to pay careful attention to each standard operating procedure to ensure proper documentation and record keeping
      - The documentation should demonstrate consistency of operations
      - The documentation should also demonstrate the accuracy of the day-to-day dispensing.
- Any major deviation from the standard operating procedure defined as a material change that could impact the quality of batch must be documented, recorded and maintained at the retail dispensing location.
  - Registered employees are required to document any major deviation in production of a batch from the standard operating procedure

**Deviation/Material Change to Standard Operating Procedures**

Upon recognizing the need for or making a material change to a standard operating procedure, registered employees will be required to document the material change within the *Material Change to SOPs* log sheet and update the current SOP to reflect the material change.



<b><u>Deviation/Material Change to SOP's</u></b>		
<b>Date:</b>	<b>Registered Employee:</b>	<b>Deviation in Production:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Reason for the deviation</b> ( <i>identify and describe in detail the deviation from the SOP</i> ):		
<b>SOP requiring material change:</b>		
<b>Material Change made to the SOP</b> ( <i>please describe in detail</i> ):		
<b>SOP Updated?</b> <input type="checkbox"/> YES	<b>Date Updated:</b>	<b>Update By:</b>
<b>Manager/Supervisor Awareness and Approval:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Manager/Supervisor Signature:</b>	
<b>Sample of production batch with deviation sent to independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Sample of production batch with deviation determined to meet specifications for the variety by BPH and the independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>Medical Cannabis Batch Released for Distribution?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Additional Notes/Comments:</b>	
<i>After documentation of a material change to a standard operating procedure, registered employees will be required to maintain the record of material change within a limit-access and secured area of the Licensed Premise.</i>		



<b>Standard Operating Procedure:</b> State Regulatory Compliance Training
<b>Purpose:</b> To explain the regulatory compliance needed to be adhered to in the State of Hawai'i.
<b>Scope:</b> To cover the regulations enacted within Hawaii pertaining to legally operating a marijuana business.
<b>Initial Training:</b> training done on individual time

**Required Documents**

- 1) State Laws
- 2) Local/City Regulations (*if applicable*)

**The Principles of State Regulatory Compliance Training**

BPH will require all registered employees to read and become familiar with the State and Local/City regulations that have been enacted pertaining to operating a legal, licensed marijuana business.

BPH will keep a physical, up-to-date copy of any and all laws and regulation in which you must operate under at every licensed facility. Every registered employee will receive a hard copy of the laws and regulation which they can read and become familiar with.

Key State Laws Employees Should be Familiar With:

- Who can have access to the facility
  - Visitor process
- Packaging and labeling compliances and requirements
- Allowed purchase amounts (quantities and distribution timeframe)
- Hours of allowed operation
- Inventory tracking and required record keeping
- Security procedures and protocols
- Laboratory testing requirements
- Transportation of marijuana products
- Etc.

**State of Hawaii**

- <http://health.hawaii.gov/medicalmarijuana/>

*BPH and registered employees of BPH will not distribute any medical marijuana to any person if BPH or registered employee knows, or may have reason to know, that the distribution does not comply with any provision of the Hawaii regulations.*

*BPH will ensure that BPH or a registered employee thereof will not distribute any medical marijuana to any person if BPH or registered employee knows, or may have reason to know, that the medical marijuana does not comply with any regulations of Hawaii.*



**Standard Operating Procedure: Record Keeping and Documentation**

**Purpose:** To ensure that all required marijuana dispensing records and data are properly recorded and documented.

**Scope:** Procedures covering record keeping and documentation for activities within retail dispensary locations.

**Initial Training:** 4-8 hours

**What is the Purpose of Record Keeping and Documentation?**

The marijuana retail dispensary locations operate in a highly regulated industry, as such proper record keeping and documentation are essential within the retail dispensary locations.

**Equipment/Tools Required**

- 1) Pen or pencil
- 2) Clipboard
- 3) Log Sheets

**Principles of Record Keeping and Documentation**

Adherence to all applicable state and local laws pertaining to the dispensing of marijuana within the retail dispensary locations is of utmost importance. Having a good understanding of the state and local laws is the first step in being educated on the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within a regulated market.

Required records and documentation are noted throughout the written Standard Operating Procedures; BPH’s registered employees will be required to make such records and documentation as part of their job responsibilities. Employees will be required to make two sets of all records and documentation; one set of records and documentation will be made within the BioTrackTHC™ inventory control system, and a second set of records and documentation will be made using physical log sheets and templates. The physical records and documentation will be maintained on at the retail dispensary location within a limited access area. Failure to create and maintain records and documentation will be grounds for disciplinary action and/or job termination.

Record Keeping and documentation are noted within other SOPs where documentation is required. The SOPs will also reference which documentation records and log sheets are required to be filled out and maintained.

**Dispensary Licensed Premise Records:**

- 1) Cash Drawer Balances
- 2) Receiving Marijuana Products (Incoming Shipments)
- 3) Closing Log Sheet
- 4) Marijuana Waste Log
- 5) Cleaning and Sanitation Log
- 6) Product Recall Log
- 7) Employee List
- 8) Emergency Situation Documentation
- 9) Primary Patient List
- 10) Visitor Sign-In
- 11) Etc.

**Secondary Records**

BPH will maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution. BPH will require employees to maintain secondary records on the Licensed Premise. The physical records and documentation log sheets will serve as secondary, back-up records and documentation that will be maintained independent of the inventory control system.

Per Hawaii regulations, records required to be maintained separate of the inventory control system:

- **Records of Each Distribution**
  - Records of distribution must include:
    - The name and address of the qualified patient
    - The quantity dispensed
    - The name, strength, batch number, and lot number of the product
    - Date and time of distribution

#### **Requirements of Secondary Records:**

- Records must be maintained independent of the inventory control system
  - Physical records will be maintained within a file cabinet, separate from the inventory control system
- Records must be searchable
  - Records will be organized and filed alphabetically according to recipient name
- Records must be secure
  - Records will be maintained within the Licensed Premise, located within a limited-access area inside a manager office equipped with an independent security alarm system. The records will be held within a lockable filing cabinet inside the secure office.
- Records must be tamper-evident
  - The file cabinet where secondary records are to be maintained will have a secure, tamper-evident locking mechanism on it.

#### **Certifying Physician Records Request**

BPH will require registered employees to provide in a reasonable time and manner to a certifying physician a copy of the record of each distribution by BPH to a qualifying patient of the certifying physician of the quantity delivered, name, strength, batch number and lot number of medical marijuana.

- Reasonable time to be defined as within 48 hours of receipt of request

#### **Records and Documents Storage Retention**

Unless otherwise specified, BPH will retain and maintain all records and duplicate sets of records for a minimum of six (6) years.

#### **Duplicate Records and Off-Site Storage**

As per State of Hawaii regulations, BPH will maintain duplicate sets of all records required by regulation. These duplicate copies of BPH records will be maintained at a secure, off-site location. This location will only be disclosed to personnel with proper security clearance. The off-site record storage will be secured with a security alarm and surveillance system to ensure access is limited to authorized personnel only.

#### **Quarterly Report**

BPH will submit a quarterly report to the department on January 15, April 15, July 15, and October 15. In the event that those dates fall on a weekend or holiday, the report can be submitted the following business day.

- This report must include but not limited to:
  - Records of entry and exit for all individuals who entered a dispensary facility
  - Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale
  - Amounts by category of marijuana and manufactured marijuana products sold
  - A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed

- A summary of financial statement
- Laboratory results of all tests conducted
- Description of any breach or halt in its security system and tracking system
- Any other information requested by the Department of Health

The inventory report can be created through the inventory control system

- Within the inventory control system, BPH will be able to generate a list of all the products along with their specifications that were offered for distribution
- This list can be generated for all products offered with specific date ranges



<b>Standard Operating Procedure:</b> General Security/Diversion Prevention Training
<b>Purpose:</b> To explain the general security and diversion prevention training needed to be adhered to.
<b>Scope:</b> To understand security and diversion prevention training requirements.
<b>Initial Training:</b> 4-8 hours

**Diversion and Trafficking Prevention Training**

Diversion and trafficking prevention will primarily be done using the various security alarm and surveillance equipment installed and utilized at BPH’s retail dispensing locations. The various security alarm and surveillance equipment utilized is explained in more detail within the Security Plan which is a separate, additional document that can be viewed upon request. All BPH registered employees will be trained on all security equipment, measures and policies prior to commencing work within the retail dispensing location.

BPH will utilize BioTrackTHC’s inventory control system and industry best practices and policies to reduce the risk of diversion and theft of marijuana products. All marijuana plants will be tagged, recorded and tracked through the inventory control system from seed-to-sale.

The use of professional security systems from Securitas that will be installed at all of organization facilities will also help to reduce the risk to diversion, loss, theft or unauthorized access.

If any marijuana or manufactured marijuana product loss or discrepancy noticed by a registered employee, management shall be made aware of the loss immediately. Inventory discrepancies should be easily noticeable with the use of the inventory control system. The diversion or product loss must be documented on the **Product Loss** log sheet which can be seen below.

<b><u>Product Loss Log Sheet</u></b>				
<b><u>Date:</u></b>	<b><u>Product Name/Category</u></b>	<b><u>Product Attribute # or Unique ID #</u></b>	<b><u>Total Quantity</u></b> <b><u>Loss:</u></b>	<b><u>Product Loss</u></b> <b><u>Valuation:</u></b>
				\$
<b><u>Reporting</u></b> <b><u>Employee:</u></b>	<b><u>Manager/Supervisor:</u></b>	<b><u>Product Loss Due To:</u></b>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<b><u>Internal</u></b> <b><u>Investigation:</u></b>	<b><u>Required Authorities</u></b> <b><u>Notified:</u></b>	<b><u>Authorities Notified (list all) :</u></b>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<b><u>Note/Comments:</u></b>				

### **Video Surveillance System.**

Securitas will design video surveillance systems at BPH's retail dispensary facilities that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

### **Alarm System.**

Each retail dispensary location operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

### **System Failure.**

In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

### **Other Security Measures.**

All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH-approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

### **Retail Dispensary Location (RDL) Specific Security.**

BPH will implement and follow specific security procedures and policies for all RDL operations including: written SOPs for admitting registered patients and primary caregivers with valid government-issued photo identification cards issued pursuant to HRS Chapter 329 into the secure rooms for sales. BPH will design and construct each RDL with separate, secure room(s) for sales wherein marijuana and manufactured marijuana products are secured and locked in display cases for viewing.

As required by HAR §11-850-53(3), BPH will follow written policies and procedures to ensure that a maximum occupancy limit ratio is maintained in all secured sales rooms of two customers to everyone RDL employee. BPH will store all marijuana products within a locked room, vault or in a locked container securely affixed to a wall or floor. All RDLs shall have exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities.

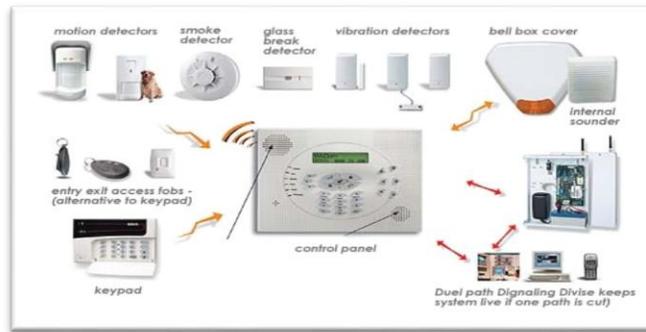
### **Transportation Security.**

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.



3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH’s tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

**Alarm Surveillance**—a primary alarm system will be installed at all BPH registered dispensary facilities by Securitas, a licensed alarm companies. An advanced security alarm system on all perimeter entry points, perimeter windows, and secured interior rooms. Motion detection equipment and camera equipment will be used to ensure the entire facility(s) is continuously safe from intrusion and product diversion.



**Video Surveillance**—an advanced video surveillance and recording system at all BPH facilities. All cameras will record in digital format and be maintained to meet the requirements outlined by State and local regulations. Video cameras will be maintained in each room and be used to identify any activity occurring within the room and be capable of recording and viewing in low light conditions. An onsite DVR and an additional offsite DVR will be utilized to store all footage; all video surveillance recording will be stored for a minimum of one year.



**Security Lighting**—security lighting around the entire perimeter of the production center to allow surveillance in low light conditions and deter potential intrusion.



**Motion Detector Alarms**—the professional security alarm system will utilize motion detectors that will detect intrusion and will automatically notify the proper authorities.



**Panic-Button Alarm**—employees will be required to wear a panic-button alarm that is discrete and can notify authorities in the case of an emergency.



**Hold-Up Alarm**—the security and alarm system will have a hold-up alarm that will be a silent alarm signal that is generated by manual activation of a device which will signal a robbery in progress and automatically notify the local police authorities.



**Duress Alarms**—the security and alarm systems will utilize a duress alarm button on the alarm panels that can be pushed by employees in the case of an emergency. Different duress alarm buttons can be pushed to automatically notify the proper authority; police, fire or emergency services.



**On-Site Electronic Monitoring**—facility security rooms will have a large screen call-up monitor (at least 19") and a video printer capable of immediately producing a clear still photo from all video cameras.



**Commercial Grade Door Locks**—commercial-grade, non-residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas. Key-card access door locks may also be utilized to further limit access at facilities.



American Cannabis Company  
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**Safes and Product Storage**—Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana products and cash.





<b>Standard Operating Procedure:</b> Perpetual Inventory Control System
<b>Purpose:</b> To explain the principles and concepts of the perpetual inventory control system
<b>Scope:</b> To educate and train registered employees and licensed premise employees on the perpetual inventory control system
<b>Initial Training:</b> TBD

**Principles of the Perpetual Inventory Control System**

BPH will utilize a perpetual inventory system from a regulated marijuana industry-specific inventory system provider, BioTrackTHC™. This inventory control system has been developed specifically for the regulated marijuana industry and has been customized to include all marijuana business operational needs. The systems have been designed to be user friendly, the ability to be mobile, and with inventory control capabilities to track every medical marijuana plant and product from seed to sale. The inventory control system will be designed to have the ability to promptly identify a discrepancy in stocks of marijuana and manufactured marijuana products. BPH administrators of the system will be notified of a substantial reduction in an inventory stock level and be prompted to investigate the inventory levels to insure no theft, diversion or discrepancies occurred. Administrators and users can run inventory reports from the inventory control system to check inventory stock levels that have been recorded in the inventory control system against a physical inventory audit to further determine inventory discrepancies.

**Inventory Control /POS System**—the tracking of all marijuana products from seed to sale will be done through inventory management through the use of template log sheets, computer systems, Secure Information Systems (SIS) and selected Point-of-Sale systems (POS). All medical marijuana plants and products are to be tagged, recorded and tracked through the inventory control system. Failure to do so can result in disciplinary action and/or job termination.



*\*Inventory control system and/or Point-of-Sale (POS) system training will be provided by an expert or consultant from the inventory control system supplier, BioTrackTHC™. This 3<sup>rd</sup> party training will be required for all BPH registered employees prior to working within the production center.*

Registered employees will be required to utilize the inventory control system to identify, record, monitor and track all marijuana and products from the time the marijuana product is delivered to a licensed retail dispensary location. The standard operating procedures detail multiple situations when product monitoring and recording activities are required by registered employees within the retail dispensary location. Marijuana products will be given a unique attribute number, assigned to a production batch which and recorded in the inventory control system. The product will then be given a new and unique tag with the products identification and specifications and be recorded in the inventory control system, the tag will remain with the product throughout the products lifecycle enabling the plant to be identified and tracked. The inventory control system intended to be utilized within BPH’s retail dispensary locations will aid in the event of a serious adverse event by having the ability to track any marijuana plant or product back to the originating source, including the ability of tracking marijuana from a qualifying patient back to the source of the marijuana. The marijuana believed to have caused a serious adverse event should have a product label with product information and specifications such as the product name, unique attribute number, batch number and originating entity. With this information, the marijuana product will be able to be traced back to the originating source of the medical marijuana.



<b>Standard Operating Procedure:</b> OSHA Compliance and Training
<b>Purpose:</b> To explain the principles and concepts of OSHA regulations.
<b>Scope:</b> To understand OSHA requirements to create a safe work environment.
<b>Initial Training:</b> 4-6 hours

**OSHA Training**

Registered employees have the right to a safe workplace, and BPH intends to provide a safe work environment for all registered employees at all BPH facilities. The Occupational Safety and Health Act of 1970 (OSH Act) was passed into law as a preventative measure for workers from being killed or seriously harmed while at work. The law requires employers to provide employees with working conditions that are free from known dangers.

The OSH Act created the Occupational Safety and Health Administration (OSHA). This regulatory agency sets and enforces protective workplace safety and health standards. OSHA is also charged with providing information, training and assistance to workers and employers to educate and train individuals on workplace safety. Employees may file a complaint if they feel necessary which will result in OSHA to inspect the workplace if they feel OSHA standards are not being met or that there may be serious hazards or danger. More information on the Occupational Safety and Health Administration can be found online at the website: <https://www.osha.gov/>.

**OSHA’s Mission**—With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

**OSHA Training**—The OSHA Outreach Training Program for General Industry provides training for workers and employers on the recognition, avoidance, abatement, and prevention of safety and health hazards and dangers in workplaces in general industry. This program also provides information regarding workers' rights, employer responsibilities, and how to file a complaint. Employees can attend a 10-hour or 30-hour class delivered by OSHA-authorized trainers. The 10-hour class is intended for entry level workers, while the 30-hour class is more appropriate for supervisors or workers with some safety responsibility. OSHA training helps to ensure that workers are more knowledgeable about workplace hazards, dangers and their rights.

Under the OSH Law, employers have a responsibility to provide a safe workplace free from known hazards or dangers. The OSHA website provides a short summary of employer responsibilities with which BPH will ensure compliance.

- Provide a workplace free from serious recognized hazards and comply with standards, rules and regulations issued under the OSH Act.
- Examine workplace conditions to make sure they conform to applicable OSHA standards.
- Make sure employees have and use safe tools and equipment and properly maintain this equipment.
- Use color codes, posters, labels or signs to warn employees of potential hazards.
- Establish or update operating procedures and communicate them so that employees follow safety and health requirements.
- Employers must provide safety training in a language and vocabulary workers can understand.
- Employers with hazardous chemicals in the workplace must develop and implement a written hazard communication program and train employees on the hazards they are exposed to and proper precautions (and a copy of safety data sheets must be readily available). See the OSHA page on Hazard Communication.
- Provide medical examinations and training when required by OSHA standards.
- Post, at a prominent location within the workplace, the OSHA poster (or the state-plan equivalent) informing employees of their rights and responsibilities.
- Report to the nearest OSHA office all work-related fatalities within 8 hours, and all work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours. Call our toll-free number: 1-800-321-OSHA (6742); TTY 1-877-889-5627. [Employers under federal OSHA's jurisdiction were required to



begin reporting by Jan. 1, 2015. Establishments in a state with a state-run OSHA program should contact their state plan for the implementation date].

- Keep records of work-related injuries and illnesses. (Note: Employers with 10 or fewer employees and employers in certain low-hazard industries are exempt from this requirement.)
- Provide employees, former employees and their representative's access to the Log of Work-Related Injuries and Illnesses (OSHA Form 300). On February 1, and for three months, covered employers must post the summary of the OSHA log of injuries and illnesses (OSHA Form 300A).
- Provide access to employee medical records and exposure records to employees or their authorized representatives.
- Provide to the OSHA compliance officer the names of authorized employee representatives who may be asked to accompany the compliance officer during an inspection.
- Not discriminate against employees who exercise their rights under the Act. See our "Whistleblower Protection" webpage.
- Post OSHA citations at or near the work area involved. Each citation must remain posted until the violation has been corrected, or for three working days, whichever is longer. Post abatement verification documents or tags.
- Correct cited violations by the deadline set in the OSHA citation and submit required abatement verification documentation.
- OSHA encourages all employers to adopt an Injury and Illness Prevention Program. Injury and Illness Prevention Programs, known by a variety of names, are universal interventions that can substantially reduce the number and severity of workplace injuries and alleviate the associated financial burdens on U.S. workplaces. Many states have requirements or voluntary guidelines for workplace Injury and Illness Prevention Programs. Also, numerous employers in the United States already manage safety using Injury and Illness Prevention Programs, and we believe that all employers can and should do the same. Most successful Injury and Illness Prevention Programs are based on a common set of key elements. These include: management leadership, worker participation, hazard identification, hazard prevention and control, education and training, and program evaluation and improvement. OSHA's Injury and Illness Prevention Programs topics page contains more information including examples of programs and systems that have reduced workplace injuries and illnesses.

### **Plan for OSHA Compliance**

Below details BPH's plan for compliance with OSHA will begin by ensuring that all organizational facilities are free from known hazards and/or dangers. Although OSHA is a federal organization and we are not currently held to OSHA standards, BPH feels it is best practices to be aware of OSHA guidelines and adhere to said guideline within our operations.

All registered employees will be provided basic training covering workplace safety pertaining to identifying and preventing potential hazards and or dangers such as trip hazards. This basic training will begin with training all new employees on policies and procedures. Proper and adequate training can help to reduce workplace accidents through educating and training employees on operations, policies and procedures. Employees will be given a tour of the facility property and areas in which the employee will have access to (limited or restricted). Other training to be included in BPH's plan for OSHA compliance will include:

- Training on SOPs
- Regulatory compliance training (laws and regulations pertaining to medical marijuana cultivation, processing or dispensing)
- Basic training on workplace safety
- Recognition of potential workplace hazards or dangers



**Standard Operating Procedure: Employee Dress Code and Personal Hygiene**

**Purpose:**

To explain the employee dress code required.

**Scope:**

Covers the dress code requirements for employees.

**Principles of Employee Dress Code**

The dress code to be implemented at retail dispensary locations will be casual or business casual and may include a company logoed polo shirt, and nice jeans, khakis pants or nice shorts or a shirt; all clothing must be free of holes and tears.

Employees are expected to arrive at facilities in clean working attire ready to begin the scheduled work shift.

**Personal Hygiene Policy**

This policy has been set forth in order to ensure that all employees are practicing good personal hygiene to ensure that are products are produced in safest and most sanitary means possible. The personal hygiene policy includes but is not limited to the following:

- A. Maintaining adequate personal hygiene
  - a. Arrive to work clean in appearance/clean clothes.
  - b. Showering every day is essential
  - c. Deodorant and a clean personal smell is required
- B. Men must be neatly groomed/shaven
  - a. Mustaches or beards allowed if maintained
  - b. We reserve the right to ask you to wear a beard cover if we deem it necessary
- C. Long hair must be constrained in a neat manner to avoid hair coming into contact with marijuana and/or manufactured marijuana products
  - a. A hat or hairnet is preferred
  - b. Jewelry of any kind is not permitted
    - i. This includes earrings, rings, bracelets, watches, etc.
- D. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and
- E. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

**General Sanitary Requirements**

BPH will take all reasonable measures and precautions to ensure that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for medical marijuana products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.



BPH will have hand-washing facilities that are convenient and furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

That all registered employees working in direct contact with processing, preparation, weighing or repackaging of medical marijuana products shall conform to hygienic practices while on duty, including but not limited to:

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the processing, preparation, weighing or repackaging of medical marijuana products and at any other time when the hands may have become soiled or contaminated; and
- Refraining from having direct contact with preparation of medical marijuana products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical marijuana products.

Registered employees are required to ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical marijuana products are exposed. Registered employees are required to ensure that floors, walls, and ceilings are adequately cleaned and kept clean and kept in good repair.

That the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

Registered employees must ensure that all contact surfaces, including utensils and equipment used for the preparation of medical marijuana products shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used with medical marijuana and used in accordance with labeled instructions;

BPH requires all toxic cleaning compounds, sanitizing agents, solvents used in the production of medical marijuana and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of medical marijuana products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. That medical marijuana products that can support the rapid growth of undesirable microorganisms will be held in a manner that prevents the growth of these microorganisms; and the storage and transport of finished medical marijuana products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.



Limited Access Areas

<b>Standard Operating Procedure:</b> Limited Access Areas
<b>Purpose:</b> To explain Limited Access Areas, who is allowed in these areas, and procedures to follow within the Limited Access Area.
<b>Scope:</b> Covers the steps involved in escorting visitors in limited access areas.
<b>Initial Training:</b> 1 hour

**The Principles of Limited Access Areas**

A Limited Access Area is a building, room, or other contiguous area upon the Licensed Premises where marijuana is stored, weighed, packaged, sold, or processed for sale, under control of the retail dispensary location. Limited Access Areas are areas within the licensee’s facilities where only certain people will have the required permission to access.

Limited Access Areas may have people in them without the proper permission as long as the State required protocols are followed. Typically this involves following the *Visitor SOP*; being escorted by a licensed employee at all times while in the facility and Limited Access Areas.

Limited access areas should be limited to State licensed, facility employees only. If a visitor needs to access the limited access areas, registered employees will be required to follow the written *Visitor SOP*.





## **Standard Operating Procedure: Patient Confidentiality**

### **Purpose:**

To explain the steps involved for handling patient confidentiality.

### **Scope:**

Covers the steps involved to protect patient confidentiality.

## **The Principles of Protecting Patient Confidentiality**

This section will cover the best practices in patient privacy and confidentiality. When operating a business within the marijuana industry it is important to ensure that your patient's records and information are secured and kept private. A breach in such privacy can result in HIPAA violations, legal ramifications and a potential cease and desist order. Below you will find some helpful tips in keeping patient information private.

### **Patient Record Privacy & Confidentiality Tips**

- 1) Keep all patient records in a secure lockbox or lockable cabinet. Having these records all in one place can help to ensure that no patient records are being kept in exposed areas where it is possible for an information breach.



- 2) When patient records are gathered for the first time, be sure to place the information in a secured and lockable location.
- 3) Upon acceptance of new patient records, provide a verbal disclosure statement to the patient. This verbal statement should make the patient aware that their records are being kept per state law and that they will be maintained in such a way that their information will remain confidential and kept from public view or oversight.
- 4) Have only employees who can be trusted and held responsible to work with and maintain patient records.
- 5) Train ALL registered employees to never disclose the specific names of patients with non-employees. It is important that the names of patients not be shared with the public in any way, as this would result in a HIPAA violation.
- 6) Store patient records in a secure place that is away from any cash or inventory vault. By keeping this location separate and secured you will minimize the chance that records could potentially go missing, get stolen, etc.



- 7) NEVER leave patient records out on a receptionist's desk or patient intake desk while the station is unattended.
- 8) Get HIPAA trained! It would be beneficial to have all employees' complete basic HIPAA training. This training will provide employees with HIPAA compliance training and ensure patients with more peace of mind knowing that the employees understand HIPAA privacy rules and procedures. See <http://www.hipaatraining.com/>
- 9) Host a monthly or bi-monthly meeting with all employees to go over privacy and confidentiality measures. This will provide further accountability on all staff levels to make sure privacy/legal compliance is met.
- 10) Designate record maintaining/record processing employees and limit patient records access. By doing this you will limit the potential for complications within your internal operations.



**Standard Operating Procedure: HIPAA Compliance Training**

**Purpose:**

To explain the steps involved with becoming HIPAA-compliant trained.

**Scope:**

Covers the steps involved to obtain certified HIPAA training.

The primary goal of the federal HIPAA law is to make it easier for people to keep health insurance, protect the confidentiality and security of healthcare information and help the healthcare industry control administrative costs. **HIPAA** provides for the protection of individually identifiable health information that is transmitted or maintained in any form or medium. The privacy rules affect the day-to-day business operations of all organizations that provide medical care and maintain personal health information, this includes medical marijuana businesses and establishments.

Patient confidentiality will be of utmost importance during operations and maintaining patient records as confidential and properly stored and secured on the premise will be done according to required laws and regulations.



All patient records or files that are maintained as a “hard” or physical document will be properly stored in a locking file cabinet within a limited or restricted access area of the premise. If patient records or files are maintained electronically, said records or files will be maintained on a secure, HIPAA-compliant computer which will also be stored securely within a limited or restricted access area of the premise. The computer will be secure from physical theft but also electronic theft of records through the use of virus protection and secured servers on other security measures. Access to confidential patient records and files will be limited to BPH employees with proper clearance levels.

**General HIPAA Policies:**

- All employees that will have direct contact with confidential patient information will complete basic HIPAA training. This training will help employees understand HIPAA privacy rules and procedures. Visit the website: <http://www.hipaatraining.com/>



- Upon acceptance of new patient records, provide a verbal disclosure statement to the patient. This verbal statement should make the patient aware that their records are being kept per State law and that they will be maintained in such a way that their information will remain confidential and kept from public view or oversight.
- Access to confidential patient records will be limited to employees with the proper clearance level. These records will be accessible only by ownership, management and patient advocates. Limiting employee access



to confidential patient records will help reduce the risk to exposure. Additional employees may be granted the proper clearance level to access confidential patient records as needed in the future.

- Keep all patient records in a secure locking file cabinet or lockable filing system within a limited or restricted access area of the premise. Having all confidential patient files centrally located in can help ensure that no confidential patient records are being kept in exposed areas where it is possible for an information breach.



- When patient records are initially gathered, be sure to create a new patient folder and place the patient records within said folder. All folders should be marked confidential and place in a secured and lockable file cabinet within a limited or restricted access area of the facility (e.g. the general manager's office).



- ALL employees will receive training to never disclose the specific names of patients with non-employees or parties outside the organization. It is important that the names of patients not be shared with the public in any way, as this would result in a HIPAA violation.
- NEVER leave patient records unattended or unsecure within the file cabinet.
- Organization will host a monthly or bi-monthly meeting with all employees to go over privacy and confidentiality policies, procedures and measures. This will provide further accountability on all staff levels to make sure privacy/legal compliance is met.



<b>Standard Operating Procedure:</b> Patient Education
<b>Purpose:</b> To explain what is expected from employees regarding patient education.
<b>Scope:</b> Covers what educational materials should be offered at retail dispensary, house menus, effects, dosage, etc.
<b>Initial Training:</b> TBD

**Educational Documents**

- 1) State and/or local laws/regulations
- 2) Dispensary menu—brochure of all product offering, descriptions, test results, etc.
- 3) Patient education materials
- 4) Other educational materials as BPH sees fit
  - a. Medicate responsibly materials
  - b. Drug abuse prevention materials
  - c. Signs of impaired driving materials
  - d. Etc.

**The Principles of Patient Education**

Medical marijuana is a new treatment option for qualifying patient’s and as such, said patients will need to be educated on marijuana as a medicine. Medical marijuana patients will work closely with their physicians to determine the optimal medical marijuana treatment plan including routes of administration, dosage and usage recommendations and quantities of medical marijuana products to be dispensed. Patients will also have a close relationship with the dispensary staff who will be dispensing the medical marijuana products and as a result patients will most likely discuss their conditions with dispensary staff.

Individual patients will have different reactions to the medical marijuana products available, so patients will need to be educated about the potential effects of each medical marijuana product. A knowledgeable dispensary staff will be able to reference patient ailments with the medical marijuana products available and ultimately be able to recommend a medical marijuana product suitable for the patient. Medical marijuana patients will need to take the recommendations from dispensary staff to their physician to discuss routes of administration, dosage rates and quantities to be dispensed. The medical marijuana patient’s physician will determine what they feel is the best treatment option for said patient.

Patient education at a minimum will cover the following:

1. Medical marijuana’s effect on the human body
2. Physical effects based on route of administration of marijuana derivative product
3. Amount of time to feel impairment
4. Visible signs of impairment
5. Recognizing the signs of impairment
6. Packaging and labeling
- 7.

Patient education is detailed below; BPH will also create and provide detailed educational materials to be distributed to qualifying patients at the retail dispensary locations.

**1. Medical Marijuana’s Effect on the Human Body**

Medical marijuana will have different effects on every individual person and the effects may vary depending on quantity consumed, dosage rate, whether or not the marijuana was vaporized or ingested and other factors may contribute to the effects on the human body. The information below will describe some common effects associated with consuming medical marijuana products.



## 2. Physical Effects Based on Route of Administration of Marijuana Derivative Product

Medical marijuana is a new treatment option for patients in the State of Florida and patients seeking medical marijuana as a treatment option will need to be aware of the physical effects marijuana can have. Marijuana has an active ingredient called THC, which is what makes people feel 'high'. THC and other compounds in marijuana can also affect the way your body works. Marijuana affects almost every organ in the body, the nervous system and immune system. Vaporizing marijuana can increase the heart rate by as much as two times and can increase bleeding, lower blood pressure, and affect blood sugar. When vaporizing marijuana, the body absorbs THC immediately into the blood stream via capillary action in the lungs, if you consume or ingest a baked good or another marijuana-infused item, it may take much longer for the body to absorb THC because it has to break down in your stomach before it enters the bloodstream.

Other physical effects of marijuana consumption include:

- Dizziness
- Shallow breathing
- Red eyes and dilated pupils
- Dry mouth
- Increased appetite
- Slowed reaction time

Smoking marijuana can have less-pleasant effects on one's mind and mood such as:

- A distorted sense of time
- Random thinking
- Paranoia
- Anxiety
- Depression
- Short-term forgetfulness

## 3. Amount of Time to Feel Impairment

The amount of time it takes to feel impairment will differ and vary for everyone. Generally speaking, effects are typically immediate after consuming marijuana through vaporizing but the time to feel the effects after consuming marijuana through eating or ingesting could take up to 2 or 3 hours.

## 4. Visible Signs of Impairment

The most immediate signs of marijuana impairment are:

- Red eyes and dilated pupils
- Increased heart rate
- Increased appetite
- Memory impairment
- Difficulty paying attention or solving problems
- Dizziness
- Shallow breathing
- Dry mouth

## 5. Recognizing Signs of Impairment

The following information is being provided to assist persons in recognizing the signs and/or symptoms of marijuana impairment and for purposes of determining if an individual may be under the influence. This information is intended for informational purposes only and is not intended for use as training material, or to assist individuals in becoming drug recognition experts and should not be used in lieu of recommendations or advice from qualified professionals.

Generally speaking, if you notice an individual having trouble with balance, trouble walking or using motor functions, the individual may be impaired from consuming marijuana or marijuana-infused products. Redness of the eyes, dilated pupils and dryness of the mouth can also be indicators of impairment. If you suspect a patient is impaired or under the influence of marijuana or any other substance, do not let them drive or operate a motor vehicle of any kind. Offer to call a taxi or to arrange another means of transportation for the patient.



### 6. Packaging and Labeling

It is important for qualifying, registered patients’ to understand the importance of packaging and labeling medical marijuana products. Proper packaging and labeling will achieve two primary objectives; 1) the medical marijuana product will be properly be labeled to identify who the product is intended for, dosage rates and instruction and other important information pertaining to the patient or the medical marijuana derivative products, and 2) proper child-resistant packaging will help to ensure children cannot easily access the medical marijuana derivative product(s).

Child Resistant Packaging to be used for pill-form edibles (*capsules*)



Child Resistant Packaging to be used for oils (*for sublingual administration*)



Metered Dosage Packaging to be used for oils (*vaporization administration*)



Tamper-Evident Packaging to be used for pill-form edibles (*capsules*)



Tamper-Evident Packaging to be used for oils (*for sublingual administration*)



Tamper-Evident Packaging to be used for oils (*for vaporization*)



**Exit Packaging**—this exit packaging will be used to place the pre-package medical marijuana product(s) in at the medical dispensary prior to patients and/or a patients’ legal representative exiting the dispensary. This exit packaging will create a double redundancy to ensure children cannot unintentionally access the medical marijuana derivative product(s). Exit packaging will be opaque concealing the contents inside and will allow patients and/or caregiver discretion upon exiting the dispensary. Exit packaging is also utilized to minimize the risk to product diversion or the medical marijuana product(s) falling into the wrong hands.

The Satchel™ is a pouch-like case designed as a high-quality, child-resistant exit package solution for the regulated marijuana industry. The Satchel™ meets child-safety requirements of the Consumer Products Safety Commission (CPSC), making it compliant in all states. The Satchel™ is also tested and approved by the American Society for Testing and Supplies (ASTM). The Satchel™ features a child-resistant closure completely concealing the contents inside.

***THE SACHEL™***



American Cannabis Company  
growing the next frontier



### **Other Education**

Employees of the retail dispensing locations will need to be very knowledgeable not only on the relevant State and Local laws and regulations, but they will also need to be very knowledgeable on all of the dispensaries product offerings, recommended dosage rates, potential side effects, and other pertinent information.

Individual patients will have different reactions to the medical marijuana strains available, so patients will need to be educated about the potential effects of each marijuana strain. A knowledgeable retail staff will be able to reference patient ailments with the marijuana strains available and ultimately be able to recommend a marijuana strain suitable for the patient. Registered employees are encouraged to educate themselves on marijuana as a medical treatment option.



### Opening Procedure

<b>Standard Operating Procedure:</b> Opening Procedure
<b>Purpose:</b> To explain the steps involved with the opening procedure.
<b>Scope:</b> Covers the steps involved to open the store for daily business activities.
<b>Initial Training:</b> 1 hour

### Documentation Log Sheets Required

- 1) Cash Drawer Balances

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels
- 4) Child-Resistant Exit Packaging

### The Principles of Opening Procedure

The opening responsibilities will primarily be comprised of getting the retail sales floor ready for daily activities. This will consist of the following:

- Entering the store, disable security alarm, clock in for a work shift
- Inventory management:
  - Stocking display cases with various medical marijuana products and manufactured marijuana products
  - Ensuring the retail sales floor has sufficient amounts of product for sale during shift (back-stock supply)
- Balancing and assigning cash drawer to each POS terminal

### **Opening Procedure:**

- 1) Enter the store
- 2) Disable security alarm
- 3) Clock-in for work shift
- 4) Prepare sale floor for daily activities:
  - a. Ensure sales floor is clean:
    - i. Sales counters are clean (Dust and Windex surfaces)
    - ii. Floors are free of debris (sweep, mop, vacuum, etc.)
  - b. Count and balance cash drawers for POS system(s)
    - i. Record beginning cash drawer balance on *Cash Drawer Balances* log sheet.
  - c. Retrieve marijuana products and marijuana-infused products from safe/vault.
  - d. Set up display cases with marijuana products and marijuana-infused products.
- 5) Ensure retail dispensary is adequately stocked with product to support the daily sales activity
  - a. You may need to place an order to receive more product from the cultivation facility and/or 3<sup>rd</sup> party organizations.
- 6) Turn on 'OPEN' sign and begin daily sales operations.





Example of Cash Drawer Balance log sheet (see below):

<u>Cash Drawer Balances</u>							
Date:	Employee:	Drawer 1		Drawer 2		Drawer 3	
		Open	Close	Open	Close	Open	Close





<b>Standard Operating Procedure:</b> Patient and Caregiver Intake
<b>Purpose:</b> To explain the processes involved to process patients and/or caregivers into the retail dispensary.
<b>Scope:</b> Covers the required steps to allow patients and/or caregivers into the facility.
<b>Initial Training:</b> 2 hours

### **The Principles of Patient and Caregiver Intake**

Patients and caregivers wishing to patron any retail dispensing facility will need to have a valid state Medical Marijuana Program Registration Card. After entry into retail dispensing facility, team members will verify the validity of each patient's Medical Marijuana Program Registration Card through the state electronic verification system in the reception room. After the verification process has been completed, the patient and/or caregiver will be allowed entry into the secured sales rooms.

The retail facility manager will create and maintain a database within the POS system for inventory and tracking purposes. This will enable team members to adhere to all laws regarding the quantities of medical marijuana products patients and/or caregivers are allowed to have in a given time period.

#### **Electronic Verification**

Facility employees will verify each and every patient's and/or caregiver's Medical Marijuana Program Registration Card prior to entry into any secured sales rooms. The electronic verification process will need to be completed for every single patient and/or caregiver *EVERY* time they wish to patron the facility.

- 1) **Medical Marijuana Program Registration Card**—Accept patient and/or caregivers state-issued medical marijuana license
  - a. Ensure the state-issued medical marijuana license is current (check expiration date on Card)
- 2) **State-Issued ID**—Patients and/or caregivers must also have a current and valid State-issue ID (passport, Driver's License, etc.)
  - a. Ensure that the state-issued ID is current (check expiration date on ID)
- 3) **Verification**—Verify the validity of the state-issued Medical Marijuana Program Registration Card
  - a. Verify validity of the Medical Marijuana Program Registration Card license through the state electronic verification system
- 4) **Access**—Allow or deny access to patient and/or caregiver
  - a. Allow entry to retail dispensary if the patient and/or caregiver has a valid state-issued Medical Marijuana Program Registration Card.
  - b. Deny entry to retail dispensary if the patient and/or caregiver does not have a valid state-issued Medical Marijuana Program Registration Card.
    - i. If you feel the patient and/or caregiver is trying to use a fake or fraudulent Medical Marijuana Program Registration Card; confiscate said Medical Marijuana Program Registration Card and contact required state authorities.



Visitors

<b>Standard Operating Procedure: Visitors</b>
<b>Purpose:</b> To explain the processes involved to accept/allow visitors into the retail dispensary.
<b>Scope:</b> Covers the required steps to follow to allow visitors into the facility.
<b>Initial Training:</b> 1 hour

**Requirements**

- 1) Visitor Log Sheet
- 2) Visitor pass

Pursuant to 329D-15 and 329D-16, unauthorized access to retail dispensing locations and/or a production center is a Class C felony. Due to the strict penalties for infractions, BPH will take steps to identify all potential subcontractors, maintenance workers, and any other individual identified as needing to visit one of BPH retail dispensing locations or our production center. Such steps will allow said individuals to submit proactively to fingerprint cards and background checks and be aware of the information submitted to the Department. In order to obtain Department approval, BPH also intends to identify secondary, back-up individuals who can be utilized as resources if the primary resource is unavailable; these secondary subcontractors and resources will also be required to submit fingerprint cards and authorize consent for background investigations to ensure the individual does not have any felony convictions or other offenses listed in §11-850-17.

**The Principles of Visitor Protocol**

BPH’s visitor protocol will follow industry best practices and current regulations. There will be situations that arise that will require someone to enter the registered dispensary facility premises who is not a State-licensed industry worker or not a State-registered patient or caregiver but they will need access to the facility. Common visitors typically will be support-type businesses such as HVAC, electric and plumbing, general contractors, etc.

All visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

Approved visitors will be required to provide a BPH registered employee with a current, valid government-issued identification. The registered employee will confirm the individual is on the BPH’s Department-approved list, make a photocopy of the visitor’s ID and maintain the photocopy with the visitor log book; visitors will be required to sign in and out with a registered employee and provide a written reason for the visit (e.g. maintenance work, HVAC, repairs, etc.). Upon completing these requirements, the registered employee will issue a ‘visitor badge’ for the visitor to wear and display while at any BPH registered dispensary facility. BPH will also require a registered employee to remain with the visitor for the duration of the visit to ensure the visitor does not interact with or handle any marijuana plant, material, product, or manufactured marijuana product.

- **Government-Issued ID**—all visitors must have a current and valid government-issued ID (passport, Driver’s License, military ID)
  - Ensure that the government-issued ID is current (check expiration date on ID)
- **Verification**—Verify the validity of the government-issued ID and that the visitor is on the current Department-approved list
- **Photocopy**— Make photocopy of visitor’s government-issued ID
  - Make a photocopy of visitor’s ID; Photocopy is to remain with *Visitor Log Sheet*

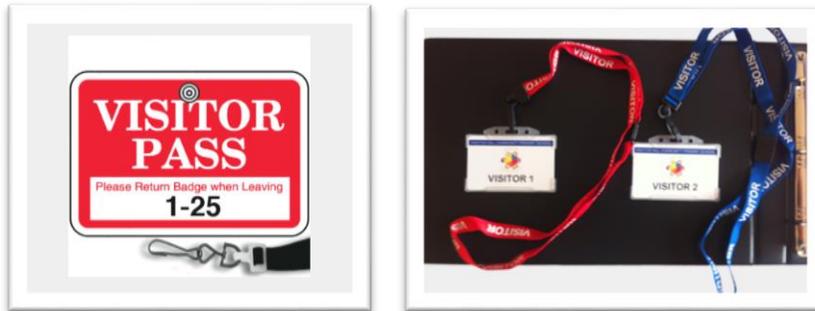


- **Access**—Allow or deny access to the facility
  - Allow entry to dispensary if the visitor has a valid government-issued ID.
  - Deny entry to the facility if the visitor does not have a valid government-issued ID.
- **Record/Documentation**—Have visitor fill out the *Visitor Log Sheet*
  - *Visitor Log Sheet* will document visitors name, company, date, time-in, time-out, signature, reason for the visit
  - Maintain photocopy of visitor ID with the *Visitor Log Sheet*
  - This record of visit must be retained and maintain on the licensed premise for a minimum of two (2) years.

**Visitor Access Process:**

- 1) Check visitors ID and credentials at the check-in station
  - a. Make photocopy of Visitor’s ID
- 2) Verify with management that visitors are expected and on the current Department-approved list
- 3) Fill out *Visitor Log Sheet*
- 4) Have said visitor sign-in and date the *Visitor Log Sheet*
- 5) Give visitor a ‘*Visitor Pass*’
- 6) When visitor is finished at the licensed premises:
  - a. Have visitor sign-out on *Visitor Log Sheet*
  - b. Collect the ‘*Visitor Pass*’ from said visitor

*Example of a Visitor Pass can be seen below:*



*Example of Visitor Sign-In Documentation Log Sheet:*

<u><b>Visitor Sign-In Documentation Log Sheet</b></u>							
<u>Date</u>	<u>Time In</u>	<u>Time Out</u>	<u>Visitor Name</u>	<u>Visitor's Company</u>	<u>Visitor Signature</u>	<u>Reason for Visit</u>	<u>Registered Employee Escort</u>





Receipt of Material

<b>Standard Operating Procedure: Receipt of Materials</b>
<b>Purpose:</b> Explain procedure and requirements for receiving raw materials
<b>Scope:</b> To educate and train licensed premise employees on the procedures and requirements involved with receipt of materials.
<b>Initial Training:</b> 1-2 hours

**Principles of Receipt of Material**

The process of receipt of material or receiving raw materials is not as simple as just taking the marijuana product materials into the retail dispensary location. There are regulations, guidelines and procedures to follow when receiving marijuana product materials or other inventory into the retail dispensary locations.

Upon receiving any raw materials, inventory or other items used in operations said items will be placed in a quarantine storage area within the receiving area of the licensed premise. These items will include but not be limited to:

- Marijuana flower product
- Manufactured marijuana products

**Receipt of Materials**—upon receiving materials into the licensed premise, registered employees and/or licensed premise employees will need to document the receipt of materials on the *Receipt of Materials* log sheet.

*Example of Receipt of Materials Log Sheet can be seen below:*

<b>Receipt of Materials</b>							
							
<u>Date of Receipt:</u>	<u>Receiving Employee #1:</u>	<u>Receiving Employee #2:</u>	<u>Product/Strain/Attribute ID #:</u>	<u>Quantity Received:</u>	<u>Received From:</u>	<u>Materials Placed in Quarantine:</u>	<u>Materials Pass Visual Inspection:</u>
						YES NO	YES NO
<i>Describe why Materials did not pass visual inspection:</i>				<i>Corrective action to be taken:</i>			
<u>Materials Pass Visual Inspection after Corrective Action:</u>		<i>Describe why Materials did not pass visual inspection after corrective action:</i>			<i>Next corrective action to be taken:</i>		
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>If materials passed visual inspection, and are determined to be acceptable for use as intended, said materials may be released from the quarantine areas and used as intended.</i>							
<u>Date of Release of Materials:</u>	<u>Employee(s)/Supervisor Releasing Materials:</u>		<u>Product/Strain/Attribute ID # of Released Material(s):</u>		<u>Quantity Released:</u>		
<u>Record of Receipt of Materials Made in Perpetual Inventory Control System (POS)?</u>		<u>Required POS Records:</u> <i>date of receipt, quantity of material, types/variety of material date of release</i>		<u>Employee Making POS Record Entry:</u>		<u>Employee Witnessing POS Record Entry:</u>	
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>Notes/Comments:</i>							

**Inspection**—after received inventory items/materials are placed in quarantine, the items will need to be inspected to ensure there are no defects or contamination. All received items/materials will remain in a secure area until said material pass inspection and is determined to be acceptable for use as intended.

- Registered employees will be required to inspect all materials for visible defects and contamination



**Release**—upon the received materials passing inspection and being determined to be acceptable for use as intended, the materials will be released from the quarantine receiving/storage area. At this time the materials can be used within the licensed premise for their intended use.

- Release materials if they pass initial inspection

**Documentation and Record**—upon the materials being released from quarantine and determined to be acceptable for use as intended BPH registered employees and/or licensed premise employees will be required to log the materials into the inventory control system.

- Document and record new materials released from quarantine in the inventory control system (POS system)
- Ensure record is accurate with physical inventory on hand
- Ensure the *Receipt of Material* log sheet is filled out properly and completed



<b>Standard Operating Procedure:</b> Weights and Measurements and Scale Calibration
<b>Purpose:</b> To explain how to use certified scales for weights and measurements
<b>Scope:</b> To train registered employees on proper use of NTEP certified scales to be used for weights and measures as well as scale calibration/certification
<b>Initial Training:</b> 1 hour

BPH will pre-package all marijuana and manufactured marijuana products at the production center. Due to this fact, BPH should not have the use for a commercial scale at the retail dispensary locations, however BPH will keep certified scales on the premise in case a need should arise.

**Types of Scales to be used**

BPH will utilize NTEP-certified scales for the weighing of all medical marijuana, medical marijuana products, medical marijuana waste and all green waste.

**NTEP Certification**— The National Conference on Weights and Measures issues an NTEP Certificate of Conformance following successful completion of an evaluation of a device. It indicates that the device(s) described in the Certificate is/are capable of meeting applicable requirements of the *NIST Handbook 44*.\* <http://www.ncwm.net/ntep/faqs#WhatIsNTEPCertificate>

**Scale Use**

All medical marijuana harvested at BPH’s licensed premise will be weighed and packaged using NTEP-certified scales certified for legal trade and that have been calibrated and certified ISO/IEC 17025 accredited by a Hawaii calibration service supplier.

**Scale Calibration and Frequency**

BPH will ensure that all scales and balances are calibrated by an accredited calibration service supplier. The frequency of having BPH scales calibrated will be on a six (6) month basis. This routine calibration will be documented on the Scale Calibration Log sheet and maintain on the licensed premise.

*Example of the Scale Calibration Log Sheet:*

<b><u>Scale Calibration</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Scale Serial #/ID #:</u>	<u>Calibration Service Supplier:</u>	<u>Scale Calibrated</u>	<u>Notes/Comment:</u>
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	



**Standard Operating Procedure: Dispensing/Sales Procedure**

**Purpose:** To explain the processes involved in the sales procedure at the retail dispensing facility.

**Scope:** Covers the steps to follow when making a sale.

BPH will ensure that all retail dispensary sales are conducted at the retail dispensary location within a secure sales room. BPH will also have policies and procedures in place to ensure there are more more than 2 qualifying patient to every 1 registered dispensary employee within the secure sales rooms.

**The Principles of the Sales Procedure**

The sales procedure needs to be completely accurate for every sales transaction. If sales records are not accurate, then the inventory will reflect discrepancies that could result in regulatory compliance issues. Retail team members will complete extensive training on the POS system and the sales process before commencing operations.

Prior to making a sale, registered employees will have checked a government-issued ID from the qualified patient/caregiver. (*refer to qualified patient/caregiver intake SOP*)

**Making a Sale**—Prior to initializing a sale, a retail team member should make sure the current medical marijuana patient information is in the POS system and/or electronic database; if it is the patient’s first visit to the retail facility, the team member will need to create a new record for that patient. After verifying the medical marijuana patient’s information, the retail team member should check the POS system to determine how much/many medical marijuana products the patient is allowed to purchase. Quantity limits will be set forth in individual qualified patient records within the inventory control system.

Blue Planet Healing will ensure compliance with §11-850-42 by utilizing BioTrackTHC™, an inventory tracking system that will ensure registered employees dispense the correct amount of marijuana or manufactured marijuana products to registered patients. The state regulatory measure §11-850-42 dictates sales limits for qualifying patients. BPH will educate and train all registered employees to ensure sales limits are strictly adhered to. BPH will not dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that exceeds four (4) ounces of marijuana or its dry weight equivalent during a period of fifteen (15) consecutive days, and will not exceed eight (8) ounces of marijuana or its dry weight equivalent during a period of thirty (30) consecutive days.

**Department Data Network**

Before any distribution or dispensing of medical marijuana, BPH will require a registered employee to query the Department data network. Registered employees will be required to query the Department data network to:

- Verify that the qualifying patient or caregiver is currently registered.
- Verify that a verifying physician issued a valid written certification to the qualifying patient.
- Verify that the amount of medical marijuana already dispensed pursuant to the written certification.
  - To ensure qualified patients do not receive any combination of marijuana or marijuana manufactured products that exceed 4 ounces of marijuana during a period of fifteen (15) consecutive days.
    - Every sale of marijuana is measured on a scale and added up towards the tally
    - Manufactured marijuana products will all have the amount of marijuana used to produce the product labeled on its packaging and listed on the BioTrackTHC inventory system to be added up towards the tally
- Confirmations of Department of Health data network queries will be recorded by the registered employee into the Applicant’s inventory control system, and maintained as part of the qualified patient or caregiver electronic file.



- This entry is automatically time-date stamped and require the agent's electronic signature to attest to the verification of the Department of Health data network query. This protocol is required prior to every distribution, dispensing and/or transaction involving medical marijuana products.

**Packaging and Labeling Compliance**—all medical marijuana products will be packaged according to all applicable state and local laws. Employees will place all medical marijuana products into opaque, child-resistant, tamper-evident, and re-sealable containers prior to dispensing to any patient or caregiver.

**Sales Tax**—all sales transactions will be subject to applicable sales tax rates. The proper sales tax rates will be programmed into each POS system to ensure sales tax is being collected.

**Cash Handling**—all cash handling at the POS area should be done in view of a surveillance camera. This will help ensure honesty and reduce theft by employees. Also see Cash Handling SOP.

*Record of Dispensed Marijuana Product(s) (see below):*

Record of Distributed Medical Cannabis Products			
	Retail Dispensary Location License #:		Dispensary Phone #:
	Location Address:		
Qualified Patient Name:		Patient Address (street, city, state, ZIP) :	
DOB:	Patient Registry ID #:		
Patient Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender			
Fill Out Caregiver Information IF Applicable			
Designated Caregiver Name:			
DOB:		Caregiver Registry ID #:	
Dispensing Information			
Date Marijuana Product was Dispensed:	Quantity of Medical Marijuana Product(s):	Marijuana Product Attribute #:	Number of Days Supply that was Dispensed:
Product Batch #:		Date Distributed:	
Payment Method: <input type="checkbox"/> Cash <input type="checkbox"/> Credit <input type="checkbox"/> Other		Payment Amount: \$	



<b>Standard Operating Procedure:</b> Inventory Reconciliation Procedure
<b>Purpose:</b> To explain the purpose and processes involved with inventory reconciliation.
<b>Scope:</b> Covers the steps involved with inventory reconciliation.
<b>Initial Training:</b> 4-6 hours

### The Principles of Inventory Reconciliation

It is recommended to perform physical inventory on weekly or monthly basis. At minimum, a monthly inventory reconciliation is to be performed at each facility. This is where every product within the facility will be physically counted, documented and then reconciled (*compared*) with the inventory recorded in the POS system or computer inventory system.

The physical inventory on-hand that is counted should be identical to the inventory that is recorded within the POS system. If there are deviations in these numbers then action must be taken to determine the shortage(s).

- 1) Count **ALL** on-hand inventory at the retail dispensary location
  - Marijuana flower product
  - Manufactured marijuana products
- 2) Document all counted on-hand inventories on the appropriate ***Marijuana Products Inventory*** (*daily, weekly, or monthly*) log sheet.
- 3) Reconcile counted on-hand inventories against on-hand inventories in the POS system
  - Document discrepancies on the appropriate ***Marijuana Products Inventory*** (*daily, weekly, or monthly*) **log** sheet between the counted on-hand inventory and POS inventory.
  - Investigate all discrepancies
- 4) Inventory Discrepancies—discrepancies between the inventory stock and the inventory within the inventory control system (*outside of normal weight loss due to moisture loss and handling*)
  - Investigate all discrepancies within one (1) business day
    - Perform inventory audit and reconciliation
    - Review transactions within the inventory control system
    - Review security surveillance footage
  - Report theft or diversion to the Department of Health AND Honolulu Police Department within one business day
    - Contact the Department of Health and Honolulu Police Department in multiple fashions as a redundancy
      1. Contact directly through phone conversation
      2. Contact electronically through email, fax or other electronic means
  - Within 30 days
    - the inventory discrepancy investigation must be conducted and completed
    - the standard operating procedures amended (*if needed*)
    - send an investigation report and audit to the Department of Health



Example of Receiving Marijuana Products (Incoming Shipment) log sheet:

<b>Receiving Marijuana Products (Incoming Shipments)</b>						
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Product Name/Attribute ID #/ Strain:</u>	<u>Quantity Received:</u>	<u>Quantity Fulfilled:</u>	<u>Fulfilled By:</u>	<u>Wholesaled To:</u>

Example of Marijuana Products Inventory log sheet:

<b>On-Hand Marijuana Product Inventory Log Sheet</b>								
<u>Date:</u>	<u>Product Name:</u>	<u>Batch#/Unique ID #:</u>	<u>Quantity On Hand:</u>	<u>Quantity in POS System:</u>	<u>Discrepancy Amount:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Notes:</u>

Example of Product Loss log sheet:

<b>Product Loss Log Sheet</b>				
<u>Date:</u>	<u>Product Name/Category</u>	<u>Product Attribute # or Unique ID #</u>	<u>Total Quantity Loss:</u>	<u>Product Loss Valuation:</u>
				\$
<u>Reporting Employee:</u>	<u>Manager/Supervisor:</u>	<u>Product Loss Due To:</u>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<u>Internal Investigation:</u>	<u>Required Authorities Notified:</u>	<u>Authorities Notified (list all):</u>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<u>Note/Comments:</u>				



**Standard Operating Procedure: Cleaning of Equipment/Displays**

**Purpose:** To explain the purpose and processes involved with cleaning the retail dispensary locations.

**Scope:** Covers the steps involved with required daily cleaning.

**Principles of Cleaning**

BPH prides itself on the cleanliness and presentation of the dispensary sales floor area and the entire retail dispensary location as a whole. Registered employees will be required to maintain the cleanliness and appearance of the entire Licensed Premise with a specific attention to detail regarding the service areas.

The maintenance of the cleanliness of any and all building or equipment used to store or display medical marijuana will be required as an essential job function of registered employees. Employees will be required to clean certain areas, equipment and other property on a routine basis.

Registered employees will be required to maintain the cleanliness of the following:

- Medical marijuana display cases
- Medical marijuana display jars/containers
- Service area sales counters
- Service area sales equipment—POS system

BPH will require that medical marijuana is always handled by employees with stainless steel forceps, which shall be decontaminated in 70 percent isopropyl alcohol soak overnight, or while donning non-latex, non-powdered gloves.

Routine hand washing is required for employees and agents shall be required to wear company issued work attire while working in the dispensary Licensed Premise. (*refer to employee dress code SOP*)

Medical marijuana shall be handled for processing and repackaging only in the operations area, and the area shall be cleaned between handling different batches. Registered employees will document, record and maintain cleaning logs.

No individual other than a registered employees are permitted to handle medical marijuana or medical marijuana-infused products at any time.

**Required Cleaning**

BPH will require registered employees to routinely clean the service area of the Licensed Premise periodically throughout each day of operations. The cleanliness of the Licensed Premise should mirror the cleanliness one would find in a pharmacy; qualified patients and caregivers will expect a clean facility where medical marijuana is dispensed. This will include the cleanliness of the areas of the building where medical marijuana products are dispensed, equipment used to store, display or dispense medical marijuana products and the registered employee dispensing the medical marijuana. (*refer to employee dress code SOP and personal hygiene policy*)

- Registered employees will be required to maintain the cleanliness of the service area.
  - The service area of the Licensed Premise is where the medical marijuana products are dispensed to qualified patients and caregivers and this area should be held to the highest standard for cleanliness at the premise.
- Medical marijuana displayed in a jar or container:
  - The jar or container used to store and/or display medical marijuana will need to be cleaned and maintained daily.
  - Registered employees will be required to wipe down the jar or container after every use with a cloth to remove oils and/or resins if present.
  - The jar/container will be required to be thoroughly cleaned on a weekly basis.



- Registered employees will be required to clean the jar/container with 70 percent isopropyl alcohol to remove any plant oil, resins or contaminants.
- This weekly cleaning is to be documented within the cleaning and sanitation of jars log sheet.
- Stainless steel forceps must be kept clean and sanitary
  - Registered employees are required to handle stainless steel forceps while wearing non-latex, non-powdered nitrile gloves
  - If gloves are not used during forceps use, registered employees must store the forceps in 70% isopropyl alcohol overnight



Cash Handling

<b>Standard Operating Procedure: Cash Handling</b>
<b>Purpose:</b> To explain the steps involved with daily cash handling.
<b>Scope:</b> Covers the steps involved to handle cash and assemble weekly deposits.
<b>Initial Training:</b> TBD

**The Principles of Cash Handling**

This section will cover how to properly handle cash at the dispensary level. Specifically, this section will be split into subsections that will easily guide the employee/manager through all requirements necessary to mitigate risk as it pertains to the constant physical handling of cash.

Many of these procedures are performed in “**dual control**” meaning that two members of the staff are to simultaneously observe the action being taken as well as sign off on the completion or verification of said action. *Note:* In dual control, at least one of the two employees must be, at minimum, a manager.

The Licensee or Owner of the establishment should assign a “**drawer limit**” to all POS cash drawers. This limit indicates the maximum amount of cash allowed in the drawer at any given time. As soon as a drawer limit is reached or surpassed, it is the responsibility of the employee running the POS cash drawer to notify his/her manager of the occurrence. The employee and manager will then go into “dual control” where the cash overage will be transferred from the POS drawer to the vault. For more details, see the below subsection entitled “Drawer Limit Transfers.”

**Cash Handling – Opening Procedure**

- 1) In dual control, open the vault.
- 2) Once vault is opened, each employ in dual control signs the *Cash Vault Opening/Closing Log* signifying that the vault is now open.
- 3) In dual control, the manager will take out the proper amount of cash necessary to place into the appropriate POS cash drawer(s).
- 4) Both the manager and the employee count the cash that will be extracted from vault and place correct amount of cash into the appropriate POS cash drawer(s).
- 5) Once cash has been counted and placed into the POS drawer(s), dual control employees will complete the *Cash Transfer Log*, detailing the amount of cash leaving the vault and each bill denomination placed into each individual POS drawer. The amount of cash being transferred to the POS drawer will be considered that drawer’s beginning balance for the day.
- 6) Update the *Vault Balance Sheet* to reflect the new balance of the vault (no physical cash count of the entire vault is necessary at this point)
- 7) In dual control, close the vault.
- 8) Once the vault is closed, dual control employees sign the *Cash Vault Opening/Closing Log*.
- 9) Remaining in dual control, employees will take POS cash drawers to the appropriate POS station.
- 10) Engage in sales operations!

**Cash Handling – Mid-Day Procedure**

- 1) Throughout the day, it is the duty of the manager to perform at least one Random Drawer Audit (RDA) on each employee as they are signed on to a cash drawer. The manager will complete a *Random Drawer Audit (RDA) Form* ensuring that the cash balance reflects what the tracking system shows. These audits are to be unannounced so that employees may be held accountable for a balanced drawer at all times.



Manager's Note: While RDAs are to be performed routinely, do not perform audits at the same time daily. It is important to perform these audits as randomly as possible to help mitigate risk.

- 2) Once the RDA has been complete, both the manager and the employee being randomly audited will initial/sign the **RDA Form**, signifying that the cash is in balance.

**Cash Handling – Closing Procedure**

- 1) Once inventory has been reconciled at the end of the business day, the cash in each POS cash drawer will be counted in dual control with at least one manager present.
- 2) The dual control employees will complete an **End-of-Day Drawer Balance Sheet**, detailing all cash located in the drawer, including the denomination of each bill.
- 3) Remaining in dual control, the manager and employee will transfer all of the cash from the drawer to the vault, using the **Cash Transfer Log** to track the transfer.
- 4) Once vault is opened, each employ in dual control signs the **Cash Vault Opening/Closing Log** signifying that the vault is now open.
- 5) When all cash has been transferred to the vault, the dual control members will make complete straps of cash (See **Cash Strapping Procedures** below).
- 6) Once cash has been strapped appropriately, the dual control members will update the **Vault Balance Sheet** to reflect the amount of cash secured.
- 7) Once all cash is fully secured in the vault, the dual control members will complete the **Cash Vault Opening/Closing Log** ensuring that the vault has been closed.

**Vault Balancing**

- 1) A physical hard count of the cash in the vault should ideally be completed at the end of each business day. It is up to the Owner/Licensee how frequently a hard count of the vault cash should be performed.
- 2) In dual control, employees will open the vault.
- 3) Once vault is opened, each employ in dual control signs the **Cash Vault Opening/Closing Log** signifying that the vault is now open.
- 4) The dual control members will unstrap cash, perform a physical count of the cash, and then re-strap the cash (you can use the original strap to re-strap currency)
- 5) Once all cash has been counted and re-strapped, record balance and denominations on the **Vault Balance Sheet** and note on the sheet that a physical count was performed.
- 6) Once all cash is fully secured in the vault, the dual control members will complete the **Cash Vault Opening/Closing Log** ensuring that the vault has been closed.

**Cash Strapping Procedures**

- 1) Cash should be strapped using the bank standard format:

\$1's    X 100 = \$100  
 \$5's    X 100 = \$500  
 \$10's   X 100 = \$1,000  
 \$20's   X 100 = \$2,000  
 \$50's   X 100 = \$5,000  
 \$100's X 100 = \$10,000



2) Coin should be rolled using the bank standard format:

Pennies	X 50	= \$0.50
Nickels	X 40	= \$2.00
Dimes	X 50	= \$5.00
Quarters	X 40	= \$10.00
Half-Dollar	X 20	= \$10.00
Dollar	X 25	= \$25.00



### Drawer Limit Transfers

- 1) It is strongly recommended that POS cash drawers be designated with a Drawer Limit. This limit represents the maximum amount of cash allowed inside the drawer at all times. The purpose of establishing a Drawer Limit is to ensure that cash is controlled. If in the event that robbery/theft occurs, the loss can be minimized if the Drawer Limit threshold is not surpassed. When RDAs are performed on employees, managers should be checking to make sure that the drawer limit has not been reached.
- 2) If an employee's drawer limit is reached, a manager should be notified immediately
- 3) Once manager is notified of the drawer limit being reached, the employ and manager will be put into dual control
- 4) The dual control members will collect the cash necessary to bring the drawer limit down, and record the information on the *Cash Transfer Log*.
- 5) The vault is then opened, and each employ in dual control signs the *Cash Vault Opening/Closing Log* signifying that the vault is now open
- 6) The dual control members place the cash into the vault and strap the currency if need be.
- 7) The dual control members adjust the *Vault Balance Sheet* to reflect the cash added to the vault.
- 8) Once all cash is fully secured in the vault, the dual control members will complete the *Cash Vault Opening/Closing Log* ensuring that the vault has been closed.

*Example of Cash Vault Opening/Closing Log Sheet:*



<b>Cash Vault Opening/Closing Log</b>							
Date	Time	Open Amount	Close Amount	Employee 1 Name	Employee 1 Signature	Employee 2 Name	Employee 2 Signature
12/5/2015	4:00	12500	27500	John Smith		Jack John	

*Example of Vault Balance Sheet can be seen below:*

<b>Vault Balance Sheet</b>				
Date Updated	Time	Updated Vault Balance	Physically Counted? (Y/N)	Denominations - If Physically Counted
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>

**Weekly Deposits/Outgoing Cash**

- 1) Once cash is ready to leave the establishment, dual control members of the company will open the vault.
- 2) The vault is then opened, and each employee in dual control signs the **Cash Vault Opening/Closing Log** signifying that the vault is now open.
- 3) The dual control members will then extract the straps of currency/rolls of coin needed to be transferred out of the establishment.
- 4) The currency to be transferred out of the facility will then be unstrapped/unrolled and physically counted in dual control.



- 5) Once currency is counted, it should be re-strapped and re-rolled, ready to transfer.
- 6) The **Vault Balance Sheet** should then be updated to reflect the amount of money leaving the vault.
- 7) The strapped cash and rolled coin ready for transport is then placed inside of a tamper-evident bag. See example below:



- 8) Once the money is placed inside the tamper-evident bag, record the amount placed as well as the bag number.
- 9) The dual control members will then complete the **Cash Transfer Log** indicating how much currency is leaving the location and where the tamper-evident bag is being delivered.

Cash Transfer Slip		Cash Transfer Slip	
Date:		Date:	
<b>Amount</b>		<b>Amount</b>	
Pennies		Pennies	
Nickels		Nickels	
Dimes		Dimes	
Quarters		Quarters	
Half Dollars		Half Dollars	
Dollar Coins		Dollar Coins	
1's		1's	
2's		2's	
5's		5's	
10's		10's	
20's		20's	
50's		50's	
100's		100's	
<b>Total:</b>	\$	<b>Total:</b>	\$
From:	Initials #1:	From:	Initials #1:
To:	#2:	To:	#2:

Cash Transfer Slip		Cash Transfer Slip	
Date:		Date:	
<b>Amount</b>		<b>Amount</b>	
Pennies		Pennies	
Nickels		Nickels	
Dimes		Dimes	
Quarters		Quarters	
Half Dollars		Half Dollars	
Dollar Coins		Dollar Coins	
1's		1's	
2's		2's	
5's		5's	
10's		10's	
20's		20's	
50's		50's	
100's		100's	
<b>Total:</b>	\$	<b>Total:</b>	\$
From:	Initials #1:	From:	Initials #1:
To:	#2:	To:	#2:

### **Cash Transportation**

- 1) The Licensee/Owner of the establishment will determine whether or not an armed guard courier service is necessary to transport cash.
- 2) If no armed guard courier service is utilized, all cash that is transported should be done in dual control. One of the members of dual control must be a high-level manager or Owner of the establishment. The cash will be guarded at all times in dual control until the tamper-evident bags have arrived safely at the destination.
- 3) Once the cash has been safely delivered, the dual control members must receive some kind of document proving receipt of currency transferred
- 4) The dual control members will then take the documented receipt and deliver it back to the licensed establishment. The receipts of cash transfers should then be filed in the establishment's business records.



**Standard Operating Procedure: Customer Complaints and Returns**

**Purpose:** To explain the steps involved for handling customer complaints and product returns.

**Scope:** Covers the steps involved to handle customer complaints and product returns appropriately.

**Documentation Log Sheets Required**

- 1) Customer Complaint Form
- 2) Returned Marijuana Products Log Sheet
- 3) Returned Marijuana Products Waste

**The Principles of Handling Customer Complaints and Product Returns**

It is important to have proper procedures in place for the handling of customer complaints and/or product returns. By having these initiatives in place you can ensure the most satisfied customer base possible. Below are best practice steps to take when confronted with a customer complaint and/or product return.

**Handling Customer Complaints** – When confronted by a customer with a complaint, perform the following:

- 1) Listen to the customer’s complaint fully and completely so that you can better understand the scope of the problem or issue needing to be addressed (Hint: Be open and reflect understanding of the customer’s problem. Repeat back to the customer your understanding of the complaint and recognize that the customer is not attacking you personally so there is no reason to get defensive).
- 2) Be empathetic, and display genuine care for the customer (Hint: Try to imagine being in the customer’s shoes. By doing so you will not only understand the problem more clearly, you will also display a calmer tone and more open demeanor towards the customer).
- 3) Ask clarifying questions to further understand the issue at hand.
- 4) Apologize for the inconvenience that was caused, however, do not resort to placing blame on anyone or the company.
- 5) Provide at least one solution for the customer. The more solutions you provide the customer, the more they will feel that you genuinely want to help (regardless of whether or not any solution provided is acceptable to the customer).
- 6) Provide the chosen solution, or if the solution is not in your capacity, connect with the appropriate co-worker or upper management employee that will provide the solution.

**State of Hawaii Requirements**

- In the event a complaint is associated with a serious adverse event, BPH will require registered employees to:
  - Promptly report the complaint to the BPH management
  - Report the complaint to the other BPH licensed retail dispensary location that may have received a shipment containing marijuana from the batch determined to cause the complaint
- In the event a complaint associated with a serious adverse event, BPH will be required to promptly report the complaint to, (1) the Department, (2) either the licensed grower from which the medical marijuana originated, or the licensed processor from which the marijuana and/or manufactured marijuana product originated.
  - BPH’s registered employees will report to the Department in the event a complaint is associated with a serious adverse event.
    - Within 24-hours registered employees must report the complaint to the Department



**Recalling of Medical Marijuana**—if a batch of marijuana is determined through testing to fail to meet specification, BPH will do the following:

- Order a recall of all products derived from or included in the batch
- Notify all retail dispensary locations and/or qualified patients and/or primary caregivers who may have obtained marijuana products from such a batch of the recall
  - Using the inventory control system and/or physical documentation log sheets/records to identify all dispensary locations and/or qualified patients that may have received a distribution containing marijuana from the production batch
  - After identifying the dispensaries and/or patients, registered employees will be required to directly notify said parties.
- Offer and pay reimbursement for any returned marijuana product
  - Offer to replace the marijuana product free of charge or offer full monetary reimbursement.

**Handling Customer Complaints**—when a customer wishes to make a formal complaint, follow the following procedures:

- Have customer wishing to form a complaint to complete the *Customer Complaint Form*
- File complaint within the customer complaint folder located within a limited-access area within the Licensed Premise
- Notify management of the formal complaint
- Notify the Department of the formal complaint

	<i>Customer Complaint Form</i>	
	Date:	Location:
	Customer Name:	
	Employee Documenting Complaint:	Supervisor on Duty:
	Description of Complaint:	
	Corrective Action to be Taken:	
	Customer Comments:	
Customer Signature:	Date:	
Employee Signature:	Date:	

In the event of a formal complaint regarding the quality or safety of medical marijuana is received, BPH will require registered employees to review and investigate the complaint within 24-hours to determine:

- If the complaint is substantive or reports a serious adverse event
- Determine the batch number of the marijuana—this can be accomplished using the records and documentation maintained throughout the cultivation process to determine if there were any deviations in production



- If the complaint is substantive or reports a case of a serious adverse event, registered employees will determine the batch number of the marijuana
- Registered employees will be required to investigate the record and circumstances of the production of the batch and lot to determine:
  - If there was a deviation from the standard operating procedure in the production of the medical marijuana by reviewing production logs, records and documentation
    - Test retention samples of the batch and lot to an independent testing laboratory.
      - Send retention samples from batch and lot in question to licensed testing laboratory for testing
        - If testing reveals that the batch or lot fails to meet specifications, follow steps for recall below in following SOP
        - Notify any and all patients, caregivers and dispensaries who may have obtained medical marijuana products from such a batch or lot of the recall
          - Use the inventory control system and physical records to determine who may have received a batch of medical marijuana from the recalled batch
          - Upon identifying retail dispensary locations that have received marijuana from the batch in recall, registered employees will need to notify the licensed dispensary directly with two means:
            - Via phone call, AND
            - Via email

**Investigation of Complaint**—BPH will require registered employees to investigate all complaints regarding the quality or safety of medical marijuana. Registered employees will be required to review records and documentation from the cultivation operations to determine if there was any deviation from production.

- Review all cultivation records and documentation log sheets
  - Try to determine if there were any deviation in production
  - If there is a deviation in production, see **Standard Operating Procedures SOP**
  - Determine the batch number and/or lot number of the medical marijuana
    - Reviewing records and documentation for substantive changes in production
- Meet with complainant to understand the serious adverse event (*if applicable*)
  - Meeting with the complainant registered employees may be able to identify the medical marijuana batch associated with the complaint
- Order a recall of the medical marijuana batch if necessary; follow **Product Recall SOP**

**Handling Customer Returns** – When a customer wishes to return a product, perform the following procedure:

- Acquire the product needing to be returned and begin the process of completing the Returned Marijuana Products Log Sheet
- Ask for the reason as to why the product is being returned and record this information.
- Log the product as being returned into the electronic inventory tracking system
- Offer and pay reimbursement for the medical marijuana products tracking system.
- Ensure that the Returned Marijuana Products Log Sheet is completed and filed.

**Example of a Returned Marijuana Products Log Sheet:**



<b><u>Returned Marijuana Products Log Sheet</u></b>					
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Patient/Caregiver Returning Cannabis Product:</u>	<u>Marijuana Product Returned (Name/Attribute#):</u>	<u>Quantity/Weight:</u>	<u>Reason for Product Return</u>

*Example of a Returned Marijuana Waste Log Sheet:*

<b><u>Returned Marijuana Waste Log Sheet</u></b>						
<u>Date:</u>	<u>Registered Employee:</u>	<u>Qualified Patient/Caregiver:</u>	<u>Marijuana Product to Dispose:</u>	<u>Waste Weight:</u>	<u>Mixed With:</u>	<u>Total Weight to Dispose:</u>

Product Recall

<b>Standard Operating Procedure:</b> Product Recall
<b>Purpose:</b> To ensure that all required steps and procedures are take when there is a need to recall a marijuana product.
<b>Scope:</b> Procedures covering voluntary and involuntary product recalls.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required Within the Cultivation Facility**

- 1) Product Recall Log

**Principles of Product Recall**

Manufacturers, importers, distributors and retailers of consumer goods are liable for the products they provide to consumers and face the potential of product recalls for potentially dangerous or hazardous products. The same is true for the marijuana businesses as manufacturers and retailers of consumer medical marijuana products, for the facility may need to conduct a product recall in the future. For most consumer products the recall process is handled and regulated by the Consumer Product Safety Commission (CPSC), and for all intents and purposes the marijuana business recall plan will follow the guidelines of the CPSC.

The Consumer Product Safety Commission (CPSC) has compiled resources to assist companies that manufacture, import, distribute, retail, or otherwise sell consumer products. CPSC has developed a Recall Handbook that can be utilized in case a product recall needs to be ordered. The Recall Handbook details how to recognize potentially hazardous consumer products as soon as possible. The book explains how to develop and implement a “corrective action plan” (called a CAP) to address the hazards; it explains CPSC’s Fast Track Program. The Recall Handbook also discusses how to communicate recall information to consumers and how to monitor product recalls. The Consumer Product Safety Commission’s Recall Handbook will be a valuable tool utilized by the company if the need for a product recall ever arises.

The Recall Handbook should be referenced to determine exact protocol for recall and the requirements from the Consumer Product Safety Commission. The Recall Handbook can be obtained online from <http://www.cpsc.gov/PageFiles/106141/8002.pdf>.

### **When to Recall Medical Marijuana Products**

As a manufacturer, distributor, and/or retailer of consumer products, the cultivation facility has a legal obligation to immediately report the following types of information:

- 1) A defective product that could create a substantial risk of injury to consumers;
- 2) A product that creates an unreasonable risk of serious injury or death;
- 3) Marijuana or manufactured marijuana is determined to contain a contaminate of some kind
- 4) Marijuana or manufactured marijuana batch did not successfully pass required testing but was released for distribution

Failure to fully and immediately report this information may lead to substantial civil or criminal penalties. Consumer Product Safety Commission's staff advice is "when in doubt, report." BPH will ensure communication with the required state and local authorities within 24 hours of becoming aware of the need for a product recall. BPH will then proceed to the recalling protocol and how to recall the product.

### **How to Recall Medical Marijuana Products**

The facility will develop a recall plan following guidance from the Recall Handbook provided by the CPSC. Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by state law will ensure a stream-lined recall process if ever necessary.

#### **Corrective Action Plan (CAP)**

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and steps needed to be taken by the facility once a product recall is required.

#### **Step One: Industry Notification**

If a marijuana or manufactured marijuana product is believed to need a recall, BPH will contact all retail dispensary locations to notify them of the situation and the need for product recall. BPH will also contact required state and local authorities within 24 hours of obtaining reportable information. As the cultivator and/or manufacturer of the product needing to be recalled, BPH will need to contact the end users of the recalled product; contacting qualified patients will prove to be difficult, but will be possible through the utilization of the inventory control and POS systems. At this stage of the recall, retail dispensary locations will need to ensure that they have a proper recall process in place to contact qualified patients that were dispensed the product being recalled.

#### **Step Two: Public Notification**

The cultivation facility or dispensing establishment will post notifications about the product recall on its website as well as make partnering cultivation centers and dispensing organizations aware of the product recall. The actual recalling processes will be handled by both the cultivation center and the dispensing organizations.

As the dispensing organization issuing a recall notice, it will be important to reach the end users or the recalled product. The facility will post notification about the recall on Facility websites and social media as well as post written notices of the recall on location for patients and customers to view. The recall notice will include all pertinent information regarding the product being recalled, contact information and other information relating to the recall. Information will include but not be limited to:



- 1) Product name and unique attribute number
- 2) Product batch number
- 3) Dispensing date range of recalled product
- 4) Retail dispensary locations

Once the recall notification has been issued to all applicable dispensing organizations and medical marijuana patients, the facility will wait to receive recalled products from dispensing organizations and/or licensed medical marijuana patients and caregivers. Once recalled products have been received, the facility will properly dispose of all recalled products. The disposal of these products should conform to the state law for waste disposal.

**Step Three: Procurement**

BPH issuing a product recall to qualified patients and primary caregivers will need to be ready to obtain and secure recalled products from qualified patients. Patients should be able to bring in the products being recalled to the retail dispensary location. It will be at BPH’s discretion whether to issue a refund, replace the recalled product at no cost, or to take other measures.

- Upon receiving recalled marijuana and/or manufactured marijuana products, registered employees will document the return of the recalled marijuana product
- After documentation, registered employees will securely store the recalled marijuana product in segregated storage until disposal
  - Recalled medical marijuana must be securely stored until properly destroyed and disposed of.

**Step Four: Documentation and Record Retention**

BPH will maintain all documentation all records regarding any and all product recalls issued. Registered employees will be required to fill out the required *Product Recall Log Sheet*.

<b><u>Product Recall Documentation Log Sheet</u></b>				
<u>Date:</u>	<u>Product Name</u>	<u>Product Attribute # or Unique ID #</u>	<u>Quantity to be Recalled</u>	<u>Supervisor</u>
List Potential Patient/Caregivers to Notify:				
Regulatory Agencies Notified: <input type="checkbox"/> MMCC <input type="checkbox"/> FDA <input type="checkbox"/> CSPA <input type="checkbox"/> Other				
<u>Date:</u>	<u>Quantity Collected:</u>	<u>Collected From (Patient/Caregiver):</u>	<u>Accepting Employee:</u>	<u>Notes/Details</u>

### Step Five: Disposal

The facility will ensure that any and all recalled marijuana products are disposed of according to all state and local regulations. The facility will follow marijuana waste disposal and destruction procedures outlined within these SOPs for proper disposal of recalled medical marijuana.

- Recalled material must not be destroyed or disposed of until authorized by the Department of Health.
  - Recalled medical marijuana will need to be stored and segregated until the disposal of recalled material is authorized by the Commission.
    - Stored recalled material in the quarantined secure storage area of the Licensed Premise.
- Once receipt of notification from the Department of Health that the disposal of recalled medical marijuana is authorized, registered employees will dispose of the medical marijuana according to the *Marijuana Waste Disposal SOP*.
  - Registered employees must dispose of medical marijuana within 24-hours of Department of Health authorization.



<b>Standard Operating Procedure:</b> Marijuana Waste Destruction and Disposal
<b>Purpose:</b> To explain required and proper disposal processes for marijuana waste.
<b>Scope:</b> Covers marijuana waste grinding, mixing and disposal measures within the retail dispensing facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Marijuana Waste Disposal Log

**Equipment/Tools Required**

- 1) Wood chipper/plant grinder
- 2) Mixing material (material to mix marijuana waste with at 50/50 ratio)
- 3) Trash bags
- 4) Dumpster/trash compactor

**Requirements of Marijuana Waste Disposal**

All marijuana waste, byproducts, undesired materials, green waste and returned/recalled marijuana will be destroyed by rendering the waste unrecognizable, unusable and unrecoverable.

BPH will require registered employees to weigh, document, record and destroy all marijuana waste according to the written standard operating procedures. All marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated will be destroyed and disposed of according to the written SOP.

**Secure, Segregated Storage**—all medical marijuana waste will be stored in secure, segregated storage on the Licensed Premise until receipt of authorization from the Department of Health of destroy and dispose of the medical marijuana waste.

- The secure, segregated storage will promote good growing and handling practices.

**Marijuana Waste Disposal**—all medical marijuana waste, byproducts and undesired products will be destroyed and disposed of according to all applicable state and local regulations. Facility management will ensure proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state law. Record all required information on the *Marijuana Waste Log Sheet*.

**Disposal**—Disposal of any marijuana product waste must be rendered unrecognizable, unusable and unrecoverable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.



American Cannabis Company  
growing the next frontier

Cannabis Stalks (waste)



**Grinding Marijuana Waste (Stalks, Stems, Leaves and Other Material)**



Cannabis Waste



Wood Chipper



Chip/Grind Cannabis Waste



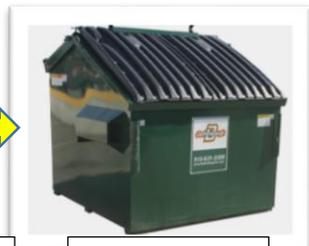
Mix Ground Cannabis Waste with Additive  
(50/50 MIX RATIO)



50/50 Mix Ratio

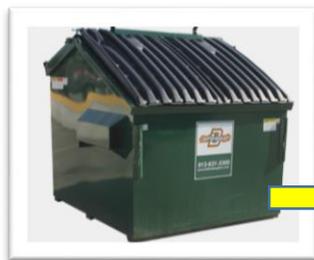


Bagged Waste Ready for Disposal



Waste Receptacle

**\*\*BPH shall not dispose of marijuana product waste in an unsecured waste receptacle not in possession and control of the licensed premise. It is recommended to have a lock on the physical dumpster as well as the area where the dumpster is maintained.**



Waste Receptacle



Locked Waste Receptacle



Locked Waste Holding Area

*Example of Marijuana Waste Documentation Log Sheet (see below):*





Equipment Operation

<b>Standard Operating Procedure:</b> Equipment Operation
<b>Purpose:</b> To identify the various equipment to be utilized within the facility
<b>Scope:</b> To identify the equipment to be utilized, and where employees can obtain copies of the manufacturer
<b>Initial Training:</b> 4-8 hours

**The Principles of Equipment Operation**

For all 3<sup>rd</sup> party equipment being utilized within the facility it is recommended to refer to the manufacturer instructions and user manuals for proper operation, set-up, maintenance, cleaning or any other equipment information. Manufacturer instructions and user manuals should have been provided as a hard copy with all original equipment. If the original user manual has been lost or misplaced, refer to the manufacturer company website or contact them directly for a replacement manual.

Some manufacturing companies offer user manuals and instructions as an electronic version which can be obtained online from the company website. Below are some of the specific equipment utilized by ACC along with the company website where user manuals and/or manufacturer instructions and suggests can be obtained.

**1) Patriot Electric Wood Chipper**

- a. Website: <http://www.patriot-products-inc.com/P/31/WoodChipperLeafShredder15hpElectricInternational>
- b. User Guide: <http://www.patriot-products-inc.com/Content/files/electsvmanual.pdf>

**2) 26 Quart High Performance Blender**

- a. Website: <http://www.webstaurantstore.com/26-quart-high-performance-vertical-tilting-blender-110v-220v/915LAR25.html>
- b. User Guide: [http://www.webstaurantstore.com/documents/pdf/omcan\\_blendr\\_operating\\_manual.pdf](http://www.webstaurantstore.com/documents/pdf/omcan_blendr_operating_manual.pdf)

**3) Digital Scale**

- a. Website: [http://www.coleparmer.com/Product/A\\_D\\_FX\\_2000iN\\_NTEP\\_Tploading\\_Balance\\_2200\\_g\\_x\\_0\\_1g/EW-11115-82](http://www.coleparmer.com/Product/A_D_FX_2000iN_NTEP_Tploading_Balance_2200_g_x_0_1g/EW-11115-82)



<b>Standard Operating Procedure:</b> Closing Procedure
<b>Purpose:</b> To explain the steps and process involved in closing the sales floor/store on a daily basis.
<b>Scope:</b> Covers closing responsibilities and procedures.
<b>Initial Training:</b> TBD

**The Principles of the Closing Procedure**

The closing responsibilities will primarily be comprised of closing the retail sales floor and securing product for safe storage throughout the night. Closing responsibilities will consist of the following:

- 1) Close the POS system(s) for the day
  - a. Run daily sales report
  - b. Remove cash drawer to count/balance
- 2) Cash balancing and reconciliation
  - a. Count the cash drawer; record numbers on **Closing Log Sheet** (cash, credit, check, payout, etc.)
  - b. Once all CASH is counted, hold back enough cash to ‘rebuild’ the cash drawer till (this should be ~\$200.00/drawer)
    - i. Record the ‘new till’ amount on the **Cash Drawer Balance** (close)
  - c. Complete **Closing Log Sheet**
- 3) Pull all medical marijuana products and marijuana-infused products located in display cases to be stored in a safe/vault, located in a secure access area, for nightly storage.
- 4) Close retail sales floor and secure facility for nightly closure
  - a. Ensure all entrances/exits are locked and secured
  - b. Arm the security alarm panel
  - c. Exit facility; ensure that the door you are exiting closes completely and is locked/secure for the evening.

**Nightly Product Storage**—Management will ensure that all marijuana and manufactured marijuana products are securely stored each night on the retail dispensary locations. All marijuana products shall be safely stored in a limited access area within a secured storage vault or safe. Management will be responsible for ensuring that the storage area meets or exceeds state requirements for the storage environment.

*Example of Close-Out Sheet (see below):*



Date:	Employee:	Register:
Cash	\$ _____	
	+	
Credit Cards	\$ _____	
	+	
Checks	\$ _____	
	+	
Payouts	\$ _____	
	=	
Total On Hand	\$ _____	
	-	
Less Starting Cash Balance	\$ _____	
	=	
Daily Total	\$ _____	
	X	
Tax Rate	\$ _____	
	=	
Daily Sales	\$ _____	
	-	
Daily Total	\$ _____	
	=	
Daily Tax	\$ _____	

*Example of Cash Drawer Balances Log Sheet:*

<u>Cash Drawer Balances</u>							
Date:	Employee:	Drawer 1		Drawer 2		Drawer 3	
		Open	Close	Open	Close	Open	Close



Emergency Protocol

<b>Standard Operating Procedure:</b> Emergency Protocol
<b>Purpose:</b> To describe all steps and protocols to be followed by employees should an emergency occur within the facility.
<b>Scope:</b> Procedures covering emergency situations occurring within the facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Emergency Situation Documentation Sheet

**Equipment/Tools Required**

- 1) Panic Alarm/Button
- 2) Fire Extinguisher
- 3) Chemical Spill Kit
- 4) Emergency eye wash station(s)
- 5) First Aid Kit
- 6) Emergency defibrillator

**The Principles of Emergency Protocols**

A facility emergency management plan is designed to educate and train facility employees on the actions and procedures to follow in the event of an emergency. In the case of an emergency, facility employees will need to respond quickly and think strategically in order to successfully manage the emergency situation. Having a good understanding of the facility emergency management plan will enable employees to better adapt to and handle emergencies.

The most important thing to remember during an emergency situation is to try to stay calm, if the emergency situation is out of your control and you need assistance, contact emergency services immediately if possible.



**Burglary:** Burglary is legally defined as the criminal offense of breaking and entering a building illegally for the purpose of committing a crime. Burglaries generally will occur at the Licensed Premise after operating hours and while there are no registered employees present. Typically burglaries occur during the night and are not discovered until the next day during normal operating hours.

- If upon entering the Licensed Premise and a registered employees notice something is afoul and upon investigation a burglary was determined to have occurred in the previous night, then registered employees will be required to document the incident and notify all required authorities.
  - Registered employees will be required to report the incident of burglary to:



- The Department of Health
- Local medical marijuana authority (if applicable)
- Honolulu Police Department

**Robbery or Theft:** Robbery is legally defined as the taking of money or goods in the possession of another, from his or her person or immediate presences, y force or intimidation. The number one rule registered employees will need to follow when/if dealing with a robbery is to comply with all robber demands

- If you are being robbed at gunpoint or if you feel as if your life is in danger, comply with all requests from perpetrator/suspect. Give them whatever they ask for.
- Try to signal for help using the personal security panic buttons provided, by activating one of multiple, strategically placed panic alarm buttons, or through the panic button/police services button located on the alarm panel.
- Contact law enforcement as soon as possible
- Notify any required State or local authorities immediately (within 24 hours)
  - Honolulu Police Department
  - The Department of Health
- Comply with all applicable laws and regulations
- Document the situation in the *Emergency Situation Documentation* log sheet



Alarm Panel

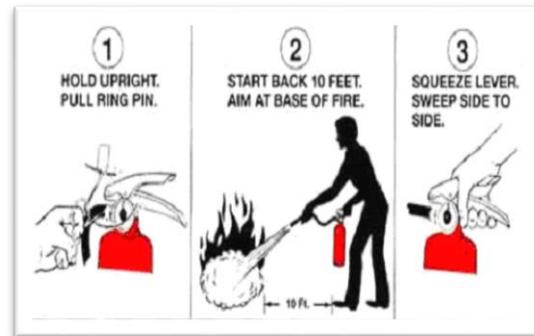
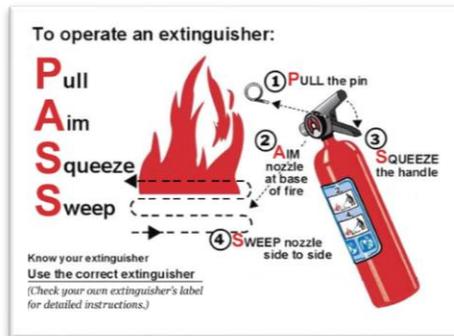
Panic Alarms/Buttons



**Fire Emergency:**

- If a small isolated fire is present, try to exhaust the fire with one of the fire extinguishers on site
- In case of a fire emergency, first leave the facility; once clear of the facility dial 911 and/or local fire authority for Fire Emergency Services or push the symbol on the alarm panel for fire emergency upon exiting the facility
- Document the situation in the *Emergency Situation Documentation* log sheet

**Fire Emergency Cont.**



**Chemical Emergency:**

- Dangerous Substance/Chemical Exposure:
  - If an employee accidentally has their eyes exposed to toxic, poisonous or dangerous substances or chemicals; said employee will need to locate the installed emergency eye



wash station(s) to properly flush and clean their eyes. Notify emergency medical services for further assistance

- Chemical Spill:
  - Try to use a chemical spill kit for smaller incidents of chemical spill
  - If a chemical spill is large or you do not know how to handle the situation; get the facility manager to handle the situation and/or contact proper emergency services
    - Posted near or included with the chemical spill kit should be an emergency contact information sheet displaying which emergency services should be contacted.
      - For the BPH and the State of Hawaii this will include but not be limited to:
        - Environmental Protection Agency (EPA)
          - For emergencies and other sudden threats to public health, such as:
            - oil and/or chemical spills,
            - radiation emergencies, and
            - biological discharges,
              - call the National Response Center at 1-800-424-8802.
            - For **pesticide poisoning**, call 911 if the person is unconscious, has trouble breathing, or has convulsions. Otherwise, call **Poison Control at 1-800-222-1222**.
- Document the situation in the *Emergency Situation Documentation* log sheet



### Medical Emergency:

- If it is a minor medical situation such as a small cut, scrape or minor burn; retrieve the first aid kit on site and treat wound with items found in the first aid kit
- If the situation appears to be a severe medical situation such as someone suffering from a heart attack, retrieve the emergency defibrillator and follow the instructions provided; notify 911 or local medical emergency services for further assistance
- If the medical situation is an emergency; contact medical emergency services immediately. This can be done through activating the medical response button found on the alarm panel, or by calling 911 for medical emergency services
- If a serious injury occurs while an employee is working, such as a slip and fall resulting in possible broken bones or a cut requiring stitches, BPH facility management will need to complete a worker compensation insurance claim form prior to the employee seeking medical assistance. This procedure does not take long, but the form will need to be completed in order for the injured employee to have a workers compensation medical claim.
- Document the situation in the *Emergency Situation Documentation* log sheet



American Cannabis Company  
growing the next frontier



**Other Emergencies:**

- Contact 911 if it is a current emergency. Contact your local police and/or State regulatory authorities for break-ins or burglaries that may have occurred when the facility operations were closed
- Contact any required State or local authority in cases of theft, break-ins or burglaries
- Document the situation in the *Emergency Situation Documentation* log sheet



**Example of Emergency Situation Documentation Log Sheet:**

<u><b>Emergency Situation Documentation</b></u>		
Date:	Reporting Employee:	Manger on Duty:
Type of Emergency: <input type="checkbox"/> Robbery of Theft <input type="checkbox"/> Fire Emergency <input type="checkbox"/> Chemical Spill <input type="checkbox"/> Medical Emergency <input checked="" type="checkbox"/> Other Emergency		
Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO	Which Authorities:	
Description of the Incident:		





**Standard Operating Procedure: Loss of Personnel**

**Purpose:** To describe all steps and protocols to be followed prior to or after the loss of personnel.

**Scope:** Procedures covering loss of personnel situations occurring within the facility.

The following will cover procedures to follow when terminating a key employee as well as when a key employee decides to leave the organization on their own accord.

**Job Termination**—if the need arises to terminate the position of a key personnel there will be some basic steps and procedures to follow within operations.

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e., employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel
4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e., mutual separation and key personnel is always welcome back at SFN facilities under visitor status, employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was previously filled by key personnel. Key personnel positions will need to be filled as soon as possible by ownership and/or management without sacrificing quality of applicant pool. Some basic steps should be followed to find and place a suitable replacement for the vacant position.

1. Review resumes and applications from qualified applicants
2. Call said qualified applicants to conduct an informal, initial phone interview
  - a. If you get a good response from applicant, schedule an in-person interview
3. Conduct in-person interviews with qualified applicants
4. Review interviewed applicants
  - a. Select applicant who is most qualified for the vacant position
5. Contact said applicant and offer the vacant position
6. If applicant accepts the job offer, proceed with normal hiring procedure and required paperwork



# Attachment 2.7



## American Cannabis Company, Inc. (“ACC”) Company Profile

### Executive Summary

- Based in Denver, Colorado
- Consult, advise, & provide equipment and supplies to businesses entering or currently operating in *regulated* cannabis industries
- Currently serve clients in 14 states & Canada
- Have assisted clients in winning 10+ licenses in 5 five states
  - Business & operational plans, pro-forma, market study, & application
  - Facility design, equipment selection, & construction management
  - Facility roll-out, employee training, & on-going cultivation management
  - On-going retail, operational, & compliance monitoring

### Industry Successes

American Cannabis Company					
Year	State	W	L	Total	Cumulative Client W %
2013	Connecticut	1	0	1	100%
2013	Massachusetts	1	2	3	50%
2014	Nevada	6	1	7	73%
2014	Minnesota	1	0	1	75%
2014	Illinois	2	4	6	61%
<b>Total</b>		<b>11</b>	<b>7</b>	<b>17</b>	<b>61%</b>

### Vision

We are redefining society’s relationship with cannabis through responsible stewardship.

### Mission Statement

With our expert teams we establish and service regulated cannabis markets globally providing best in industry solutions that continue to exceed the requirements of the evolving cannabis industry thus ensuring our client’s success through superior service and deep industry knowledge.

### Core Values

1. Accountability & Professionalism
2. Integrity
3. Open, Transparent, & Respectful Communication
4. Passionate Teamwork
5. Sustainability

### About The American Cannabis Company

American Cannabis Company (ACC) was founded to meet the needs of the rapidly developing cannabis industry, including: medical, commercial and industrial hemp operators. We are experienced in cultivation, infused products and retail operations within regulated cannabis markets, as well as, establishing successful companies within the emerging limited licenses markets. From merit based applications, to facility design and deployment, to managing ongoing operations ACC has the experience and expertise to guide your business in the competitive cannabis space. Currently, we’ve operated in nine states and in the country of Canada. Our company focuses on providing services and products to the cannabis industry through our two operating divisions:



## Attachment 2.7



### **Company Ownership & Legal Entity**

American Cannabis Company, Inc. is a Delaware corporation with its headquarters in Denver, Colorado. ACC Inc. is a public company and trades under the stock ticker AMMJ on the OTCQB stock exchange. Services, Equipment & Supplies

Through its two divisions American Cannabis Consulting and The Trade Winds, American Cannabis Company provides its customers a full solution for success. From bringing your idea to a reality to ensuring it performs beyond expectation, ACC has the people, partners and products to ensure success.

### **Services**

American Cannabis Consulting is the premier advisory agency for those seeking to achieve success in the highly competitive and rapidly expanding commercial cannabis industry.

Whether you're preparing to enter the market or already have a footprint, our team of industry leaders can help your business reach its potential while meeting the necessary regulatory framework. With first-hand experience in regulated commercial Cannabis cultivation since 2009 and backed by accomplishments in related industries such as healthcare and horticulture, we have the knowledge and resources to guide you through every aspect of growing your Cannabis business.

### **Cannabis Industry Research & Design**

Our knowledgeable team identifies needs in the marketplace and develops next generation products to fill those needs. Our in-house products include:



- The Cultivation Cube™: The foundation for a complete, commercial-scale grow operation, the Cultivation Cube provides exceptional environmental control, speed-to-market, production, space efficiency, lean manufacturing and security.



## Attachment 2.7



- SoHum Living Soil™: A 100% organic growing medium, SoHum Soil prevents an improper balance of nutrients, improves plant immunity, and is more cost-effective than traditional soil and fertilizer growth methods.

- The Satchel™: The Satchel is a pouch-like case for Cannabis and Cannabis-infused products that was designed to meet regulatory compliance with laws that require child-resistant exit packaging for licensed medicinal and recreational Cannabis businesses.

### Equipment & Supplies

From cultivation necessities to retail goods to ancillary products like office supplies and cleaning agents, The Trade Winds can address your business' needs quickly and cost-effectively. The products we carry are carefully selected by our professionals and represent best-in-class solutions for the developing commercial cannabis markets. We continue to strive to realize solutions that improve our Client's business operations.



The Trade Winds group purchasing organization (GPO) provides clients with a comprehensive supply chain. Membership in the GPO gives your business significant buying power with substantial savings over retail costs, and it concentrates all your needs into a single outlet to save you time as well as money.



American Cannabis Company is proud to offer compliant, solution-based products and services to commercial cannabis cultivation and cannabis retail businesses.

### Management Consulting

With hands-on experience in commercial cannabis cultivation, the team at American Cannabis Company has the knowledge and resources to help your crop and your business realize their potential. From Cultivation, through processing and into retail sales, our team has firsthand knowledge and experience.

Our goal is to lead you through a successful development and launch process, and to work with you to help your cultivation business grow into the future. As part of the design and build out of your business, our advisory services will focus on key elements that include:

- Business and operational plan
- Pro-forma financials
- Business plan writing
- Standard operating procedures
- Protocol based workflow
- Retail Strategies
- Retail Operations
- Regulatory compliance
- Market modeling and forecasting
- Security and safety measures
- Equipment and technology purchasing
- Quality control



## Attachment 2.7

- Direct staffing and/or recruitment and training
- Facility design and build-out
- Construction Management
- Patient centric strain selection
- Methodology selection
- Perpetual harvest and workflow requirements to meet patient demand
- Environmental controls
- Integrated pest management

### **Management Team & Client Advisors**

#### ***Corey Hollister, Co-Founder & Chief Executive Officer***

In March 2013, Mr. Hollister co-founded ACC, and from March 2013 to May 2014, Mr. Hollister served as a Managing Director of ACC. From September 2009 to July 2013, Mr. Hollister co-owned and was director of The Village Green Society, a Colorado-based Medical Marijuana Center. From September 2009 to June 2010, Mr. Hollister served as the Director of Operations of Colorado Kind Care LLC, where he oversaw all aspects of operations, including legal, accounting, regulatory compliance, seed-to-sale tracking, security, staff management and production. From October 2007 to September 2009, Mr. Hollister owned and operated Built-to-Last Fitness, a private health and wellness company focused on exercise and nutritional guidance for individuals, companies and schools. Prior to this, Mr. Hollister was based in Boston, MA and worked in Marketing and Advertising.

#### ***Ellis Smith, Co-Founder & Chief Development Officer***

In March 2013, Mr. Smith co-founded ACC, and from March 2013 to May 2014, Mr. Smith served as a Managing Director of ACC. From September 2010 to July 2013, Mr. Smith co-owned The Village Green Society, a Colorado-based Medical Marijuana Center, where he was responsible for managing the operations and protocols supporting the growth and production of medical marijuana. From 2008 to 2010, Mr. Smith founded and operated The Happy Camper Organics Inc., a medical marijuana company focused on the growth of wholesale cannabis for sale to medical marijuana businesses. From 2005 to 2010, Mr. Smith founded and operated Bluebird Productions, a video production company. Mr. Smith has been published and recognized for his horticultural experience and organic gardening in the cannabis industry, and he is known for assisting in identifying the Hemp Russet Mite and working with SKUNK magazine to educate the industry.

### **Key Client Advisors**

#### ***Brett Eaton, Director of Horticulture***

Mr. Eaton graduated from Colorado State University with honors and a bachelor's degree in Horticulture in 2003 during which time he researched an array of plants and food crops at the campus University Plant Environment Research Center during his time there. Mr. Eaton brings over 12 years of horticulture experience to ACC, primarily from the commercial fresh cut flower industry. This led to the development of his expertise in facility design and maintenance, organic cultivation, greenhouse and indoor production and cultivation of cannabis. Furthermore, Mr. Eaton has experience in a variety of cannabis cultivation methods including; organics, inorganics and hydroponics with an understanding of a wide range of grow systems associated with these processes.

#### ***Sam Leuschen, VP of Operations***

Sam holds a Bachelor's degree in Restaurant and Resort management with a minor in business administration and a Master's degree in Management Practices from Colorado State University. Sam is a new generation of college graduates, transitioning from the university into his professional career within the legal and regulated cannabis industry. Sam is one of the first young professionals to take this approach using his degrees and college experience to help bring the regulated cannabis industry into the forefront of the consumer goods industry. Upon completion of his Master's program, Sam began working at a local dispensary as a budtender and quickly worked his way up the ladder becoming the operation's master grower and later transitioned to the position of General Manager, highlighting his work ethic and higher education. While in the position of General Manager, Sam managed the growth from one retail location with one cultivation license to two retail locations and three cultivation licenses. Sam was responsible for



## Attachment 2.7

everything from obtaining state and local licensing, regulatory compliance, cultivation activities including being the head grower, staff recruitment and training, inventory monitoring and reconciliation, order purchasing, and all daily operations of the business.

### ***Brent DeArmond, Cultivation Project Manager***

Brent attended the College of Charleston where he obtained degrees in both Biology and Geology. Upon completion, Brent worked as a fish research technician for the State of South Carolina. He then went on to become a fish farmer for a leading global provider of caviar where he was tasked with utilizing environmentally responsible fish farming practices focused on fish sustainability. Brent leveraged his experience gained as a fish farmer to transition into the position of Head Grower at one of the original medicinal and recreational dispensaries in Denver, CO. He held this position for the last three years prior to joining ACC. As the Head Grower Brent was tasked with designing organic fertilizer programs, yield and quality maximization, managing cultivation and processing teams, diagnosing and treating pest and disease, establishing and implementing Integrated Pest management, ensuring compliance with laws and regulations with regard to inventory through development of monitoring processes and procedures, and developing operating processes and procedures to ensure the tracking of plants and products from clone to final sale to ensure compliance. Brent brings a wealth of knowledge to our clients to ensure they are always operating as efficiently as possible through best practices around cultivation methodologies and operating procedures.

### ***Tyler Schloesser, Operations Manager and Regulatory Compliance Advisor***

Tyler graduated from the University of Colorado at Boulder receiving double majors with honors in Psychology and Philosophy. He then went on to work in Denver, Colorado at two national banks followed by a local credit union gaining experience as a banker, senior banker, sr. bank compliance auditor and lastly management. Working in the Colorado banking industry has provided Tyler with the first-hand experience of understanding the issues that cannabis businesses face with banking. Tyler assists our clients with developing policies, procedures, processes, and risk mitigation best practices to ensure our clients are compliant with the evolving cannabis industry regulatory regulations.



## Attachment 2.8

### Letter of Support

GOVERNOR GEORGE R. ARIYOSHI



January 26, 2016

State of Hawai'i  
Department of Health  
Medical Marijuana Dispensary Licensing  
Kinau Hale  
1250 Punchbowl Street  
Honolulu, HI 96813

To Whom It May Concern:

Please accept this letter of support for Blue Planet Healing, LLC, in receiving a medical marijuana dispensary license for the County of Honolulu.

Henk Rogers is the founder and chairman of Blue Planet Foundation (BPF), an organization with a mission to end the use of carbon based fuel here in Hawaii. As a board member of BPF, I have witnessed Henk's leadership and positive impact in Hawaii's movement toward sustainability. As my successor as chairman for PISCES (Pacific International Space Center for Exploration Systems) organization, Henk has also demonstrated an unwavering commitment to Hawaii's future.

Furthermore, under the direction of Henk's daughter, Maya Rogers, both Blue Planet Software (Tetris) and Blue Startups (Venture Accelerator) continue to thrive and positively influence our business community. As longtime business leaders and philanthropists in Hawaii, Henk and his family have been key economic drivers who have created new jobs and industry for our community.

I am confident that Blue Planet Healing, will be a responsible corporate citizen addressing the needs of patients as well as communities in which they do business.

Sincerely,





### Application Response Question 3

If awarded the Medical Marijuana license, BPH will be financing the build-out of the facilities and start-up of operations through a [REDACTED] equity contribution plus an additional [REDACTED] loan (if needed) from its majority equity-holder, Rogers Medicinals, LLC (RM). RM is owned by Henk Rogers, who will be funding this effort through his wealth gained from the sale of Blue Lava Wireless, LLC in 2005.

In 1987 and 1988, Henk discovered Tetris at the Consumer Electronics Show in Las Vegas. He acquired the Tetris Video game rights for Japan, developed the game for the personal computer and Nintendo NES console, and successfully sold 2 million copies. In 1989, Henk traveled to Russia and met Alexey Pajitnov, the creator of the Tetris video game, and was able to obtain the rights to sell Tetris on the Nintendo device, GameBoy. The game was packaged along with the device and 35 million copies were sold. In 2002, Henk acquired the mobile rights for Tetris and developed and sold Tetris on mobile phones through his company Blue Lava Wireless. In 2005, Blue Lava Wireless, which owned a 15 year license to sell Tetris on mobile phones, was acquired by Jamdat Mobile for approximately [REDACTED]. Henk maintains his wealth in a managed portfolio of stocks, bonds and cash which is managed by Merrill Lynch. See attached is an asset verification letter signed by Merrill Lynch confirming that Henk has [REDACTED] at his discretion. Also attached is a certification signed by Henk and his wife, Akemi Rogers, certifying that they will use these funds at Merrill Lynch to fund Blue Planet Healing, LLC and its effort to build a medical marijuana business (See Attachments “3.1” and “3.2”, respectively)

Henk is currently involved with four other businesses, Tetris/Blue Planet Software, Blue Planet Foundation, Blue Startups and Blue Planet Energy Systems. (See Attachment “3.4”)



### Application Response Question 3

Perhaps one of the most critical elements in a business' propensity to succeed is a detailed financial plan that simultaneously contemplates numerous market scenarios and rigorously stress tests those assumptions. Through engaging in these financial simulations, Blue Planet Healing, LLC., ("BPH" or "Company") has gathered the necessary knowledge and insights to successfully operate a business whose sole mission is to provide, to duly registered patients, in strict compliance with Hawai'i law, safe and quality pharmaceutical grade marijuana in the form of unprocessed flower buds and the marijuana infused products permitted pursuant to Hawai'i Revised Statutes ("HRS") § 329D-10 and § 11-850-72 of the Hawai'i Administrative Rules ("HAR").

Following a meticulous dive into initial market conditions and contemplating a considerable number of influencing factors such as the patient adoption rate, population growth, demographics, and consumption patterns (all of which are described in detail in BPH's Financial Plan; See Attachment "3.3"), BPH has established its base-case financial plan and concluded a capital raise of \$6mm USD will be sufficient to achieve escape velocity of BPH. As detailed above, BPH has access to significant additional sources of financing and capital should additional funds be required.

For instance, in our current Pro Forma, we contemplate an additional [REDACTED] of internally sourced debt financing, at a rate of [REDACTED]. Sustainability initiatives are deeply important to BPH, and we feel it necessary to maintain an adequate reserve of capital to accelerate our timeline for setting the gold standard of sustainably produced cannabis. The nuances of the associated technologies of this endeavor are discussed in our business plan. (See Attachment "3.4")



### Application Response Question 3

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Our analysis reflects a CapEx deployment of [REDACTED] [REDACTED] to complete the “retro-fit” for flowering, vegetative, harvesting, curing, processing, and administrative functions of the space, including equipment and structural upgrades to the building. It is estimated that permitting, construction, staffing, and training, will conservatively span 6-months. Once the cultivation facility is complete and receives a certificate of occupancy, production will commence to bring cannabis and cannabis infused products to our primary RDL location in January of 2017.

To reiterate, this is simply base case. In an effort to achieve more rapid speed to market, BPH is seeking to achieve a Certificate of Occupancy on a smaller sub-section of our initial cultivation facility, which is zoned as a separate unit and not explicitly contemplated in the base case of the pro forma. This would allow the BPH cultivation team to commence growing a small number of mothering plants, which can serve two functions. First, this allows BPH to potentially open the doors of its RDL earlier than January 2017, thus providing faster access to a variety of pharmaceutical grade cannabis products. Second, this initial space can allow BPH to grow a

[REDACTED]



### Application Response Question 3

significant number of vegetative plants, which can then be cloned to assist in accelerating the production schedules of the larger flowering rooms of Ala Moana.

Additionally, as reflected in the Consolidated P&L tab of the Pro Forma model, BPH foresees roughly [REDACTED] to train and educate staff across the entire vertical of disciplines (dispensing, cultivation, processing) in preparation of the opening of BPH RDL locations starting in January of 2017. Rigorous training for RDL staff will commence two months prior to opening. As highlighted in the BPH business plan, we have considerable insight into the staffing requirements based on our assumptions of the market size and BPH market share. Our assumptions are grounded in over 10 years of collective experience in the regulated cannabis industry by both BPH's ACC and HCH affiliates.

In 2017, BPH anticipates another [REDACTED] to expand its flowering room presence and meet anticipated demand. Additional capital expenditure is bucketed in later years bringing the total required amount to just over [REDACTED].

[REDACTED] which is commonly described as "Good" for US consumers. However, as no debt will be incurred by Henk for his equity and loan to BPH, a [REDACTED] [REDACTED] is not pertinent for this application.

[REDACTED]. Please refer to attached Declaration confirming this. (See Attachment "3.5")

Certificate of  
Henk B. Rogers and Akemi Rogers:

---

1. Henk B. Rogers and Akemi Rogers, hereby certify, represent and warrant, as follows:
2. We, and/or family trusts controlled solely by us, intend to invest into Blue Planet Healing, LLC. ("BPH"), if it receives a license to grow and distribute medical marijuana from the Department of Health, State of Hawaii:
  - a. A minimum of [REDACTED] 000 in equity; plus,
  - b. An additional up to [REDACTED] in the form of loans from us to BPH; or
  - c. A total of up to \$ [REDACTED]
3. We own over [REDACTED] in our own accounts at Merrill Lynch. These accounts are solely and fully controlled by us.
4. Please find attached a letter from [REDACTED] the amount of [REDACTED] "readily available" as of January 21, 2016 for our discretionary use.
5. We intend to solely finance the moneys needed by BPH to get started in business up to the amount [REDACTED] without the help of any other investors or the need for BPH to borrow any money.
6. We understand and acknowledge that the Department of Health, State of Hawaii will be relying upon the truthfulness, correctness, and completeness of the above information; and, we hereby certify, represent and warrant that the above information is true, correct and complete.

[REDACTED]

Henk B. Rogers  
Date:

[REDACTED]





## **Attachment 3.3** **Financial Plan**

### **Blue Planet Healing LLC - Pro Forma Narrative**

#### **Introduction**

As state medical marijuana markets across the US step into the community of regulated businesses, the qualified applicants that are fortunate enough to exhibit their merit and be awarded the initial licenses must recognize and act upon their concomitant responsibilities as pioneers in this emerging and evolving space. This means taking the necessary steps to ensure ethical, sustainable, and safe business practices are implemented with the needs of patients in mind. To accomplish this end, expectations cannot be inexorable. A critical element in achieving success in any new market is maintaining flexible market forecasts. In other words, operators in a market undergoing initial self-discovery would be wise to some degree to expect the unexpected. Delayed reactionary behaviors to unforeseen market dynamics could jeopardize the health of the entity, the industry, and most importantly the safety of patients and compliance with law.

When establishing our business plan, CPM, and quantitative market forecasts, Blue Planet Healing, LLC (“BPH”) has done so with an open frame of mind as BPH feels that will provide the operational agility to confront market dynamics as they unfold. As detailed below, BPH’s analysis incorporates and references the lessons learned from other states in the emerging medical marijuana industry, but does so while recognizing Hawai‘i is still its own unique place, with its own unique set of variables (demographics, cultural attitudes, etc.). Only then can BPH respond to changes in the regulatory scheme or market conditions should they exhibit a degree of variance from the base case, whether that is weaker demand and lower initial patient participation or excess demand and greater participation.

BPH’s collective experience in multiple fields including software, medicine, finance, sustainable energy, real estate, legal and, most importantly the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of Hawai‘i’s nascent medical marijuana market. BPH has the experience and is prepared to respond according to market conditions.

Specifically, as it relates to medical marijuana, BPH’s High Country Healing (HCH) and American Cannabis Consulting (ACC) consultants have an established 6+ year track record in Colorado’s medical marijuana market. Since 2009, HCH has successfully navigated the tumultuous waters of perpetual regulatory and structural market change. Over this entire time, HCH has operated successfully and achieved a blemish free record of operational compliance in both the medical and recreational marijuana cultivation and dispensing businesses. Part of HCH’s dedication to excellence has been a commitment by HCH to educate its employees, and by extension its patients regarding the safe and efficacious use of medical marijuana (see .edu attachments “X”). HCH is one of the first dispensaries in Colorado to enroll its employees in “Responsible Vendor Training” in



### **Attachment 3.3**

2015 by the Trichome Institute as soon as the curriculums were validated and sanctioned by the State of Colorado’s Marijuana Enforcement Division (MED).

It is this rich experience in the medical marijuana industry that cautions us against overconfidently forecasting market conditions. If BPH’s expectations are inflexible, this will inhibit the type of reactions required in order to maintain public and patient safety according to the law. BPH’s business plan, CPM, and attached financial projections reflect BPH’s initial assumptions on the growth of the medical marijuana market in Hawai‘i based on empirical analysis, industry experience, and an understanding of the host cultural and local attitudes towards marijuana in Hawai‘i.

#### **Medical Marijuana Patient Adoption Rates – Current & Forecast**

Currently, there are approximately **2,836** duly registered medical marijuana patients on the island of Oahu as of 10/31/15, representing a significantly smaller number of registered patients than the other less densely populated islands (Hawai‘i, Kauai, and Maui). This can be interpreted as reflecting a variance in social norms regarding medical marijuana between the urban professional business center of Honolulu and the more rural communities of the neighbor islands.

**Figure 1: Hawai‘i Medical Marijuana (329) Registry Program**

Valid for October 31, 2015<sup>1</sup>

<b>County</b>	<b>MMJ Patients</b>	<b>Population<sup>2</sup></b>	<b>% Card Holders</b>
Hawai‘i	4,998	196,520	2.54%
Maui	2,979	165,228	1.80%
<b><i>Oahu</i></b>	<b><i>2,893</i></b>	<b><i>1,000,715</i></b>	<b><i>0.29%</i></b>
Kauai	1,686	71,320	2.36%
<b>Total</b>	<b>12,499</b>	<b>1,433,783</b>	<b>0.87%</b>

\* [http://files.hawaii.gov/dbedt/economic/data\\_reports/2040-long-range-forecast/2040-long-range-forecast.pdf](http://files.hawaii.gov/dbedt/economic/data_reports/2040-long-range-forecast/2040-long-range-forecast.pdf)

Current data indicates that **2.54%** and **2.36%** respectively, of the Hawai‘i and Kauai County population, are duly registered card-holding medical marijuana patients. Thus, these are approximately 9x as many residents holding medical marijuana cards on said islands, as a percentage of the population, compared to Oahu island, where just **0.29%** of the population are currently registered in the program. Only 1.8% of Maui’s population are registered patients.

#### **Lessons from the Colorado Experiment**

<sup>1</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>

<sup>2</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>



### **Attachment 3.3**

Colorado, for example, which provides the largest and most robust data sample for legal marijuana markets, started at a similarly modest initial medical patient base as Oahu (0.1% adoption state-wide) before the introduction of a legal dispensary system (“LDS”) in mid-2009. After just two years of profound growth, the Colorado MMJ patient base peaked at **2.5%** of the population base in Q4 2011 before leveling out at **2.2%**, where it stands today.

As Figure 2 below illustrates, there was a decline from 2.5% towards 2% in Colorado’s market, but this simply reflects the State’s inability to expediently process patient card renewals because the LDS’s success was grossly underestimated. For instance, the actual market size was 111% greater than initial projections by the Colorado Center for Law and Policy. Nevertheless, Colorado adapted and allowed for patients awaiting renewal to continue to purchase MM as it expanded its operational capacity. In any event, the key takeaway is that Colorado’s adoption rate grew from just **0.1%** to over **2.0%** in just two-years. This greater than 2% adoption rate is currently the highest seen in any U.S. state medical MM market. Oregon, California, Michigan and Washington, fall into the second tier, with patient adoption rates between 1.4% and 2%.<sup>3</sup>

Looking through the lens of nominal data, Colorado experienced impressive growth in the medical marijuana patient base from 5,000 patients under the caregiver framework in late-2009, to 125,000 patients in Q4 2011, with a population of just over 5 million residents. Extrapolating from this data, Hawai‘i medical marijuana companies and the State would be wise to prepare to handle significant patient registration volumes, but at the same time must not fall victim to heuristic based assessments and succumb to availability bias. To assume that Hawai‘i would experience similarly profound growth is not a base case.

Synthesizing the data from the mainland with the county data in Hawai‘i, one could logically extrapolate that the patient adoption rate on the Hawai‘i Island is relatively close to saturation with some reasonable potential for growth on the margin coinciding with onset of a regulated dispensary network. On the other hand, Oahu has much more significant potential for growth in the long-run, even if peak adoption rates eventually reach levels seen in the other counties in Hawaii or other states across the nation. As a result, BPH sees the greatest need in Oahu for seasoned operators who can leverage their experience in the medical marijuana industry to respond to a burgeoning market in a timely and compliant manner. This offers the best opportunity for patients to receive safe access to medicine without risking product quality or patient safety.

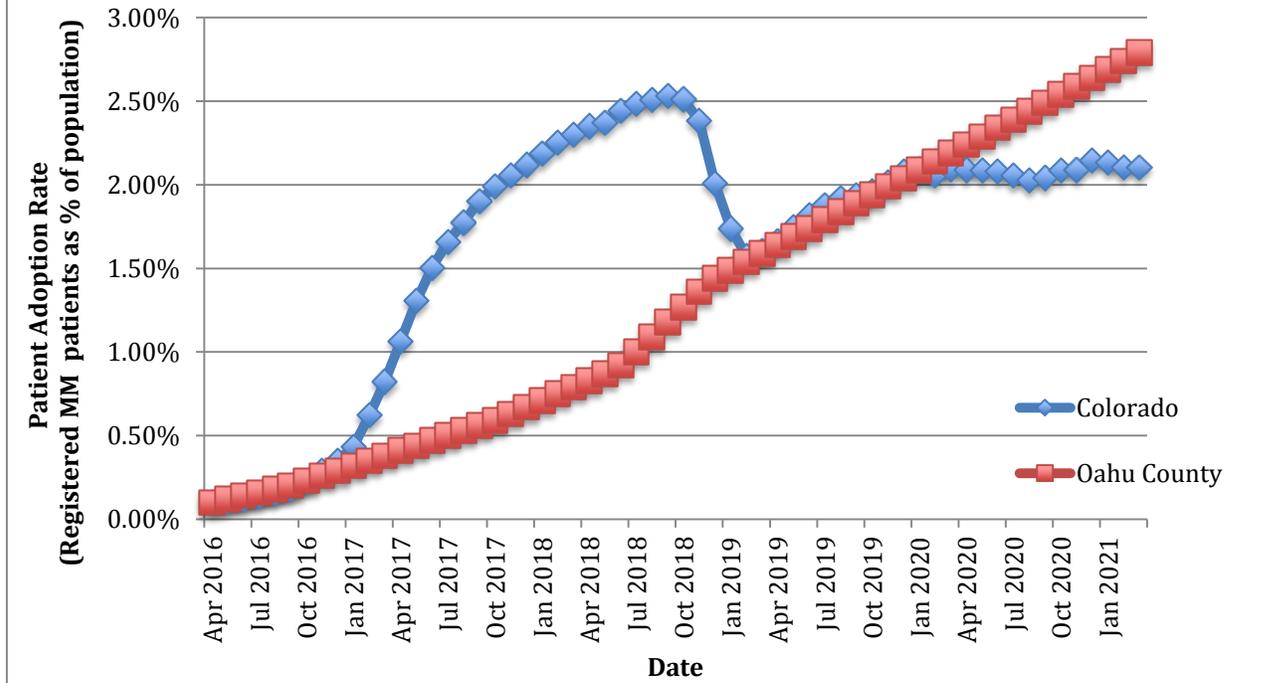
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<sup>3</sup> <http://medicalmarijuana.procon.org/view.resource.php?resourceID=005889>



### Attachment 3.3

#### Figure 2: Forecasted Oahu Patient Adoption Rate vs. Colorado Adoption Rate (historical overlay)



BPH’s analysis for Oahu reflects an expectation for a healthy growing medical marijuana patient base in 2016 as citizens anticipate the opening of retail dispensing locations in the second half of the year. As the program matures and stigma recedes, we suspect an increase in the adoption rates moving into 2017 to just under 1% and acceleration in 2H 2018 (to 1.5%) as additional licensees and reciprocity comes into play. Eventually, in BPH’s base case forecast, it sees a peak adoption rate of around **2.8%** by 2020. This peak adoption rate in the program is consistent with the current patient base level in other counties in Hawai‘i and is the base case for Oahu. BPH is cautiously optimistic that participation will be *higher* given the already meaningful participation in the caregiver framework despite the lack of a regulated LDS network. Other market simulations project participation rates +/- 20% from this level and BPH’s flexible cultivation methodologies and sufficient financial resources illustrate an ability to adapt to conditions within these bounds plus a contingency buffer for anomalous statistical outcomes. Nevertheless, we also felt it prudent to engage in more rigorous stress testing scenario analysis.

#### Market Share – 2018 Reciprocity & New Licensees

Additionally, BPH’s analysis assumes that BPH’s market presence will grow with the growth of the overall market, but with declining market share over time as more medical marijuana businesses are awarded licenses and come online in 2018. The base case reflects a capture of 1/3 of the market share until other LDS’s come online as early as



### **Attachment 3.3**

mid-2018, and dropping to high single digits shortly thereafter. These assumptions are in response to increased demand from both the growth in the patient base as well as a modest influx of tourists from other states that can participate in the state's reciprocity program, which is set to take effect as early as July, 2018.

BPH has factored in the State's desire to meet patient need by having no more than one dispensing location per 500 registered patients, but through collective experience and planning, BPH is preparing to handle volumes well in excess of 500 patients should market demand outpace the LDS network. Long-term, if this **2.8%** peak participation level were achieved as expected, that would theoretically result in a maximum of 40 dispensing locations in the county of Oahu by 2021 at the time of market maturation.

Reciprocity will bring very marginal additional tourism business to the state starting in mid-2018, and will be less of a driver of the market than de-stigmatization on the island itself. To capture the impact of reciprocity on the market, we looked at the monthly tourism data from the mainland and distilled how many medical marijuana patients were represented from each state that currently has a medical marijuana program. Subsequently, using average visit lengths (9.54 days<sup>4</sup>) and cannabis consumption patterns<sup>5</sup>, we were able to estimate the marginal revenue generation from these customers. Specifically, the bulk of this tourism injection will come from the mainland Pacific region (CA, AK, WA, OR, NV), which is largely comprised of states with medical marijuana programs. We factored in growth in the patient bases from each of these states, particularly California, which has significant potential for growth once its regulatory scheme is more firmly established in coming years. Nevertheless, we estimate the impact of medical marijuana patient reciprocity to initially be marginal at best, but contribute in larger fashion in longer-term forecasts.

### **Price of Medical Marijuana**

A major driving motivation of BPH team is to provide sustainably produced, pharmaceutical quality, and affordable medicine to patients in need. If Hawai'i's market emerges with prohibitive prices, it will deleteriously impact those in need most and potentially incentivize black market consumption. The medical marijuana movement, is not about capturing market share in a new potentially lucrative industry, rather, it is about educating patients, researching medical marijuana, and illuminating upon the values and benefits of what BPH feels is the most healing plant on earth. To share in the healing powers of this plant, BPH is dedicating resources to employee and customer education as well as research.

These initiatives, like research and education, will absorb financial resources, but BPH feels they are vital as the more we understand the plant and its benefits, the closer we are to optimizing patient health and well being. The effects of this positive feedback loop,

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<sup>4</sup> <http://dbedt.hawaii.gov/visitor/>

<sup>5</sup> <https://www.colorado.gov/pacific/sites/default/files/Market%20Size%20and%20Demand%20Study,%20July%209,%202014%5B1%5D.pdf>



### **Attachment 3.3**

will reverberate through society as a whole. Therefore, when it comes to product pricing, BPH realizes that if BPH is fortunate to be one of the initial players in this market, we seek to offer reasonably priced medicine as dictated by market dynamics and internal financial considerations. A significantly regulated market framework, will naturally require marginally more costly medicine than the caregiver framework currently

labor in Hawai‘i versus other states are likely key contributors to sustaining higher than average prices.

As it is BPH’s goal to produce pharmaceutical grade medical marijuana, its base forecast

An overarching theme of BPH’s approach to this new market is to have an open mind with respect to market dynamics. Thus are preparing to manage price volatility, with a predetermined understanding of what such price variances could mean for the bottom line and the health of the organization. BPH feels confident that its business acumen, expertise in medical marijuana, and deep financial resources position it favorably to deliver high quality medicine to those in need, while being able to weather considerable market volatility.

#### **Consumption Behaviors**

In additional to forecasting the patient base, another key consideration is the consumption pattern of those patients. Unlike Colorado at the onset of its market, with numerous states medical marijuana programs already online, there is a more robust empirical data set to use to cross-reference demand assumptions.

In Colorado, for example, a large part of the State’s underestimation of initial demand was expectations on the “heavy user” (daily user) segment of the population. According to the 2014 National Survey on Drug Use and Health, 23% of the user population in Colorado consumes almost daily, compared with just 17% nationwide.

The mosaic of data and cultural attitudes in Hawai‘i as exemplified by the relatively high adoption rate state-wide before the onset of a true regulated dispensary framework, suggests that relatively high consumption rates by the daily user segment of the patient base will be higher than the national average of 17% but not necessarily higher than 23%. Therefore, in BPH’s forecasts BPH chose to be conservative and baked in higher than average use, but also ran multiple scenario analysis to account for some variance (again, bullish and bearish scenarios +/- 20% in addition to more rigorous stress testing).

#### **Demographics**



### **Attachment 3.3**

One of the key differentiators of Hawai‘i’s current duly registered medical marijuana patient base is the age distribution. As it relates to gender, Hawai‘i is consistent with many other states including Colorado, showing roughly 2/3 (68% vs. 64% in CO) of the base being male and 1/3 (32% vs. 36% in CO) being female<sup>6</sup>. Yet, which age group represents the largest share of patients reflects an interesting contrast to other states. In Hawai‘i, the largest cohort of patients comes from the 56-65 year old segment (27.6%) vs. the 21-30 year old segment in Colorado (23.2%). This data is heat-mapped in Figure X below for illustrative purposes.

**Figure 3: Hawai‘i Medical Marijuana Patient Distribution  
(by Age)**

<b>AGE</b>	<b># of Patients</b>	<b>Percentage of Base</b>
<17	25	0.20%
18-25	573	4.58%
26-36	2,098	16.79%
36-45	2,084	16.67%
46-55	2,381	19.05%
56-65	3,450	27.60%
66-75	1,681	13.45%
76-99	207	1.66%
<b>Total</b>	<b>12,499</b>	

The larger proportion of the patient base in the 55-65yo demographic is consistent with experience in Colorado from the onset of the LDS program. For instance, in 2009 when HCH first opened its doors, a higher percentage of patients were near retirement age. Further anecdotal evidence reflects that medical marijuana was selected as an organic remedy following many years (decades) of battling the side effects of synthetic pharmaceutical prescriptions, mainly opiates. Pain relief, after all, is by far the most common mentioned reason for consuming medical marijuana. 92% of patients in Hawai‘i and 94% of patients in Colorado list this as justification for obtaining their medical marijuana cards.

Taking this one step further, it is the belief of BPH, through HCH and ACC’s real-time experience in the industry in Colorado and other states, that this older segment of the population consumes a larger proportion of infused products (oils, pills, lozenges) rather than inhaled products (flower) for actual and perceived health reasons. For instance, the longer duration and intensity of ingested medication (4-6h of relief vs. 1-2h for inhaled)

<sup>6</sup> <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/FY16-October-31-Statistics-FINAL-11-30-15.pdf>



### **Attachment 3.3**

make it a superior choice to address physical pain, auto-immune, and neuropathic conditions and thus a welcomed remedy for many elder patients. BPH's collective realization of this dynamic was an important consideration in its partnership with Chief Medical Officer (CMO) Dr. Bradley Willcox, who as a UH affiliated scientist and researcher has deep experience in the area of geriatrics and gerontology.

While this assessment is not empirically robust, it does hint as to how things might unfold and thus caution and prepare BPH for a different set of circumstances than are currently reflected in today's data. Qualitative experience oftentimes is shunned over the more concrete and tangible nature of quantitative analysis due to BPH's collective desire for control and greater comfort with numbers than abstract ideas, yet quantitative approaches too have their own pitfalls such as data mining and confirmation bias.

Even though the cumulative consumption basket is challenging to quantify with precision, current evidence signals to us that we should be prepared to offer a relatively greater selection of products in the infused category in anticipation of larger initial demand. It was also a motivating factor in creating a vast array of non-inhaled, infused products, including sprays, lozenges, oils, and pills. This distinction between flower and infused products is quite significant to BPH's business plan as the different product sets have varying costs of production and shelf life. For example, medical marijuana that is grown to be smoked, requires much greater dedication to the nuances of growing the plant to produce the proper flower structure as well as terpene (essential oil) yields, while infused products (pills, lozenges, oils) place the greatest emphasis on simple trichome (cannabinoid) production.

So, looking ahead, it is critical for BPH to maintain accurate up-to-date empirical data on the patient base on Oahu in order to better serve the patient's medical needs and forecast their needs with greater accuracy. For instance, the current adoption rate in Oahu County is just 0.29%. The expectation is for this to increase roughly 10x within 5 years. It is possible that the 26-36yo segment experiences more significant growth, which would redistribute consumptions patterns over time, yet, perhaps the most likely outcome is that the 55-65yo segment that grows most significantly.

According to the most recent census data, which shows Oahu County expected to grow at **0.6%** per annum from 2015-2020, **16.1%** of the Hawaiian population is over 65, versus **14.5%** as the national average. Colorado, on the other hand, is younger, with just **12.7%** above the age of 65. Using this data as a guide and not gospel, BPH reasonably anticipates a relatively higher consumption of infused products compared to inhaled products, especially at the onset. Yet again, BPH feels it is absolutely critical to maintain meticulous oversight on each of these market variables to ensure BPH's greatest chances at continuing to provide medicine to patients in need and react to market developments in real-time.

### **Cultivation Methodologies – Maintaining Flexibility**



### **Attachment 3.3**

Under Hawai'i law, all licensees are restricted to 3,000 plants per cultivation center, for a maximum of 6,000 plants. Additional licensees are set to be considered by the State at the end of 2017 for launch in mid-2018 should market conditions dictate the need for extra capacity. But what if demand surpasses the needs of patients before additional licenses are awarded in 2018? BPH, for one, is ready to confront such challenges by maintaining flexible cultivation methodologies that allow for varying plant counts per light (and thus plant size) in order to meet excess demand. Through the collective experience of HCH and ACC, BPH is prepared to confront these challenges and efficiently adapt to shifting market dynamics. It is BPH's goal with its initial production centers to maintain a high level of flexibility in production to meet many potential demand scenarios while BPH moves towards the longer goal of building a state of the art, sustainable cultivation facility, leveraging BPH's team's depth of experience in energy.

#### **Summary**

BPH's collective track record in various realms of business, including the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of the Hawaiian medical marijuana market. BPH's approach is not inexorable, nor is it dogmatic. BPH's initial cultivation center is strategically poised to navigate the volatility of a new market while sewing the seeds of the long term vision of Hawaii's 2015 CEO of the Year, Henk Rogers, which is to create the gold standard for sustainable cultivation practices in the medical marijuana industry.

While BPH acknowledges the uncertainties of a new market, the base case assumptions are grounded in over 6 years of experience within the marijuana industry and a combination of qualitative and quantitative analysis of the Hawaii market. BPH has evaluated initial market conditions and made calculated estimations on the market's development from the awarding of licenses in April 2016. BPH's analysis factored in consumption patterns, demographics, population growth, reciprocity, and more to achieve a base case forecast, which was then subjected to rigorous stress testing.

Armed with the knowledge gained from both experience in Colorado and analysis of the Hawaii market, BPH feels confident in its ability to deliver pharmaceutical grade, sustainably produced medical marijuana to Hawaii consumers in 2016. BPH has the business acumen and deep financial resources to accomplish its goal and the passion to share what BPH believes to be the most healing plant on earth with those who are suffering and in need.



# **BUSINESS PLAN**

Medical Marijuana Cultivation, Manufactured  
Marijuana Products and Retail Dispensing Facilities



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# Executive Summary

## Mission Statement

"To provide relief that Hawai'i patients deserve through the highest quality, sustainable, and responsibly grown medical cannabis."

Hawaii is the most beautiful and pleasant place to live in the US if not the world. The weather is perfect, nature is beautiful, culture is rich, and most importantly; the people live with aloha. Residents of Hawaii know how lucky we are to live in paradise. However, the universe works in mysterious ways, and we do not always get everything we want. Many of us either know of people close to us or are themselves suffering from health issues that prevent them from enjoying their lives, or live in constant pain. Many of these ailments have no known cure or require prescription drugs with devastating side effects. For the first time in history, Hawaii has the opportunity to improve the quality of lives of these with varieties of medicinal marijuana that were researched and developed to provide direct relief to these patients. Blue Planet Healing was formed to provide relief that Hawaii patients deserve through the highest quality, sustainable, and responsibly grown medical marijuana.

Blue Planet Healing, LLC. (BPH) is a family owned local company dedicated to improving the quality of lives of the people of Hawaii. The company is comprised of highly experienced and talented individuals that gathered under the cause of improving the lives of our neighbors. It is an organization that allows them to achieve what they alone can not. These members bring together with them expertise in business, medicine, horticulture, community, sustainability, technology and the medical marijuana industry to create a team that will set the bar in the medical marijuana industry. BPH will create a patient centric medical marijuana dispensary system that brings the most benefit to the patients while being professional and innovative.

BPH along with its consultants, bring the highest quality of products and services to the patients. Colorado has the most mature medical marijuana industry in the United States. BPH's team include a member recognized to produce the highest quality medicinal marijuana and a member recognized to produce the highest quality marijuana manufactured products. Their experience navigating through the constantly evolving industry and regulations will be vital to BPH.

BPH includes in its mission a notion for a sustainable operation. As Marijuana production is such a heavy consumer of electricity, BPH has taken the concept of sustainability and stewardship into its mission. The unique experiences and background in clean energy, software, and other technologies, BPH has the capability to turn this industry from the heaviest of polluters to one of the cleanest.

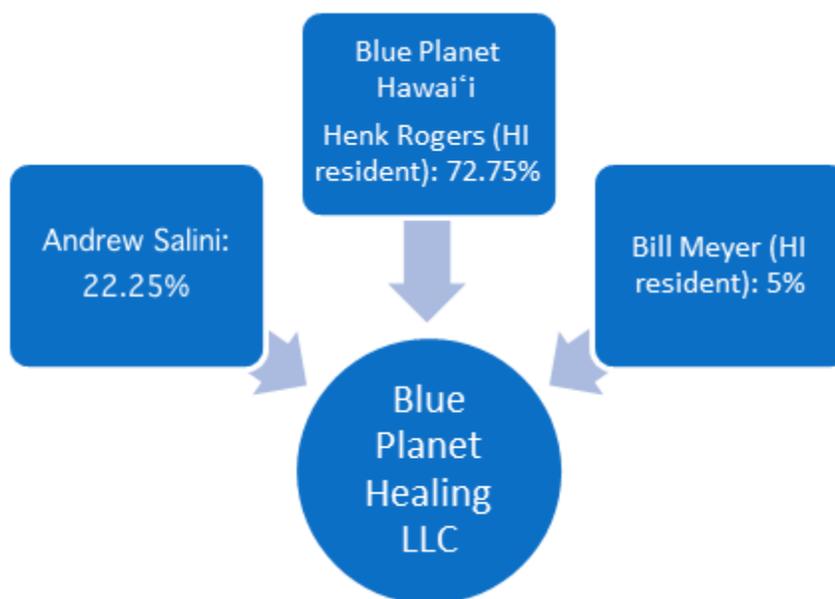


Following the mission with conviction and fortitude, BPH will be the most beneficial operator of a medical marijuana dispensary business for the people of the state of Hawaii and the medical marijuana industry globally.

## Company Profile

Blue Planet Healing, LLC., (“BPH”) a family owned company, and is uniquely qualified to operate a business whose sole mission is to provide, to duly registered patients, in strict compliance with Hawai‘i law, safe and consistent pharmaceutical grade marijuana in the form of unprocessed flower buds and the marijuana infused products permitted pursuant to Hawai‘i Revised Statutes (“HRS”) § 329D-10 and § 11-850-72 of the Hawai‘i Administrative Rules (“HAR”).

BPH is owned by Rogers Medicinals, LLC and High Country Healing Hawaii LLC, and Bill Meyer. The total ownership interest of BPH by Hawai‘i residents is 77.75% as shown below.



In order to accomplish this mission, BPH has assembled a team of highly qualified professionals with long histories and deep roots in the local business, medical, scientific, horticultural, and legal communities. This talented group of individuals comprise the core BPH team and possess vast knowledge and business experience in: regulated industries; horticulture: commercial manufacturing; operating a medical marijuana business which includes experience with retail sales, protecting confidential customer information, secure inventory control and tracking and the utilization of 24-hour security monitoring. BPH’s core team members have the ability and experience required to successfully operate a business. BPH has created this business plan and financial plan (financial pro-forma model) for the guidance, implementation and deployment of its organizational and operational goals and objectives.



BPH's individual applicant, Henk Rogers ("Henk") is an internationally recognized entrepreneur, philanthropist and community leader who was recognized as Hawai'i's 2015 CEO of the Year. A longtime resident of Hawai'i who studied computer science at the University of Hawai'i, Henk has skillfully assembled a dynamic group of individuals with the necessary education, training, skills and real life experience necessary and advisable to start and successfully operate a business that will accomplish the statutory goals of HRS Chapter 329D.

In addition, BPH has unconditional access to all of the necessary financial resources needed to execute its startup and roll out plans.

In addition to Henk, the owners/principals ("Principals") of BPH include Andrew Salini, who is a Princeton University in Economics and Finance and the Chief Operating Officer of High Country Healing ("HCH"), which is one of the first medical marijuana ("MM") dispensaries in the State of Colorado. Andrew will act as BPH's Chief Operations Officer ("COO").

Over the last 6 years, HCH has successfully, cultivated, produced and distributed high quality pharmaceutical grade MM in full compliance with Colorado's laws and regulatory scheme which, among other things, requires: maintaining strict inventory control, tracking and reporting; and protecting confidential customer information. HCH operates three Colorado based MM retail dispensing locations ("RDL"), as that term is defined in HRS § 329D-1, and three recreational marijuana ("RM") stores all under the watchful eye of a comprehensive and effective 24 hour security monitoring system. HCH employs and manages a team of over 57 skilled workers in its operations.

As a result of their development and implementation of a comprehensive financial and business plan, HCH has grown from one RDL and Production Center ("PC"), as that term is defined in HRS § 329D-1, to three (3) RDLs and three (3) RM stores (consisting of ≈9,000 sq. ft.) and three PCs and three (3) RM production centers (consisting of ≈ 35,000 sq. ft.). HCH has obtained high profile recognition within the industry for its quality products and kudos from Colorado's law enforcement community for its exemplary behavior and legal and regulatory compliance. HCH brings extensive knowledge and experience in: regulated industries; horticulture; commercial manufacturing; operating a medical marijuana business which includes experience with retail sales and other relevant experience to BPH for the successful operation of its business.

To further strengthen BPH's operational strategy, BPH has entered into a consulting agreement with UNDRNWMNGMNT, LLC. ("UNM"), an established marijuana product manufacturing-licensing company headquartered in Colorado since 2010. Under its agreement with UNM, BPH will have the exclusive right, in Hawai'i, to manufacture marijuana infused products using UNM's proprietary techniques and processes. UNM will also provide consultation and serve as an advisor to BPH in all aspects of manufacturing marijuana products. UNM licenses its proprietary manufacturing methods, industry experience and compliance services to clients in several states.



UNM specializes in pharmaceutical-grade marijuana extraction, production, formulation, packaging and branding of dosed and tested products for regulated MM markets. UNM has been consistently recognized by dispensaries, physicians and patients for the quality and consistency of the MM products created using their proprietary techniques. MM industry experts have also awarded UNM multiple honors for the quality of their products and approach toward patient education and the safe use of MM.

The other principals of BPH will all bring additional relevant expertise and business acumen to the table.

Maya Rogers Kiyomura ("Maya") will be the CEO of BPH. For the last several years she has helmed Blue Planet Software, one of Hawai'i's most successful high tech companies, through the highly complex and competitive high-tech world with international sophistication and a sense of local pride and style. As co-founder and Partner of Blue Startups, Hawai'i's premier Business Accelerator Organization and a 2015 top 20 US Accelerator, Maya assists and trains promising start-up entrepreneurs to compete on a global scale using a mentor driven model that reaches networks throughout Hawai'i, Asia and Silicon Valley.

BPH's Chief Financial Officer, Kent Otsu, has significant finance experience working for some of Hawai'i's most notable companies and will be the executive responsible for the financial control and planning of BPH. Kent will oversee all financial and accounting functions including: (1) cash control, (2) preparing budgets and financial statements, (3) coordinating financing (4) monitoring expenditures and liquidity, (5) managing tax issues, (6) reporting financial performance to the board, (7) providing timely financial data to the CEO and (8) working with appropriate financial and other government regulators.

BPH's distinguished Board of Advisors includes:

1) Dr. Bradley Willcox M.D., a UH affiliated scientist, researcher and practicing physician who will act as BPH's Chief Medical Advisor ("CMA") and, among other things, provide guidance to BPH regarding the latest credible scientific research involving MM and will act as the Company's information gatekeeper in connection with the preparation and dissemination of medical and scientific information to registered patients as permitted by the Department of Health, State of Hawai'i ("DOH"). Dr. Willcox is an investigator in the area of geriatrics and gerontology at the Pacific Health Research and Education Institute and is a clinical assistant professor in the Department of Geriatric Medicine at the John A. Burns School of Medicine, University of Hawai'i. As his attached profile attests, Dr. Willcox's education, training, background and experience make him particularly well suited to provide scientific and medical guidance to a MM dispensary business. DOH has recently compiled and published information regarding the demographics of the roughly 12,000+ MM patients in the State of Hawai'i. The DOH data indicates that an overwhelming number of these patients use MM to alleviate pain from (their physician certified) debilitating medical condition. Accordingly, it appears that a substantial number of Hawai'i's registered MM patients use MM to treat symptoms associated with many of the chronic diseases that afflict Hawai'i's kūpuna. Dr. Willcox's medical and scientific background nicely fits this



demographic. In addition, the recent expansion of the definition of "debilitating medical condition," for which physicians may prescribe MM, to include "post-traumatic stress disorder" increases the relevance of Dr. Willcox's skill set to BPH's mission.

2) Dr. Andrew Bachman, M.D. is a co-founder of LeafLine Labs, a MM research and manufacturing company located in Minnesota. Dr. Bachman earned his medical degree from Georgetown University School of Medicine and his undergraduate degree in biology from Amherst College and will provide advice and guidance to BPH regarding early stage development of its MM dispensary operations.

3) Greta Inofer, R.N. is a registered nurse with over five years experience in patient case management and care coordination. Under the guidance of Dr. Willcox, Greta will facilitate dissemination of patient information and provide face-to-face patient consultation regarding the safe use of MM.

4) Dr. Marisa Kesaji, Pharm.D. is a graduate of Roosevelt High School (Summa Cum Laude) received her Doctor of Pharmacy from the University of Southern California. Dr. Kesaji will provide advice and guidance to BPH regarding pharmacological issues and working in consultation with BPH's CMO and CHA.

5) Dr. Kenneth Leonhardt, Ph.D., also a UH affiliated scientist, will act as the Company's Chief Horticultural Advisor ("CH") and provide BPH with guidance regarding the best horticultural practices necessary to economically produce quality pharmaceutical grade MM for Hawai'i's patients. Dr. Leonhardt will work closely with BPH's Cultivation Manager.

BPH's Cultivation Manager will be Michael Rogers a graduate in Horticulture Science from the College of Tropical Agriculture at the University of Hawai'i at Mānoa.

Finally, BPH has engaged a team of local business and regulatory attorneys and a nationally recognized cannabis law attorney, Greg Anton, Esq. to provide the legal advice, counsel and guidance necessary to assure that BPH complies with all applicable state laws and regulations and understands the complexities inherent in operating a business that is legal under state law but in violation of the federal Controlled Substances Act (21 USC § 801 et. seq.). Attorney Greg Anton has been a champion of medical cannabis patients for over 35 years; working to help ensure safe access to this valuable medicine. Greg has litigated issues of cannabis law at all levels of State and Federal courts, including the US Supreme Court. (In 2015 he achieved a landmark legal victory with an unprecedented ruling that his client can distribute medical cannabis without Federal interference). Besides working with state and local government officials to develop safe, effective regulations; Greg has provided legal counsel to all aspects of the medical cannabis industry. Greg represents the first licensed medical cannabis dispensary in the United States.

This highly credentialed and competent team possesses the required business savvy and will provide the necessary training, guidance and oversight to the employees, contractors, and vendors of BPH to ensure that BPH is not only successful from a business standpoint but that it sets the standard for excellence in patient care and safety for Hawai'i's registered MM patients.



## Company mission statement

Mission Statement: To provide relief that Hawai'i patients deserve through the highest quality, sustainable, and responsibly grown medical cannabis.

We hold patient safety as number one, and are committed to providing a safe, consistent, high quality medical marijuana to the registered patients. How we will differ from others will be in the care in which the medical marijuana will be grown. Our operating partners, High Country Healing, has won several awards for its quality product. They make up our core team and will be bringing their cultivation expertise. We have also recruited on our team a Chief Horticultural Advisor, an established Ph.D at the University of Hawai'i

## Blue Planet Software

The Tetris brand is one of the leading and most distinctive video game brands and franchises in the world with over 500 million mobile downloads, and over a billion games played online per year. In the game's 31 year history, Tetris has partnered with the likes of Electronic Arts, Ubisoft, Sega and Hasbro and continues to be one of the most widely recognized video games of all time.

Some other interesting facts of Tetris:

- Tetris is played in more than 185 countries
- Tetris has been translated into more than 50 languages
- Tetris has been released on over 50 platforms
- Over 35 million units of Tetris were sold for the original Game Boy platform
- More than 23 billion games of Tetris Battle on Facebook have been played to date, making it one of the social platform's most popular games
- Hundreds of millions of Tetris products have been sold around the world.

Blue Planet Software, Inc. (BPS), the sole Agent for Tetris, was established in Hawaii 20 years ago. Currently, with a dozen employees all based in downtown Honolulu, BPS continues to develop the Tetris brand identity that millions of fans have grown to love. As its sole agent, BPS delivers brand consistency and represents Tetris in all licensing relationships including the following:

- Product ideation
- Product quality assurance and approvals
- Promotional and public relations support
- Global Intellectual property protection

For more information, visit [www.tetris.com](http://www.tetris.com)

## Blue Planet Energy Systems



Founded in 2015, Blue Planet Energy Systems is a Honolulu based energy storage company. Working in partnership with Sony, Blue Planet Energy has created the “Blue Ion” solution which combines solar, energy storage and an energy efficiency management software to help homes and businesses become energy self-sufficient. Blue Ion is used to help homes and business maximize renewable energy, shift energy from low energy periods to peak periods and provide standby power protecting against black-outs.

Henk Rogers provided the vision and inspiration behind Blue Planet Energy Systems. In his Hawai‘i homes, Henk installed solar panels and reduced his energy consumption with efficient lighting and electric vehicles but after doing so he felt there was more that could be done. So he began exploring different battery technologies by purchasing and installing different options. In Sony he found a technology that was safe, powerful and cool.

He struck a relationship with Sony’s corporate leadership and negotiated an exclusive relationship to resell Sony’s industry leading and proprietary Fortelion™ chemistry.

Today Blue Planet Energy is one of the leaders in Energy Storage with its Blue Ion systems deployed in homes, commercial facilities in Hawai‘i and California.

For more information, visit [www.blueplanetenergy.com](http://www.blueplanetenergy.com)

## **Blue Startups**

Blue Startups is a Honolulu-based venture accelerator founded by Henk Rogers and Maya Rogers Kiyomura. Blue Startups invests and provides hands-on mentorship to capital-efficient and scalable-technology companies, including Internet, software, mobile, gaming and e-commerce. Blue Startups is a nexus of entrepreneurial activity not only in Hawai‘i, but also between Asia and the Continental U.S.

Blue Startups concentrates on helping scalable-technology companies including web, software, mobile, gaming and e-commerce compete on a global scale. A member of the Global Accelerator Network, Blue Startups follows the Techstars mentor-driven accelerator model, reaching networks in Hawai‘i, Asia and the Silicon Valley.

Blue Startups has a network of more than 80 mentors reaching from Hawaii and Japan to Silicon Valley. The interaction of mentors with teams will assist in developing Hawai‘i as a node of entrepreneurship by bringing in expertise, capital and other resources from across the Pacific. Our premise is that people make innovation happen, that growth follows effective execution, and that sustained success will require access to global resources.

Blue Startups has 50 companies in its portfolio to date, has deployed over \$1 million dollars in funding, and the companies have gone on to raising over \$25 million in follow-on funding. Over 75% of the companies have received outside capital, and the average raise of each graduate company is \$500,000. Today, Blue Startups is ranked as top 20 accelerators in the U.S. as ranked by TechCrunch.



For more information, visit: [www.bluestartups.com](http://www.bluestartups.com).

## **Blue Planet Foundation**

Henk founded the Blue Planet Foundation in 2007 as a 501(c)(3) nonprofit organization. Blue Planet Foundation's mission is to clear the path for 100% clean energy, starting in Hawaii. Blue Planet Foundation's vision is a world powered by abundant renewable energy that sustains all life on Earth. The Foundation focuses on implementing transformative clean energy policy and developing innovative and scalable energy engagement programs by directing its efforts in three areas of change: (1) encouraging leaders to make policy changes that accelerate cost-effective, secure, renewable energy; (2) engaging communities through smart, replicable renewable energy and energy efficiency solutions; and (3) inspiring everyone, through creative communications, to believe in the power and possibility of a future beyond fossil fuels. By leveraging activities in these three programmatic areas of advocacy, action, and awareness, Blue Planet Foundation is making meaningful change on an issue that touches every aspect of our lives and economy.

### *Advocacy*

Blue Planet Foundation's advocacy work seeks to implement innovative legislative and regulatory policy solutions to remove barriers and accelerate the transition to 100% clean energy. The Foundation advocates at the state legislature and Public Utilities Commission and acts as a resource at conferences and in working groups like the Hawaii Clean Energy Initiative. Blue Planet Foundation also convenes world renowned experts to help decision leaders make smart policy choices. In 2015, Blue Planet Foundation led the campaign to pass the nation's first 100% renewable energy requirement, as well as a community renewables bill that could dramatically increase access to renewable power.

### *Action*

Blue Planet Foundation's action programs provide tools to the community to control their energy consumption and allow them to support renewable energy. A clear example of this is the Foundation's WEfficiency crowdfunding program. Since its launch in 2014, WEfficiency has enabled individuals to fund projects that will displace 200,000 gallons of oil, avoid 5 million pounds of carbon pollution, and save local nonprofits \$1.2 million. Nonprofits such as YWCA, Damien Memorial School, Boys & Girls Club, and others have used WEfficiency to decrease their carbon footprints while increasing their capacities to serve our community.

### *Awareness*

Blue Planet Foundation's awareness initiatives engage communities in a new conversation about energy, helping to build understanding about the damage caused by fossil fuels and the solutions available through renewable energy and smarter energy use. Blue Planet Foundation tracks Hawaii's progress toward 100% clean energy with its Energy Report Card, published annually in print and online. Developed to inform decision leaders and the public, the report evaluates the annual progress in five categories of energy transformation: transportation, efficiency,



renewables, smart grid, and economics. Blue Planet Foundation also increases awareness through its Island Pulse kiosks. The kiosks help make the invisible, visible, by providing a real-time breakdown of our energy use as well as the sources of that energy (solar, wind, coal, etc.). The Island Pulse was developed in partnership with Hawaiian Electric, who provided the energy data for the first time publicly.

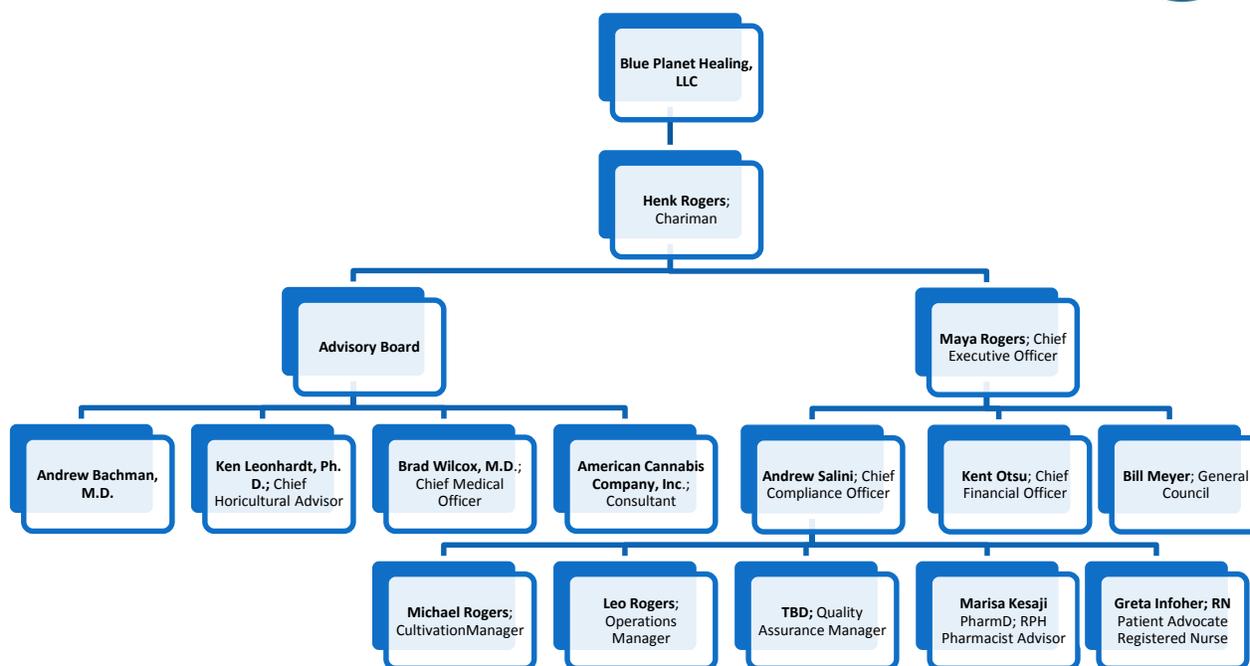
Although distinct, Blue Planet Foundation's three programmatic approaches are implemented synergistically with activities in each approach reinforcing the others. By addressing community needs in each category, Blue Planet Foundation is the leader that is unifying Hawaii's transformation to 100% clean energy with precision and determination.

BPH will operate a Dispensary Facilities (as that term is defined to include cultivation, processing/manufacturing and dispensing marijuana and manufactured marijuana products in full legal compliance with the State of Hawai'i. BPH will cultivate, manufacture and dispense marijuana and manufactured marijuana products for dispensing to qualifying and registered medical marijuana patients in the State of Hawai'i. BPH will ensure compliance with all applicable state and county law and regulations while becoming a valuable member of the business community and surrounding areas.

BPH's focus will be on cultivating the highest quality medical marijuana for the Hawai'ian medical marijuana industry and to operate safe, patient-friendly retail dispensing locations. Through the use of established industry best practices pertaining to the cultivation of marijuana and manufacturing of marijuana products, BPH will cultivate and manufacture high quality marijuana and manufactured marijuana products at the registered dispensary facilities. BPH will cultivate all marijuana on the registered production facility utilizing various cultivation techniques and methodologies including True Living Organics (TLO), Integrated Pest Management (IPM), sustainable and environmentally friendly operations and other programs and policies to ensure compliance with state law. The BPH registered dispensary premises will be within a structure to prevent unauthorized entry and ensure no activities or operations can be seen or viewed from the exterior of the facility BPH will also manufacture marijuana products of the highest quality, including oils and oil extracts, capsules, lozenges, pills, tinctures, ointments, and skin lotions. The patient-centric retail dispensing operations will focus on patient accessibility and safety and be conducted according to all state and county law.

For more information, visit [www.blueplanetfoundation.org](http://www.blueplanetfoundation.org)

## **Management and Organization** **Organizational Hierarchy Chart**



## Blue Planet Healing Organizational Members

### **Henk B. Rogers** – *Sole Applicant, Chairman & Spokesperson*

Considered one of the visionaries of computer games, Henk Rogers helped change the face of the industry as the entrepreneur responsible for bringing the Tetris® game to the United States and world market. Under Henk’s direct leadership, the Tetris game has become one of the world’s top-selling video game brands with hundreds of millions of products sold, and after 30 years since its “birth,” that number is still growing. Today Rogers serves as Managing Director of The Tetris Company, the exclusive licensor of the Tetris brand and Chairman of Blue Planet Software, the sole agent for the Tetris franchise, founder of Blue Planet Foundation, a nonprofit clean energy advocate, and founder of Blue Startups, Hawai’i’s first venture accelerator.

A heart attack in 2005 gave Henk the opportunity to rethink the rest of his life and reevaluate the purpose of his life’s work. Henk is determined to end the use of carbon-based fuel on the planet, starting with fossil fuel use in Hawai’i, his adopted home. To fulfill his mission, Henk established Blue Planet Foundation, which has become the frontline organization in the fight for indigenous renewable energy in Hawai’i. As Blue Planet Foundation’s principal and visionary philanthropist, Henk Rogers is committed to the mission of stewarding the environment through developing non-carbon, clean energy sources. He is personally devoted to helping our planet reduce and eventually eliminate its dependence on fossil fuels.

Furthermore in 2015, Henk founded Blue Planet Energy Systems, becoming a leader in energy storage solution systems home and commercial usage.

Henk’s community recognitions include:



- 2015 – Hawai‘i Business Magazine, CEO of the Year
- 2015 – Honorary Doctorate of Human Letters, University of Hawai‘i
- 2014 – Hawai‘i Institute for Public Affairs (HIPA) Ho‘ulu Award
- 2013 – Hawai‘i Business News Business Leadership Award Finalist
- 2011 – Hawai‘i Business Innovation Showcase “City & Council of Honolulu” Finalist
- 2010 – Hawai‘i Business Magazine “Five for Today” leadership recognition
- 2009 – Hawai‘i Venture Capital Association “Entrepreneur of the Year”
- 2008 – Hawai‘i Venture Capital Association “Venture Capital Deal of the Year” Honorable Mention – Avatar Reality

Henk currently sits on the board of East West Center Foundation, is the Chairman of Science Engineering Expo - Innovation Technologies (Chairman, SEE-IT), as well as the Chairman of Pacific International Space Center Exploration Systems (PISCES).

**Other Affiliations:**

Honorary Consul of Netherlands, Waialae Country Club, Waikiki Yacht Club, Honolulu Club, Sunrise Rotary, University of Hawai‘i, College of Engineering Dean’s Advisory Council, Plaza Club.

**Personal:**

Rogers and his wife Akemi currently share their time between residences in Honolulu and Kailua-Kona, Hawai‘i. They have four children: Maya, Julie, Michael and Leonard.

In his spare time, Rogers is an avid photographer, world traveler, and designer, and he enjoys playing squash and golf.

**Maya Rogers Kiyomura – Chief Executive Officer**

Maya Rogers Kiyomura is President and CEO of Blue Planet Software, the sole agent for the Tetris® brand. With a history that spans more than 30 years, Tetris is one of the leading and most distinctive video game brands and franchises in the world. Rogers has spent the last eight years leading the Tetris brand’s worldwide business initiatives, including and more than 12 years in the video game industry in Japan, China and the U.S. Prior to Tetris, Rogers steered cross culturalization and development efforts with Sony Computer Entertainment America and American Honda.

In 2012, Maya co-founded Blue Startups, Hawai‘i’s first venture accelerator that helps early stage startups with investments and mentoring. Fifty companies have gone through the Blue Startups program and received capital from the Blue Ventures Fund, and have attracted approximately \$25



million in funding. In March 2015, Blue Startups placed #17 in TechCrunch's annual ranking of top US accelerators.

Prior to Tetris, Maya held management roles with Sony Computer Entertainment America, where she steered localization efforts for games such as the Gran Turismo and Hot Shots Golf franchises. Rogers began her career working with cars at American Honda before making the switch over to working on virtual cars at SCEA.

Maya is a board member with the American Red Cross Hawai'i Chapter, and is a member of the Tiffany Circle Society of Women Leaders, a national Red Cross program comprised of women leaders and philanthropists who dedicate their time and talents to support community Red Cross efforts. Rogers also serves as a member of the advancement committee and advisory board of the Smithsonian Asian Pacific American Center. She is also actively involved in eGlobal Family, an organization that links orphaned and vulnerable children in developing countries to compassionate and responsible supporters. The Rogers family is also a proud member of the Family Business Center of Hawaii, part of the Pacific Asian Center for Entrepreneurship at UH Manoa Shidler College of Business.

In March 2015, Maya was awarded "20 for the Next 20" recognition by Hawai'i Business Magazine as one of 20 emerging leaders who have made major contributions to the state of Hawai'i, and are expected to have a significant impact on the state over the next two decades. In 2016, Pacific Business News honored Maya with the Women to Watch recognition.

Maya currently is involved with the State of Hawaii's Workforce Development task force, which is tasked to come up with plans to increase jobs under the Workforce Investment and Opportunity Act (WIOA), passed by signed into law in 2014. She also is working with the Chamber of Commerce Economic Development and Innovation Committee to provide advice from the entrepreneurial community.

Maya grew up in Japan and the US, and currently resides in Hawai'i. She holds a B.S. in Business Administration and an MBA from Pepperdine University.

**Kent Otsu** – *Chief Financial Officer*

Kent Otsu is Chief Financial Officer (CFO) of Blue Planet Software (BPS), the sole agent for the iconic video game Tetris. As CFO, he oversees all administrative and financial matters for BPS including accounting, tax reporting and compliance, and budgeting. In addition, Kent oversees legal and human resources for BPS. Kent and his team also provide similar services to all companies under the direction of Henk Rogers which include Blue Startups, a nationally-recognized accelerator, and Blue Planet Foundation, a non-profit organization dedicated to end the use of carbon-based fuels in Hawai'i.

Prior to working at BPS, Kent worked for KPMG in Honolulu where he worked on financial audits of electric utilities, healthcare and real estate entities, and he earned his Certificate of Public Accounting at this time. He then spent 12 years as Controller for LVMH Fashion Group Hawai'i, whose brands include Louis Vuitton, Celine and Fendi. His responsibilities included producing financial statements in accordance with GAAP and IFRS, income tax reporting and compliance,



and overseeing all audits including State Income Tax, General Excise Tax, Department of Labor, Internal Revenue Service and US Customs. In addition, Kent was responsible for creating and maintaining internal controls over cash and inventory, which included procedures around the point-of-sale, and inventory receiving, transferring, and physical counts.

Kent graduated from Iolani School, and then attended University of Colorado - Boulder where he earned a Bachelor of Science in Accounting. Today, Kent enjoys spending his free time with Debbie, his wife of 21 years, and his daughters Jessica and Deanna. He also enjoys an occasional round of golf, and supporting his alma mater, Iolani School.

**Andrew Salini – Chief Compliance Officer & Chief Operations Officer**

Andrew Salini has acted as the Chief Operations Officer & Chief Strategist at High Country Healing's Retail & Cultivation Facilities from 2014 to present. Andrew's management experiences include HCH operations, retail/cultivation/financial strategy and analytics, as well as brand and business development. Formerly, Andrew was the Chief Strategist at EMF Fixed Income Fund from 2011-2014, specializing in fixed income relative value arbitrage. He was also previously an Associate at Credit Suisse in the Fixed Income Division of the investment bank from 2010-2011 and began his career at Deutsche Bank Securities where he was an Associate Proprietary Trader and Portfolio Manager in the [Global Finance & Foreign Exchange Division](#) from 2006 to 2009.

Andrew received an A.B. in Economics, a Certificate in Finance, and a Certificate in French Language & Culture from Princeton University in 2006. He is an academic All-American in Baseball and is Princeton Baseball's All-time hits leader, 3-time Ivy League Champion and a 2002 Graduate of Phillips Academy in Andover, MA.

**William G. Meyer, III – General Council**

Mr. Meyer began practicing business law in Hawai'i in 1979. His practice emphasizes intellectual property law (including copyright, trademark and right of publicity licensing and registration, entertainment, trade secret, art and advertising matters); government relations; real estate matters; and related dispute resolution including litigation, arbitration and mediation.

For more than three decades, Mr. Meyer has provided creative legal and business guidance to a broad spectrum of individuals, companies and educational institutions, both in Hawai'i and on the mainland, including intellectual property owners, licensors and licensees such as artists, writers, photographers, television and film producers, composers, software and game developers, publishers, advertisers, broadcasters, art gallery owners, entertainers, recording artists, musicians, record labels, architects, scientists, apparel designers and merchandisers. Mr. Meyer's clients have included the University of Hawai'i at Mānoa, the University of Hawai'i at Hilo, national and international entertainment companies and many of Hawai'i's top recording artists, record labels and filmmakers.

Mr. Meyer's government relations work has promoted the diversification of Hawai'i's economy through the adoption of legislation which has enhanced the development of the creative and high tech industries. Mr. Meyer's real estate related practice has focused on the resolution of complex



disputes involving real estate development and sales transactions, land use, eminent domain, construction defects, government bid disputes and real estate broker issues.

Mr. Meyer has taught at the William S. Richardson School of Law, University of Hawai`i at Mānoa; the Pacific New Media Workshop, University of Hawai`i at Mānoa; and the Hawai`i Music Institute at Windward Community College and served as a court appointed mediator for the United States District Court for the District of Hawai`i in connection with intellectual property issues. Mr. Meyer is past Chair of the Intellectual Property & Technology Section of the Hawai`i State Bar Association, and a frequent speaker on intellectual property, music, art, advertising, e-commerce and Internet law topics, and has authored numerous articles and other materials on these topics, including continuing legal education materials for the Hawai`i State Bar Association and other organizations and publishers. Mr. Meyer was selected for inclusion in the 2008, 2009, 2010, 2011, 2012, 2013, 2014 and 2015 “Hawai`i Super Lawyers” in intellectual property and is peer review rated “AV” (preeminent) by Martindale-Hubbell, the highest rating available for legal ability and professional ethics.

Mr. Meyer is active in community organizations dedicated to the promotion of literacy, the preservation of Hawai`i’s host culture and the arts, devotes time to a pro bono practice which assists creative individuals with their legal and business issues and mentors young lawyers interested in the creative industries. Mr. Meyer has served on the Board of Governors of the Hawai`i Academy of Recording Arts, a Hawai`i non-profit organization, which each year presents the “Nā Hōkū Hanohano Awards” (which is similar to the Grammy® Awards and recognizes outstanding achievement in the recording arts in the State of Hawai`i) and the annual Lifetime Achievement Awards (which honors those who have made significant contributions to the music, culture and related arts of Hawai`i and/or the host culture of Hawai`i). See <[www.nahokuhanohano.org](http://www.nahokuhanohano.org)>. Mr. Meyer also serves on the Board of the Kaua`i Music Festival, the oldest and largest songwriters conference in the State of Hawai`i (see <[www.kauaimusicfestival.com](http://www.kauaimusicfestival.com)>) and acts as special counsel to the Hawai`i International Film Festival.

**Michael Rogers—*Cultivation Manager***

Michael Rogers holds a deep passion for sustainability and human welfare from his former career running an international gemstone trading business. Michael spent much time in the bush of Africa and Madagascar creating deep relationships with the poorest people of the world learning firsthand about the lives and woes of the “bottom billion”, at which point Michael made a decision to study sustainable agriculture and community development to improve people’s lives. Michael folded his business and attended the University of Hawai`i at Mānoa where he earned a degree in Plant Production and Management from the department of Tropical Plants and Soil Sciences in the College of Tropical Agriculture and Human Resources (CTAHR). During his time at the university, Michael was highly active in extracurricular activities being the president of the Horticultural Society, publishing articles regarding genetics and plant disease management, and creating a community composting facility with forced aeration to accelerate the composting process.

He is a certified permacultural designer and has work experience at a modern 2,500 acre farm where he was responsible for irrigation management, soil conservation projects, native plant



landscaping, plant disease management, and tractor operation. Currently, Michael serves on the board of advisors for Kumuola Foundation, a local non-profit organization based on a farm in the rainforests of Mānoa whose mission is to promote sustainable island living through agriculture, community, education, and practice of Hawai‘ian arts. Michael has a deep understanding of Hawai‘ian culture having a long history of dancing hula and receiving honors at the Merrie Monarch Hula Festival.

**Leo Rogers—Operations Manager**

Leo Rogers is a graduate of Roosevelt High School, and attended the University of Hawaii where he studied Kinesiology and Rehab Science. Being fully bilingual, Rogers spent 8 years working in the hospitality industry in various positions working both as a front-end and a back-end operator. He now works for Blue Planet Software as a project coordinator where he manages various projects including, digital assets, events, websites, and so on. His education, multi-cultural background, and years of experience working with customers, allows him to operate while having the medical patients best interest in mind.

**Advisory Board Members**

**Ken W. Leonhardt, Ph. D**

Ken has considerable experience in plant breeding, having created and introduced over 100 new varieties to Hawai‘i growers. Ken’s professional research focus is on polyploidy induction and creating sterility (seedless clones). Tetraploid forms of 22 species have been created. Only 2 other labs in the US focus on this kind of research (Dr. Ranney at North Carolina State U, and Dr. Contreas at Oregon State U). Tetraploid forms of Marijuana will have higher concentrations of CBDs and THCs.

Ken has familiarity with all sectors of agribusiness in Hawai‘i for 43 years and has acted as a crop science educator for the past 39 years. He was the owner/operator of a commercial ornamental plant nursery for 13 years (1975-1988).

As Chairman of the undergraduate program at the UH department of Tropical Plant and Soil Sciences, Ken is familiar with the top graduates, thus when BPH is looking to hire technicians with a crop science background, Ken will be able to source the top candidates. Ken also sits on the board of advisors for Medical & Product Testing – Hawai‘i MDs.

**Bradley J. Willcox, MD, M.Sc**

Bradley J. Willcox M.D., M.Sc. trained in Medicine at the University of Toronto, Internal Medicine at the Mayo Clinic, and Geriatric Medicine at Harvard Medical School. Dr. Willcox is Principal Investigator of the National Institute on Aging-funded Kuakini Hawai‘i Lifespan Study and Kuakini Hawai‘i Healthspan Study, which are ancillary studies on aging from the Kuakini Honolulu Heart Program. He is also Professor and Director of Research at the Department of Geriatric Medicine, John A. Burns School of Medicine, University of Hawai‘i, located on the Kuakini Health System campus. Dr. Willcox is the Co-Principal Investigator of the Okinawa Centenarian Study and has been investigating mechanisms of aging for almost two decades with this study. Clinically, he runs the Long Term Care Hospitalist Program at The Queen’s Medical Center, where he is a three time nominee for Physician of the Year.



Dr. Willcox’s research teams have identified several important genetic and environmental risk factors for aging and aging-related chronic diseases. His research team in Okinawa identified the first longevity-associated gene, and his research team in Hawai’i was the first to identify the association of the FOXO3 gene with human longevity and he has greater than 150 peer-reviewed scientific publications.

Dr. Willcox is on the Editorial Board of several leading gerontological journals, including the Journals of Gerontology. He has been recognized with a Dorothy Dillon Eweson Award for Advances in Aging Research, the Henry Christian Award from the American Federation for Medical Research, a Director’s Citation from the Centers for Medicare and Medicaid Services, and other honors. Dr. Willcox is also the author of a New York Times best-selling book on healthy aging, *The Okinawa Program*. His work has appeared in cover articles of *Time Magazine*, *National Geographic*, and on *Oprah*, *Good Morning America*, *NOVA Science*, *BBC*, and other media.

## **Consultants**



### **American Cannabis Company, Inc. (“ACC”) Company Profile**

BPH has hired and retained American Cannabis Company, Inc. (“ACC”), a marijuana-industry consulting firm that offers advisory and consultation services related to establishing operations, the implementation and execution of the operating plan, staff training, compliance, and other critical operational needs. ACC collectively brings over twenty years of knowledge and practice operating within the regulated, legal medical marijuana industry. The company has particular expertise in marijuana cultivation methods on a commercial scale and manufactures multiple industry-specific cultivation and retail solutions. As BPH’s consulting partner, ACC will help ensure that BPH has the knowledge and expertise necessary to establish compliant operations rapidly while achieving its quality goals for the brands it produces for qualifying patients in the State of Hawai’i.

### **Executive Summary**

- Based in Denver, Colorado
- Consult, advise, & provide equipment and supplies to businesses entering or currently operating in *regulated* cannabis industries
- Currently serve clients in 14 states & Canada
- Have assisted clients in winning 10+ licenses in 5 five states
  - Business & operational plans, pro-forma, market study, & application
  - Facility design, equipment selection, & construction management
  - Facility roll-out, employee training, & on-going cultivation management
  - On-going retail, operational, & compliance monitoring

### **Industry Successes**



American Cannabis Company					Cumulative
Year	State	W	L	Total	Client W %
2013	Connecticut	1	0	1	100%
2013	Massachusetts	1	2	3	50%
2014	Nevada	6	1	7	73%
2014	Minnesota	1	0	1	75%
2014	Illinois	2	4	6	61%
<b>Total</b>		<b>11</b>	<b>7</b>	<b>17</b>	<b>61%</b>

### **ACC Vision**

We are redefining society's relationship with cannabis through responsible stewardship.

### **ACC Mission Statement**

With our expert teams we establish and service regulated cannabis markets globally providing best in industry solutions that continue to exceed the requirements of the evolving cannabis industry thus ensuring our client's success through superior service and deep industry knowledge.

### **ACC Core Values**

1. Accountability & Professionalism
2. Integrity
3. Open, Transparent, & Respectful Communication
4. Passionate Teamwork
5. Sustainability

### **About The American Cannabis Company**

American Cannabis Company (ACC) was founded to meet the needs of the rapidly developing cannabis industry, including: medical, commercial and industrial hemp operators. We are experienced in cultivation, infused products and retail operations within regulated cannabis markets, as well as, establishing successful companies within the emerging limited licenses markets. From merit based applications, to facility design and deployment, to managing ongoing operations ACC has the experience and expertise to guide your business in the competitive cannabis space. Currently, we've operated in nine states and in the country of Canada. Our company focuses on providing services and products to the cannabis industry through our two operating divisions:



### **Company Ownership & Legal Entity**

American Cannabis Company, Inc. is a Delaware corporation with its headquarters in Denver, Colorado. ACC Inc. is a public company and trades under the stock ticker AMMJ on the OTCQB stock exchange.

### **Services, Equipment & Supplies**

Through its two divisions American Cannabis Consulting and The Trade Winds, American Cannabis Company provides its customers a full solution for success. From bringing your idea to a reality to ensuring it performs beyond expectation, ACC has the people, partners and products to ensure success.

### **ACC Services**

American Cannabis Consulting is the premier advisory agency for those seeking to achieve success in the highly competitive and rapidly expanding commercial cannabis industry.

Whether you're preparing to enter the market or already have a footprint, our team of industry leaders can help your business reach its potential while meeting the necessary regulatory framework. With first-hand experience in regulated commercial Cannabis cultivation since 2009 and backed by accomplishments in related industries such as healthcare and horticulture, we have the knowledge and resources to guide you through every aspect of growing your Cannabis business.

### **Cannabis Industry Research & Design**

Our knowledgeable team identifies needs in the marketplace and develops next generation products to fill those needs. Our in-house products include:



- The Cultivation Cube™: The foundation for a complete, commercial-scale grow operation, the Cultivation Cube provides exceptional environmental control, speed-to-market, production, space efficiency, lean manufacturing and security.



- SoHum Living Soil™: A 100% natural growing medium, SoHum Soil prevents an improper balance of nutrients, improves plant immunity, and is more cost-effective than traditional soil and fertilizer growth methods.



- The Satchel™: The Satchel is a pouch-like case for Cannabis and Cannabis-infused products that was designed to meet regulatory compliance with laws that require child-resistant exit packaging for licensed medicinal and recreational Cannabis businesses.

### **ACC Equipment & Supplies**

From cultivation necessities to retail goods to ancillary products like office supplies and cleaning agents, The Trade Winds can address your business' needs quickly and cost-effectively. The products we carry are carefully selected by our professionals and represent best-in-class solutions for the developing commercial cannabis markets. We continue to strive to realize solutions that improve our Client's business operations.

American Cannabis Company is proud to offer compliant, solution-based products and services to commercial cannabis cultivation and cannabis retail businesses.

### **ACC Management Consulting**

With hands-on experience in commercial cannabis cultivation, the team at American Cannabis Company has the knowledge and resources to help your crop and your business realize their potential. From Cultivation, through processing and into retail sales, our team has firsthand knowledge and experience.

Our goal is to lead you through a successful development and launch process, and to work with you to help your cultivation business grow into the future. As part of the design and build out of your business, our advisory services will focus on key elements that include:

- Business and operational plan
- Pro-forma financials
- Business plan writing
- Standard operating procedures



- Protocol based workflow
- Retail Strategies
- Retail Operations
- Regulatory compliance
- Market modeling and forecasting
- Security and safety measures
- Equipment and technology purchasing
- Quality control
- Direct staffing and/or recruitment and training
- Facility design and build-out
- Construction Management
- Patient centric strain selection
- Methodology selection
- Perpetual harvest and workflow requirements to meet patient demand
- Environmental controls
- Integrated pest management

**Andrew W. Bachman, MD, FACEP**



**LeafLine Labs, LLC, cultivates, processes, and distributes medical cannabis formulations in Minnesota.**

Founded in 2014 by Board-Certified Emergency Medicine physician, Andrew Bachman, MD, and his team, LeafLine Labs, LLC, is registered to cultivate, process, and distribute medical cannabis formulations in Minnesota’s “extraction-only” medical program. It provides expertly-crafted medicine and compassionate care for suffering patients with currently approved conditions such as cancer with specified complications, glaucoma, HIV/AIDS, Tourette’s Syndrome, ALS, Intractable Seizure Disorders, Muscle Spastic Conditions (e.g., Multiple Sclerosis), Crohn’s Disease, Terminal Illness, and Intractable Pain.

LeafLine Labs actively cultivates dozens of selected medical cannabis strains in a specifically-designed and newly-constructed 42,000 SF pharmaceutical-grade facility, ideally situated on 24 acres, optimized for plant health, production, sustainability and reproducibility. All medicinal compounds are then efficiently separated from the fibrous plant material using industry-leading scientific techniques and technology by our medically-experienced extraction team, which allows for innovative medicine formulation with NO harsh diluents, additives or toxic solvents employed.

Every lot of “whole plant extract” medicine is rigorously tested for chemical composition, potential contamination, consistency and purity at one of only two independent, state-sanctioned



and regulated laboratories in Minnesota. Our medication formulations contain standardized, proprietary cannabinoid profiles, including set ratios of CBD, THC, etc., that aid in the treatment of a variety of medical conditions and ameliorate a variety of medical symptoms for Minnesota's suffering patients with qualifying conditions. The final preparations are then clearly packaged as capsules, oils for vaporization, syrups & suspensions, tinctures, and sublingual sprays, and labelled accordingly to pharmaceutical-grade specifications.

LeafLine Labs' Headquarters and primary production facility is located in the Minneapolis/St. Paul suburb of Cottage Grove, MN, with our flagship cannabis care center opened in Eagan, MN, on July 1, 2015. A care center in St. Cloud, MN, (in close proximity to one of the nation's largest V.A. Hospitals) is nearing completion presently, with subsequent care centers in St. Paul and Hibbing, MN, slated to open by July 1, 2016. LeafLine Labs is well-supported & well-capitalized with nearly \$16M raised through vetted and approved investors to date, many of whom are physicians and/or professional caregivers in Minnesota and beyond.

#### **Marisa Kesaji** - Pharmacist Consultant

Marisa Kesaji, a graduate of Roosevelt High School (Summa Cum Laude) received her Doctor of Pharmacy (PharmD) degree from the University of Southern California. Kesaji has extensive experience as a registered pharmacist in both Hawai'i and California. Being a former Chief Pharmacist, she will be able to help develop policies and procedures to ensure safety and monitoring of products.

#### **Greta Inofer, R.N.** – Patient Advocacy Nurse

With over 5 years of experience as registered nurse, Greta's brings with her expertise in case management, care coordinating, private practice clinic, skilled nursing, and dermatology. She currently works as a registered nurse as a case manager, facilitating face-to-face patient visits to ensure that their current medicinal needs are met. As a health and wellness coach, Greta also bring her skills to work with individuals on how to be healthier mentally and physically through proper nutrition and functional fitness. Prior to this, Greta managed administrative operations at a care home, maintaining 26 staff members at a 24 bed facility. It was there where she established and implemented care protocol ensuring all regulations were met. Greta is recognized as an excellent team leader and problem solver with expertise in health and wellness, quality, utilization, and risk management. Greta is a member of the American Cannabis Nurses Association, the only nursing educational and advocacy organization representing endocannabinoid therapeutics in the United States.

#### **Licensing Agreements**

To further strengthen BPH's operational strategy, BPH has entered into an agreement with UNDRNWMNGMNT, LLC. ("UNM"), an established marijuana product manufacturing-licensing company headquartered in Colorado since 2010. Under its agreement with UNM, BPH will have the exclusive right, in Hawai'i, to manufacture marijuana infused products using UNM's proprietary techniques and processes. UNM will also provide consultation and serve as an advisor to BPH in all aspects of manufacturing marijuana products. UNM licenses its proprietary manufacturing methods, industry experience and compliance services to clients in several states. UNM specializes in pharmaceutical-grade marijuana extraction, production, formulation,



packaging and branding of dosed and tested products for regulated MM markets. UNM has been consistently recognized by dispensaries, physicians and patients for the quality and consistency of the MM products created using their proprietary techniques. MM industry experts have also awarded UNM multiple honors for the quality of their products and approach toward patient education and the safe use of MM.

UNM currently operates within Colorado's legal marijuana industry and will provide deep industry knowledge and experience to BPH upon deployment of BPH manufacturing operations. BPH will utilize established standard operating procedures, extraction methods, and recipes for the manufacturing of all marijuana products.

### **Mission Statement**

To provide relief that Hawai'i patients deserve through high quality, sustainable, and responsibly grown medical cannabis.

### **Goals and Objectives**

In order to fulfill the mission statement, BPH has a set of goals and objectives that guide the business.

1. Develop a dispensary environment that gives the most access and relief to the patients
  - a. Dispensary shall be located in a location with ample parking at a central location
  - b. Dispensary shall have a welcoming look and feel that provides the patient with comfort through their retailing experience
  - c. Patient will be supported with professional consult and education
  - d. Product will be offered at an affordable price
  - e. Patient needs will be met with the availability of most appropriate and high quality medicine
2. Develop a cultivation and manufacturing facility that is sustainable and responsible
  - a. Quality of the products produced shall meet the highest standards for the benefit of the patients
  - b. High biosecurity standards will be put in place to minimize introduction of pests and disease
  - c. All product will be subject to high standards of cleanliness and consistency as a medical grade product
  - d. Create a safe working environment with zero work-related accidents
  - e. Achieve maximum energy efficiency and use clean energy sources
  - f. Create a sustainable material flow where inputs and wastes are minimized
  - g. Wastes are collected and disposed of in a secure manner
3. Inventory will be tracked, secured, and kept clean at all times
4. Every facility and transportation of product will be entirely secure 24/7
5. BPH will continuously strive to achieve excellence and everyday will be an improvement of the last
  - a. The most latest and reliable medical information will be sought after and implemented to benefit the patients
  - b. New technologies and methodologies will be sought after and implemented to benefit the patients



- c. Regular employee training will cover all aspects of their operations as well as promote a corporate culture of human resource development and community development

### **Business Philosophy**

BPH's business philosophy is to cultivate, produce, manufacture, and dispense marijuana and manufactured marijuana products of the highest quality and with the highest regard for health, safety, security and efficacy for registered employees, business partners and qualifying patients.

### **Business Market**

The marijuana and manufactured marijuana products offered by BPH will be intended for retail dispensing to qualifying, registered patients and primary caregivers in Hawai'i. The end consumer of the products produced by BPH will be registered patients in the State of Hawai'i. Currently there are more than 12,000 qualified, registered medical marijuana patients within the state of Hawai'i. The current business market for BPH products is further explained within BPH's financial pro-forma model. The financial pro-forma model is a separate, additional document detailing financial forecasts, ROI, growth opportunities and estimated capital requirements.

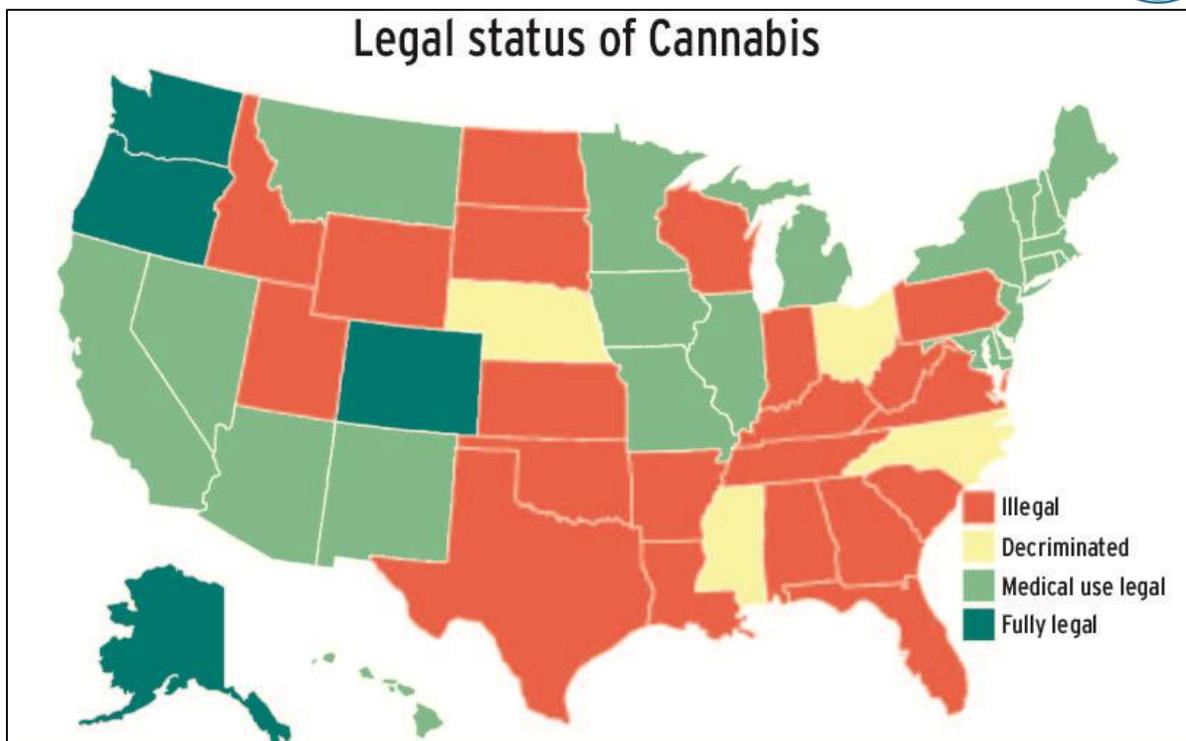
### **Industry Description**

The medical marijuana industry is an industry experiencing rapid growth and advancement. There are currently 23 states and the District of Columbia with medical marijuana laws on the books, 3 states with pending medical marijuana legislation and the states of Colorado, Washington, Oregon and Alaska with legal recreational marijuana laws.

With advances in modern medical research and marijuana research; we feel the medical marijuana market will continue to expand and develop in the years to come. More states each year are drafting legislation for medical marijuana as well as recreational use of marijuana and this trend does not show signs of decline.

### **History**

In 1996, nearly 60 years after the US government outlawed marijuana, California became the first state to legalize marijuana for medical use. Since then, 22 additional states as well as Washington DC have followed suit, bringing the total to 24.



\* <http://universe.byu.edu/2015/06/27/advocates-of-medical-marijuana-fight-for-its-legalization-in-utah/>

Despite the growing number of states involved, the medical marijuana industry remained fairly small for years, with only a limited number of dispensaries, primarily in California, operating under the constant threat of government raids.

A big breakthrough came in 2009 in the form of the “Ogden Memo,” a document instructing federal prosecutors to refrain from focusing their resources on prosecuting medical marijuana operations in states with medical marijuana laws. (<http://www.justice.gov/opa/blog/memorandum-selected-united-state-attorneys-investigations-and-prosecutions-states>)

This led to the opening of several thousand dispensaries across the country. For the next few years, the industry became very erratic due to numerous legal limitations on both the federal and local level. Due to the constant changing regulations and the reluctance from the investor community, the 2011 “breakout year” never materialized. The industry shrank by an estimated 15-20% as hundreds of dispensaries closed and patient numbers dropped.

The industry persisted through 2012 and the momentum rapidly changed. The US Department of Justice released the 2013 “Cole Memo”, which essentially authorized the medical marijuana industry. (<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>) Several new states began legalizing medical marijuana while other states that were in a holding pattern moved forward with plans to allow dispensaries to open up under tight regulations. Massachusetts was one of the states that made significant progress with their dispensary programs, setting the stage for 2014.



Medical marijuana states showed growth in 2014 from both former medical marijuana markets as well as new ones that just started awarding business licenses. The federal government released new guidance for financial institutions when dealing with medical marijuana dispensaries, providing relief for the industry; the FinCEN Memo. ([http://www.fincen.gov/statutes\\_regs/guidance/pdf/FIN-2014-G001.pdf](http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2014-G001.pdf).)

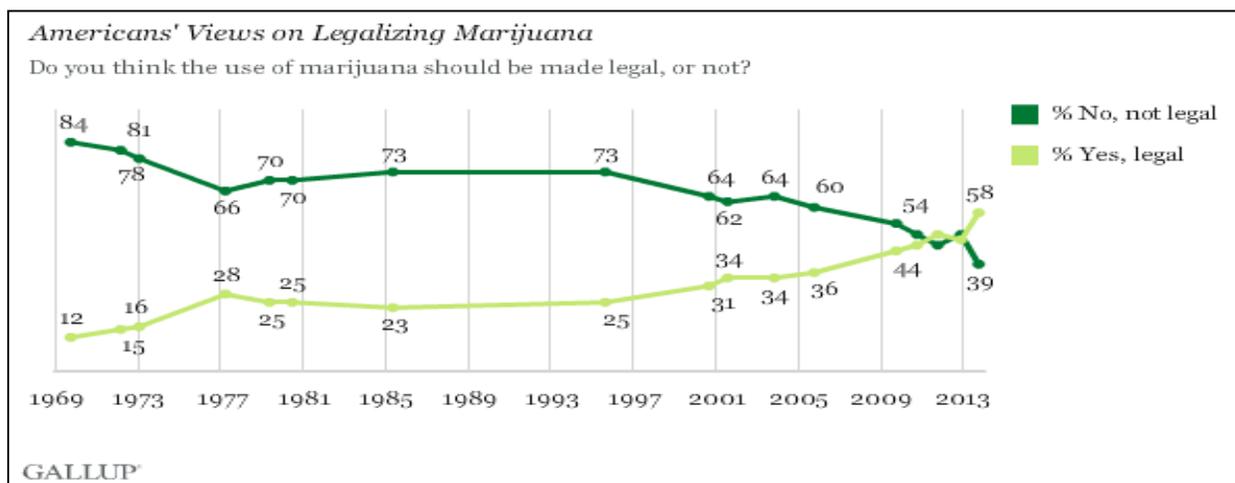
The FinCEN memo provides clarity to enhance the availability of financial services for marijuana businesses promoting greater financial transparency in the marijuana industry mitigating the dangers associated with conducting an all-cash business. The memos guidance also helps financial institutions file reports that contain information important to law enforcement.

### Trends in Social Acceptance

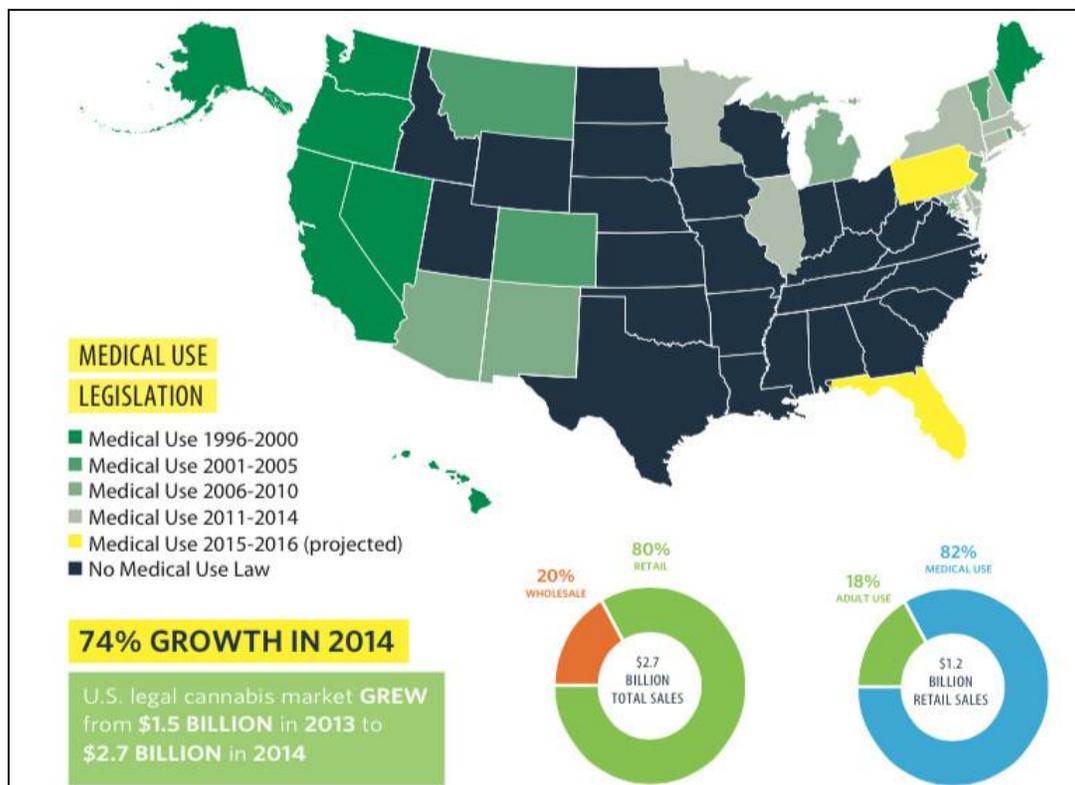
The unique therapeutic properties of pharmaceutically active compounds embedded within the marijuana plant genus have been globally neglected and overlooked for most of the 20th century, due to the classification of the plant and its active cannabinoid ingredients as “Schedule I” substances that allegedly have no medical use or benefit.

In recent years, public opinion on this matter has changed rapidly as more and more social awareness groups have promoted the full or partial legalization of the marijuana plant, while a substantial amount of scientific data, that illustrate the medical benefits of marijuana, has been generated by clinical and basic science researchers.

This social consciousness change has been dramatically illustrated by a poll performed in 2013, in which, for the first time in decades, a majority of Americans polled for approval of legalization of marijuana in the United States.



\* <http://www.thefiscaltimes.com/Columns/2014/01/03/Why-Legalizing-Marijuana-Smart-Fiscal-Move>



\* [http://www.huffingtonpost.com/2015/01/26/marijuana-industry-fastest-growing\\_n\\_6540166.html](http://www.huffingtonpost.com/2015/01/26/marijuana-industry-fastest-growing_n_6540166.html)

### **Company Strengths and Core Competencies**

BPH strengths and core competencies will be the cultivation and manufacturing process and techniques utilized by BPH. The cultivation techniques utilized by BPH will produce high grade medical marijuana of pharmaceutical quality for the qualifying patients of Hawai‘i. Through the adoption of well-established cultivation processes and methodologies from BPH’s operating partners HCH and HCH’s experience within the regulated marijuana industry will prove most beneficial for BPH’s success with organization goals and objectives.

BPH intends to produce and dispense medical marijuana and manufactured marijuana products of the highest pharmaceutical grade quality. BPH’s operating partner HCH will spearhead the implementation and execution of organization plans and goals pertaining to cultivation and retail dispensing operations. HCH brings years of knowledge and practice within the legal medical marijuana industry to the table. HCH currently operates three (3) medical marijuana retail dispensary locations and three (3) recreational marijuana stores and six (6) production centers in Colorado, all in full legal compliance with state and county law.

HCH will bring operational knowledge and experience to BPH and will become the “boots on the ground” for the deployment of BPH cultivation and retail dispensary operations. HCH will fully prepare BPH registered employees on all aspects of the business before commencing any operations. Training and education will be all encompassing; covering regulatory compliance, seed-to-sale tracking, patient advocacy, Point-of-Sale training, security and diversion, health and



safety, sanitation, transportation, also including all cultivation processes and applications, manufacturing of edibles and infused products.

A patient-centric focus at the retail dispensing locations will set BPH apart from other registered retail dispensary locations. All dispensing registered employees will receive training and education to acquire vast knowledge regarding medical marijuana; including genetic and strain varieties, recommended dosage rates, possible effects, etc. This will allow dispensing registered employees to be able to offer recommendations suited for each individual qualified patient.

BPH also has strengths in the high tech industry that would be vital in placing the company at the fore front of the industry. BPH intends to utilize its expertise to create smart, efficient, and effective systems at every aspect of its operations including energy efficiency, controlled cultivation, manufacturing, and patient outreach.

### **Legal Form of Ownership**

BPH is a Limited Liability Company (“LLC”). BPH chose this entity form for various reasons including the taxation structure of an LLC. A Limited Liability Company is a legal form of a company that provides limited liability to the owners. An LLC is a business structure that combines the pass-through taxation of a partnership or sole proprietorship with the limited liability of a corporation.

Hawai‘ian residents own 77.75% of the total ownership interest of BPH.



## Products and Services

The products offered by BPH will be a wide variety of marijuana strains as well as a vast product line of manufactured marijuana products including oils and oil extracts, tinctures, topicals such as skin lotions and ointments, capsules, pills and lozenges. BPH goal is to legally source high quality marijuana strain varieties that are specifically geared towards the treatment and alleviation of symptoms associated with qualified medical marijuana patients.

BPH intends to produce pharmaceutical grade marijuana products that unlock the palliative properties of the plant and deepen our understanding of the endocannabinoid system and its role in human health. We have a three point strategy to achieve this. First we will produce products with stringent quality standards. Next, selecting strains/genetics with desirable palliative qualities and from these produce product options that don't conflict with a doctor's normal ethical treatment protocols such as smoking or eating unhealthy foods. The strains intended to be utilized will be high in cannabidiol (CBD) or have Tetrahydrocannabinol/cannabidiol (THC:CBD) ratios that have demonstrated efficacy for qualifying conditions. Finally, through production and product strategies coupled with rigorous testing we will overcome one of the most significant hurdles for the medical marijuana industry, which is consistency of dosage and cannabinoid profile.

The cultivation of marijuana will include a wide variety of marijuana strains; all strains will be unique and have different medical values and benefits. Marijuana varieties will include different strains from indica, sativa, hybrid and CBD dominant genetics. Patients will experience different desired effects from different marijuana variety strains and genetics.

BPH will process the high grade medical marijuana produced into various manufactured marijuana products using only high quality ingredients for final products. BPH has entered into a licensing agreement with UNM, a well-known manufacturer of marijuana-infused products. UNM currently has legal operations in full compliance with the regulations in Colorado. UNM will provide established operational procedures, methods and recipes for BPH manufacturing operations allowing BPH to deploy operations with pre-established, proven recipes. This will allow BPH to immediately start manufacturing marijuana products that are consistent and reproducible for qualifying patients.

### **Marijuana Flower**

- *Description*—BPH intends to cultivate and dispense approximately 10-15 strains of marijuana ranging from those with a high level of THC and low level CBD to those with a high level of CBD and low level of THC. These strains will include Indica varieties, Sativa varieties, and hybrid strains that will be a blended variety with effects similar from both sativa and indica varieties.
  - Besides appearance, indica and sativa plants are commonly believed to have different effects on their user. These effects include sativa being more uplifting and energetic, and best suited for day use while Indica is considered more relaxing and calming and is best suited for night use.
- *Benefits*—the evidence is overwhelming that medical marijuana can relieve certain types of pain, nausea, vomiting and other symptoms caused by such illnesses as multiple



sclerosis, cancer and AIDS – or by the medical compounds frequently used to treat them. Additionally, it has proven benefit in the management of post-traumatic stress disorder.

- *Strengths*—medical marijuana can treat symptoms remarkably safely and considered less toxic than many pharmaceuticals.
- *Weaknesses*—because marijuana is federally illegal, there has not been enough scientific research done to determine the true effectiveness of the medicine. Patients are not able to get exact dosing recommendations from medical professionals.

### **Medical Manufactured marijuana Products and Concentrates**

BPH will create products that are convenient for administration of the active ingredient, medical marijuana. Our goal is to create various dosage forms that will make administration of medical marijuana convenient, easy, and palatable for qualified, registered patients in Hawai'i.

- *Product Description*—manufactured marijuana products are made with marijuana as an ingredient. They can come in the form of oils and oil extracts, capsules, pills, lozenges, sublingual tinctures, and topical(s) such as skin lotions or ointments.
- *Product Benefits*—the benefit of manufactured marijuana products is that they offer patients an alternate delivery means to experience the effects of cannabinoids without smoking or vaporizing marijuana. Alternative ingestion methods that offer consumers cannabinoid delivery formats other than smoking are one of the fastest growing segments of the marijuana industry.
- *Product Strengths*—an easily administered option for taking medical marijuana products. It improves dosing calibration and benefits from the convenience of portability.
- *Product Weaknesses*—it can take longer to feel the effects of the medical marijuana product. It is often considered to have stronger effects than inhalation of medical marijuana products.

### **Products Blue Planet Healing intends to produce include:**

#### **1) Inhalable Marijuana Products**

**a. Raw Flower:** Multiple genetics and strain varieties of indica, sativa, and hybrid marijuana will be cultivated. Different medicinal values and benefits will be obtained through different indica, sativa, and hybrid marijuana strains. Raw flower will typically be smoked or vaporized by qualified patients.

- Indica marijuana strain varieties
- Sativa marijuana strain varieties
- Hybrid marijuana strain varieties
  - Flower products will be packaged in quantities of:
    - a. 1 gram packages (1 gram)
    - b. 1/16<sup>th</sup> packages (1.75 grams)
    - c. 1/8<sup>th</sup> packages (3.5 grams)
    - d. Ounce packages (28.35 grams)

**b. Marijuana Concentrates:** Marijuana concentrates are a concentrated form of marijuana, the concentrated form is very potent and high in THC content.



Marijuana concentrates are made from extracting the cannabinoids from the marijuana plant material. Marijuana concentrates can be made into various forms and products including but not limited to CO<sub>2</sub> oil and oil extracts, sublingual tinctures, capsules and topical(s) like skin lotions or ointments. Once extracted, the concentrated marijuana oil will be used to make all BPH manufactured marijuana products.

- CO<sub>2</sub> Oil and Oil Extracts
  - Pre-filled vaporizer cartridges (250 mg and 500 mg)
  - Pre-filled metered dosage syringe
  - Shatter (1g quantity)
  - Wax (1g quantity)
- Ingestible Marijuana Products
  - Capsules
  - Pills
  - Lozenges
  - Tinctures
- Topicals
  - Skin lotions
  - Ointments

## 2) Ingestible Marijuana Products

- a. **Sublingual Tinctures:** Tinctures are a form of liquid ingestible marijuana. Tinctures will be consumed by placing the liquid tincture under the patients tongue, drinking the liquid tincture alone or mixing the tincture with tea or some other beverage.
- b. **Pill-Form/Capsules:** Edible pill form marijuana products will be beneficial to patients that cannot or prefer to not vaporize marijuana. Medical marijuana patients will ingest the edible pills in order to receive the medicinal benefits of marijuana.

## 3) Topical Marijuana Products—*ointments and skin lotions*

- a. **Topical(s):** Topical(s) will include ointments and lotions that can be utilized by medical marijuana patients looking to alleviate ailments through topical use. Topical(s) are rubbed on the skin or area needed by a medical marijuana patient.

## Quality of Products

Cultivating marijuana of the highest quality will be the driving force behind BPH's marijuana cultivation efforts. The marijuana is being cultivated for medicinal purposes; qualifying, registered patients in the State of Hawai'i with debilitating medical conditions will be consuming the marijuana to alleviate ailments and as such we believe in utilizing natural cultivation methodologies and techniques to produce marijuana of the highest quality. All marijuana cultivated by BPH will be free of any residual contaminates or pests and will pass all required state testing standards.



BPH will identify State-licensed testing laboratories located in Hawai‘i to conduct product testing on every batch of marijuana cultivated as well as all manufactured marijuana products batches as required by regulations. BPH will utilize a quality management program to ensure there are no deviations in the cultivation or manufacturing processes.

### **Product Pricing**

BPH’s will endeavor to make medical marijuana and manufactured marijuana products affordable and accessible to the registered patients of Hawai‘i. BPH has created a financial pro-forma model that details estimated pricing for cultivated marijuana and manufactured marijuana products. This financial model is a separate, additional document that can be seen in full for a more detailed breakdown of the pricing strategies.

Pricing for all BPH marijuana and manufactured marijuana products will be based on the current fair market value of said items. Pricing will also be computed to ensure BPH is profitable and able to continue operations and pursue growth strategies. Different pricing structures and strategies will be utilized by BPH for determining pricing on cultivated marijuana and processed manufactured marijuana products. Pricing structures will be identified upon deployment of operations to ensure all cost associated with the marijuana product or the manufactured marijuana products are captured to, at a minimum, be able to recoup the cost of production.

**Cultivated Marijuana:** Pricing will be based on cost of production, harvest yield, cost of dispensing, and fair market value of marijuana. The pricing model used to forecast cultivated medical marijuana pricing was based from numbers and figures from the regulated marijuana market in Colorado.

**Manufactured Marijuana Products:** Pricing will be based on cost of production, cost of dispensing, and fair market value for manufactured marijuana products. The pricing model used to forecast processed medical manufactured marijuana products pricing is based upon publically available data and use figures from the regulated marijuana market in Colorado.

*\*Please see financial pro-forma model for a detailed breakdown of BPH estimated pricing structures.*

BPH will also develop and implement a patient hardship program. The patient hardship program will be created for the purpose of helping state registered patients obtain medical marijuana in the situations where said patients cannot financially afford the medication.

### **Patient Hardship Pricing Program**

BPH will coordinate with registered dispensary customers (i.e. qualifying, registered patients) to provide financial assistance to patients who are unable to afford medicinal marijuana and/or manufactured marijuana products. BPH will strive to ensure that financial issues do not prevent qualifying patients from seeking or receiving care. BPH will use the Federal Poverty Level as a guide to provide discounted medicine to individuals who meet the policy’s criteria. BPH will rely upon the Census Bureau’s definition of a family and family income when computing federal poverty level guidelines. If the qualifying patient’s income and household falls within 300% of the published guidelines, the qualifying patient will be provided medicine at a reduced cost according to the following conditions:



1. For those qualified patients who are between 0 to 300% of the federally recognized poverty level the price will be at a 30% reduction;
2. For those qualified patients who are at or below the federally recognized poverty level the price will be 50% to 75% reduced, depending on circumstance;
3. For hospice patients, veteran's home residents, and veterans, there shall be a reduced price, depending upon the financial circumstance.

Eligibility will be based upon a determination of financial needs in accordance with the policy. In order to receive financial hardship benefits, qualifying patients must fill out a required application. The application will include mandatory attachments that document proof of income. Applicant will have the option to submit all of the following documents: W-2, paycheck stubs, income tax return, forms from Medicaid or other state-funded medical assistance programs, or forms from employers or welfare agencies. Other circumstances that will be taken into consideration are bankruptcy settlements and catastrophic situations (death, disability in family, divorce). Applicants without the above mentioned proof must provide documentation that shows the patient is unable to pay their medical marijuana bills and still be able to pay for other basic necessities. It shall not take into account age, gender, race, social or immigrant status, sexual orientation, or religious affiliation. This application must be completed annually in order to be placed in the BPH financial hardship program. Any denial of the discount/no cost request will be documented as such, and instructions for reconsideration will be provided by the BPH. All applicants and their records will be kept confidential. Patients are expected to contribute to the cost of care based on their ability to pay. This policy assures access to medicine and protects the assets of financially needy qualifying patients. Individuals with the financial means to pay for medicine shall be urged to do so within the guidelines of federal law. BPH shall notify qualifying patients of its financial assistance policy by posting notices at the registered dispensary locations and on the company website and providing the information directly to qualifying patients.

### **Proposed Location**

The proposed location BPH is considering for the production center is located in the county of Honolulu. The proposed location BPH is considering for the retail dispensing locations will also be located in the county of Honolulu. BPH will ensure locations meet all zoning requirements and that all applicable state and county law will be complied with. There will be ample parking on site for registered employees at the cultivation/production facility; there will also be ample parking for registered employees and qualifying patients and customers at the retail dispensing locations. Both locations will be of adequate size and space for the cultivation, manufacturing and dispensing of marijuana and manufactured marijuana products.

[REDACTED]

- Easy access – excellent location for patients being in the Kapiolani corridor in the heart of Honolulu, adjacent to Ala Moana shopping center



- [REDACTED]
- [REDACTED]
- [REDACTED]
- Welcoming dispensary look & feel – the dispensary location will focus first and foremost on the patient’s comfort and accessibility.
- The dispensary location will be clinical, using medical grade furniture, ADA compliant.



## Operational Plan

Operations is an area of greatest significance to BPH. Success will be dependent on navigating a complex series of actions and adaptations. BPH has enlisted the help of expert consultants and operators to provide and follow detailed operating procedures. In addition, these operators and consultants have aided our careful and innovative building designs. The focus in Operations will be continuous improvement, product safety and customer satisfaction. BPH will foster communication between registered employees and track performance measurement in all areas to optimize efficiency and effectiveness. We will strive to maximize product yields and potency using best practices gleaned from across the regulated marijuana industry.

### Education and Training

BPH will utilize the operational experience and knowledge from HCH to provide extensive training and education for all registered employees. All BPH employees will receive extensive training prior to commencing work in any BPH registered dispensary facility. Registered employees will be required to read the relevant state and county law pertaining to medical marijuana in order to have a general understanding of the laws and regulation with which that they must comply. Training for all cultivation and retail dispensing operations will be provided by our operating partners HCH, training will also be provided from selected 3<sup>rd</sup> party security vendor Securitas, BioTrackTHC™ inventory control systems and POS vendors, UNM for manufacturing operations and CO<sub>2</sub> extraction machine vendors, and other subject matter experts. Training will include an extensive hands-on approach and the use of Standard Operating Procedures (SOP's) and various other materials and methods as deemed appropriate.

BPH will utilize targeted training materials and programs for different operations occurring at BPH licensed facilities. There will be specific training for registered employees involved within cultivation operations, processing/manufacturing operations, and retail dispensing operations. Ongoing and cross-functional training will be continued as operations commence. All registered employees will also be required to receive training on general sanitary requirements. Registered employees will be required to read and agree to comply with the company Employee Handbook, SOP's, and other materials BPH deems necessary prior to commencing work in any BPH facilities.

HCH will fully prepare facility staff on all aspects of the business before operations are commenced. Training and education will be all-encompassing, covering regulatory compliance, seed-to-sale tracking, patient service and advocacy, point-of-sale training, dispensing, security and diversion prevention, health and safety protocols, sanitation, transportation, also including all cultivation, extraction and manufacturing processes, and organizational functioning within a vertically-integrated operation. Registered employee training will cover but not be limited to the following:

- Standard Operating Procedures (SOP's)
  - Cultivation Operations SOP's
    - Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH cultivation operations.
  - Manufacturing Infused Products (MIP) Operations SOP's



- Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH manufacturing infused products operations.
- Retail Dispensing Operations SOP's
  - Standard Operating Procedures detailing and explaining the various daily operations, activities, tasks, and responsibilities associated with BPH retail dispensing operations.
- Log Sheets and Templates
  - Numerous log sheets and templates for proper record keeping and documentation for all operations including cultivation, MIP, and dispensing
- Responsible vendor training
- Patient education information
- On-site training
- Initial job training
- Job shadowing
- Employee educational information

**Laws and Regulations/Compliance Training**—Adhering to all state, county, and company regulations is of utmost importance to create an end product with efficacy for patients. All BPH registered employees will be required to have a general knowledge of all applicable laws and regulations dealing with the regulated cultivation, manufacturing, and dispensing of medical marijuana and manufactured marijuana products.

- **Federal Laws**— BPH management will make available to its employees copies of various Federal laws and memos concerning medical marijuana, including:
  - *Controlled Substances Act:*  
<http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm>
  - *Ogden Memo:* <http://www.justice.gov/opa/blog/memorandum-selected-untied-state-attorneys-investigations-and-prosecutions-states>
  - *Cole Memo:*  
<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>
  - *FinCEN Memo:* [http://www.fincen.gov/statutes\\_regs/guidance/pdf/FIN-2014-G001.pdf](http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2014-G001.pdf)
- **Policies Regarding Regulations**—it is the duty of BPH management to ensure regulatory requirements are followed at all times by all registered employees. Management shall maintain a zero tolerance policy for any infractions that would violate state, local, or company-level regulatory measures.
- **Current Regulations**—access to the current State of Hawai'i medical marijuana laws and regulations will be provided to all BPH employees prior to commencing work in any BPH facilities.



- **State of Hawai'i Regulations**—The State of Hawai'i laws and regulations regulating the medical marijuana industry can be obtained from State of Hawai'i Department of Health
  - <http://health.Hawai'i.gov/medicalmarijuana/submenu/doh-medical-use-of-marijuana-administrative-rules-effective-july-18-2015/>
- **New Regulations**—All new regulations shall be followed as of their effective date. Training of new employees regarding newly enacted State regulatory measures shall take place before the effective date of said newly enacted State regulation(s) in order to ensure that all team members have a complete understanding of such measures and can fully comply with the same.
- **Confidentiality**—Patient and/or caregiver confidentiality is of the utmost importance. All patient and/or caregiver records are to be considered confidential. All registered employees must ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) laws.
  - The confidentiality policy that will be put in place within all BPH facilities requires all employees and former employees to maintain confidentiality with respect to information and records pertaining to BPH operations. Confidential information will include but not be limited to:
    - Qualifying patient and/or primary caregiver personal records (HIPAA)
    - Company financial records
    - Company human resource records
    - Registered employee records or personal information
    - Operation activities
      - Cultivation methods/techniques
      - Production methods/techniques
  - The confidentiality policy is a legal requirement and respects the rights of employees and the importance of sensitive company information. Prior to commencing work at any BPH facilities, all employees and volunteers will be required to agree to and sign a Confidentiality Agreement Form.
    - **Breach of Confidentiality**—defined as “the disclosure of information, intentionally or unintentionally, to an individual or entity that is not entitled to said information.”
      - The disclosure of confidential information may result in disciplinary action and/or immediate job termination.

**ServSafe Training**—ServSafe is a training program for the food service industry, which teaches basic food safety for preparing and serving food. The program teaches about foodborne illness, how to prevent and how to train employees in food sanitation. This program will help employees become aware of good personal hygiene practices and safety measures to be utilized for the manufacturing of marijuana products.



BPH will require that all employees involved with processing operations will be required to complete ServSafe Safe Food Handlers training. Employees will be required to complete the ServSafe training course and successfully pass the competency test to become ServSafe certified prior to commencing work within the facility. ServSafe will help educate and train employees on personal hygiene, food safety, sanitation, and cleaning procedures and protocols.

Employees will be required to pass the ServSafe exam with at least a 75% passing score in order to be certified. Upon completion of the ServSafe course and successfully passing the exam, employees will receive a ServSafe certification that will be valid for three (3) to five (5) years.

**Responsible Vendor Program Training**— BPH will utilize a training program developed by ACC entitled “The Responsible Vendor Program”. This program is intended to help train dispensary operations staff members on different activities and information needed for daily operations. “The Responsible Vendor Program” will train employees on different educational content and materials, including but not limited to:

- Proper checking of identification and spotting false IDs
- Understanding the conduct, rules, and regulations of a licensed cannabis establishment
- Governing enforcement agencies: Their roles and how all licensed employees should work with them
- Cannabis plant biological structure and native geography
- Cannabis quality control, variety types and their various effects
- The medicinal value of marijuana and its extracts
- Methods of consumption
- Identifying indicators of intoxication

The program will aid in training and educating all BPH employees on different aspects of marijuana as a medicine. Retail dispensary employees will gain information on the various marijuana strains and products offered, their medicinal benefit, possible side effects, delivery methods, and other relevant information. This will help dispensary employees identify and recommend marijuana varieties and forms for different patients to help treat their specific qualified condition. All BPH retail dispensary registered employees will be trained on “The Responsible Vendor Program.”

**Security Measures/Protocols Training**—all BPH registered employees will receive extensive training detailing facility security measures and protocols. Security measures and protocols are explained in more detail within the Standard Operating Procedures Security Plan.

**Laws and Regulations/Compliance Training**—Adhering to all state, county laws and company specific regulations is of utmost importance to create an end product with the highest efficacy for patients. All BPH registered employees will be required to read current state law and have a basic



knowledge and understanding of the laws and regulations they must comply with in daily operations. Compliance training is detailed more thoroughly in the SOP's.

**Point of Sale (POS) Training**—BioTrackTHC™ will provide the inventory control system and POS computer systems to be utilized in all BPH registered dispensary facilities. BioTrackTHC™ will provide initial training on the systems. POS training efforts will be supported by HCH and their deep understanding and experience with BioTrackTHC™ systems. POS training is covered in more detail in the Retail SOP's.

**Patient Advocacy Training**—Qualifying patients are the reason for the medical marijuana industry and therefore proper patient advocacy training is essential in order to have a successful retail dispensing operation. Patient confidentiality is of utmost importance; any and all patient information is confidential and is to remain secured on location. Any unauthorized release of patient information will be grounds for immediate job termination. Patient advocacy and confidentiality are explained in more detail within the Standard Operating Procedures.

**Training Record**— BPH management team will be responsible for maintaining training records for each registered employee. Such records will include, at a minimum, documentation of all required training for the different operations and functions including:

- The name of the person receiving the training;
- The dates of the training;
- A general description of the topics covered;
- The name of the person supervising the training; and
- The signatures of the person receiving the training and the facility manager.

All registered employees will receive training prior to beginning work within any BPH registered dispensary facility. A continuing education program will aid in developing registered employees and preparing them for further advancement within the company. It is the responsibility of management to ensure training takes place for all registered employees prior to commencing work within any BPH registered dispensary facility.

### **Cultivation and Manufacturing**

Production will consist of the entire marijuana cultivation process from seed germination and propagation to harvesting, curing, and packaging. Production will also consist of marijuana processing for the manufacturing of marijuana products. The production process and procedures are explained in detail in the SOPs. The SOPs will cover all cultivation processes as well as all manufacturing marijuana product operations.

#### *Methods of Production:*

- *Marijuana Cultivation:* Various cultivation techniques will be utilized within the cultivation facility. See the separate, additional Cultivation SOPs document for more information on cultivation techniques.



- *Manufacturing Marijuana Products:* Processing techniques and procedures for manufactured marijuana products are explained in detail in the separate, additional Manufactured Marijuana Products SOP document.

### **Production Center Location**

All marijuana cultivation and manufacturing of marijuana products will be conducted at BPH's registered production centers. BPH will ensure that all facilities will comply with applicable zoning laws, are secured and at a minimum meet or exceed all state and county law pertaining to facility security requirements.

the unique environmental advantages of being both relatively dry and offering some of the best sunlight exposure. Sunlight will be used for directly providing diffused natural light through the white translucent roof and for capturing the energy through Photovoltaic (PV) panels. As dehumidification is one of the largest power draws at the facility, being able to vent out humid air and intake dry outdoor air. Sensors will allow the climate control computer system to determine the optimum timing in the day when the humidity and temperatures are at a combined low to intake air that decreases the combined power draw of the AC and the dehumidifiers the most.

**Square Footage**—the production center will be approximately 24,000 sq ft consisting of a 16,000 sq ft main warehouse space, 3,000 sq ft secondary warehouse, and 5,000 sq ft of office space split into two floors. The building sits on a 50,000 sq ft lot where the remainder of the land will feature shaded parking with PV panels on the roof, climate appropriate landscaping, and a loading area.

**Type of Building**—the production center will be a newly constructed warehouse building featuring modern building materials that increase HVAC efficiency. The walls will be made of metal Structural Insulated Panels (SIPs) which are high insulation solid foam core sandwiched between rigid metal panels. The high insulation of the walls will decrease the power demand on the HVAC system.

Water absorbs heat and hot air rises. Roof ventilation at the ridge of the roof will open at optimal times to vent out hot air through a insect proof mesh screen of 300 micron mesh size or less. This will release the hottest and most humid air from the interior from the building. Air intake will occur at the lowest points of the walls from the coolest side of the building at the time. The intake air will be filtered and run through a UVA and/or ozone air sterilizing unit to eliminate incoming pests and pathogens.

**Zoning**—The facility is located on I-2 zoned land. I-2 means that the land is classified for intensive industrial use, allowing for a large amount of power (3-phase, 480V) to be pulled to the building, a necessity for a large power use facility. Nursery productions are allowed on agricultural lands and industrial lands, and thus making this facility on the most ideally zoned land.

**Construction Costs**—current estimates are around [REDACTED]



## **Quality Control**

BPH will utilize industry best practices developed for established operations within Colorado’s regulated marijuana industry and quality assurance programs to continuously measure and improve customer satisfaction. Customer satisfaction will be a top priority of BPH as we want to cultivate, manufacture and dispense marijuana and manufactured marijuana of the highest quality. BPH will utilize a patient feedback form to gather feedback and input from qualifying patients regarding our marijuana products, manufactured marijuana products, the qualifying patients’ overall experience, and feedback regarding the retail dispensary location, registered employees, and any other information or comments qualifying patients wish to provide to BPH. This patient feedback form will be reviewed by BPH in order to assess the qualifying patient feedback to continuously improve our process and products to offer qualifying patients the best experience possible when procuring from BPH.

To ensure qualifying patient and public safety, BPH has committed to establish, document, implement and maintain an appropriate Quality Management System. To this end, BPH is committed to the following Quality Management Principles:

- Customer Focus; Leadership; Involvement of People; Process Approach; System Approach to Management; Continual Improvement; Factual Approach to Decision Making; Mutually Beneficial Supplier Relationships

To assure adequate establishment, implementation, documentation and maintenance of the Quality Management System (“QMS”), BPH has taken guidance from ISO 9001 and will hire a full-time Manager of Quality Management who is certified as a Manager of Quality and Organizational Excellence by the American Society of Quality. The Manager of Quality Management will be responsible for using the guidance from ISO 9001 to develop the appropriate QMS for BPH in accordance with Hawai‘i state regulations. BPH’s Quality Management System will be based from the QMS document which is as an additional document and can be viewed upon request.

*Cultivation Operations*—Quality control measures will be created and implemented within the cultivation facility to ensure quality and consistency of products produced within the facility. BPH will utilize established and proven SOP’s for all cultivation operations. The SOP’s have been developed and tested within Colorado’s regulated medical marijuana market by our retained marijuana industry consultants ACC. BPH will use standard operating procedures (SOP’s) to promote good growing and handling practices including:

- All aspects of:
  - Irrigation, propagation, cultivation, fertilization;
  - Harvesting, drying, curing;
  - Rework or reprocessing;
  - Packaging, labeling, and handling of medical marijuana products, byproduct; and
  - Waste products, and the control thereof, to promote good growing and handling practices.

BPH will require that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical marijuana has received the training, education, or experience



necessary to perform assigned functions; and will also require that all employees practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

Automated climate controls developed through data tracking with a robust sensor system and analysis will develop an increasingly consistent and optimal cultivation system over time. BPH takes quality and excellence seriously and will always look for ways to operate at a higher level.

BPH will require employees to follow the protocol for Receipt of Material including:

- BPH shall quarantine received material that will be used to produce marijuana and/or manufactured marijuana products
- BPH shall inspect materials for defects and contamination.
- Material may not be released from quarantine by a BPH until the material:
  - Passes inspection; and
  - Is determined to be acceptable for use as intended.

*Manufacturing Operations*—Quality control measures will be created and implemented within manufacturing operations to ensure quality and consistency of products produced within the facility. BPH will utilize established and proven SOP's for all processing operations. The SOP's have been developed and tested within Colorado's regulated medical marijuana market by UNM, a licensed manufacturer of marijuana products in Colorado, Nevada and Arizona. BPH and UNM have a licensing agreement which will enable BPH access to recipes, methods and other intellectual property required for successful manufacturing operations.

*Dispensing Operations*—Quality control measures will be created and implemented within the retail dispensing locations to ensure quality and consistency of products dispensed to qualified, registered patients. BPH will utilize established and proven SOPs for all dispensing operations. The SOPs have been developed and tested within Colorado's regulated medical marijuana market by HCH.

## **Inventory**

All BPH registered dispensary facilities will need to maintain inventories on-site for the cultivation, manufacturing and/or retail dispensing processes. There will essentially be two unique process within the cultivation facility; cultivating and manufacturing, each with differing processes and needing different on-hand inventories. The retail dispensary locations will have marijuana and manufactured marijuana products as on-hand inventory for dispensing to qualified patients.

### **Cultivation Inventory**

- Cultivation equipment
- Plant fertilizer
- Pesticides
- Fungicides
- Insecticides
- Growing mediums
- Cleaning supplies



- Etc.

### **Manufacturing Inventory**

- Raw marijuana materials
- Kitchen equipment
- Extraction equipment
- Packaging materials
- Labeling materials
- Etc.

### **Retail Dispensing Inventory**

- Packaged marijuana
- Packaged manufactured marijuana products
- Exit packaging supplies
- Cleaning supplies
- Etc.

### **Inventory Value**

Valuation of on-hand inventories will be based on current fair market value for said inventories, the exact inventory values will be determined upon deployment of operations.

### **Inventory Management and Control**

BPH will utilize a perpetual inventory system in all operations—cultivation, processing/manufacturing, and retail dispensing. BPH will utilize a marijuana industry specific system from BioTrackTHC™ that will have the capabilities of linking all operational inventories together to operate as a vertically integrated business operation. Inventory control measures will be created and implemented to ensure inventory quantities are accurate and for state required seed-to-sale tracking of all marijuana and manufactured marijuana products. Proper inventory controls ensure the right amount of inventory is on hand and in production so as not to negatively impact the company and the market in general.

The inventory control system that will have the ability to identify and track all marijuana products from the time the marijuana is propagated from a seed or cutting to the time it is delivered to a retail dispensary location and dispensed to a qualified, registered patient or primary caregiver.

The inventory control system will be designed so that it can promptly identify a discrepancy in any marijuana or manufactured marijuana product stock. The system will deter loss from theft or diversion since every gram of marijuana and manufactured marijuana product will be logged and tracked through the inventory control system. The system will be capable of tracking marijuana products from a qualified, registered patient or primary caregiver back to the source of the marijuana product in the case of the development of a serious adverse event. The inventory control system will be utilized in tandem with the Product Recall Policy developed in case the need for a product recall should ever arise.

During the cultivation process all marijuana plants being cultivated will be tagged with a unique tag ID number. This tag will remain with the marijuana plant throughout its entire lifecycle. The



IG tag information will be input into the inventory control system to correlate with the attached marijuana plant. The information in the system will be changed and updated as the plant matures through its lifecycle.

### **Suppliers**

BPH will utilize numerous different suppliers for the cultivation process and for the manufacturing of medical marijuana edibles and manufactured marijuana products. Suppliers for cultivation activity will consist of a network of gardening equipment retailers and wholesalers. Suppliers for manufacturing activity will consist of grocery retailers and wholesalers, restaurant equipment companies.

BPH's suppliers will be identified upon successfully obtaining Hawai'i state licensure and the subsequent deployment of operations. BPH will use expertise provided by the American Cannabis Company, Inc. to minimize costs while obtaining high quality equipment. On a macro level BPH anticipates the need, at minimum, for the following suppliers:

- Security and surveillance equipment
- Cultivation equipment
- Processing equipment
- Dispensing equipment
- Inventory tracking equipment
- Building materials and equipment
- Point of sale equipment
- Packaging equipment

### **Distribution Channels**

BPH only distribute its medical marijuana through its registered Retail Dispensing Locations, vertically integrated with BPH operations. BPH intends to cultivate and manufacture marijuana and manufactured marijuana products for dispensing to state qualifying and registered medical marijuana patients and primary caregivers.

### **Transportation**

This section details how BPH will transport medical marijuana products to the retail dispensary(s). All applicable state and county law pertaining to the transportation of medical marijuana products will be strictly followed by all BPH team members.

**Transportation Agent Requirements**—all agents responsible for transporting marijuana products or manufactured marijuana products must:

- 1) Possess a current and valid state-issued marijuana industry worker license;
- 2) Possess a current and valid government-issued driver's license;
- 3) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or manufactured marijuana products pursuant to regulation, all transporting agents shall:



- 1) Carry a copy of the *manifest/trip plan* with him or her for the duration of the trip;
- 2) Wear their registered employee identification card;
- 3) Use a vehicle without any marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or manufactured marijuana products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation; and
- 5) Ensure that the marijuana products or manufactured marijuana products are not at all visible to the public.
- 6) Ensure there are at least two agents at any moment on a delivery, one of which will sit with the marijuana products to ensure a high level of security

**Delivery**—Transporting agents arrive at the dispensary location receiving the marijuana product(s).

- 1) Transporting agents arrive at the transportation destination
- 2) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the transport manifest/trip plan
- 3) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

### **Post-Delivery**

**Post-Delivery Protocol**—after transporting marijuana products or manufactured marijuana products, pursuant to the regulations the registered employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.

**Documentation of Delivery**—both the transporting dispensing facility agent and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Department for review upon request. The dispensary agent shall record in the inventory control each item dispensed including batch number and the weight and quantity of the marijuana and/or manufactured marijuana products that were dispensed.

**Deviations from Transportation Plan**—the transporting registered employee shall immediately report all diversion due to loss or theft of marijuana or manufactured marijuana products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the Department as required per state law. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



## **Compliance**

BPH will ensure compliance with all state and local laws and regulations, specifically H.B. 321, Chapter 329D and Administrative Rule §11-850. BPH will make all books, records, and production and dispensing facilities available to the Department or its authorized representatives for monitoring, audits, and on-site inspections at any time upon request. BPH will only cultivate, manufacture and dispense approved medical marijuana products, per requirements set forth in §11-850-71, §11-850-72 and §329D-10, in an enclosed, secure indoor facility located in the State of Hawai‘i and in the County of Honolulu. BPH will not grow marijuana or manufacture marijuana products at any site other than the production centers approved by the Department. BPH will not dispense medical marijuana or manufactured marijuana products from the production center and will only dispense marijuana and manufactured marijuana products to qualifying, registered patients and primary caregivers from retail dispensary locations.

**Registered Employees**—all employees hired and retained by BPH will be free of any criminal felony convictions and their hiring will be conditioned upon successfully passing a background check and comprehensive drug screen.

**Visitors and Activity at a Licensed Dispensary**—all visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

**Qualifying Patient Intake**—Qualifying patients and caregivers wishing to purchase products at a BPH retail dispensing location will need to have a valid state medical marijuana registration card. Patients entering the retail dispensary location will not be allowed beyond a “holding area” until a BPH employee verifies the validity of each patient’s medical marijuana registration card through the state electronic verification system. After the verification process has been completed, the patient and/or caregiver will be allowed entry into the retail dispensing portion of the premises.

The retail dispensing location manager will create and maintain a database within the inventory control system for inventory and tracking purposes. This will enable registered employees to adhere to all laws regarding the quantities of marijuana and manufactured marijuana products registered patients and/or primary caregivers are allowed to have and purchase in a given time period.

**Qualifying, Registered Patient Verification**—registered employees will verify each and every qualifying patient’s and/or primary caregiver’s state-issued medical marijuana license prior to entry into the retail dispensing center. The electronic verification process will need to be completed for every single patient and/or caregiver *EVERY* time they wish to purchase products at the facility.

- 1) **Medical Marijuana License**—Accept patient and/or caregivers state-issued medical marijuana license



- a. Ensure the state-issued medical marijuana license is current (check expiration date on License)
- 2) **Government-Issued ID**—Patients and/or caregivers must also have a current and valid government-issued ID (passport, Driver’s License)
  - a. Ensure that the state-issued ID is current (check expiration date on ID)
- 3) **Verification**—Verify the validity of the state-issued medical marijuana license
  - a. Verify validity of the medical marijuana license through the state electronic verification system
- 4) **Access**—Allow or deny access to the qualified patient and/or primary caregiver
  - a. Allow entry to retail dispensary location if the patient and/or caregiver has a valid state-issued medical marijuana license.
  - b. Deny entry to retail dispensary location if the patient and/or caregiver does not have a valid state-issued medical marijuana license.
    - i. If you feel the patient and/or caregiver is trying to use a fake or fraudulent medical marijuana license; confiscate said medical marijuana license and contact required Hawai’i state authorities.

**Dispensing Procedure**— BPH will implement and follow specific security procedures and policies for all RDL operations including: written SOPs for admitting registered patients and primary caregivers with valid government-issued photo identification cards issued pursuant to HRS Chapter 329 into the secure rooms for sales. BPH will design and construct each RDL with separate, secure room(s) for sales wherein marijuana and manufactured marijuana products are secured and locked in display cases for viewing. As required by HAR §11-850-53(3), BPH will follow written policies and procedures to ensure that a maximum occupancy limit ratio is maintained in all secured sales rooms of two customers to every RDL employee. BPH will store all marijuana products within a locked room, vault or in a locked container securely affixed to a wall or floor. All RDLs shall have exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities.

BPH will ensure compliance with all regulatory requirements prior to dispensing any marijuana or manufactured marijuana products, BPH will ensure compliance with the following dispensing procedures:

- BPH’s registered employees shall dispense marijuana and manufactured marijuana products only to a qualified, registered patient or primary caregiver who has presented a government-issued identification card.
- Before any distribution of medical marijuana, BPH’s dispensary agent(s) shall verify that:
  - The qualified, registered patient or caregiver is currently registered with the Department;
  - The amount of marijuana and/or manufactured marijuana products that have already been dispensed does not exceed sales limits established by the regulations.
    - Four (4) ounces within a consecutive fifteen (15) day period
    - Eight (8) ounces within a consecutive thirty (30) day period
- BPH’s dispensary agent(s) may provide information on:
  - The available types of marijuana, marijuana varieties, and manufactured marijuana products



- Methods by which medical marijuana can be used; and
- How unused marijuana may be returned for disposal.
- Registered employees may decline to dispense marijuana and/or manufactured marijuana products to a qualified, registered patient or caregiver if, in the opinion of the registered employee, the qualified patient or caregiver appears to be visually impaired.
- BPH will not distribute any samples of marijuana or manufactured marijuana products or offer any marijuana products free of charge.

### **Packaging and Labeling**

BPH will package all marijuana and manufactured marijuana products on site at the production center within opaque, child resistant packaging that will protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.

BPH will package all marijuana and manufactured marijuana products in child resistant packaging prior to dispensing said product to a qualified, registered patient or caregiver. Child-resistant packaging is special packing used to reduce the risk of children ingesting dangerous items. For BPH's purposes, child-resistant packaging will be used to reduce the risk of children ingesting marijuana and/or manufactured marijuana products.

**Cultivation and Manufacturing Packaging**—BPH will pre-package all products containing marijuana and manufactured marijuana products in child-resistant and opaque containers at the production center prior to being shipped to BPH retail dispensary locations. The packaging will be constructed of tamper-evident opaque material and sealed with tamper-evident tape.

**Retail Dispensary Packaging**—BPH will package all medical marijuana and manufactured marijuana products in child-resistant packaging. We also intend to take our child-resistant packaging to the next level and utilize best practices from Colorado's medical marijuana industry in that we will also require all marijuana products leaving BPH retail dispensary locations to be placed in a child-resistant exit package. BPH will also utilize exit packaging for all marijuana and manufactured marijuana products leaving retail dispensary locations. The exit packaging will be child resistant and opaque and aid in product safety. Exit packing is not required under current Hawai'i regulations, however BPH intends to use exit packaging as an industry best practice.

**Labeling**—BPH will label all marijuana and manufactured marijuana products as required by state law. BPH will not label any marijuana product or manufactured marijuana product as organic. All labels will use only black lettering on a white background with no pictures or graphics. BPH will utilize the inventory control and POS system to generate all product and qualified patient labels. BioTrackTHC's inventory control and POS system will be able to automatically generate both the product-specific and patient-specific labels as required by Hawai'i regulations. BPH will ensure that every marijuana and manufactured marijuana product package will be affixed with the required labels containing all required information on said label.

BPH will ensure that the information printed on the package shall be in English, in black lettering at least one-sixteenth of an inch high. BPH will print a product-specific label for every package of marijuana and/or manufactured marijuana products as well as a patient-specific label for all



qualified, registered patient prior to dispensing said product. If requested by a qualified, registered patient or caregiver, BPH may also print a label in another language. BPH will not distribute a package of marijuana and/or manufactured marijuana products without a label securely attached. BPH will state on all labels of a package the following as required under current regulations:

- Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
  - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
  - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
- The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
- The batch number and date of packaging;
- A computer tracking inventory identification number barcode generated by tracking software;
- Date of harvest or manufacture and a "use by date";
- Instructions for use;
- The phrases "For medical use only" and "Not for resale or transfer to another person";
- The following warnings:
  - "This product may be unlawful outside of the State of Hawai'i and is unlawful to possess or use under federal law";
  - "This product has intoxicating effects and may be habit forming";
  - "Smoking is hazardous to your health";
  - "There may be health risks associated with consumption of this product";
  - "This product is not recommended for use by women who are pregnant or breast feeding";
  - "Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug"; and
  - "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"
- A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
- The name of the laboratory that performed the testing

BPH labels will not contain any false or misleading statement or design or include any statement, image or design that may not be included on the package.

### **Waste Disposal**

BPH will utilize marijuana industry best practices to properly dispose of medical marijuana waste. Adherence to all applicable state and county laws pertaining to the destruction and disposal of marijuana waste within the facility is very important to ensure no marijuana waste products are being diverted. All medical marijuana waste, byproducts, and undesired products will be destroyed and disposed of according to all applicable state and county law. Facility management will ensure



proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state law. Record all required information on the *Marijuana Waste Log Sheet*.

**Disposal**—Disposal of any marijuana product waste must be rendered unusable and unrecognizable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.

### **Hours of Operation**

BPH hours of operation within the facilities may vary depending on the numerous factors such as types of operations being performed, the time of year, environmental factors such as weather and temperatures, etc. Hours of operation will fall within the state allowed hours of operation per regulations. BPH retail dispensary locations will remain closed during Hawai‘i state holidays and federal holidays. These State holidays will be represented by the days shown in the figure below which was obtained from the State of Hawai‘i Department of Human Resources Development website.

<b>Retail Dispensary Location(s)</b>	<b>Hours of Operation</b>	
	<b>Open</b>	<b>Close</b>
<i>Monday</i>	8:00	8:00
<i>Tuesday</i>	8:00	8:00
<i>Wednesday</i>	8:00	8:00
<i>Thursday</i>	8:00	8:00
<i>Friday</i>	8:00	8:00
<i>Saturday</i>	8:00	8:00
<i>Sunday</i>	CLOSED	CLOSED



## Year 2016 HAWAII STATE HOLIDAYS

<u>(Hawaii Rev. Statutes, Sec. 8-1)</u>	<u>Day Observed in 2016</u>	<u>Official Date Designated in Statute/Constitution</u>
New Year's Day.....	Jan. 1 Friday.....	The first day in January
Dr. Martin Luther King, Jr. Day.....	Jan. 18 Monday.....	The third Monday in January
Presidents' Day.....	Feb. 15 Monday.....	The third Monday in February
Prince Jonah Kuhio Kalaniana'ole Day.....	Mar. 25 Friday.....	The twenty-sixth day in March
Good Friday.....	Mar. 25 Friday.....	The Friday preceding Easter Sunday
Memorial Day.....	May 30 Monday.....	The last Monday in May
King Kamehameha I Day.....	June 10 Friday.....	The eleventh day in June
Independence Day.....	July 4 Monday.....	The fourth day in July
Statehood Day.....	Aug. 19 Friday.....	The third Friday in August
Labor Day.....	Sept. 5 Monday.....	The first Monday in September
General Election Day.....	Nov. 8 Tuesday.....	The first Tuesday in Nov. following the first Monday of even-numbered years. ( <i>Hawaii State Constitution, Article 2 – Section 8</i> )
Veterans' Day.....	Nov. 11 Friday.....	The eleventh day in November
Thanksgiving.....	Nov. 24 Thursday.....	The fourth Thursday in November
Christmas.....	Dec. 26 Monday.....	The twenty-fifth day in December

\* <http://dhrd.Hawaii.gov/state-observed-holidays/>

### **Adverse Events/Product Recall Policy**

BPH will liaise with its retained marijuana industry consultant ACC in the event of the emergence of an adverse event or the need for a product recall. ACC has developed previous adverse event and product recall policies and standard operating procedures to educate, train and guide businesses how to handle such situations. BPH and ACC will together develop an adverse event and product recall policy customized for the state of Hawai'i. Below highlights some of the information that will be included in our policy.

#### *How to Recall Medical Marijuana Products*

Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by Hawai'i state law will ensure a streamlined recall process if ever necessary.

#### *Corrective Action Plan (CAP)*

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and necessary steps to be taken by the facility once a product recall is required. A typical CAP includes five (5) primary steps:

1. Step One: Industry Notification
2. Step Two: Public Notification



3. Step Three: Procurement
4. Step Four: Documentation and Record Retention
5. Step Five: Disposal

### **Retail Operations**

All BPH retail dispensary locations will be selected and designed with patient safety, environment and accessibility in mind and will be ADA compliant featuring handicapped parking, handicap accessibility and restrooms. The retail dispensary locations will fulfill these goals:

- Develop a dispensary environment that gives the most access and relief to the patients
  - Dispensary shall be located in a location with ample parking at a central location
  - Dispensary shall have a welcoming look and feel that provides the patient with comfort through their retailing experience
  - Patient will be supported with professional consult and education
  - Dispensary will be secure at all times
  - Product will be offered at an affordable price
  - Patient needs will be met with the availability of most appropriate and high quality medicine

### **Retail Dispensary Locations**

BPH will ensure that all facilities comply with all applicable zoning laws.

The initial retail dispensing location will be located on the third floor of the Ala Moana Building in room 304, on the corner facing Ala Moana Mall across the mall level parking lot. There is ample parking at the 7 level parking structure right in front of the Ala Moana building. This location offers super accessibility from its central location in town, connection to the largest and busiest shopping mall in the state, unmatched parking availability, the busiest bus depot, and being in a large medical building with a large bank located on the ground floor.

**Square Footage**— 1832 sq ft with approximately 90 ft of parking lot frontage with a built in reception area and desk.

**Type of Building**—A concrete building with 23 floors built on 31,000 sq ft of land. The building is equipped with 6 elevators and central air conditioning. The building has security guards stationed 24/7 and the parking structure is closed at night with security guards, making the facility inaccessible during the night.

### **Daily Retail Processes**

The daily retail processes are explained in more detail in the Retail Standard Operating Procedures which is a separate, additional document that can be viewed upon request. Below is a high-level overview of various process involved with the daily retail dispensary location operations.

**Opening Responsibilities**—the opening responsibilities will primarily be comprised of getting the retail sales floor ready for the day. This will be detailed in the Retail SOP's.



**Closing Responsibilities**—the closing responsibilities will primarily be comprised of closing the retail sales floor and securing product for safe storage throughout the night. Closing responsibilities will be detailed in the Retail SOP's.

**Patient Intake**—Patients wishing to patron the retail dispensing location will need to have a valid state medical marijuana patient license. Before entry into the retail dispensing location team members will verify the validity of each patient's medical marijuana license through the state electronic verification system. After the verification process the patient will be allowed entry into the retail dispensing location.

**Dispensing/Sales Procedure**—the sales procedure needs to be completely accurate for every sales transaction. If sales records are not accurate inventory will have discrepancies and could result in compliance issues. Retail team members will go through extensive training on the POS system and the sales process before commencing operations. The sales procedure is explained in the Retail SOP's.

**Customer Service**—Customer service policies will be created to ensure good working relationships with dispensing organizations and licensed patients within the State of Hawai'i. These procedures will cover requirements for handling customer complaints and returns of products. BPH is focused on patient well-being with a focus on patients' medical history and symptoms to recommend the right products for an optimal outcome. BPH will solicit and respond to patient feedback after using our products to further improve effectiveness and patient satisfaction.

### **Legal Environment**

The legal environment surrounding BPH and the medical marijuana industry in the State of Hawai'i will be discussed in this section. Various state laws are discussed in more detail within the Standard Operating Procedures, Employee Manuals, Code of Conduct, etc.

**Licensing**—BPH will ensure that all required state and county licensing are acquired and in good standing prior to launching any cultivation, processing, or dispensing of medical marijuana. All required licensure will be kept on-site at the location facility and clearly displayed.

**Permits**—BPH will ensure all required permits are obtained prior to beginning any tasks or projects. Permits will be obtained for all construction projects or any other work requiring a permit.

**State Law**—BPH will ensure full compliance with all applicable law involving HRS Chapter 329D and HAR Chapter 11-850.

**Zoning**—BPH will ensure that all facility locations are in properly zoned and approved areas for medical marijuana cultivation, processing and dispensary operations.

**Building Codes**—BPH will ensure that all building codes are properly followed and enforced by all contractors, construction crews, or maintenance workers.



**Insurance**—BPH will ensure it is protected with all required and applicable forms of insurance. Insurance will include, but not be limited to, general liability insurance and workers compensation insurance.

### **Recruiting, Benefits, Hiring, Loss of Personnel**

BPH will properly train all of its employees before they are permitted to work in any BPH facility operations.

Prior to being offered an employment position with BPH, all potential applicants will be required to pass a background check to ensure the potential applicant does not have any criminal felony convictions or have been convicted of the crimes listed in HAR §11-850 (2)-(6) and otherwise is of good moral character.

BPH intends to offer competitive wages and salaries, as well as benefits packages that include paid time off and health insurance, to all employees. Exact compensation and benefits plans and packages are in the process of being developed. It is BPH's goal to pay salaries that are, at a minimum, equitable and commensurate with salaries paid for similar work within the labor market. Accordingly, positions will generally be classified and then assigned a salary range that defines a minimum and maximum pay rate. An employee's salary may advance within the salary range as the result of performance reviews, promotions, market conditions and other business considerations. Such increases in pay are considered merit adjustments which are not guaranteed and may vary in timing and degree from employee to employee.

In accordance with State legal requirements, employees will be compensated for hours worked in excess of forty (40) hours per week. Non-exempt employees will be paid one and one-half times their regular rate of pay for hours worked in excess of forty (40) hours in a workweek. Overtime pay is based on actual hours worked. Paid time off for holidays and vacations does not count as "hours worked" for overtime purposes. Any overtime hours worked by a non-exempt employees will be required to be approved in advance by the employee's supervisor. Non-exempt employees are not to work before, beyond or outside their normal working hours without such prior approval. Employees who fail to work scheduled overtime or who work overtime without prior authorization from a supervisor may be subject to disciplinary action, up to and including termination of employment.

**Number of Employees**—exact number of employees employed by BPH is to be determined upon deployment of operations and the establishment of personnel requirements; the breakdown of these requirements can be seen below within the job description section.

**Type of Labor**—the team at BPH will comprise skilled, unskilled, and professional workers. The various positions within the organization will call for different laborers with different skill sets. The cultivation manager will need to be very skilled in the cultivation of marijuana, whereas an entry-level cultivation laborer will likely be unskilled and trained to the job requirements and functions.

**Pay Structure**—BPH will determine this upon deployment of operations and the establishment of personnel requirements. Employee compensation will be competitive with industry standards



**Job Termination**—all termination actions will follow standard procedures. Basic steps include:

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e. employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges, or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel
4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e. mutual separation and key personnel is always welcome back at SFN facilities under visitor status, employee is no longer allowed on the premise, and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was vacated. Key personnel positions will need to be filled as soon as possible by management without compromising the quality of potential candidates.

### **HR Compliance**

BPH will utilize an Employee Handbook/manual that is compliant with all Hawai'i labor laws and will be utilized at all facilities. All registered employees will be required to read the Employee Handbook prior to commencing work in any BPH registered dispensary facility. The Employee Handbook will outline various company policies that must be followed. The handbook will also explain all Human Resources (HR) functions, employee benefits, and other company programs and policies.

### **Workplace Policies**

Prior to the deployment of any operations, BPH will develop and implement multiple workplace policies including an Employee Handbook, Drug and Alcohol Free Workplace Policy, Personal Hygiene Policy, and Code of Conduct. All BPH registered employees will be required to adhere to all policies and programs while employed for BPH.

**Employee Handbook**—BPH will develop and implement an Employee Handbook that will highlight the policies and procedures that employees will need to adhere to while working for



BPH. All employees will be required to read and sign the Employee Handbook prior to commencing work in any BPH facility.

**Drug and Alcohol Free Workplace Policy**—BPH will develop and implement a Drug and Alcohol Free Workplace Policy that will highlight the policies and procedures that employees will need to adhere to while working in any BPH facility. All employees will be required to read and sign the Drug and Alcohol Free Workplace Policy prior to commencing work in any BPH facility.

**Personal Hygiene Policy**—BPH will develop and implement a Personal Hygiene Policy that will highlight the personal hygiene policies and procedures that employees will need to adhere to while working for BPH. All employees will be required to read and sign the Personal Hygiene Policy prior to commencing work in any BPH facility.

**Code of Conduct**—BPH will develop and implement a Code of Conduct that will highlight the policies and procedures relating to employee conduct and ethics that will need to adhere to while working for BPH. All employees will be required to read and sign the Code of Conduct prior to commencing work in any BPH facility.

### **Job Descriptions, Personnel Development and Reviews**

Below details BPH’s employment structure for four (4) distinct operations of the organization 1) cultivation operations 2) manufacturing operations 3) retail dispensary operations and 4) security operations. The information displayed below details the anticipated organizational employment positions, the job descriptions and a potential number of employees for each job description upon deployment of operations.

**TBD, Sustainability Manager**

This person reports to the Chief Operations Oversee sustainable projects from design and build of the facilities, responsible for efficiencies and detecting issues that may related. Remain current with new technologies pertaining to sustainable and renewable technologies.

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### **1) Cultivation Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Chief Operating Officer: Andrew Salini; Responsible for overall operation of entire facility; oversight of cultivation operational activities, processing operational activities, and security operational activities. All department managers will report directly to the GM.*
  - *Security Clearance: Restricted Area Access*
  - *Employees at Full Capacity: 1*
- *Cultivation Manager: Michael Rogers; Responsible for oversight of cultivation operational activities. Must ensure compliance with all laws and regulations and maintain accurate records and documentation. All cultivation department manager report directly to the Cultivation Manager. Reports directly to the General Manager.*



- *Security Clearance:* Restricted Area Access
- *Employees at Full Capacity:* 1
  
- *Vegetative Manager:* Responsible for oversight of all vegetative areas. Responsible for proper record keeping and documentation. Reports directly to Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Laborers are responsible for daily cultivation activities within the vegetative areas. Reports directly to the vegetative manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 4/TBD
  
- *Flowering Manager:* Responsible for oversight of all flowering areas, proper record keeping, and documentation. Reports directly to the Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Responsible for daily cultivation activities within the flowering area. Reports to the flowering assistant manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 8/TBD
  
- *Harvest Manager:* Responsible for oversight of all harvesting processes. Direct supervision of all managers in the harvest process. Reports directly to the Cultivation Manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
- *Trim/Cure Manager:* Responsible for oversight of trimming process and laborers, proper record keeping, and documentation and responsible for oversight of curing process and laborers, proper record keeping and documentation. Reports to the harvest manager.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
  
  - *Laborer(s):* Responsible for daily trimming activities and duties as well as responsible for daily curing activities. Reports to the trim/cure manager.
    - *Security Clearance:* Limited Area Access
    - *Employees at Full Capacity:* 8/TBD
  
  - *Packaging and Labeling Manager:* Responsible for oversight of packaging and labeling activities, laborers and proper record keeping, and documentation.
    - *Security Clearance:* Restricted Area Access
    - *Employees at Full Capacity:* 1



- *Laborer(s)*: Responsible for daily packaging and labeling activities. Reports to the packaging and labeling manager.
  - *Security Clearance*: Limited Area Access
  - *Employees at Full Capacity*: 6/TBD

## **2) Manufacturing Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Director of Manufacturing*: Responsible for oversight of entire infused products area and processes. Direct supervision of all department managers within the infused products area. Reports directly to the facility GM.
  - *Security Clearance*: Restricted Area Access
  - *Employees at Full Capacity*: 1
  - *Infused Products Manager*: Responsible for oversight of kitchen area and activities, laborers and proper record keeping, and documentation. Reports directly to MIP Manager.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: Responsible for daily kitchen activities and duties. Reports to kitchen manager.
      - *Security Clearance*: Limited Area Access
      - *Employees at Full Capacity*: 2/TBD
  - *Extraction Manager*: Responsible for oversight of daily extraction processes, laborers and proper record keeping, and documentation. Reports to the infused products manager.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: Responsible for daily extraction processes and activities. Reports to the extraction manager.
      - *Security Clearance*: Limited Area Access
      - *Employees at Full Capacity*: 4/TBD
  - *Packaging and Labeling Manager*: Responsible for oversight of packaging and labeling activities, laborers and proper record keeping, and documentation.
    - *Security Clearance*: Restricted Area Access
    - *Employees at Full Capacity*: 1
    - *Laborer(s)*: responsible for daily packaging and labeling activities. Reports to packaging and labeling manager.
      - *Security Clearance*: Limited Area Access



- *Employees at Full Capacity: 6/TBD*

### **3) Retail Dispensary Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Director of Dispensary Operations:* Responsible for entire facility operations, ensuring full compliance with state law, organizational goals and objectives, etc.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1
- *Assistant Manager(s):* Oversees daily retail operations, reports directly to GM
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full capacity:* 2/TBD
- *Patient Advocacy Manager:* Responsible for educating patients with information regarding the use of medical marijuana, etc. Reports to the assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 2/TBD
- *Sales Floor Supervisor(s):* Responsible for oversight of dispensary sales agents and supervision of sales floor activity.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 4/TBD
- *Dispensary Agent(s):* Responsible for daily sales procedures, customer service, patient education, etc. Reports directly to assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 30/TBD
- *Intake Specialist(s):* Responsible for patient check-ins, reports to the assistant manager.
  - *Security Clearance:* Limited Area Access
  - *Employees at Full Capacity:* 4/TBD

### **4) Security Operations**

*\*The responsibilities described below for each job function are NOT all inclusive.*

- *Security Manager:* Responsible for security operations at the licensed facility. Responsible for oversight of security agents and transportation agents.
  - *Security Clearance:* Restricted Area Access
  - *Employees at Full Capacity:* 1



- *Security Agent(s)*: Responsible for facility entry protocol; ensuring proper identification of any visitors and ensures said visitors have proper security clearance to enter.
  - *Security Clearance*: Restricted Area Access
  - *Employees at Full Capacity*: 1
  
- *Transportation Agent(s)*: Responsible for transporting marijuana and manufactured marijuana products to BPH registered retail dispensary locations.
  - *Security Clearance*: Limited Area Access
  - *Employees at Full Capacity*: 2/TBD

**Personnel Development**—BPH management will be responsible for making a commitment to the on-going education and professional development of BPH registered employees. Once commencing work within a BPH facility, there will be multiple opportunities for continuing education and advancement within the organization. BPH management will be responsible for establishing a development path where registered employees learn from experience and work directly with their crew leaders to learn all aspects of their job. Crossover opportunities will be available and encouraged so employees can learn other areas of the business if they wish to advance to another department, such as a trimmer learning the basics of processing or growing.

In addition to comprehensive training records, BPH management will be responsible for tracking employee development through the use of a development checklist. The development checklist provides a clear visual of the level of training an employee has received as well as their eligibility for additional responsibilities. Once minimum training levels have been reached, crew leaders and management will foster further development of individual employees. Employees may view their progress and choose to take a roll in their own development through expressing interest in learning new processes and utilizing provided reading materials to advance their knowledge. As procedures and topics are mastered, employees will earn “checks” on the development checklist from their crew leaders and production facility management.

**Performance Reviews**—BPH will implement periodic performance reviews that will be utilized to evaluate registered employee performance on an individual level. Employee performance reviews will be conducted on a semi-annual basis and maintained within the registered employees personnel file.

## **Personal Financial Statement**

*Include personal financial statements for each owner and major stockholder, showing assets and liabilities held outside the business and personal net worth. Owners will often have to draw on personal assets to finance the business, and these statements will show what is available. Bankers and investors usually want this information as well.*

## **Startup Expenses and Capitalization**

*You will have many startup expenses before you even begin operating your business. It’s important to estimate these expenses accurately and then to plan where you will get sufficient capital. This*



*is a research project, and the more thorough your research efforts, the less chance that you will leave out important expenses or underestimate them.*

*Even with the best of research, however, opening a new business has a way of costing more than you anticipate. There are two ways to make allowances for surprise expenses. The first is to add a little “padding” to each item in the budget. The problem with that approach, however, is that it destroys the accuracy of your carefully wrought plan. The second approach is to add a separate line item, called contingencies, to account for the unforeseeable. This is the approach we recommend.*

*Talk to others who have started similar businesses to get a good idea of how much to allow for contingencies. If you cannot get good information, we recommend a rule of thumb that contingencies should equal at least 20 percent of the total of all other start-up expenses.*

*Explain your research and how you arrived at your forecasts of expenses. Give sources, amounts, and terms of proposed loans. Also explain in detail how much will be contributed by each investor and what percent ownership each will have.*

## **Financial Plan**

### **Blue Planet Healing - Pro Forma Narrative**

#### **Introduction**

As state medical marijuana markets across the US step into the community of regulated businesses, the qualified applicants that are fortunate enough to exhibit their merit and be awarded the initial licenses must recognize and act upon their concomitant responsibilities as pioneers in this emerging and evolving space. This means taking the necessary steps to ensure ethical, sustainable, and safe business practices are implemented with the needs of patients in mind. To accomplish this end, expectations cannot be inexorable. A critical element in achieving success in any new market is maintaining flexible market forecasts. In other words, operators in a market undergoing initial self-discovery would be wise to some degree to expect the unexpected. Delayed reactionary behaviors to unforeseen market dynamics could jeopardize the health of the entity, the industry, and most importantly the safety of patients and compliance with law.

When establishing our business plan, CPM, and quantitative market forecasts, Blue Planet Healing, LLC (“BPH”) has done so with an open frame of mind as BPH feels that will provide the operational agility to confront market dynamics as they unfold. As detailed below, BPH’s analysis incorporates and references the lessons learned from other states in the emerging medical marijuana industry, but does so while recognizing Hawai‘i is still its own unique place, with its own unique set of variables (demographics, cultural attitudes, etc.). Only then can BPH respond to changes in the regulatory scheme or market conditions should they exhibit a degree of variance from the base case, whether that is weaker demand and lower initial patient participation or excess demand and greater participation.

BPH’s collective experience in multiple fields including software, medicine, finance, sustainable energy, real estate, legal and, most importantly the regulated medical marijuana industry, make it



uniquely equipped to confront both the known and unknown challenges of Hawai‘i’s nascent medical marijuana market. BPH has the experience and is prepared to respond according to market conditions.

Specifically, as it relates to medical marijuana, BPH’s High Country Healing (HCH) and American Cannabis Consulting (ACC) consultants have an established 6+ year track record in Colorado’s medical marijuana market. Since 2009, HCH has successfully navigated the tumultuous waters of perpetual regulatory and structural market change. Over this entire time, HCH has operated successfully and achieved a blemish free record of operational compliance in both the medical and recreational marijuana cultivation and dispensing businesses. Part of HCH’s dedication to excellence has been a commitment by HCH to educate its employees, and by extension its patients regarding the safe and efficacious use of medical marijuana (see .edu attachments “X”). HCH is one of the first dispensaries in Colorado to enroll its employees in “Responsible Vendor Training” in 2015 by the Trichome Institute as soon as the curriculums were validated and sanctioned by the State of Colorado’s Marijuana Enforcement Division (MED).

It is this rich experience in the medical marijuana industry that cautions us against overconfidently forecasting market conditions. If BPH’s expectations are inflexible, this will inhibit the type of reactions required in order to maintain public and patient safety according to the law. BPH’s business plan, CPM, and attached financial projections reflect BPH’s initial assumptions on the growth of the medical marijuana market in Hawai‘i based on empirical analysis, industry experience, and an understanding of the host cultural and local attitudes towards marijuana in Hawai‘i.

### **Medical Marijuana Patient Adoption Rates – Current & Forecast**

Currently, there are approximately **2,836** duly registered medical marijuana patients on the island of Oahu as of 10/31/15, representing a significantly smaller number of registered patients than the other less densely populated islands (Hawai‘i, Kauai, and Maui). This can be interpreted as reflecting a variance in social norms regarding medical marijuana between the urban professional business center of Honolulu and the more rural communities of the neighbor islands.

**Figure 1: Hawai‘i Medical Marijuana (329) Registry Program**

Valid for October 31, 2015

<b>County</b>	<b>MMJ Patients</b>	<b>Population</b>	<b>% Card Holders</b>
<b>Hawai‘i</b>	4,998	196,520	2.54%
<b>Maui</b>	2,979	165,228	1.80%
<b>Oahu</b>	<b>2,893</b>	<b>1,000,715</b>	<b>0.29%</b>
<b>Kauai</b>	1,686	71,320	2.36%



<b>Total</b>	12,499	1,433,783	0.87%
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\* [http://files.hawaii.gov/dbedt/economic/data\\_reports/2040-long-range-forecast/2040-long-range-forecast.pdf](http://files.hawaii.gov/dbedt/economic/data_reports/2040-long-range-forecast/2040-long-range-forecast.pdf)

Current data indicates that **2.54%** and **2.36%** respectively, of the Hawai‘i and Kauai County population, are duly registered card-holding medical marijuana patients. Thus, these are approximately 9x as many residents holding medical marijuana cards on said islands, as a percentage of the population, compared to Oahu island, where just **0.29%** of the population are currently registered in the program. Only 1.8% of Maui’s population are registered patients.

### **Lessons from the Colorado Experiment**

Colorado, for example, which provides the largest and most robust data sample for legal marijuana markets, started at a similarly modest initial medical patient base as Oahu (0.1% adoption state-wide) before the introduction of a legal dispensary system (“LDS”) in mid-2009. After just two years of profound growth, the Colorado MMJ patient base peaked at **2.5%** of the population base in Q4 2011 before leveling out at **2.2%**, where it stands today.

As Figure 2 below illustrates, there was a decline from 2.5% towards 2% in Colorado’s market, but this simply reflects the State’s inability to expediently process patient card renewals because the LDS’s success was grossly underestimated. For instance, the actual market size was 111% greater than initial projections by the Colorado Center for Law and Policy. Nevertheless, Colorado adapted and allowed for patients awaiting renewal to continue to purchase MM as it expanded its operational capacity. In any event, the key takeaway is that Colorado’s adoption rate grew from just **0.1%** to over **2.0%** in just two-years. This greater than 2% adoption rate is currently the highest seen in any U.S. state medical MM market. Oregon, California, Michigan and Washington, fall into the second tier, with patient adoption rates between 1.4% and 2%.

Looking through the lens of nominal data, Colorado experienced impressive growth in the medical marijuana patient base from 5,000 patients under the caregiver framework in late-2009, to 125,000 patients in Q4 2011, with a population of just over 5 million residents. Extrapolating from this data, Hawai‘i medical marijuana companies and the State would be wise to prepare to handle significant patient registration volumes, but at the same time must not fall victim to heuristic based assessments and succumb to availability bias. To assume that Hawai‘i would experience similarly profound growth is not a base case.

Synthesizing the data from the mainland with the county data in Hawai‘i, one could logically extrapolate that the patient adoption rate on the Hawai‘i Island is relatively close to saturation with some reasonable potential for growth on the margin coinciding with onset of a regulated dispensary network. On the other hand, Oahu has much more significant potential for growth in the long-run, even if peak adoption rates eventually reach levels seen in the other counties in Hawaii or other states across the nation. As a result, BPH sees the greatest need in Oahu for seasoned operators who can leverage their experience in the medical marijuana industry to respond to a burgeoning market in a timely and compliant manner. This offers the best opportunity for patients to receive safe access to medicine without risking product quality or patient safety.



BPH's analysis for Oahu reflects an expectation for a healthy growing medical marijuana patient base in 2016 as citizens anticipate the opening of retail dispensing locations in the second half of the year. As the program matures and stigma recedes, we suspect an increase in the adoption rates moving into 2017 to just under 1% and acceleration in 2H 2018 (to 1.5%) as additional licensees and reciprocity comes into play. Eventually, in BPH's base case forecast, it sees a peak adoption rate of around **2.8%** by 2020. This peak adoption rate in the program is consistent with the current patient base level in other counties in Hawai'i and is the base case for Oahu. BPH is cautiously optimistic that participation will be *higher* given the already meaningful participation in the caregiver framework despite the lack of a regulated LDS network. Other market simulations project participation rates +/- 20% from this level and BPH's flexible cultivation methodologies and sufficient financial resources illustrate an ability to adapt to conditions within these bounds plus a contingency buffer for anomalous statistical outcomes. Nevertheless, we also felt it prudent to engage in more rigorous stress testing scenario analysis.

### **Market Share – 2018 Reciprocity & New Licensees**

Additionally, BPH's analysis assumes that BPH's market presence will grow with the growth of the overall market, but with declining market share over time as more medical marijuana businesses are awarded licenses and come online in 2018. The base case reflects a capture of 1/3 of the market share until other LDS's come online as early as mid-2018, and dropping to high single digits shortly thereafter. These assumptions are in response to increased demand from both the growth in the patient base as well as a modest influx of tourists from other states that can participate in the state's reciprocity program, which is set to take effect as early as July, 2018.

BPH has factored in the State's desire to meet patient need by having no more than one dispensing location per 500 registered patients, but through collective experience and planning, BPH is preparing to handle volumes well in excess of 500 patients should market demand outpace the LDS network. Long-term, if this **2.8%** peak participation level were achieved as expected, that would theoretically result in a maximum of 40 dispensing locations in the county of Oahu by 2021 at the time of market maturation.

Reciprocity will bring very marginal additional tourism business to the state starting in mid-2018, and will be less of a driver of the market than de-stigmatization on the island itself. To capture the impact of reciprocity on the market, we looked at the monthly tourism data from the mainland and distilled how many medical marijuana patients were represented from each state that currently has a medical marijuana program. Subsequently, using average visit lengths (9.54 days) and cannabis consumption patterns, we were able to estimate the marginal revenue generation from these customers. Specifically, the bulk of this tourism injection will come from the mainland Pacific region (CA, AK, WA, OR, NV), which is largely comprised of states with medical marijuana programs. We factored in growth in the patient bases from each of these states, particularly California, which has significant potential for growth once its regulatory scheme is more firmly established in coming years. Nevertheless, we estimate the impact of medical marijuana patient reciprocity to initially be marginal at best, but contribute in larger fashion in longer-term forecasts.

### **Price of Medical Marijuana**



A major driving motivation of BPH team is to provide sustainably produced, pharmaceutical quality, and affordable medicine to patients in need. If Hawai'i's market emerges with prohibitive prices, it will deleteriously impact those in need most and potentially incentivize black market consumption. The medical marijuana movement, is not about capturing market share in a new potentially lucrative industry, rather, it is about educating patients, researching medical marijuana, and illuminating upon the values and benefits of what BPH feels is the most healing plant on earth. To share in the healing powers of this plant, BPH is dedicating resources to employee and customer education as well as research.

These initiatives, like research and education, will absorb financial resources, but BPH feels they are vital as the more we understand the plant and its benefits, the closer we are to optimizing patient health and well being. The effects of this positive feedback loop, will reverberate through society as a whole. Therefore, when it comes to product pricing, BPH realizes that if BPH is fortunate to be one of the initial players in this market, we seek to offer reasonably priced medicine as dictated by market dynamics and internal financial considerations. A significantly regulated market

[REDACTED]

[REDACTED] Hawai'i versus other states are likely key contributors to sustaining higher than average prices.

[REDACTED]

better understand the operational feasibility of price fluctuations. An overarching theme of BPH's approach to this new market is to have an open mind with respect to market dynamics. Thus are preparing to manage price volatility, with a predetermined understanding of what such price variances could mean for the bottom line and the health of the organization. BPH feels confident that its business acumen, expertise in medical marijuana, and deep financial resources position it favorably to deliver high quality medicine to those in need, while being able to weather considerable market volatility.

## **Consumption Behaviors**

In additional to forecasting the patient base, another key consideration is the consumption pattern of those patients. Unlike Colorado at the onset of its market, with numerous states medical



marijuana programs already online, there is a more robust empirical data set to use to cross-reference demand assumptions.

In Colorado, for example, a large part of the State’s underestimation of initial demand was expectations on the “heavy user” (daily user) segment of the population. According to the 2014 National Survey on Drug Use and Health, 23% of the user population in Colorado consumes almost daily, compared with just 17% nationwide.

The mosaic of data and cultural attitudes in Hawai‘i as exemplified by the relatively high adoption rate state-wide before the onset of a true regulated dispensary framework, suggests that relatively high consumption rates by the daily user segment of the patient base will be higher than the national average of 17% but not necessarily higher than 23%. Therefore, in BPH’s forecasts BPH chose to be conservative and baked in higher than average use, but also ran multiple scenario analysis to account for some variance (again, bullish and bearish scenarios +/- 20% in addition to more rigorous stress testing).

### Demographics

One of the key differentiators of Hawai‘i’s current duly registered medical marijuana patient base is the age distribution. As it relates to gender, Hawai‘i is consistent with many other states including Colorado, showing roughly 2/3 (68% vs. 64% in CO) of the base being male and 1/3 (32% vs. 36% in CO) being female. Yet, which age group represents the largest share of patients reflects an interesting contrast to other states. In Hawai‘i, the largest cohort of patients comes from the 56-65 year old segment (27.6%) vs. the 21-30 year old segment in Colorado (23.2%). This data is heat-mapped in Figure X below for illustrative purposes.

**Figure 3: Hawai‘i Medical Marijuana Patient Distribution**

(by Age)

AGE	# of Patients	Percentage of Base
<17	25	0.20%
18-25	573	4.58%
26-36	2,098	16.79%
36-45	2,084	16.67%



<b>46-55</b>	2,381	<b>19.05%</b>
<b>56-65</b>	3,450	<b>27.60%</b>
<b>66-75</b>	1,681	<b>13.45%</b>
<b>76-99</b>	207	<b>1.66%</b>
<b>Total</b>	12,499	

The larger proportion of the patient base in the 55-65yo demographic is consistent with experience in Colorado from the onset of the LDS program. For instance, in 2009 when HCH first opened its doors, a higher percentage of patients were near retirement age. Further anecdotal evidence reflects that medical marijuana was selected as an organic remedy following many years (decades) of battling the side effects of synthetic pharmaceutical prescriptions, mainly opiates. Pain relief, after all, is by far the most common mentioned reason for consuming medical marijuana. 92% of patients in Hawai‘i and 94% of patients in Colorado list this as justification for obtaining their medical marijuana cards.

Taking this one step further, it is the belief of BPH, through HCH and ACC’s real-time experience in the industry in Colorado and other states, that this older segment of the population consumes a larger proportion of infused products (oils, pills, lozenges) rather than inhaled products (flower) for actual and perceived health reasons. For instance, the longer duration and intensity of ingested medication (4-6h of relief vs. 1-2h for inhaled) make it a superior choice to address physical pain, auto-immune, and neuropathic conditions and thus a welcomed remedy for many elder patients. BPH’s collective realization of this dynamic was an important consideration in its partnership with Chief Medical Officer (CMO) Dr. Bradley Willcox, who as a UH affiliated scientist and researcher has deep experience in the area of geriatrics and gerontology.

While this assessment is not empirically robust, it does hint as to how things might unfold and thus caution and prepare BPH for a different set of circumstances than are currently reflected in today’s data. Qualitative experience oftentimes is shunned over the more concrete and tangible nature of quantitative analysis due to BPH’s collective desire for control and greater comfort with numbers than abstract ideas, yet quantitative approaches too have their own pitfalls such as data mining and confirmation bias.

Even though the cumulative consumption basket is challenging to quantify with precision, current evidence signals to us that we should be prepared to offer a relatively greater selection of products in the infused category in anticipation of larger initial demand. It was also a motivating factor in creating a vast array of non-inhaled, infused products, including sprays, lozenges, oils, and pills. This distinction between flower and infused products is quite significant to BPH’s business plan as the different product sets have varying costs of production and shelf life. For example, medical marijuana that is grown to be smoked, requires much greater dedication to the nuances of growing the plant to produce the proper flower structure as well as terpene (essential oil) yields, while



infused products (pills, lozenges, oils) place the greatest emphasis on simple trichome (cannabinoid) production.

So, looking ahead, it is critical for BPH to maintain accurate up-to-date empirical data on the patient base on Oahu in order to better serve the patient's medical needs and forecast their needs with greater accuracy. For instance, the current adoption rate in Oahu County is just 0.29%. The expectation is for this to increase roughly 10x within 5 years. It is possible that the 26-36yo segment experiences more significant growth, which would redistribute consumption patterns over time, yet, perhaps the most likely outcome is that the 55-65yo segment that grows most significantly.

According to the most recent census data, which shows Oahu County expected to grow at **0.6%** per annum from 2015-2020, **16.1%** of the Hawaiian population is over 65, versus **14.5%** as the national average. Colorado, on the other hand, is younger, with just **12.7%** above the age of 65. Using this data as a guide and not gospel, BPH reasonably anticipates a relatively higher consumption of infused products compared to inhaled products, especially at the onset. Yet again, BPH feels it is absolutely critical to maintain meticulous oversight on each of these market variables to ensure BPH's greatest chances at continuing to provide medicine to patients in need and react to market developments in real-time.

### **Cultivation Methodologies – Maintaining Flexibility**

Under Hawai'i law, all licensees are restricted to 3,000 plants per cultivation center, for a maximum of 6,000 plants. Additional licensees are set to be considered by the State at the end of 2017 for launch in mid-2018 should market conditions dictate the need for extra capacity. But what if demand surpasses the needs of patients before additional licenses are awarded in 2018? BPH, for one, is ready to confront such challenges by maintaining flexible cultivation methodologies that allow for varying plant counts per light (and thus plant size) in order to meet excess demand. Through the collective experience of HCH and ACC, BPH is prepared to confront these challenges and efficiently adapt to shifting market dynamics. It is BPH's goal with its initial production centers to maintain a high level of flexibility in production to meet many potential demand scenarios while BPH moves towards the longer goal of building a state of the art, sustainable cultivation facility, leveraging BPH's team's depth of experience in energy.

### **Summary**

BPH's collective track record in various realms of business, including the regulated medical marijuana industry, make it uniquely equipped to confront both the known and unknown challenges of the Hawaiian medical marijuana market. BPH's approach is not inexorable, nor is it dogmatic. BPH's initial cultivation center is strategically poised to navigate the volatility of a new market while sewing the seeds of the long term vision of Hawaii's 2015 CEO of the Year, Henk Rogers, which is to create the gold standard for sustainable cultivation practices in the medical marijuana industry.

While BPH acknowledges the uncertainties of a new market, the base case assumptions are grounded in over 6 years of experience within the marijuana industry and a combination of



qualitative and quantitative analysis of the Hawaii market. BPH has evaluated initial market conditions and made calculated estimations on the market's development from the awarding of licenses in April 2016. BPH's analysis factored in consumption patterns, demographics, population growth, reciprocity, and more to achieve a base case forecast, which was then subjected to rigorous stress testing.

Armed with the knowledge gained from both experience in Colorado and analysis of the Hawaii market, BPH feels confident in its ability to deliver pharmaceutical grade, sustainably produced medical marijuana to Hawaii consumers in 2016. BPH has the business acumen and deep financial resources to accomplish its goal and the passion to share what BPH believes to be the most healing plant on earth with those who are suffering and in need.

*are expressed as a percent of total sales.) Include all assumptions upon which your break-even calculation is based.*

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]









## **Community Plan**

As an organization we realize that when we begin operations we will become a member of the surrounding communities and as such we want to become a valuable and productive member within said communities. Safety for our employees and the surrounding communities is of utmost importance to our organization. With the presence of our facility and the security systems planned for the facility and surrounding area, should help to reduce crime. We have plans to develop and implement community outreach programs. Such programs and events will include food and clothing drives for local food banks, churches, and others. A plan to donate a certain percentage of yearly profits to schools and infrastructure of the surrounding community is also in development. BPH will also adhere to the 'Good Neighbor Policy' at all facility locations.

### **Good Neighbor Policy**

The facility management team is committed to building and maintaining good relationships with all of its neighbors – including local business improvement districts, building owners, small businesses, and residents alike. The facility team shall make every effort respect the perspectives of our neighbors and to address their concerns. The following steps shall be made to ensure any concerns within the community are addressed:

- Introduction meetings with all surrounding businesses, building owners, and residents.
- Educational information sessions to discuss the benefits of marijuana and the company's overall mission and goals.
- Open feedback channels so any new concerns can be immediately addressed through our website, telephone, or mail.
- Complete compliance with all state and local ordinances.
- Non-obtrusive business practices shall ensure our business is discreet and operates like any other business.
- No blatant signage with offensive symbols or verbiage.
- Unmarked discreet transportation vehicles.

In addition, the facility will use carbon air filters to ensure no noxious odors from production are released into the surrounding neighborhoods.

### **Environmental Impact Plan**

Conservation and the reduction of our carbon footprint within the communities we operate in will be a primary objective of the organization. This will be implemented throughout the entire organization and at every facility. We will look for new and innovative ways to reduce our carbon footprint within every facility of the organization. 'Reduce, Reuse and Recycle' will be implemented on an organization-wide scale.

Environmental sustainability is of the highest priority in order to promote a sustainable community and ensure the impact of business is positive and influential in achieving future environmental goals. In order to reach this goal we have contracted designers, engineers and consultants who shall design intelligently, utilize energy intelligently, and strive for procedures that lead to zero waste. Various factors will be considered thoroughly when planning equipment, procedures, and methodology: Air quality, climate, ecological health, energy efficiency, water

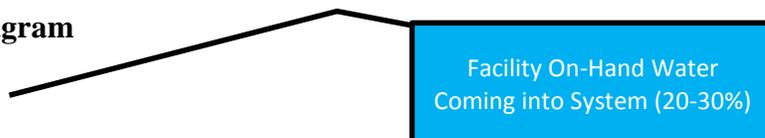


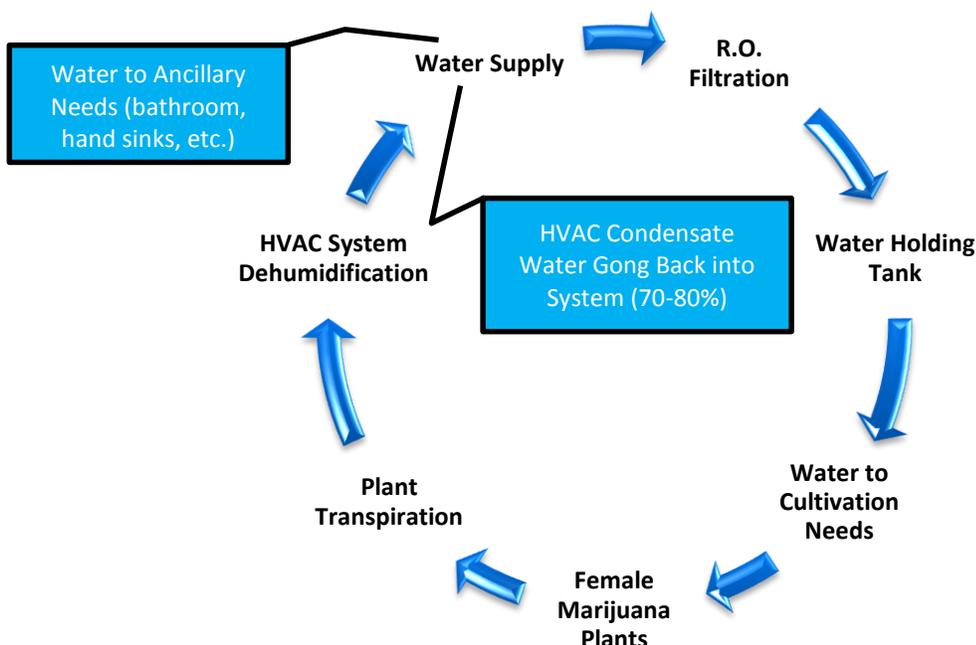
quality, transportation, and waste.

**Energy Conservation**—BPH has unique access to technologies through its team members and the network of scientists and engineers that allow the creation of a sustainable operation. BPH recognizes that power consumption by marijuana producers in other states have been a significant concern for the local government, community members, and the utility companies. Reports estimate California’s 3% to 5% of total power consumption is drawn by the marijuana cultivation industry. With cooperation from alternative energy companies, bioengineering companies, and tech companies, BPH will design and construct a cultivation facility of the highest efficiency and sustainability without sacrificing quality of the produced product. Natural sunlight diffused through a solid non see-through translucent roof with an infrared blocking coating will provide much of the light required for growing. Next generation dimmable LED grow lights, 20% more efficient than conventional LED grow lights in the market in 2015, tailored for hybrid use will supplement the diffused light with precise wavelengths optimal for the current growth stages of the plants. Every environmental factor is monitored by a robust sensor system with over 80 types of sensors that communicate in real time to each of the lights, HVAC equipment, irrigation equipment, and to the cultivation employees; allowing for a real time automatic and/or remote manual control of every aspect of the indoor cultivation environment. Plant biology and conditions will be monitored in order to optimally control the reaction of the plants to the environment and vice versa, allowing the creation of a system in which the plants and the facility will breathe at the same rhythm. By controlling light quality and quantity at the transition of light periods, the system can eliminate a bulk of the spike in relative humidity caused by the transpiration by controlling the closure of the stomata, the pores on the leaf surfaces. The level of precision , monitoring, and control will allow for a massive reduction in power demands by the cultivation facility. The reduced demands will be easily met with renewable energy sources that could include but not limited to solar, wind, hydro power, and hydrogen fuel cells coupled with the advanced energy storage solutions offered by BPES to create the world’s first sustainable marijuana cultivation facility using 100% renewable energy.

**Water Conservation**—In keeping with the sustainable approach, BPH will be collecting moisture from the air through dehumidification with the HVAC system and diverting it back to the Reverse Osmosis (RO) System to re-water the plants. As plants grow, they transpire approximately 70%-80% of the water they drink into the air and this raises humidity levels. As the environmental control systems maintain the parameters needed for optimal plant growth, the HVAC system will be required to provide adequate dehumidification. This dehumidification would produce condensate that typically would be discharged outdoors or in the sewer system as waste water, but BPH will be recapturing this condensate and piping it back to the RO System to be filtered and sent back to out to water the plants. This significantly reduces water consumption to provide environmental and financial benefits.

### Cultivation Facility Water Flow Diagram





BPH management will also create and implement an employee conservation plan. The employee conservation plan will detail specific actions employees can take for conservation efforts to try and reduce their carbon footprint. A possible reward program may be created and implemented to reward facility employees for conservation efforts.

**Employee Conservation:** Team members of BPH will be encouraged to recycle all paper and plastic waste products. Energy efficient lights and equipment will also be utilized within the facility. We will also create programs within the organization that will encourage and reward employees for their personal conservation efforts; such as carpooling and riding a bike to work. Waste products from the facility will be composted on site or mixed with biodegradable products for disposal.

### **Community Benefits Program**

Blue Planet Healing, LLC. (BPH) will contribute a percentage (to be determined after six months of operation) of net profit to organizations with tax-exempt status under Section 501 (c)(3) of the U.S. Internal Revenue Code working to strengthen the community. BPH will direct its contributions to areas that the Board of Directors believe are important to the future of community development, education, and human services. BPH's first priority is to support programs and organizations whose chief purpose is health and community education.

BPH will support organizations and programs that support **education**, specifically programs that:

- Work to eliminate pre-K – 12<sup>th</sup> grade achievement gap in public education through curriculum-based or school-sponsored programs
- Support post-secondary education
- Support booster programs for drug abuse prevention, awareness, and treatment



BPH will support organizations and programs that support **health**, specifically programs that:

- Support research into cures and treatments for qualifying conditions
- Support further research into effective marijuana treatments of qualifying conditions
- Support programs that will improve the health of the community

BPH will support the improvement of low and moderate income communities through programs that:

- Create and sustain affordable housing
- Facilitate literacy
- Provide job training and workforce development
- Revitalize and stabilize community
- Education

BPH will consider requests from organizations that work to enhance community diversity through **arts and culture** and provide:

- Access to and participation in cultural experiences for low and moderate income individuals
- Availability of a broad array of artistic opportunities and venues that reflect the community's diversity

BPH will consider requests from organizations that work to enhance a community's quality of life through projects involving **civic engagement** through:

- Public policy
- Community beautification
- Civic leadership
- Citizen education
- Cultural diversity

BPH is committed to building strong **environmental practices** through programs that:

- Conserve natural resources
- Protect endangered species
- Preserve the environment

BPH will consider requests from social and **human service organizations** that:

- Enable and sustain independence for individuals and families
- Ensure access to health education programs and quality health care

If organizations meet BPH's eligibility requirements and fit in with our philanthropic goals and objectives, we will accept requests and review them throughout the year. Local decisions are made with priority.

### **Substance Abuse and Prevention**

BPH intends to be pro-active in recognizing and preventing substance abuse. In the event that, based on data collected or observation, a potential substance abuse problem is identified; the



patient will be notified and provided with a list of local providers for patient assistance, drug and alcohol treatment and family services that patients may access without BPH involvement. It is at dispensary's agent discretion the extent to which they will provide additional assessment, evaluation, counseling, and/or referral for treatment. BPH employees will be provided training on identifying substance abuse problems.

BPH dispensary staff members will be trained on the physical effects of marijuana on the human body, recognizing the signs of marijuana impairment and what to do should the team member feel that dispensing medical marijuana to a patient and/or caregiver is not in their best interest and could result in negative consequences. All BPH professional staff members have the authority to deny dispensing medical marijuana and/or medical manufactured marijuana products to any Hawai'i qualified, registered patient or caregiver if they reasonably suspect there could be substance abuse problems with said patient or caregiver.



## Appendices

- Financial Pro-Forma Model
- Standard Operating Procedures
  - Cultivation
  - Manufacturing
  - Retail dispensing
  - Log Sheets
- Employee Handbook
- Security Plan















# **Securitas Company Profile**

## **Executive Summary**

### **Introduction**

- Securitas is the industry leader in Protective Services.
- Local Focus - Securitas USA has nearly 500 local branch managers throughout the United States. Each branch manager offers the commitment of a small business owner, with P&L responsibility for his/her local business operation. Every client is equally important.
- Global Presence - Securitas is the world's largest provider of security officers and related services. We are established in 54 countries including the U.S., Canada, Mexico, Europe, South America and Asia. We have a network of partners in many other areas of the world as well and provide security services in over 105 countries.
- World Class: It is Securitas USA's ongoing goal to set the industry standard and continually raise the bar. To this end, we have implemented a comprehensive Total Quality Management approach to doing business.
- Securitas USA has nearly 500 branch portfolios in Guarding, Government, Critical Infrastructure and Corporate Risk Management services.
- Securitas has approximately 90,000 U.S. employees and 350,000 employees worldwide.
- Securitas has three business segments: Security Services North America, Security Services Europe and Security Services Ibero-America.

### **Department of Homeland Security Certification and Designation - SAFETY Act**

- After an extensive review by the Department of Homeland Security (DHS) of the service standards adopted and followed by Securitas Security Services USA, the DHS has awarded Securitas USA, and its customers, the highest level of liability protection afforded by the SAFETY Act. This entitles Securitas USA to the Government Contractor Defense, which can eliminate liability for claims arising from designated acts of terrorism.

### **Company History**

- Global revenues in 2014 were over \$10.06 billion.
- Securitas acquired Pinkerton in 1999.
- Securitas acquired Burns International and smaller companies in 2000.
- In July 2003, all U.S. operations united under the single name of Securitas Security Services USA, Inc.
- In 2015, Securitas AB acquired the electronic assets of Diebold, becoming a leading provider of electronic security solutions and services to business customers.

### **Capabilities Overview**

- Securitas Security Services USA, Inc. provides Securitas Protective Services including On-site, Mobile and Remote Guarding; Electronic Security; Fire & Safety; and Corporate Risk Management through our parent company, Securitas AB.
- In Hawaii we are the 9th largest employer in the State, and have State and DOT current contracts.

### **People**

#### **Selection and Hiring**

**Recruiting sources include:**



- Career Builder's The Talent Network
- Securitas' web page (www.securitasinc.com), local newspapers, college campus placement centers, state employment commissions/development departments, veterans' groups, senior organizations, city and county social service agencies, private industry councils, JTPA programs, vocational centers, military and law enforcement organizations, job fairs, employee referrals (referral bonuses)

#### **Minimum Hiring Standards:**

- At least 18 years of age
- Reliable means of communication
- Reliable means of transportation
- Legal right to work in the United States
- Ability to effectively speak, read and write English
- High school diploma or GED
- Willingness to participate in the company's stringent pre-employment screening process
- Ability to qualify for and obtain a state security officer license, where applicable

#### **Eight Step Hiring Process:**

- Comprehensive job application
- Securitas Employment Assessment Tool
- Initial interview
- Drug screening
- Background verification
- Assignment/scheduling meeting
- Site interview with client (client can accept/decline candidates chosen for site)
- Security officer introduction/questionnaire/exam

#### **Procedures**

##### **Account Management:**

- Site Supervision: Site Manager, Shift Supervisors, Field Supervisors, Flex Force
- Branch Supervision: Area Vice President, Branch Manager, Human Resource Manager, Recruiter, Training Manager, Scheduling Manager, Accounts Payable/Receivable
- Regional Support Teams: Region President, Vice President of Sales, Vice President of Human Resources and Training, Regional Controller

##### **Post Orders Document System (PODS)**

PODS is a proprietary software program that ensures all of the client's requirements are being met in the post orders. This template ensures consistency and provides our officers with the detailed information needed to perform their jobs to your expectations.

##### **Transition Plan:**

- Detailed transition schedule with time-lines and action plans
- Transitions are typically completed within thirty (30) days of an agreement
- Implementation Plan within the first 60 days of account start up (calls for enhanced management presence on site)

##### **Training:**

- Level 1 Training: Introduction to Security



- Level 2 Training: Career Development, Site Specific Training and Advanced Certification Training (ACT)
- Level 3 Training: Specialized Training
- E-Learning and the Securitas On-line Academy
- Ongoing professional development
- Annual refresher training
- Value-added training solutions
- Additional specialized training programs per industry/market
- Supervisor training

**Tools:**

- Securitas Automated Field Enterprise System – Stand alone, proprietary scheduling system that is integrated with the PeopleSoft ERP platform and allows all account administration to be managed at the branch level.
- SecuritasConnect – A secure Client Portal that gives instant access to your facility’s critical information in real time. You have the capability to access this data 24 hours a day, 365 days a year.
- SecuritasVision – a secure scalable web-based application that helps us bring innovation, accountability and efficiency to your facility. It can be deployed at a single property or across your entire organization, and combines incident management, tour verification, task scheduling and incident alert notification in one easy-to-use application.
- Post Confirmation System – electronic, proprietary officer check-in system that verifies posts are staffed.
- Proof of Visit System – documents supervisor inspections.
- National Communications Center – 24/7 call center for clients and security officers.

**Feedback:**

- Excellence in Service Program.
- Client Service Plan – primary tool used to measure and monitor client security goals.
- Service Enhancement Plan – used to implement and monitor improvement actions.
- Service Delivery History – documents meetings/communications between client and Securitas management.
- Client Service Review – our monthly ‘report card.’ Clients help rate and define a variety of performance categories to help ensure we consistently meet or exceed your expectations.

**Securitas Awards and Recognition**

*\*See below*



*The Hawai'i Lodging & Tourism Association gives special recognition to:*

***Securitas Security Services USA, Inc.***

***2013 Na Po'e Pa'ahana Award***

***Allied Member of the Year***

***1st Place Winner***

*This prestigious annual honor is in recognition of your outstanding efforts on the job, in the community and for the visitor industry*



*George Szigeti*  
*President & CEO, The Hawai'i Lodging & Tourism Association*

*January 10, 2013*

*Date*





## *Commendation*

*- Presented to -*

### Securitas Security Service USA, Inc., Allied Member of the Year

January 10, 2013

On behalf of the people of the State of Hawai'i, I offer my congratulations and warmest Aloha.

*Mahalo* for your contribution to our visitor industry and your contribution to the community and economy of the Hawai'i.

Your commitment and dedication is appreciated and recognized and we appreciate your efforts to ensure that a visit to our beautiful islands is a special experience our visitors will never forget.

Hawai'i's visitor industry brings approximately \$12 billion annually to our State economy and we owe a great debt of gratitude to employees like you, who work so hard to make Hawai'i's tourism what it is today - our leading industry.

Your earning the Ma Po'e Pa'ahana award is richly deserved. I commend you and applaud you for your hard work, accomplishments, and for sharing the Aloha Spirit with our guests from around the world. May you enjoy continued success in all your future endeavors.

*Aloha,*



**NET. ABERCROMBIE**  
Governor, State of Hawai'i



## The Department of Homeland Security has approved **Securitas Security Services USA, Inc.** for protection under the SAFETY Act\*.



After an extensive review by the Department of Homeland Security (DHS) of the service standards adopted and followed by Securitas Security Services USA, Inc., the DHS has awarded Securitas USA, and certain of its affiliates, SAFETY Act protection (Designated).

Congress passed the SAFETY Act as part of the Homeland Security Act of 2002 to encourage the development of anti-terrorism products and services by limiting liability from claims brought as a result of a DHS-designated terrorist attack where approved anti-terror technology or services are deployed.

### **Briefly, here is what SAFETY Act protection means to our valued customers:**

When applicable, the SAFETY Act should extend the protection to all parties in the supply chain, including all of Securitas USA's government and private sector customers and subcontractors.

*\*Support Anti-terrorism by Fostering Effective Technologies Act.*

#### **Integrity**



#### **Vigilance**



#### **Helpfulness**



Securitas Security Services USA, Inc. is a knowledge leader in the security services industry. As an industry leader, Securitas USA, and its affiliates, offer a wide variety of security solutions, including on-site security officers, mobile patrol, remote security monitoring and corporate risk management. From small businesses to large corporations, our 100,000 employees are making a difference. The SAFETY Act's provisions have not been tested, and certain of the foregoing statements are based on interpretations of the SAFETY Act's provisions and the regulations promulgated thereunder. For more information about the Department of Homeland Security and the SAFETY Act, visit [www.safetyact.gov](http://www.safetyact.gov).





















































































































### Application Response: Question 5

Blue Planet Healing LLC (“BPH”) is dedicated to provide relief that Hawai‘i patients deserve through a high quality, sustainable, and responsibly grown medical marijuana (“MM”). To ensure it can achieve this goal, BPH will utilize the knowledge and experience of: its medical advisor team (see answer to Question 1); retained industry consultants, the American Cannabis Company Inc. (“ACC”); and High Country Healing (“HCH”), and BPH’s product manufacturing licensor, UNDRNWMNGMNT, LLC (“UNM”). BPH will leverage the knowledge and experience of these medical professionals and consultants, as well as its local, scientific and horticultural advisors in executing its operating plans and to ensure BPH can successfully meet the needs of qualifying patients in Hawai‘i by providing safe and legal access to pharmaceutical grade MM.

### **Patient Education.**

BPH will utilize the expertise and experience of its medical team, HCH and ACC for its patient education programs and efforts. ACC and HCH have developed and will continue to develop educational materials for qualifying patients on the pharmaceutical use of marijuana especially for patients with little or no experience using marijuana. These educational materials will, among other things, contain information regarding: the various methods of administration; dosage considerations and recommendations; information on marijuana strains; and other useful patient information. This current document can be viewed in full and has been attached to BPH’s application as “attachment “5.1”. BPH invites the Department of Health to (review and) opine on the efficacy of these materials.

Patient education is particularly important for manufactured marijuana products as many consumers may not have experience with such products. Each qualifying patient has unique circumstances associated with their qualifying medical condition, individual biology and their resulting experience with medical marijuana. Qualifying patients will require varying degrees of



### Application Response: Question 5

information about dosages, absorption, delivery methods, psychoactive effects, strains, cannabinoid ratio's and types of marijuana that have the best indicators for their qualifying medical condition so the patient can make informed decisions, and practice safe marijuana consumption.

UNM has developed and agreed to license to BPH comprehensive educational materials for the use of manufactured marijuana products. This material includes product-specific literature, such as product-safety inserts, as well as a patient education guide containing information about medicinal aspects of various cannabinoids, and the relative benefits of various delivery methods. UNM's patient education guide has been included as an attachment to BPH's application where it can be viewed in its entirety. (See Attachment "5.2") In addition, UNM has developed the educational website [www.CannabisIsSafe.com](http://www.CannabisIsSafe.com) as a means to educate the public. BPH will fully utilize these educational materials in developing its own education program specific to its product offerings. Registered employees will receive training on all BPH manufactured marijuana product lines prior to interacting with registered patients at all retail dispensing locations ("RDL").

An important aspect of patient education, as explained in more detail within UNM's patient education guide, is choosing the right MM delivery method for each individual qualifying patient based on their particular needs and qualifying medical condition. Certain methods may be more efficacious in meeting the specific needs of qualifying patients. For example, if a qualifying patient has nausea-related conditions, a sublingual delivery method would be preferable because it largely circumvents the digestive system. BPH's manufactured marijuana products will allow for the following methods of administration:

- Transmucosal (Sublingual): Tincture, Sublingual Oral Spray (Takes effect in 5-30 minutes, effects last 1-6 hours)



### Application Response: Question 5

- Oral Mucosal: Tincture, Sublingual Oral Spray (Takes effect in 5-30 minutes, effects last 1-6 hours)
- Gastrointestinal: Tincture, Capsule (Takes effect in 1-2 hours, effects last 6-8 hours)
- Transdermal: Salve, Lotion, Ointment (Takes effect in varying times, effects last for varying times)

Other topics covered in UNM's patient education guide include:

- Information about medical studies relating to medical the use of marijuana
- Determining dosage and tolerances; Side effects
- Dependence; Withdrawal symptoms and signs; and Drug interactions
- How to keep medical marijuana secure
- Unlawful distribution
- Driving, operation of mechanical equipment, child care or making important decisions while under the influence of marijuana
- Disposal of unwanted, excess or contaminated marijuana
- Marijuana laws and regulatory highlights

### **Producing and Maintaining a Supply of Marijuana.**

With the help and guidance from its marijuana industry experts HCH and ACC and its Chief Horticultural Advisor (See attachments "5.3", "5.4" and "5.5" respectively), BPH will be uniquely able to produce and maintain a supply of marijuana and manufactured marijuana products sufficient to meet the needs of qualifying patients in Hawai'i. HCH and ACC have the experience and know-how to successfully deploy and scale up commercial marijuana cultivation operations in order to timely cultivate and produce its initial harvest and thereafter a consistent and perpetual supply of pharmaceutical grade medical marijuana. With the help of BPH's consultants BPH has



### Application Response: Question 5

developed production and demand forecasts based on established marijuana markets and estimated qualifying patient consumption rates. (See Attachment “5.6”) BPH will structure its production in order to be able to meet current estimated production needs as well as having the ability to rapidly scale up in order to meet anticipated increased patient demand or accelerated adoption.

### Retail Dispensing Locations.

BPH intends to initially start its operations with a single RDL located at [REDACTED] and will plan to add a second RDL in accordance with state law and regulations in response to market demand. BPH’s first RDL is located in a convenient, easily accessible area in the [REDACTED] located within the heart of Honolulu. This RDL will feature ample parking for customers and qualifying patients as well as being situated near a major transit center for TheBus. [REDACTED]

[REDACTED] This will add a level of safety to the RDL that is similar to a bank or pharmacy thereby providing qualifying patients with a safe location to obtain their MM and manufactured marijuana products. The various security alarms, video surveillance and other security measures designed by Securitas and to be utilized at BPH’s RDL can be viewed on the floor plan that has been included as an attachment “5.7”.

### Customer Satisfaction.

BPH will utilize industry best practices developed for established operations within Colorado’s regulated marijuana industry and quality assurance programs to continuously measure and improve customer satisfaction. Customer satisfaction will be a top priority of BPH as BPH strives to cultivate, manufacture and dispense the highest quality MM. BPH will utilize a patient feedback form (See Attachment “5.8”) to gather feedback and input from qualifying patients regarding:



### Application Response: Question 5

BPH’s marijuana products; the qualifying patients’ overall experience at BPH; the location and layout of the RDL; BPH’s registered employees; and any other information or comments qualifying patients may wish to provide to BPH. This patient feedback form will be reviewed by BPH in order to improve its products, processes and procedures in order to offer qualifying patients the best experience possible with BPH.

To ensure qualifying patient and public safety, BPH will establish, implement, document and maintain an appropriate Quality Management System (“QMS”). To this end, BPH is committed to the following Quality Management Principles:

- Customer Focus; Good Science Makes Good Medicine; Leadership; Involvement of People; Process Approach; System Approach to Management; Continual Improvement; Factual Approach to Decision Making and Mutually Beneficial Supplier Relationships

To assure the adequate establishment, implementation, documentation and maintenance of the QMS, BPH will follow ISO 9001 (See Attachment “5.9”) and will hire a full-time Director of Quality Management who is certified as a Manager of Quality and Organizational Excellence by the American Society of Quality. The Director of Quality Management will be responsible for following the standards contained in ISO 9001 to develop the appropriate QMS for BPH in accordance with Hawai‘i state law and regulations. With this commitment to quality BPH will be able to produce a consistent phytopharmaceutical grade MM product. (BPH’s QMS is attached as “5.10”)



# **BASIC MEDICAL MARIJUANA INFORMATION**

For Qualifying Patients and Caregivers in Hawai'i



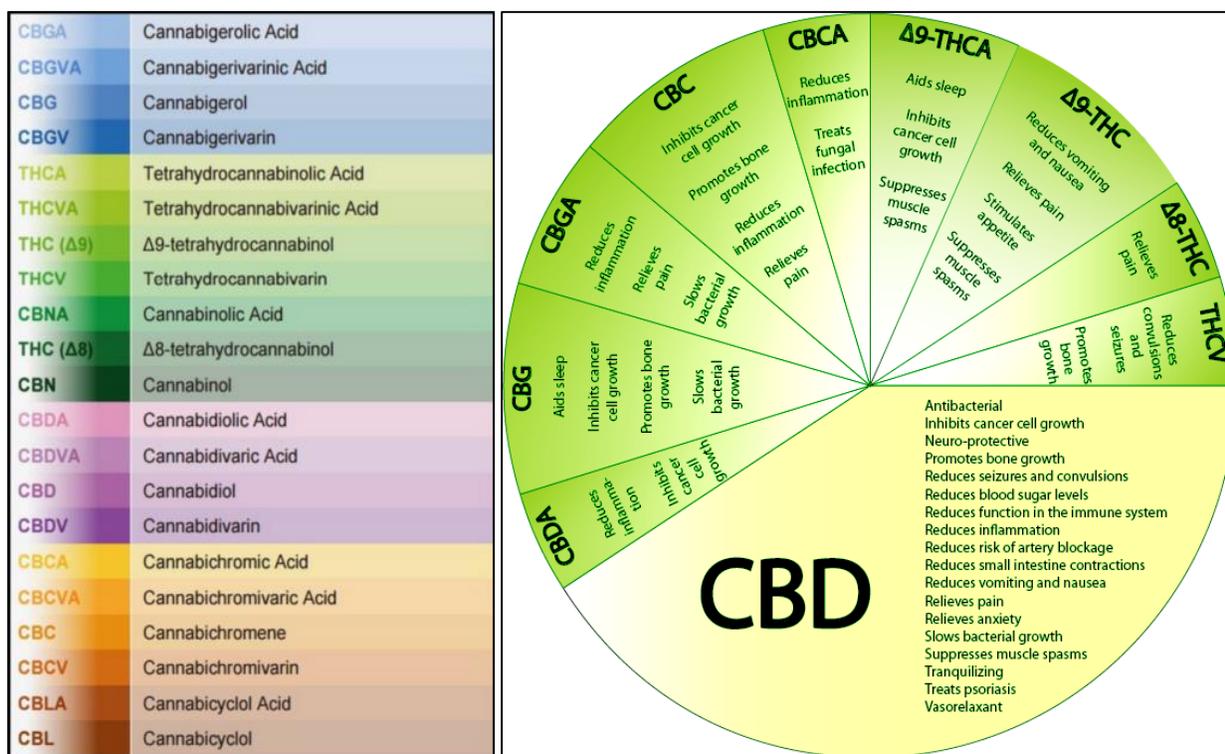
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## Introduction

Medical marijuana has proven to help alleviate a multitude of symptoms for a variety of diseases and ailments; however, the process involved in determining which marijuana strain or variety to choose can be daunting. New patients will need to experiment with a variety of strains to determine which one they receive the most relief from. Individual patients will have different reactions to the medical marijuana strains available, so patients will need to be educated about the potential effects of each marijuana strain. The information compiled in this document by Blue Planet Healing LLC (BPH) is meant for educational purposes only.

The potency of marijuana is measured and quantified by the amount of  $\Delta 9$ -tetrahydrocannabinol (THC) which is the principal psychoactive constituent (cannabinoid). The different cannabinoids present in the marijuana plant also have different medicinal values which are currently being examined. The different cannabinoids present in the marijuana plant are displayed in the charts below. One chart details the different names of cannabinoids present in the marijuana plant and the other chart identifies known medicinal values associated with the cannabinoids.



\* <http://hempedification.blogspot.com/p/cannabinoids.html>

## Types of Marijuana

A good starting point to determine which marijuana strain or variety to try is to educate yourself on the three (3) primary varieties of marijuana—indica, sativa and hybrid.



- **Indica**— Indica strains are geared more towards patients looking for pain relief and sleep aid.
- **Sativa**— Sativa strains are more uplifting and geared more towards patients looking for relief from depression.
- **Hybrid**—Hybrid strains will produce effects of both indica and sativa strains.

There are several key differences between indica and sativa marijuana strains. These include height and stature, internodal length, leaf size and structure, buds size and density, flowering time, odor, and effects. Indica plants tend to grow shorter and bushier than the sativa plants. The leaves of indica strains tend to have wide, short leaves, whereas sativa strains have long leaves. The buds of indica strains tend to be wide, dense and bulk, while sativa strains are likely to be elongated shaped flowers.

Marijuana indica has a higher ratio of THC:CBD compared to sativa varieties. Marijuana strains with relatively high CBD:THC ratios are less likely to induce anxiety than vice versa. The effects of sativa are well known for its cerebral high. Users can expect a more vivid and uplifting high, while indica is well known for its sedative effects which some prefer for night time use. Indica possesses a more calming, soothing, and numbing experience in which can be used to relax or relieve pain. Both varieties of marijuana are used as medical marijuana.

<b>sativa.</b>	<b>indica.</b>
<b>Mind Dominant</b>	<b>Body Dominant</b>
<b>Anti-Anxiety</b>	<b>Sedating</b>
<b>Anti-Depresant</b>	<b>Relaxing</b>
<b>Activating</b>	<b>Muscle Relaxant</b>
<b>Uplifting</b>	<b>Treats Accute Pain</b>
<b>Increase Alertness</b>	<b>Reduce Nausea</b>
<b>Increase Energy</b>	<b>Increase Appetite</b>
<b>Enhance Creativity</b>	<b>Increase Dopamine</b>

\* <http://www.googleweed.com/index.php?page=search/images&search=indica%20v.s%20sativa&type=images>

## Marijuana History

Marijuana has a long history of cultivation and use, a native of Central Asia, it has been purported to have come under domestic cultivation as much as 10,000 years ago. Its use as a medicine is both historically & geographically prevalent with documented use occurring in China, India, Southeast Asia, and South America, with the earliest recorded use published under the reign of Chinese Emperor Chen Nung, 5,000 years ago. In Chinese medicine it was often recommended for rheumatic pains, constipation, malaria, female disorders, absentmindedness, and as an analgesic during surgery. In India, it has been recommended to lower fevers, quicken the mind, induce sleep, stimulate appetite, relieve headaches, treat venereal disease and improve digestion. In Africa it was frequently used to treat malaria,



dysentery, and other fevers. Marijuana was also recommended as a remedy by Galen and other physicians of the Hellenistic & classical eras. In the *Anatomy of Melancholy*, published 1621, Marijuana is recommended to relieve depression. The *New English Dispensatory* of 1764 advises the application of the roots to alleviate skin inflammation. And as a final example, The *Edinburgh New Dispensary* of 1794 includes a lengthy summary of the effects of marijuana, stating that the oil is valued in the treatment of urinary incontinence, venereal disease, and coughs. (Grinspoon, 2005)

Yet, marijuana as a medicine did not flourish in the West until the mid-19<sup>th</sup> century. From 1840 to 1900 more than one hundred papers were published on the medicinal benefits of Marijuana, commonly referred to as Indian hemp at the time, in Western medical literature, recommending it for various illnesses and discomforts. In 1860, Dr. RR M'Meens reported the findings of the Committee on Marijuana Indica to the Ohio Medical Society, communicating that positive application for Indian hemp had been found in treating; dysmenorrhea, neuralgia, tetanus, convulsions, postpartum psychosis, chronic bronchitis, pain of rheumatism & childbirth. In 1887, HA Hare declared the ability of Indian hemp to subdue restlessness, anxiety, and distract a terminally ill patients mind, providing relief. In 1890, a British physician, JR Reynolds, summarizing 30 years of experience with Marijuana, recommended it for patients with senile insomnia, neuralgia, epilepsy, depression, asthma, migraine attacks & dysmenorrhea. In 1891, a physician, Dr. JB Matison referred to Marijuana as "...a drug that has special value in some morbid conditions and the intrinsic merit and safety of which entitles it to a place it once held in therapeutics." Mattison goes on to review the uses of the plant as ; an analgesic, hypnotic, useful in treating dysmenorrhea, chronic rheumatism, morphine addiction, gastric ulcer, asthma, and particularly useful in treating and preventing migraines. Mattison concludes his report

*"The young men are rarely prescribing it." To them I specially commend it. With the wish for speedy effect, it is so easy to use that modern mischief maker, hypodermic morphia, that they [young physicians] are prone to forget remote results of incautious opiate giving"*

By 1890 and into the 1900's Marijuana' use as a medicine in the West was in decline, attributed to a lack of standardization and quality of the marijuana preparations, the seeming erratic and unpredictable responses of patients, and the invention of the hypodermic needle and soluble synthetics like morphine, aspirin, barbiturates, and chloral hydrate. While these new drugs were able to provide standardized quality, predictable responses, and in some cases instant relief, they were not as safe as Marijuana. When the study of congeners (chemical relatives) of tetrahydrocannabinol become possible in 1940, one might have expected physicians to explore Cannabinoid substances for drugs that may have more specific and stable effects. However, the Marihuana Tax Act of 1937 stymied continued medical efforts, marking the beginning of the era of *Reefer Madness*, and the roots of the prohibition we still face today. While not expressively prohibiting its medical use, the act put an extensive amount of paperwork into the process, and the following anti-diversion regulation further compounded physician disenchantment, culminating in the 1941 removal of Marijuana from the U.S. Pharmacopeia and National Formulary. (Grinspoon, 2005) *Insert bit about 1970's, and drug war.*



Yet, despite such opposition, there is a resurgence of interest in the medical applications of Marijuana. With many states having established or establishing medical marijuana programs in spite of continued federal prohibition. This is very interesting as far as developmental medicine is concerned. Other than the well-known cannabinoid, tetrahydrocannabinol, the Marijuana plant contains a vast variety of chemicals with varied pharmacological effects and possible medicinal value. Approximately 483 compounds have been identified, and some are unique to the plant. Marijuana and its products contain any number of cannabinoids, terpenes, fatty acids, nitrogenous compounds including spermidine type alkaloids, various sugars, flavonoids, non-cannabinoid phenols, simple alcohols, aldehydes, ketones, acids, esters, and lactones. Cannabinoids represent a class of C<sub>21</sub> terpenophenolic compounds, are unique to the Marijuana plant, and are of the most immediate medical interest, as research indicates there is an extensive endocannabinoid receptor system distributed throughout humans. 66 cannabinoids have been identified, but many experts estimate there are over 100 unique types, these compounds are typically referred to as phytocannabinoids to distinguish them from the synthetically & endogenously produced cannabinoids. See Table 1 for a review of the so far identified phytocannabinoids, their structure, and their so understood pharmacological effects. (ElSohly 2007)

*\*This content and information provided can be seen in its original version "A History of Marijuana; The Medicinal Value of Marijuana" created by the American Cannabis Company, Inc. which contains more detailed information. Registered employees of BPH will be provided a copy of "The History of Marijuana" to become educated on the history and facts surrounding marijuana and marijuana as a viable medicinal treatment option for certain debilitating medical conditions. This documents content has also been included at the end of this document.*

## Medicinal Value of Marijuana

Evidence of any particular marijuana strain/cultivar's demonstrated success in alleviating symptoms of specific conditions is, aside from a few clinical cases in the Dutch & Israeli systems (Jack Herer & Avidelk respectively), primarily anecdotal, colloquial folk knowledge.

Much clinical research classifies marijuana as smoked marijuana, and does not delve into cultivar/strain particulars. In published research, when there is additional depth in analysis of the ingested marijuana, the major cannabinoids; Tetrahydrocannabinol (THC), Cannabidiol (CBD), & Cannabinol (CBN) are typically measured. Although there are many other cannabinoids and possible bioactive terpenes, reference standards and analytical methods are still in research and development stages. However, clinical research has evidenced that THC, CBD administered independently and together, via various routes of administration, contribute effectively to palliative treatment in a number of conditions and symptomologies. In addition to their high THC and/or CBD contents, the following cultivars have been chosen due to their optimal cannabinoid ratios.

The following Marijuana cultivars/strains are proposed for production, showing the average range of cannabinoid content, as determined by HPLC-DAD.

### Examples of THC Dominant Cultivars/Strains:

- Sour Diesel
  - THC = 14%-24%
  - CBD = .3%-.4%
  - CBN = .16%-.83%



- Blue Dream
  - THC = 15%-23%
  - CBD = .2%-.4%
  - CBN = .16%-.22%
- OG Kush
  - THC = 12%-22%
  - CBD = .36%-.46%
  - CBN = .22%-.6%
- Grape Ape
  - THC = 13%-21%
  - CBD = 0%-1%
  - CBN = 0%-1.1%
- Granddaddy Purple
  - THC = 14%-20%
  - CBD = 0%-.6%
  - CBN = 0%-1.41%
- Jack Herer
  - THC = 11%-22%
  - CBD = 0-.4%
  - CBN = 0-.25%
- Northern Lights

#### **Examples of CBD Dominant Cultivars/Strains:**

- Harlequin
  - THC; 2%-5%
  - CBD: 5%-9%
- That Kind
  - THC: 7-9%
  - CBD: 14-16%
  - CBN: 0-.2%
- Avidekel
  - THC: 0%
  - CBD:16%
  - CBN: 0%

There is much anecdotal evidence of the demonstrated success and effects of the proposed cultivars positive impact on a number of symptomologies. The following effectiveness summaries were developed, based on cross sectional composite surveys of the three largest crowdsourced marijuana databases the proposed cultivars have the following reported effects.

#### **Examples of THC Dominant Cultivars/Strains:**

- Sour Diesel
  - Appetite, Pain, Nausea, Anxiety, Sleep;
- Blue Dream
  - Appetite, Anxiety, Nausea, Pain;
- OG Kush
  - Appetite, Pain, Nausea, Anxiety;
- Grape Ape
  - Appetite, Pain, Sleep;



- Granddaddy Purple
  - Pain, Insomnia, Appetite, Spasticity;
- Jack Herer
  - Dutch Pharmacies used as medical grade strain, stress, anxiety, nausea, cachexia;

THC, the dominant cannabinoid in the Sour Diesel, Blue Dream, OG Kush, Grape Ape, Granddaddy Purple, and Jack Herer cultivars have clinically demonstrated to be effective as a palliative therapeutic various for conditions and symptomologies. Clinically, THC has been demonstrated successful at alleviating the symptomology of severe and chronic pain, nausea, vomiting, wasting, cachexia, seizures and spasms manifested during HIV/AIDS, Cancer, Multiple Sclerosis and other disorders. While clinical evidence for a specific cultivars success is nonexistent, logic dictates, and user reported case studies supports, the concept that cultivars high in THC are effective at treating the above listed symptomologies & diseases. Furthermore, given its wide safety margin, these cultivars are likely to find application in other diseases and disorders with similar symptomology. Additionally, CBD has been demonstrated to have anxiolytic and antipsychotic properties. As such, the CBD content contained in the above proposed strains may serve to reduce possible negative side effects of THC administration, anxiety & paranoia. Allowing for more effective medication and an improved patient experience.

#### **Examples of CBD Dominant Cultivars/Strains:**

- Harlequin
  - Anxiety, Nausea, Spasticity, Seizures, Sleep;
- That Kind
  - Appetite, Nausea, Pain, Spasms, Spasticity, Seizures,
- Avidkel
  - Researchers at Hebrew university have shown that Avidkel , can be used for treating diseases like rheumatoid arthritis, colitis, liver inflammation, heart disease and diabetes

CBD, the dominant cannabinoid in the Harlequin, That Kind & Avidkel cultivars, has been demonstrated successful in treating a number of conditions and symptomologies. Clinically, CBD has been demonstrated to be an effective antipsychotic as well as an anticonvulsant. CBD's anticonvulsant properties have been demonstrated in animal models since the 1970's. CBD first gained national notoriety in the striking case study, popularized by Dr. Sanjay Gupta and CNN, of Charlotte, a young girl suffering from chronic epileptic seizure. In that case study Charlotte's Web, a CBD dominant strain was found to be effective in alleviating her seizures and spasms. Since then GW pharmaceuticals has demonstrated the success of CBD in treating Dravets syndrome under Phase I & II FDA clinical trials, and is currently under Phase III. Research in animal models has demonstrated that CBD may prove useful in alleviating symptoms of anxiety related disorders, such as PTSD.

In addition to smoked Marijuana flower, there are a variety of product derivatives that have demonstrated success in alleviating various symptomologies of different conditions. Evidence of any particular marijuana strain/cultivar's extract or product derivatives demonstrated success in alleviating symptoms of specific conditions is, aside from a few clinical cases in the Dutch & Israeli systems (Jack Herer & Avidkel respectively), primarily anecdotal, colloquial folk knowledge.



However, clinical evidence has evidenced that THC, CBD administered independently and together, via various routes of administration, contribute effectively to palliative treatment in a number of conditions and symptomologies to include; cancer, glaucoma, HIV/AIDS, PTSD, Multiple Sclerosis, Parkinson's, Tourette's, Alzheimer's, Pain, Nausea, Cachexia, Spasms, Seizures, & Anxiety.

The production of all infused medical marijuana products begins with the production of an extract. Cannabinoids, being lipophilic, respond well to the following extraction methodologies; CO<sub>2</sub>, Alcohol, Hydrocarbon (Butane, Propane, Hexane, Etc.), and various fats such as coconut oil or butter.

The following types of medical marijuana extracts are proposed for development. The range of cannabinoid profiles, as determined by high performance liquid chromatography- diode array detection, are provided.

#### **Examples of THC Dominant Extracts—CO<sub>2</sub> extraction processes**

- Sour Diesel
  - THC=60-95%
  - CBD=.9-1.5%
  - CBN=.5-2.5%
- Blue Dream
  - THC= 60-95%
  - CBD= .6-1.2%
  - CBN=.5-1%
- OG Kush
  - THC= 60-95%
  - CBD= 0-2%
  - CBN=.6-1.2%
- Grape Ape
  - THC=60-95%
  - CBD=0-3%
  - CBN=0-3.3
- Granddaddy Purple
  - THC= 60-95%
  - CBD= 0-2.4%
  - CBN=0-5%
- Jack Herer
  - THC= 65-95%
  - CBD= 0-1.8%
  - CBN= 0-1%
- Northern Lights
  - THC= 65-95%
  - CBD= 0-.5%
  - CBN=0-.5%

Extracts, when vaporized and inhaled and are effective for dosing to quickly reach peak serum levels, providing fast acting acute relief, however drug half-life is shorter when compared to other routes of administration, such as ingestion, topical or suppository. Thusly, frequent re-administration may be required to maintain relief.



The cannabinoid profile of the extract will vary based the method of extraction. Additionally various compounds such as terpenes, plant fats, and waxes, are extracted with various degrees of efficiency, based on the extraction method. For instance, CO2 extractions pull out less terpenes, but a will have a higher cannabinoid percentage, than a frozen mechanically sieved hash, which can have the highest quantity of terpenes, while having a lower cannabinoid percentage, due to extraneous plant matter. These additional compounds may or may not exhibit relevant bioactivity, synergy and entourage in a patient, clinical research is required.

However, anecdotally there is ample evidence of the demonstrated success and effects of the proposed extracts positive impact on a number of symptomologies. The following effect summaries were developed, based on cross sectional composite surveys of the three largest crowdsourced marijuana databases the proposed cultivars have the following reported effects:

#### **Examples of THC Dominant—CO<sub>2</sub>, oil**

- Sour Diesel (SD)
  - Appetite, Pain, Nausea, Anxiety, Sleep;
- Blue Dream (BD)
  - Appetite, Anxiety, Nausea, Pain;
- OG Kush (OGK)
  - Appetite, Pain, Nausea, Anxiety;
- Grape Ape (GA)
  - Appetite, Pain, Sleep;
- Granddaddy Purple (GP)
  - Pain, Insomnia, Appetite, Spasticity;
- Jack Herer (JH)
  - Dutch Pharmacies used as medical grade strain, stress, anxiety, nausea, cachexia;
- Northern Lights (NL)

#### **Examples of CBD Dominant—CO<sub>2</sub>, oil**

- Harlequin, (H)
  - Anxiety, Nausea, Spasticity, Seizures, Sleep;
- That Kind (TK)
  - Appetite, Nausea, Pain, Spasms, Spasticity, Seizures,
- Avidekel (A)
  - Researchers at Hebrew university have shown that (A) , can be used for treating diseases like rheumatoid arthritis, colitis, liver inflammation, heart disease and diabetes

Marijuana extracts can be used to produce a variety of infused medical products. A THC dominant extract and CBD dominant extract made from one or a combination of the CO2 and/or alcohol extracts of the above listed strains will be blended to create the following THC: CBD ratios; 1:0, 0:1, 1:1, 2:1, 1:2, 25:1 & 1:25. Blended extracts with the previously mentioned ratios will be used to create various strengths of the following medical marijuana infused products. As a whole, medical marijuana infused products provide a reliable longer lasting alternative to smoking and vaporization, which may not be accommodating or tolerable to a patient.



- Eye drops
  - Clinically demonstrated to have a positive effect on Glaucoma, eye drops have a short onset, and a longer duration time, reducing intra-ocular pressure (IOP) protecting Glaucoma patients from nerve damage.
- Pills
  - Clinical research has demonstrated that the effects of the oral ingestion of marijuana infused products have a longer duration than administration via inhalation. Oral ingestion of marijuana infused products has been demonstrated successful as a palliative therapeutic for a variety of symptomologies and conditions to include; a reduction of IOP in Glaucoma, the spasms and seizures of multiple sclerosis, Parkinson's, & Tourette's, & the pain, nausea, and wasting associated with Cancer and HIV/AIDS.
  - A pill, as opposed to a candy or sweet, makes more sense from a medical perspective, lending themselves more easily to assurances in content uniformity, as well as near universal palatability.
  - An oral application of THC:CBD in a 1:1 ratio has been clinically demonstrated to be effective at alleviating seizures in Dravets syndrome.
- Orcomucosal Spray,
  - A THC: CBD ratio of 1:1 has been clinically demonstrated to be effective in treating spasms and seizures associated with multiple sclerosis

Evidence demonstrates the success of the above types of medical marijuana infused products as a palliative therapeutic in a handful of specific conditions. These reports are supported by an anecdotal folk knowledge. Although more clinical research is needed, given the wide safety of margin, and the types of symptomologies that the active cannabinoids have been demonstrated to alleviate; pain, nausea, anxiety, wasting, spasms, seizures, inflammation, it would be logical to pursue the treatment of other disorders with similar underlying symptomologies using medical marijuana infused products.

## Medical Marijuana Products

### Product Offerings

BPH intends to offer a variety of approved medical marijuana products for dispensing to qualified, registered patients and caregivers in the State of Hawai'i. Products BPH intends to offer include:

- Medical marijuana flower
  - Indica marijuana strain varieties
  - Sativa marijuana strain varieties
  - Hybrid marijuana strain varieties
- Manufactured marijuana products
  - Concentrates
    - CO<sub>2</sub> oil
      - Shatter
      - Wax
  - Sublingual tinctures
  - Pill-form/capsules



- Topicals; lotions, creams and/or salves

### Product Offering #1: Medical Marijuana Flower

- **Product Description**—strains of marijuana range from those with a high level of THC and low level CBD to those with a high level of CBD and low level of THC. These strains will include Indica and Sativa varieties which are excellent for pain and hybrid strains which will be a blended variety with effects similar from both sativa and indica varieties.
  - Besides appearance, indica and sativa plants are commonly believed to have different effects on their user.
- **Product Benefits**—the evidence is overwhelming that medical marijuana can relieve certain types of pain, nausea, vomiting and other symptoms caused by such illnesses as multiple sclerosis, cancer and AIDS – or by the harsh drugs sometimes used to treat them.

### Product Offering #2: Manufactured Marijuana Products

BPH will create products that are convenient for administration of the active ingredient, marijuana. Our goal is to create various dosage forms that will make administration of marijuana convenient, easy and palatable for qualifying, registered patients in Hawai‘i. BPH’s goal is to have a solution for every problem when it comes to administration of the marijuana product and Eric will help to create and formulate our various product offerings.

- **Product Description**—manufactured marijuana products are products made with marijuana as an ingredient. They can come in the form of concentrates, sublingual tinctures, capsules, topical(s), dermal patches, and suppositories.
- **Product Benefits**—the benefit of manufactured marijuana products include they offer patients an alternate delivery means to experience the effects of cannabinoids without smoking or vaporizing marijuana. Alternative ingestion methods that offer consumers cannabinoid delivery formats other than smoking are one of the fastest growing segments of the marijuana industry.
- **Product Strengths**—an easily administered option for taking medical marijuana products. It improves dosing calibration and benefits from the convenience of portability.
- **Product Weaknesses**—it can take longer to feel the effects of the medical marijuana product.

## Routes of Administration for Marijuana Consumption

There are primarily three (3) different routes of administration for marijuana consumption in the state of Hawai‘i; 1) inhalation 2) ingesting and 3) topical use.

The most popular method is inhalation, however smoking has negative health risks associated with it due to the combustion of material. Vaporizing is a form of inhalation that is gaining in popularity due to the health benefits associated with no combustion of plant material happening. The ingestible and topical marijuana products will be utilized by patients who do not want to, or cannot consume medical marijuana through inhalation.



## Inhalable Marijuana Products

- **Raw Flower:** Multiple genetics and strain varieties of indica, sativa and hybrid marijuana will be cultivated. Different medicinal values and benefits will be obtained through different indica, sativa and hybrid marijuana strains. Raw flower will typically be smoked or vaporized by qualified medical marijuana patients.
  - Indica marijuana strain varieties
  - Sativa marijuana strain varieties
  - Hybrid marijuana strain varieties
- **Marijuana Concentrates:** Marijuana concentrates are the active compounds in the marijuana extracted, usually through a solvent method such as CO<sub>2</sub>, the concentrated form is very potent and high in THC content. Marijuana concentrates are made from extracting the cannabinoids from the marijuana plant material. Marijuana concentrates can be made into various forms and products including but not limited to hashish, bubble hash, CO<sub>2</sub> oil, BHO—shatter, wax, live resin, crumble, etc.

## Ingestible Marijuana Products

- **Sublingual Tincture:** Tinctures are a form of liquid edible marijuana. Tinctures will be consumed by placing the liquid tincture under the patient's tongue, drinking the liquid tincture alone or mixing the tincture with tea or some other beverage.
- **Pill-Form/Capsules:** Edible pill form marijuana products will be beneficial to patients that cannot or prefer to not vaporize marijuana. Medical marijuana patients will ingest the edible pills in order to receive the medicinal benefits of marijuana.

## Topical Marijuana Products

- **Topical(s):** Topical(s) will include ointments and lotions that can be utilized by medical marijuana patients looking to alleviate skin irritations and lesions. Topical(s) are rubbed on the skin or area needed by a medical marijuana patient.

## Marijuana Consumption Recommendations

Start LOW, go SLOW is the best motto to follow when consuming medical marijuana and/or medical manufactured marijuana products.

- 1) More Is Not Better
  - a. Medical marijuana and manufactured marijuana products are potent, it is recommended to start with small dosages; not more than 10 mg/dose for medical marijuana-infused products. Wait 30 minutes from your first dose, if you are still in pain or suffering from ailments then consume another 10mg.
- 2) Stay Well Hydrated
  - a. It is easy to become dehydrated when consuming medical marijuana and/or manufactured marijuana products. It is recommended to drink plenty of water when consuming medical marijuana products.
- 3) Consume Responsibly



- a. Do not drive or operate motorized vehicles or equipment after consuming medical marijuana or manufactured marijuana products.
  - b. It is not recommended to combine intoxicants such as alcohol or prescription medication while consuming marijuana products.
  - c. Keep all medical marijuana and medical marijuana-infused products away from and out of reach of children.
- 4) Start Low, Go Slow
- a. Some people experience marijuana-related anxiety and paranoia from high dosages of medical marijuana and medical marijuana-infused product. So start low and go slow when consuming medical marijuana and manufactured marijuana products.

## Marijuana's Effect on the Human Body

Marijuana will have different effects on every individual person and the effects may vary depending on quantity consumed, dosage rate, whether or not the marijuana was smoked or eaten and other factors may contribute to the effects on the human body.

### Physical Effects Based on Type of Marijuana Product

Marijuana has an active ingredient called THC, which is what makes people feel 'high'. THC and other compounds in marijuana can also affect the way your body works. Marijuana affects almost every organ in the body, the nervous system and immune system. Smoking marijuana can increase the heart rate, lower blood pressure, and affect blood sugar. When inhaling marijuana, the body absorbs THC immediately, if you consume a marijuana-infused item, it may take much longer for the body to absorb THC because it has to break down in your stomach before it enters the bloodstream.

Other physical effects of marijuana consumption include:

- Dizziness
- Shallow breathing
- Red eyes and dilated pupils
- Dry mouth
- Increased appetite
- Slowed reaction time

Smoking marijuana can have less-pleasant effects on one's mind and mood such as:

- A distorted sense of time
- Random thinking
- Paranoia



- Anxiety
- Depression
- Short-term forgetfulness

### Amount of Time to Feel Impairment

The amount of time it takes to feel impairment will differ and vary for everyone. Generally speaking, effects are typically immediate after consuming marijuana through inhalation but could take up to 2 or 3 hours after consuming marijuana through ingesting.

### Visible Signs of Impairment

The most immediate signs of marijuana consumption/impairment are:

- Red eyes and dilated pupils
- Increased heart rate
- Increased appetite
- Memory impairment
- Difficulty paying attention or solving problems
- Dizziness
- Shallow breathing
- Dry mouth

### Recognizing Signs of Impairment

The following information is being provided to assist persons in recognizing the signs and/or symptoms of marijuana consumption and for purposes of determining if an individual may be under the influence. This information is intended for informational purposes only and is not intended for use as training material, or to assist individuals in becoming drug recognition experts and should not be used in lieu of recommendations or advice from qualified professionals.

Generally speaking, if you notice an individual having trouble with balance, trouble walking or using motor functions, the individual may be impaired from consuming marijuana or marijuana-infused products. Redness of the eyes, dilated pupils and dryness of the mouth can also be indicators of impairment.

## State of Hawai‘i Regulations

The State of Hawai‘i laws and regulations regulating the medical marijuana industry can be obtained from Hawai‘i Department of Health website:

- <http://health.hawaii.gov/medicalmarijuana/>
- <http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/12/Dispensary-Rules-Chapter-11-850-signed-by-Gov-12-13-15.pdf>



- <http://health.hawaii.gov/medicalmarijuana/submenu/doh-medical-use-of-marijuana-administrative-rules-effective-july-18-2015/>

## Patient/Caregiver Attestations

Before marijuana and/or manufactured marijuana products are dispensed, a qualifying, registered patient or caregiver shall be made aware that the qualifying patient or caregiver understands that the qualifying patient and caregiver are not immune from the imposition of any civil, criminal, or other penalties for the following:

- Operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or boat while under the influence of medical marijuana;
- Smoking medical marijuana in any public place;
- Smoking medical marijuana in a motor vehicle; or
- Undertaking any task under the influence of medical marijuana, when doing so would constitute negligence or professional malpractice;
- Smoking medical marijuana on a private property that:
  - Is rented from a landlord; and
  - Is subject to a policy that prohibits the smoking of medical marijuana or marijuana on the property; or
- Smoking medical marijuana on a private property that is subject to a policy that prohibits the smoking of medical marijuana on the property of an attached dwelling adopted by:
  - The board of directors of the council of unit owners of a condominium regime; or
  - The governing body of a homeowners association.

Before marijuana and/or manufactured marijuana products are dispensed, a qualifying, registered patient or caregiver shall be made aware that the qualifying patient or caregiver understands that:

- The qualifying patient or caregiver shall:
  - Keep all medical marijuana away from children other than the qualifying patient; and
  - Take steps to prevent children from obtaining or using medical marijuana;
- It is illegal to transfer medical marijuana to any person, other than the transfer by a caregiver to a qualifying patient;
- Obtaining medical marijuana does not exempt a qualifying patient or caregiver from prosecution under Federal law and the penalties provided by Federal law;
- Scientific research has not established the safety of the use of medical marijuana by pregnant women; and
- The use of medical marijuana to treat a medical condition is not approved by the U.S. Food and Drug Administration.

## Sales Limits for Qualifying Patients

The State of Hawai'i has defined sales limits for qualifying patients to be:



- Not exceed four (4) ounces of marijuana during a period of fifteen (15) consecutive days;
- Not exceed eight (8) ounces of marijuana during a period of thirty (30) consecutive days

### Patient Responsibility

A patient’s medical marijuana and/or medical marijuana products are intended SOLELY for that patient. Do NOT distribute any medical marijuana or medical marijuana-infused products to anyone for any reason.

Keep medical marijuana and medical marijuana-infused products out of reach from children. You should treat your medical marijuana and/or medical marijuana-infused products as any other prescription medication—it is recommended to store all medical marijuana and medical marijuana-infused products in a child-resistant, re-sealable container in a locked area or cabinet out of reach of children.

### Child-Resistant Packaging

BPH will package all medical marijuana and medical marijuana-infused products in child resistant packaging prior to dispensing said product to a qualified patient or caregiver. Child-resistant packaging is special packing used to reduce the risk of children ingesting dangerous items, for BPH’s purposes child-resistant packaging will be used to reduce the risk of children ingesting medical marijuana and/or medical marijuana-infused products. Some examples of child-resistant packaging are shown below.



It is important for qualifying, registered patients’ to understand the importance of packaging and labeling medical marijuana products. Proper packaging and labeling will achieve two primary objectives; 1) the medical marijuana product will be properly labeled to identify who the product is intended for, dosage rates and instruction and other important information pertaining to the patient or the medical marijuana derivative products, and 2) proper child-resistant packaging will help to ensure children cannot easily access the medical marijuana derivative product(s).



Child Resistant Packaging to be used for pill-form edibles (*capsules*)



Child Resistant Packaging to be used for oils (*for sublingual*)



Metered Dosage Packaging to be used for oils (*vaporization*)



Tamper-Evident Packaging to be used for pill-form edibles (*capsules*)



Tamper-Evident Packaging to be used for oils (*for sublingual*)



Tamper-Evident Packaging to be used for oils (*for vaporization*)



**Exit Packaging**—this exit packaging will be used to place the pre-package medical marijuana product(s) in at the medical dispensary prior to patients and/or a patients’ legal representative exiting the dispensary. This exit packaging will create a double redundancy to ensure children cannot unintentionally access the medical marijuana product(s). Exit packaging will be opaque concealing the contents inside and will allow patients and/or caregiver discretion upon exiting the dispensary. Exit packaging is also utilized to minimize the risk to product diversion or the medical marijuana product(s) falling into the wrong hands.

The Satchel™ is a pouch-like case designed as a high-quality, child-resistant exit package solution for the regulated marijuana industry. The Satchel™ meets child-safety requirements of the Consumer Products Safety Commission (CPSC), making it compliant in all states. The Satchel™ is also tested and approved by the American Society for Testing and Supplies (ASTM). The Satchel™ will meet all current exit packaging regulations; featuring a child-resistant closure completely concealing the contents inside.

# THE SACHEL™



## Labeling

BPH will use a medical marijuana industry specific Point of Sale (POS) system that will be able to automatically generate both the product-specific and patient-specific labels as required by Hawai'i regulations.

Examples of manufactured marijuana product labels can be seen below:

**SAMPLE PRODUCT LABEL: LOTION**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

**LOTION**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_ Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management.

**ALLERGEN LABELING:** This product may be unlabeled outside of the State of Hawaii and is not intended for persons or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: SALVE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

**SALVE**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_ Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management.

**ALLERGEN LABELING:** This product may be unlabeled outside of the State of Hawaii and is not intended for persons or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: SERUM**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

**SERUM**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_ Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management.

**ALLERGEN LABELING:** This product may be unlabeled outside of the State of Hawaii and is not intended for persons or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: GEL**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

**GEL**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_ Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management. This product may be used for medicinal purposes with caution or used as a recreational product. An inventory tracking barcode is provided for the purpose of product tracking and inventory management.

**ALLERGEN LABELING:** This product may be unlabeled outside of the State of Hawaii and is not intended for persons or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.





# “The History of Marijuana” from the American Cannabis Company, Inc.

## **Section 1: Cannabis, a Medicinal History**

Marijuana has a long history of cultivation and use, a native of Central Asia, it has been purported to have come under domestic cultivation as much as 10,000 years ago. Its use as a medicine is both historically & geographically prevalent with documented use occurring in China, India, Southeast Asia, and South America, with the earliest recorded use published under the reign of Chinese Emperor Chen Nung, 5,000 years ago. In Chinese medicine it was often recommended for rheumatic pains, constipation, malaria, female disorders, absentmindedness, and as an analgesic during surgery. In India, it has been recommended to lower fevers, quicken the mind, induce sleep, stimulate appetite, relieve headaches, treat venereal disease and improve digestion. In Africa it was frequently used to treat malaria, dysentery, and other fevers. Marijuana was also recommended as a remedy by Galen and other physicians of the Hellenistic & classical eras. In the *Anatomy of Melancholy*, published 1621, Marijuana is recommended to relieve depression. The *New English Dispensatory* of 1764 advises the application of the roots to alleviate skin inflammation. And as a final example, The *Edinburgh New Dispensary* of 1794 includes a lengthy summary of the effects of cannabis, stating that the oil is valued in the treatment of urinary incontinence, venereal disease, and coughs. (Grinspoon, 2005)

Yet, marijuana as a medicine did not flourish in the West until the mid-19<sup>th</sup> century. From 1840 to 1900 more than one hundred papers were published on the medicinal benefits of Cannabis, commonly referred to as Indian hemp at the time, in Western medical literature, recommending it for various illnesses and discomforts. In 1860, Dr. RR M’Meens reported the findings of the Committee on Marijuana Indica to the Ohio Medical Society, communicating that positive application for Indian hemp had been found in treating; dysmenorrhea, neuralgia, tetanus, convulsions, postpartum psychosis, chronic bronchitis, pain of rheumatism & childbirth. In 1887, HA Hare declared the ability of Indian hemp to subdue restlessness, anxiety, and distract a terminally ill patients mind, providing relief. In 1890, a British physician, JR Reynolds, summarizing 30 years of experience with Cannabis, recommended it for patients with senile insomnia, neuralgia, epilepsy, depression, asthma, migraine attacks & dysmenorrhea. In 1891, a physician, Dr. JB Matison referred to Marijuana as “...a drug that has special value in some morbid conditions and the intrinsic merit and safety of which entitles it to a place it once held in therapeutics.” Matison goes on to review the uses of the plant as ; an analgesic, hypnotic, useful in treating dysmenorrhea, chronic rheumatism, morphine addiction, gastric ulcer, asthma, and particularly useful in treating and preventing migraines. Matison concludes his report

*“The young men are rarely prescribing it.” To them I specially commend it. With the wish for speedy effect, it is so easy to use that modern mischief maker, hypodermic morphia, that they [young physicians] are prone to forget remote results of incautious opiate giving”*

By 1890 and into the 1900’s Cannabis’ use as a medicine in the West was in decline, attributed to a lack of standardization and quality of the marijuana preparations, the seeming erratic and unpredictable responses of patients, and the invention of the hypodermic needle and soluble synthetics like morphine, aspirin, barbiturates, and chloral hydrate. While these new drugs were able to provide standardized quality, predictable responses, and in some cases instant relief, they were not as safe as Cannabis. When the study of congeners of tetrahydrocannabinol become possible in 1940, one might have expected physicians to explore Cannabinoid substances for drugs that may have more specific and stable effects. However, the Marihuana Tax Act of 1937 stymied continued medical efforts, marking the beginning of the era of *Reefer Madness*, and the roots of the prohibition we still face today. While not expressively prohibiting its medical use, the act put an extensive amount of paperwork into the process, and the following anti-diversion regulation further compounded physician disenchantment, culminating in the 1941 removal of Marijuana from the U.S. Pharmacopeia and National Formulary. Which was followed by national prohibition and the start of the drug war during the Nixon administration. (Grinspoon, 2005)

## **Section 2: The Modern Medical Evidence for Marijuana& Its Derivatives**

### **Introduction**

In spite of political and legal challenge Marijuana has resurfaced as a medicine. Initially receiving attention for its efficacy in the palliative care of HIV/AIDS & Cancer. Marijuana has most recently gained notoriety for its



effectiveness as an antispasmodic, dramatically improving the quality of life for seizure-ridden children & other sufferers of epilepsy. While clinical data was still lacking, the dramatic anecdotal evidence from sufferers of Dravet's syndrome gained national notoriety when Dr. Sanjay Gupta publicized the case of Charlotte on CNN. Dr. Gupta recounted how ingestion of the now infamous *Charlotte's Web* strain (nothing more than a strain high in CBD, and likely other active terpenes, thought to be a *Harlequin* varietal), dramatically reduced the seizure intensity, frequency, and duration for Charlotte, effectively giving her a life.

Since the inception of its use, Marijuana use has been driven by anecdotal evidence, with colloquially accepted folk traditions purporting its use for a variety of ailments with wide safety margins. Anecdotal evidence still drives its use here in the United States and across globe. Yet, while the clinical evidence has gaps, leaving more to be desired, there is a growing body of evidence that supports many of the traditionally accepted purposes, and in several cases, proving efficacy and safety through blind clinical trials. In this section we review the evidence for Marijuana & medicine for a variety of diseases and symptoms where Cannabis' use and effect has been documented

## **Diseases, Disorders & Symptoms and the Evidence for the use of Marijuana & Its Derivatives**

### **Cachexia/Wasting Syndrome**

Cachexia, also known as wasting syndrome is characterized by loss of weight, appetite, fatigue & weakness, in someone whose intention is not to lose weight. Cachexia is different than anorexia and disorders that lead to similar symptoms as it is not self-imposed and is body mass loss that cannot be reversed through nutrition.

This condition is found in sufferers of cancer, AIDS, chronic obstructive pulmonary disease, multiple sclerosis, congestive heart failure, tuberculosis, familial amyloid polyneuropathy, gadolinium poisoning, mercury poisoning, and hormonal deficiency. Other conditions in which Cachexia may be present are; chronic kidney disease, cystic fibrosis, motor neuron disease, Parkinson's disease, dementia, metabolic acidosis, chronic pancreatic, some autoimmune disorders, and addiction to an amphetamine. Cachexia will physically weaken patients to a state of immobility stemming and is a positive risk factor for death. (Payne, 2012, Lainscak, 2007, Bossola, 2007)

Although the exact mechanisms for the development of cachexia are not fully understood there is substantial evidence to support the role of inflammatory cytokines, such as tumor necrosis factor-alpha, interferon gamma, & interleukin 6, and others. By themselves, cytokines are capable of causing weight loss. With respect to the beneficial role of medicinal marijuana there is ample evidence that CB1 receptor agonists, such as THC, alter appetite. Indeed, one of the most consistent effects of smoking marijuana is an increase in appetite. Some evidence demonstrates that marijuana shows clinical efficacy for the treatment of refractory nausea, pain, and appetite loss, all elements of Cachexia. (Aggarwal, 156)

### **Anorexia**

Anorexia, an eating disorder characterized by a fear of gaining weight, strong desires to be thin, food restriction, and low weight, is often comorbid with PTSD and various anxiety disorders, with PTSD occurring prior to anorexia's onset. (NIMH 2015, Gleaves 1998, Rodriguez, 2011) There appear to be some genetic components, with identical twins more often affected than non-identical twins, and cultural factors playing a strong role (Attia 2010, DSM 2013). Treatments primarily aim to restore healthy weight, with additional measures being taken to help treat anxiety or depression, symptoms of PTSD. (NIMH 2015).

The eCB system has been shown to control food intake via action on olfactory processes, this affect is often associated with the popularized *munchies* effect that marijuana is colloquially known to have. (Soria-Gomez, 2014) It was these effects that initially lead researchers to experiment with the drug on HIV/AIDs & Cancer patients suffering from Cachexia. This same line of reasoning also led researchers to explore its efficacy in treating anorexia nervosa. However, the evidence on cannabis's effect on anorexia nervosa is scarce and mixed. Studies provide evidence for a dysfunctional eCB system in eating disorders. One study, using the THC synthetic Dronabinol, found significant improvement in weight gain with patients suffering from anorexia nervosa. (Casteels, 2013, Andries, 2013) Through this mechanism as well as its appetite stimulating affect, marijuana may play a palliative role in patients suffering from Anorexia.

### **Severe/Chronic Pain**



Pain, an unpleasant sensory & emotional experience associated with potential of actual tissue damage, it can be acute or chronic, mild or severe. (Bonica, 1979) Sometimes pain can arise in spite of any detectable disease, damage, or stimulus. (Raj, 2007) One of the most common reasons for a doctor's visit, pain is a major symptom of many medical conditions, having the potential to significantly interfere with a person's quality of life. (Debono, 2013) Because it is so broad, a taxonomy of pain has developed. Woolf and colleagues attempt to classify pain by mechanism, suggesting three classes. (Woolf, 1998)

Nociceptive Pain, results from peripheral nerve fibers firing, which respond to stimuli that approach and/or exceeds harmful receptor limits. Common causes for nociceptive pain are thermal, mechanical, and chemical events. Nociceptive pain may be further divided into visceral, superficial somatic, and deep somatic. Visceral structures are very sensitive to inflammation, ischemia, & stretch, but relatively insensitive to other stimuli like cutting or burning. Deep somatic pain is initiated by stimulation of nociceptors in ligaments, bones, blood vessels, fasciae, muscles and bones, characterized by a poorly localized, dull aching pain. Superficial pain is initiated by activation of nociceptors in the skin and other superficial tissues, being sharp, defined, and localized. Minor wounds and first-degree wounds are examples of superficial somatic pain.

Inflammatory Pain associated with tissue damage and infiltration by immune system, and pathological pain due to disease states causing damage to the nervous system or its otherwise abnormal function, such as tension headaches, fibromyalgia, and irritable bowel syndrome. Neuropathic pain, a type of pathological pain associated with nervous system damage and malfunction is often described as a burning, tingling, electrical, stabbing, sensation. (Woolf, 1998) And while not addressed by Woolf, another type of pain is psychogenic pain, also known as somatoformic pain or psychalgia. Psychogenic pain can result in headache, back, stomach and other types of pain. While most pain is transitory, resolving when the stimulus is removed some conditions are chronic; such as rheumatoid arthritis, cancer, idiopathic pain, peripheral neuropathy, and some psychogenic pains. People suffering from long term pain often display other psychological disturbances and show elevated scores for hysteria, depression, and hypochondriasis. While some have argued that this neuroticism cause acute pain to developing into chronic pain, clinical evidence indicates the opposite, that chronic pain causes neuroticism, with anxiety, depression, hypochondriasis, and hysteria decreasing after chronic pain is relieved, often followed by an increase in self-esteem. (Wall, 1998)

Marijuana is especially promising in the field of pain management. Virtually every experimental pain paradigm in supraspinal, spinal and peripheral regions are inhibited by cannabis, without the possibility of a lethal overdose. (Aggarwal, 157) In a review of studies examining Marijuana & its derivatives effect on pain, a statistically significant majority of participants favored some form of THC over a placebo. (Whiting, 2015) In a different anonymous cross-sectional survey of chronic non-cancer pain patients found that 35% had used marijuana to self-medicate. (Kogan, 2015)

That withstanding, in other scenarios, just as in cognitive impairment, studies have shown that marijuana can be both an effective and ineffective analgesic. A study examining refractory neuropathic pain failed to show that THC improved pain or quality of life scores. While another study showed that a patient with familial Mediterranean fever experienced a great reduction in pain after being administered oral THC. THC induced reduction in pain has also been noted in brachial plexus root aversion, neuropathic pain and central pain (Kogen, 2015) Just as in many other areas, further research is required before concrete conclusions can be drawn.

### **Severe Nausea/Vomiting**

A review of clinical trials found that out of 748 patients given smoked cannabis and 345 given oral THC, experienced a 70-100% and 76-88% respectively, relief from nausea and vomiting. In another meta-analysis of 18 studies comparing standard antiemetics to marijuana resulted in a statistically significant preference for marijuana over traditional antiemetics such as domperidone or alizapride. (Aggarwal, 156)

### **Seizures**

Seizures, often used interchangeably with convulsions, are the physical effects following a period of aberrant brain activity. During a convulsive episode a person's body shakes rapidly without control, the muscles relaxing and contracting repeatedly. There are many types of seizures as well as underlying causes and not all seizures result in full convulsions, having instead milder symptoms without the shaking, such as staring spells. The specific symptoms depend on the underlying cause and what part of the brain is involved. Specific symptoms which may occur are; brief blackout followed by confusion, drooling/frothing at the mouth, eye movements, snorting/grunting, behavioral



changes like picking at clothes, loss of bowel and/or bladder function, mood changes such as anger, fear, joy, laughter, or panic, sudden falling, universal body shakes/tremors, the taste of metal or bitterness, teeth clenching, breathing cessation, muscle spasticity to include twitching & jerking of limbs. Symptoms may last anywhere from a few seconds to 15 minutes, and while rare, can last longer. (NLH, 2015)

While all seizures are spurred by disorganized and sudden electrical activity in the brain, specific causes can include; aberrant levels of glucose or sodium, brain infections including meningitis, stroke, drugs such as cocaine, PCP, & amphetamines, poisoning, phenylketonuria, high fevers, head injury, heart disease, epilepsy, electrical shock, brain tumor, congenital birth defects, toxemia of pregnancy, liver/kidney failure and resulting toxicity, malignant hypertension, venomous stings & bites, & alcohol withdrawal.. Once the underlying causes are treated but the seizures are not alleviated the condition is classified as epilepsy. (NLH, 2015)

### **Severe/Chronic Muscle Spasms**

Spasm may refer to an array of involuntary muscle activities. While some spasms may be due to seizure, not all are. Often spasms are due to abnormal neuronal or muscular activity. A true, hypertonic spasm is spurred by malfunctioning feedback nerves and is permanent unless treated. A spasm subtype is a colic, which results in episodic pain due to spasms in smooth muscle, such as the bile duct.

Spasms can be caused by ion imbalances & muscle overload. Menstrual cramps, diarrhea, gallbladder pain, and passing kidney stones are all known to induce painful muscle spasms. In addition, dystonia's involved abnormality with the chemicals that transmit signals to the brain, are responsible for muscle spasms. Spasms are associated with a wide array of disorders that include Amyotrophic Lateral Sclerosis (ALS), dehydration, diabetes type 1 & 2, dystonia, multiple sclerosis, claudication, pancreatic cancer, Parkinson's disease, schizophrenia, seizure, stress, toothache, hypoparathyroidism, muscle cramps, temporomandibular joint syndrome, ramsay hunt syndrome, rabies, tetanus, heat exhaustion & cramps, polio, urinary incontinence, neuromyotitis optica, anxiety (NINDS 2015)

THC has many potential benefits to ALS patients, including analgesia, muscle relaxation, bronchodilation, saliva reduction, appetite stimulation, antioxidative and neuroprotective effects. SOD1G93A mice, an ALS model, had the disease progression slowed via CB-2 agonists and life span increased when CB-1 agonists were introduced. (Kogen et al, 420)

### **Glaucoma**

Glaucoma, a type of optic neuropathy, refers to a group of eye disorders which can result in damage to the optic nerve, most often due to increased pressure in the eye. (Casson, 2012.) Glaucoma is the second leading cause of blindness behind cataracts and the leading cause of blindness among African Americans. (Rhee, 2013) However, if the condition is detected and treated early enough it is possible to arrest progression.

Mechanisms that induce Glaucoma are only partially understood, however it has been proven that increases in intraocular pressure are causal behind optic nerve damage and eventual blindness due to Glaucoma (American Glaucoma Society 2015). Therefore the mainstay of current treatment is the reduction in intraocular pressure (IOP). Beginning in 1971, smoked marijuana has been shown to directly reduce IOP. (American Glaucoma Society, 2015) The American Glaucoma Society has stated:

“It has been definitively demonstrated, and widely appreciated, that smoking marijuana lowers IOP in both normal individuals and in those with glaucoma, and therefore might be a treatment for glaucoma”

The study goes on to identify oral THC administration produces longer periods of IOP reduction than smoked cannabis. Smoked marijuana was required every three hours to maintain a consistent reduction in IOP. However THC is far from a perfect cure in its current state. Patients have expressed a dislike of the psychoactive effects. In addition to this, reduction in IOP may only be part of the problem, low blood flow may also need treatment. Localized treatment to the eye may be possible due to the presence of cannabinoid receptors in the eye but due to poor water solubility of cannabinoids, an effective eye drop formulation has yet to be tested. (Jampel, 2009)

### **Post-Traumatic Stress Disorder (PTSD)**

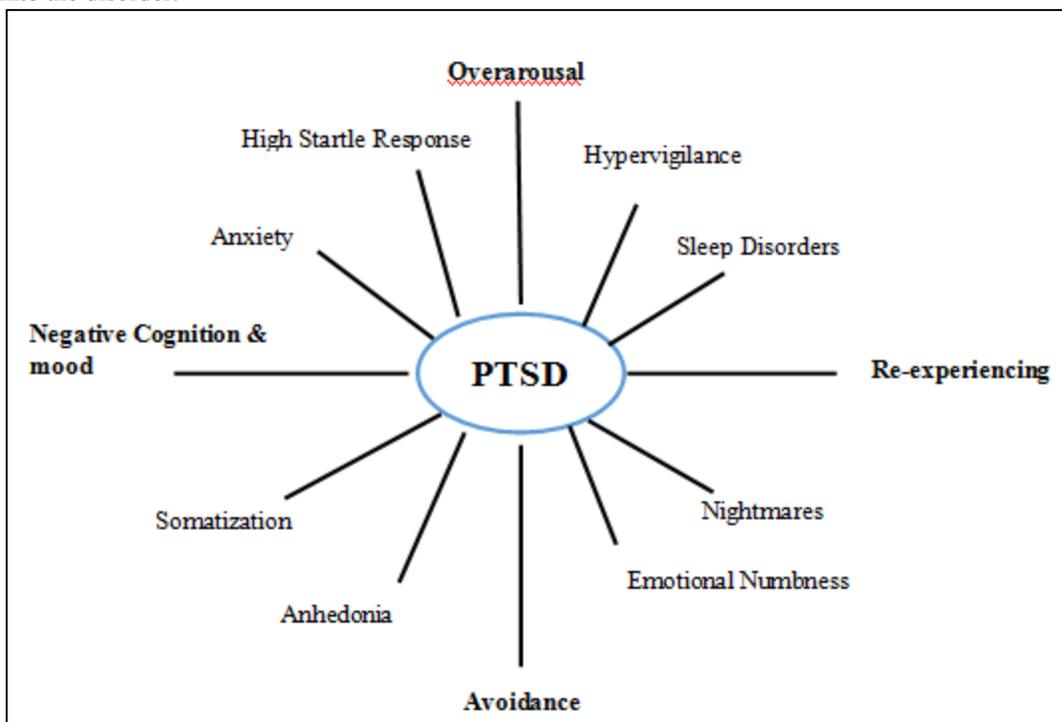
Post-traumatic stress disorder is an anxiety disorder that develops following exposure to one or more traumatic events, such as major stress, warfare, sexual assault, childhood abuse, and other threats to a person's wellbeing. (DSM, 2015)



An individual with PTSD determinedly evades thoughts, emotions, and discussions of the stressor event, sometimes experiencing amnesia for it. Yet, the event is frequently relived through invasive, recurring recollections, flashbacks, and nightmares (DSM, 2015)

The disorder is caused by a wide range of traumatic events and can occur in persons with no predisposing conditions. (NIMH, 2011) At risk individuals include those exposed to physical & emotional violence. Recently some major changes regarding PTSD took place in the latest publication of the DSM. PTSD received its own chapter and was removed from being classified as an anxiety disorder. Symptoms of PTSD are grouped into four categories as defined by the DSM-V; as opposed to three in the DSM-IV: Re-experience, avoidance/numbing, hyperarousal, & negative cognition and mood. Re-experiencing refers to the cluster of PTSD symptoms associated with vividly reliving trauma & other types of flashbacks. Avoidance-numbing symptoms are those that involve the patient trying to avoid emotional feelings, which is often disruptive to interpersonal relationships. Hyperarousal often includes irritability, heightened concern over safety, difficulty concentrating, and reduced tolerance to startling stimuli.

(Betthausen, 2015) PTSD presence and severity is assessed using a variety of patient surveys. The clinician administered PTSD Scale, CAPS, as well as the PTSD checklist for DSM-5, PCL, are common assessment tools. (PSTD VA, 2015) CAPS is an instrument used in PTSD research which was developed by the National Center for PTSD & two Veterans Affairs medical centers. CAPS asks questions about the traumatic experiences and the immediate emotional responses to them as outlined in the DSM-IV Criterion A for PTSD asking for a rating the frequency and intensity of all 17 symptoms in Criteria B,C,D on a scale of 0 to 4. These are then quantified, providing insight into the disorder.



*\*Figure X: PTSD Symptom Clusters.*

In addition to the above symptoms, Patients with PTSD are at risk for other psychological disorders to include but not limited to; generalized anxiety disorder, major depressive disorder, substance abuse, chronic pain, hypertension, and asthma. (Betthausen, 2015)

While not totally understood, the pathophysiology seems to be related to heightened sympathetic nervous system activity due to trauma(s) compounded by changes in memory processing. PTSD's physical manifestations are associated with heightened levels of norepinephrine, as well as alpha2-adrenergic receptors, which counteractively



impede the release of neurotransmitters from adrenergic presynaptic neurons. Alterations to memory processing is proposed by several sources to be the cause of the re-experiencing. Central to fear and anxiety processes as well as sympathomimetic stimulation, the amygdala and hypothalamic structures are thought to be key components of PTSD symptomology. Additionally, the changes in memory function differ in PTSD from other forms of stress. In persons with PTSD there is a significant lack of cortisol. (Betthausen, 2015) The amygdalocentric model of PTSD purports the disease's association with hyperarousal of the amygdala and inadequate top-down control via the medial prefrontal cortex along with the hippocampus during extinction. This model is consistent with the interpretation of PTSD as a syndrome of deficient extinction ability. (Milad, 2009, Stein, 2009)

PTSD causes biochemical changes in the patient, the exact mechanisms are still being deduced. Endogenous cannabinoid ligands, also known as endocannabinoids, naturally exist in the body to stimulate activity at the cannabinoid receptors. So far the CB-1 & CB-2 receptors have been identified, however others are believed to exist. Additionally G coupled receptors are also activated by Marijuana compounds which lead to the production of secondary metabolites that modulate the release of neurotransmitters from presynaptic site through both excitatory & inhibitory actions. CB-1 receptors are diffusely distributed throughout the central nervous system. These same sites are also the primary targets for modification of PTSD symptoms. CB-2 receptors are concentrated in the peripheral nervous system and elicit immunosuppressive and anti-inflammatory responses when activated. Highly lipophilic compounds, Cannabinoids can cross the lipid membranes including the blood-brain barrier, leading to fast onset, particularly when inhaled.

In mice, using a murine model, it has been demonstrated that correcting a deficiency of endogenous cannabinoids enabled mice subjected to traumatic shock treatments to overcome their conditioned response by allowing removal of the harmful stress inducing memories through inhibition of  $\gamma$ -aminobutyric acid pathways in the amygdala. This is mechanism is also thought to explain human reaction to cannabinoids. (Betthausen, 2015)

Some underlying biomarkers predict PTSD development risk, such as, a smaller hippocampal volume, heightened startle responses, and chronically low levels of serotonin (Olszewski, 2005) Studies have revealed soldiers whose leukocytes had greater numbers of glucocorticoid receptors, and had lower cortisol levels were more likely to develop PTSD after trauma. (Delahanty, 2011, Aardaal, 2001) Furthermore, overactive adrenaline responses, which help create deep neurological patterns in the brain may result in the development of PTSD, as well as the reoccurrence of its symptoms. (Rothschild, 2000) Recent experiments have shown that adrenal stress hormones, epinephrine & glucocorticoids, modulate long term memory consolidation, and that the release of norepinephrine and subsequent activation of B-adrenoceptors within the basolateral amygdala is crucial in meditating the adrenal stress hormone regulation of memory. (McGaugh, 2002) Most patients suffering from PTSD exhibit lower secretions of cortisol and higher secretions of catecholamine in the urine, with a norepinephrine to cortisol ratio higher than controls. (Hemi, 2000, Mason, 1998) In contrast to the normative fight or flight response, in which both cortisol and catecholamine levels are elevated post exposure. (Bohnen, 1991)

Due to the high levels of brain catecholamine & corticotrophin-releasing factors, an abnormality in the hypothalamic-pituitary-adrenal axis is suggested. (Kloet, 2008, Sautter, 2003, Gerocioti, 2001). Responsible for coordinating hormonal response to the stress, HPA axis abnormalities likely predicated on strong negative feedback inhibition of cortisol, likely due to heightened sensitivity of glucocorticoid receptors. (Skelton, 2012, Yehuda, 2001) This response, when translated to human conditions, provides a pathophysiological explanation for PTSD via a maladaptive learning pathway to fear response through a hypersensitive, hyper reactive, hyper responsive HPA axis. However, considerable controversy still exists regarding the neurobiology of PTSD.

While we wait on the completion of clinical trials, several cross sectional, case review, and other limited studies of the effect of Marijuana on humans with PTSD suggest its positive effect on symptom clusters with little side effects. Betthausen reviewed 59 articles identified through PUBMED & EBSCO databases. Following a quality control check, 11 articles were included in their review. A variety of study designs were represented and all analyzed work supported two general concepts; many patients suffering from PTSD use marijuana for symptomatic alleviation, with some finding benefit. (Betthausen, 2015)

Several studies supported the relationship between marijuana use and coping behaviors, with use typically positively correlated with PTSD symptom severity. The Bonn-Miller group conducted several cross sectional studies that examined this. In one study, 103 young adult marijuana users who reported at least one traumatic event were analyzed. The study found that symptom severity was related to coping oriented marijuana use motives, while simultaneously



finding that levels of post-traumatic stress was not related to other motives for marijuana use. Another cross sectional study by the Bonn-Miller group investigated the correlation between the use of marijuana as a coping mechanism and emotional regulation. The study surveyed a homogenous adult sample who reported marijuana use in the last 30 days. They found that difficulty in emotional regulation and PTSD symptom severity was significantly predictive of coping oriented marijuana use.

Following these studies Bonn-Miller executed yet another cross sectional study investigating the hypothesis that patients using marijuana for sleep might increase their use in an attempt to cope with more severe symptoms. Examining coping use motives, marijuana & alcohol use, and other outcomes, the study analyzed a sample of patients from a licensed dispensary. Two groups were formed, those with PTSD and those without, as indicated by scores on the PCL-M. The results of the study showed that PTSD patients had greater motivation to use marijuana for coping reasons & sleep than the non-PTSD group, regardless of comorbid depression or alcoholism. (Bethhauser, 2015)

In a study of Israeli military veterans (n=29) carried out by Mashiah, patients with chronic PTSD were given no more than 100g of Marijuana containing high levels of THC and no CBD or other cannabinoids. The participants were then instructed to smoke it at frequencies and volumes of their choosing. Patients were assessed three times throughout the year by a psychiatrist. In all cases the study evidenced that the average CAPS score were reduced relative to previous scores. (Bethhauser, 2015)

In the largest and most recent study, a case report evaluation, Dr. George Greer and colleagues analyzed psychometric data from 80 psychiatric evaluations of patients applying to the New Mexico Medical Marijuana Program from 2009-2011. New Mexico was the first state to list PTSD as a qualifying condition for medical marijuana use. Per their regulations, marijuana use for PTSD required a psychiatric evaluation certifying that the patient has a PTSD and its use would likely outweigh the risks, and the patient has unalleviated symptoms which other -medications have failed to address. At the time of Dr. Greer's reports assembly there were 5,495 active marijuana patients of which 1,845 (34%) had PTSD. Dr. Greer's group utilized CAPS to evaluate patient's symptoms with and without Marijuana use. Following collection of CAPS scores and statistical analysis Dr. Greer's group found significant reductions in total CAPS scores when patients were using marijuana compared with the no marijuana condition, 22.5 +/- 16.9 & 98.8 +/- 17.6, respectively. While using Cannabis, patients in the sample reported over 75% reduction in all four areas of PTSD. And while there are several co-founding variables, bias from the patients, the psychiatrist, and the possibility of marijuana withdrawal induced symptoms similar to PTSD, the results of reported symptom relief are striking. (Greer 2014)

The evidence that marijuana use can reduce symptoms of PTSD is consistent with preclinical evidence demonstrating that the endocannabinoid system (eCB) participates in the regulation of memory. Studies in animal models suggest a mechanism of action. The extensive evidence indicates that cannabinoids may mediate the extinction of aversive memories and that CB1 receptors along with other chemical cohorts are responsible for fear extinction (De bitencourt, Pamplona & Takahashi 2013) Given this role for endocannabinoid system's affect in fear extinction, logic predicates that the significant differences noted in PTSD symptomology reported with marijuana use is due to mediated fear memory extinction.

Most of the research on PTSD is limited by their use of small nonrandomized and/or self-selected samples that lack control groups and carry some potential for recall bias and type II errors. However the evaluated evidence strongly indicated that many sufferers for PTSD use Marijuana to cope and find relief in terms of insomnia, improved coping, and reduced anxiety. (Bethhauser, 2015)

## **Cancer**

Cancer is used to describe a broad spectrum of abnormal cell proliferation characterized by the potential to spread to other parts of the body. There are over 100 known cancers currently identified as human afflictions, a comprehensive description of their symptoms and mechanisms is outside the scope of this review. (WHO, 2014) However, Marijuana & its derivatives have been used to treat symptoms of cancer & side effects of its conventional treatment for some time. Pain, Nausea, & Cachexia are all symptoms to have been positively treated using cannabis. For a summary of cannabinoids effect on pain, nausea and cachexia refer to the Palliative Care section.



While much research on the cannabinoid system's effect on cancer has been performed, it has been conducted, primarily on synthetic alternatives. And while the evidence indicates a positive impact, patients often report better treatment using natural products. A case review of 131 patients using marijuana as a palliative treatment option for cancer, all cancer or anti-cancer treatment symptoms showed significant improvement, with no significant side effects other than memory lessening in those with prolonged use. (Bar-Sela, 2013)

Marijuana has been regarded by folk medicines for its curative properties regarding cancer. And while cannabinoids have been licensed for use in the palliative care for patients receiving chemotherapy, scientific evidence is just now beginning to support traditional ideas. Endocannabinoids have been shown to modulate key cell –signaling pathways associated in cancer cell growth, invasion, and metastasis. Evidence shows direct antiproliferative actions of cannabinoid agonists on several tumor cells *in vitro* and in animals via the inhibition of tumor growth as mediated by reduction in neovascularization, metastases, and cell cycle arrest through apoptosis. (Bifulco, 2006) This antiproliferative effect on tumor cells has been demonstrated in colorectal, prostate, thyroid, skin, brain, and breast cancers (Bifulco 2006).

Evidence suggests that cannabinoids exert a wide variety of effects. Dependent upon cellular context, cell type, activation of signal transduction pathways, drug context, route of drug administration, and timing of drug delivery. Studies examining routes of drug administration have yielded mixed results. Epidemiological studies evidence inconsistent association between cancer and inhalation of marijuana smoke (Chan, 1996). In a yearlong study, administration of high oral doses of THC in rats or mice did not increase tumors (Chan., 1996). In animal models, cannabinoids show direct antiproliferative effect on tumors, but other studies show that they may indirectly enhance tumor growth via inhibition of immunogenicity (Chan, 1996) this effect however, is still unsettled, and has only been demonstrated to occur in dosages far exceeding typical dosing for social or medical use.

### **Parkinson's**

A neurodegenerative disease, Parkinson's is characterized by the destruction of dopaminergic neurons in the substantia nigra, an area of the brain associated with regulating movement. Parkinson's patients experience tremors, sleep disturbance, balance issues, muscle stiffness, slowed movement, among others. While there is no cure, there are palliative treatment options available. In some instances, there is evidence to support the use of cannabinoid-based therapies. In a recent open label clinical study, Parkinson's patients who used smoked marijuana showed significant reduction in motor impairment and disability. Additionally, significant improvement was concomitantly found in rigidity, tremors, dyskinesia, pain, and sleep. Although it was a small sample size and there was no blinding, it is suggestive of the effects of THC on Parkinson's disease. Another study found that 300mg/day of CBD in patients with Parkinson's without dementia or other comorbid psychiatric conditions, increased well-being and overall quality of life. (Chagas, 2014) However, there was no improvement in motor function and other general symptoms. This study found no evidence for neuroprotective effects that THC has been shown to have in other studies.

On top of the palliative aspects of treatment for Parkinson's symptomology, Cannabinoids have been shown to be effective in treating the underlying disorder, by assisting in the prevention of damage caused by free radicals, and activation of the PPAR $\gamma$ , a receptor whose stimulation leads to the generation of new mitochondria. Additionally, growing evidence indicates that cannabinoids act as neuroprotective agents through functional improvements in mitochondria, activating cellular debris removal, anti-inflammatory and antioxidant activities. (Fishbein-Kaminitsky 2014, Fagan, 2013, Gorzo, 2012) According to Dr. Michael S. Okun, of the National Parkinson's Foundation,

“Marijuana should not be thought of as a replacement for dopaminergic and other approved therapies for Parkinson's disease. More research will be needed to understand which patients, which symptoms, and how best to safely administer Marijuana in Parkinson's disease, especially over the long-term. And, it may turn out that non-motor features such as depression, anxiety, and pain respond best.”

In human and animal trials, Cannabinoids have been demonstrated to have positive impact on symptom amelioration for Parkinson's. Antagonism of the CB1 receptor has been shown to treat the symptoms of Parkinson's disease as well as dyskinesia, an often comorbid condition resulting from the treatment of Parkinson's disease with levodopa. (Kogan et al, 418) These neuroprotective effects give cannabinoids a considerable potential as a future treatment option. Research on other neurodegenerative diseases such as Alzheimer's, Huntington's and Amyotrophic Lateral Sclerosis



is currently scarce and in need of further examination. In addition to the stated effects above, Marijuana has also been shown to be effective in managing Palliative symptoms such as chronic pain, anxiety and depression, all symptoms many Parkinson's patients suffer from.

### **Multiple Sclerosis**

Multiple sclerosis is an autoimmune inflammatory demyelinating disease afflicting the central nervous system. (Khan, 2011) The most commonly reported symptoms are fatigue, mobility related issues, including spasticity and various degrees of dystonia, and finally bowel and bladder dysfunction. Depending on the type of MS, rehabilitation may or may not alter the course of the disease. However, in all cases neuro-palliative approaches to treatment are taken. (Kahn, 2011)

Marijuana has been demonstrated to be effective as a neuropalliative treatment, superior to placebo in reducing treatment resistant spasticity. 14 studies suggest improvement in multiple sclerosis as a result of cannabinoid treatment. On average, Nabiximols, Dronabinol and THC/CBD yielded larger average improvement on the Ashworth scale for spasticity than the associated placebo. (Whiting, 2015) In a random crossover placebo controlled trial, smoked cannabis's efficacy in multiple sclerosis-induced spasticity was investigated. Patients smoked Marijuana cigarettes three times daily, scores for spasticity changed by 2.74 points over placebo, additionally, pain was also reduced 5.28 points over placebo. No serious side effects were noted during the trial. (Corey-Bloom, 2012) The effects of THC can also be enhanced with the addition of CBD, a non-psychoactive component of Cannabis. In another recent clinical trial a THC: CBD oromucosal spray was shown to reduce spasticity in treatment resistant MS spasticity with no meaningful effect on cognition or mood. After 50 weeks of continued use, two-third of patients and care groups reported improvement from baseline with no effect on cognition noted. (Fernandez, 2014) This same spray has also revealed a reduction in sleep disturbances. (Kogan, 2015)

The same neuroprotective effects noted in the previous section has also been noted in studies conducted on MS. In a study utilizing experimental autoimmune encephalomyelitis (EAE), a model for Multiple Sclerosis, mice treated with THC experienced mild to no clinical signs and had a 95% survival rate. Mice treated with a placebo had a 98% mortality rate. (Kogen, 2015) In another animal model, mice suffering from chronic relapsing experimental allergic encephalomyelitis (CREAE), a standard model for MS that mimics many hallmarks of the human equivalent, a decrease in the density of CB1 receptors in the cerebellum, Globus pallidus, & caudate-putamen was found. This helps explain the efficacy of cannabinoid agonists in improving motor functions, ataxia, spasticity, and tremor, hallmarks symptoms of MS as well as other disorders like stroke, cerebral palsy, and damaged spinal cords.

Muscle spasticity was shown to be mediated by CB1 receptors in mice, but not CB2 receptors. Clinical trials have consistently demonstrated THC's significant improvement in spasticity ratings over placebos. While inhaled marijuana worked initially, at more advanced stages of the disease oral & rectal administrations were required to achieve maximal positive benefit. It has been demonstrated that Marijuana and its derivatives can play a key role in the palliative care for sufferers of MS through a reduction in spasticity, rigidity, and pain, stimulating improved active & passive mobility. The total mechanisms are not yet elucidated, but CB1 excitation plays a role. (Kogen, 2015) Long-term use of a THC:CBD combination has shown consistent benefit in those patients who experienced an initial benefit. (Kogen, 2015)

### **HIV/AIDS**

HIV/AIDS is a grouping of conditions initially caused by a drop in immune system cell count and the subsequent infection after the decimation of the immune system. (Sepkowitz, 2001) The condition results in a dysfunctional immune system, which can result in a myriad of opportunistic diseases. While there is no known cure, courses of antiretroviral drugs can stay the course of the disease, leading to near normal life expectancy. However, there are a number of symptoms which typically develop, regardless of treatment status, which can be improved through palliative care. Marijuana and its derivatives are known to be used by the HIV/AIDS community as a palliative treatment.

Studies report that as many as 60% patients in North America report using medical marijuana for symptoms resulting from HIV/AIDS and as many as 1/3 use the medication to manage the side effects of the antiviral medications. Reports further indicate that marijuana is most often used to counter symptoms of anxiety, nausea, appetite loss and pain. Studies also found that those users who report therapeutic marijuana use are 3.3. times more likely to stick to their



antiretroviral regimens. (De Jong, 2005, Bell-Isle and Hathway 2007, Ware, 2003, Braitstein 2001, Prentiss 2004, Woolridge 2005) And even though in some studies for other disorders, extremely high doses of Cannabinoids have been found to behave as an immunosuppressant, clinical trial data indicates that marijuana does not negatively impact CD8 and CD4 T cell counts, and may even function to improve immune function. (Fogarty, 2007, Abrams, 2003, Schrier, 2010, Chao, 2008) Investigators at Columbia University concluded in 2007 that smoked marijuana has a clear medical benefit in HIV-positive subjects, finding that smoked marijuana four times a day substantially increased food intake with no observable cognitive impairment, while California researchers, in a randomized placebo controlled trial, found that smoked marijuana three times a day was found to significantly reduce HIV/AIDS associated neuropathy. (Haney, 2007, Abrams, 2007)

### **Tourette's**

Tourette's, a neuropsychiatric disorder of unknown etiology is characterized by involuntary tics. The severity varies from patient to patient and there is no known cure, although the condition tends to improve with age. Cannabis's efficacy in treating this disorder has been demonstrated in a few studies.

In an uncontrolled open clinical study, researchers in Germany reported successful treatment of a 25-year-old male using 10mg of THC administered orally, with severity assessments dropping from 41 to 7 within 2 hours. This was later confirmed in a randomized, double blind, placebo controlled, crossover, single dose trial of THC in 12 adult patients. The study reported significant improvement in tics and obsessive-compulsive behavior following THC oral administration over placebo, noting no cognitive impairments. They summarize: THC is effective and safe in treating the tics and OCB associated with Tourette's. These results were further confirmed in another double blind, placebo controlled trial with 24 patients. (Muller-Vahl, 1999, 2001, 2002). Two studies with a combined 36 participants indicated that THC greatly reduced tic severity in patients with Tourette's syndrome (Whiting, 2015) The causal link is further suggested because a positive correlation was found between a reduction in tics and the increased concentration of 11-OH-THC, a metabolite of THC. (Kogan, 2015) THC has shown to reduce chronic tics in TS patients, without causing acute or long-term cognitive injury.

### **Alzheimer's**

A form of dementia, Alzheimer's is an irreversible, progressive brain disorder that destroys memory and thinking skills, eventually wiping out the ability to carry out the simplest tasks, often resulting in death. Key characteristics are the formation of large amyloid plaques, tau tangles, and loss of connection between nerve cells. Marijuana has been shown to have a preventative effect. Mechanisms for the cause of this effect have been proposed. A preclinical trial found that THC can slow the production of beta-amyloid proteins, a characteristic of Alzheimer's. Other studies support THC's effectiveness in prohibiting the growth of the toxic amyloid plaques, which are associated with Alzheimer's. In these ways, Marijuana and its derivatives may prove to be possibly preventative for persons at risk of or having developed Alzheimer's. (Cao, 2014, Eubanks, 2006) Additionally, investigators have also found that cannabinoids may reduce the inflammation response and decrease toxicity to beta amyloid proteins, helping to prevent the neurogenerative process from taking place. (Ramirez, 2005) In a mouse model CBD was demonstrated to reduce memory loss. While, the evidence remains mixed, researchers at Ireland's Trinity College Institute of Neuroscience concluded:

*"Cannabinoids offer a multi-faceted approach for the treatment of Alzheimer's disease by providing neuroprotection and reducing neuroinflammation, whilst simultaneously supporting the brain's intrinsic repair mechanisms by augmenting neurotrophin expression and enhancing neurogenesis. ... Manipulation of the cannabinoid pathway offers a pharmacological approach for the treatment of AD that may be [more] efficacious than current treatment regimens." (Campbell and Gowran 2007)*

Cannabinoids have also been shown to competitively inhibit acetylcholinesterase (AChE), which in turn prevent AChE-induced amyloid beta-peptide (A-beta) aggregation. This aggregation is a key pathological marker of Alzheimer's disease. In fact, with no side effects observed, THC has been demonstrated to decrease the severity of disturbed behavior in Alzheimer's patients, with the effect persisting during placebo periods in the same patients. Additionally, THC treatment lead to a decrease in nocturnal activity with patients scoring lower on the



Neuropsychiatric Inventory in agitation, aberrant motor, and nighttime behaviors nocturnal motor activity was also observed. (Kogen, 2015)

In addition to the possibility of prevention and possible repair, Cannabinoids can play a role in palliative care, as Alzheimer's patients are likely to experience depression, agitation, appetite loss, all of which Cannabinoids have been demonstrated to have a positive impact on. (Walther et al 2006, Volicer, 1997)

### **Asthma**

Asthma is a chronic disease of the respiratory system whereby the airways constrict, becoming inflamed, and lined with excess mucus. Capable of asphyxiating patients, Asthma can be a life threatening illness, and consistently impairs quality of life and functionality of afflicted patients.

THC has been shown to function as a bronchodilator and is shown to be effective in treating the symptoms of Asthma. Other cannabinoids have not provided as effective bronchodilators. THC administered in a steady state aerosol to patients, increased peak expiratory flow rates and forced expiratory volume in 1 second. A mild and inconstant bronchodilatory effect for THC was found, and both oral ingestion and inhalation of THC have been found to increase airway conductance, relieving the symptoms of Asthma. THC's anti-inflammatory's effects are believed to be at work here, although mechanisms have yet to be elucidated. (Kogan, 2015) Ironically, the passage of smoke through airways tends to irritate Asthmatic symptoms, leading to the recommendation of administration via oral or vaporized THC.

### **Anxiety**

Anxiety can range in severity from a minor annoyance to completely debilitating. Cannabidiol (CBD) has been shown to have a reducing effect on anxiety over placebo. Patients taking cannabinoids for chronic pain have reported lower levels of anxiety but these reports were not restricted to diagnosed anxiety disorders (Whiting, 2015). A review of Marijuana & its derivatives' effect on anxiety, consisting of seven separate studies, showed patients favored cannabinoids over alternatives or placebos (Whiting, 2015).

The neuronal conditioning, which underlies fear, is conserved in many clinical conditions that involve fear, such as PTSD. Behavioral therapies for anxiety and PTSD, including systemic desensitization and therapies that rely on imagery, also share features with fear extinction. While high doses of THC may appear to increase anxiety in humans, low doses seem to attenuate anxiety related models in animals. Additionally, it should be noted that anxiety disorders may make people more vulnerable to marijuana abuse and dependence. Yet, this vulnerability may be dependent on patients increased sensitivity to anxiety, and that simply Marijuana functions as a coping method. While some evidence associates marijuana dependence with increased risk of panic disorders, the causal relationship was not disentangled. There is a lack of clinical investigation regarding eCB activity and anxiety, however preclinical and clinical data strongly suggest that anxiety is associated with a dampened endocannabinoid tone, leading to excessive cortical excitation. The influence on anxiety is believed to be mainly mediated by CB1 and possibly CB2 receptors, and other G protein coupled receptors which are associated with a decreased anxiety score in a variety of rodent assays, such as the elevated maze test. (Passie, 2012)

The anxiolytic effects of CBD have been shown following injection into the dorsolateral periaqueductal gray bed nucleus of the strain terminalis and prelimbic medial prefrontal cortex. Furthermore, the CB1 receptor antagonist, rimonabant, causes anxiety and depression in a significant portion of psychiatrically healthy adults. Clinical studies have demonstrated that CBD displays anxiolytic affects in persons engaged in public speaking. Neuroimaging studies have shown that CBD facilitates a change in brain activity in regions related to emotional responses, impairing connectivity between the prefrontal and subcortical regions and attenuates responses to fearful faces in the amygdala and cingulate cortex, further decreasing activation in the left amygdala-hippocampal complex and left posterior cingulate gyrus. (Passie, 2012)

### **Stress**

Stress is a ubiquitous element in modern society. In humans, it results in the secretion of the glucocorticoid hormone. Via the paraventricular nucleus (PVN) of the hypothalamus, the corticotrophin hormone is released, stimulating the anterior pituitary gland to release adrenocorticotrophic hormones into general circulation. Immediately following this signal cascade, glucocorticoid hormones like cortisol are released to mobilize energy stores, inducing a wide range of



effects on immune, metabolic, cardiovascular, & neural systems. While adaptive short-term functions can be gained from this response, deleterious effects are caused under prolonged exposure.

The eCB system has been shown to respond to and regulate the activity of the hypothalamic-pituitary-adrenal axis (HPA), which governs the secretion of stress hormones. The eCB system maintains homeostasis of the stress systems, and can act as an agonist or antagonist to the HPA axis response to stress. Data indicates that eCB system signaling is induced by glucocorticoid systems by non-genomic processes in the CRH neurons of the PVN. The induction of the eCB signaling inhibits glutamatergic inputs to the CRH neurons, thereby lowering the excitatory drive of the HPA axis. It was shown that following repeated stress, AEA is persistently decreased throughout the corticolimbic systems, however 2-AG are elevated in the amygdala. This divergent regulation contributes to distinct forms of HPA axis habituation. Intra-amygdala administration of a CB1 receptor antagonist before the stress exposure prevented the subsequent stress induced development of a basal hypersecretion of corticosterone. Providing evidence for CRH-mediated and GABAergic mechanism involved in the anxiolytic effects of THC. (Passie, 2012)

Administering of CB1 antagonists into the basolateral nucleus of the amygdala (BLA) blocks the ability of corticosterone to facilitate aversive memory consolidation. The eCB plays a role in fear dampening in highly stressful situations, independent of the corticosterone action. This dampening effect and prevention of hyperarousal is believed to play a key role in treating PTSD. (Passie, 2012)

### **Sleep**

Insomnia and other sleep-related conditions can exist independently but are generally symptomatic of an underlying condition or disease. A continually recurring palliative quality in Marijuana and its derivatives are their ability to assist with sleep disorders. Two studies, reported increase in position on sleep apnea/hypopnea index with nabilone, a synthetic derivative of THC, when compared to a placebo. The second, at low risk of bias, compared nabilone to amitriptyline, a non-cannabinoid drug currently prescribed for sleep related issues. Nabilone associated with improvements in insomnia while amitriptyline showed a greater score in sleep restfulness. In studies considering chronic pain and MS, amount of sleep was also noted. Cannabinoids showed an improvement in sleep quality with no differentiation between cannabinoid treatments. (Whiting, 2015)

### **Palliative Care**

A team based, multidisciplinary approach to medicine for serious illnesses. Focusing on improving quality of life, palliative care aims to provide symptomatic relief for physical & mental stress, suffering, regardless of the diagnosis. This approach allows the palliative care team to receive input from pharmacists, chaplains, nurses, social workers, & psychologists in addition to physicians & specialists, empowering the care to address emotional, spiritual, social, and physical concerns that manifest due to serious illness. It is appropriate at any age and stage of illness, & suitable for accompaniment to curative treatment.

Treatments & medications that relieve symptoms but have no curative effect are said to be palliative in their effect. Such as the treatment of nausea during chemotherapy, the analgesic effects of Ibuprofen or Morphine for aching related to influenza, and the antispasmodic effects of some cannabinoid combinations in Dravet's syndrome. While palliative care is not new, it has often not been the focus of physicians work, choosing instead to focus on curative therapies, as palliative care was viewed as hazardous, inviting addiction. (Seymour 2004).

Yet, Cannabis, and its derivatives are known to exhibit efficacious palliative effects for a variety of illnesses while exhibiting high safety margins. While not reserved for terminal illnesses, Cannabis's early palliative uses found application there. Palliative care for persons with cancer is recommended at all stages, and is expressly recommended in lieu of curative treatment in multiple scenarios. Marijuana & its derivatives have been demonstrated to be effective when used in this context.

One method of assessment for patients of palliative care is the *Edmonton Symptoms Scale* (ESAS). In ESAS eight visual analog scales from 0-10 indicate levels of pain, activity, nausea, depression, anxiety, drowsiness, appetite and sensation of wellbeing, are recorded and used to assess and track treatment.

Marijuana & its products have been demonstrated to have a positive impact on nausea, depression, anxiety, appetite, & sensation of wellbeing, all parameters of assessment for Palliative Care. Because of their demonstrated efficacy and wide safety margins, Marijuana & its derivatives deserve attention for not only for previously described diseases and

disorders but other disorders which share similar symptomology. Such cross over prescriptive use will expand the list of possible applications beyond that outlined within the scope of this review.

Marijuana & its derivatives will likely continue to find new and varied purpose in modern medicine. Given the complexity and depth of both the chemistries involved; the endocannabinoid (eCB) and phytocannabinoid systems (pCB), it is expected that a host of effective medicines will be uncovered, given the right bioprospecting, medical research, & production efforts.

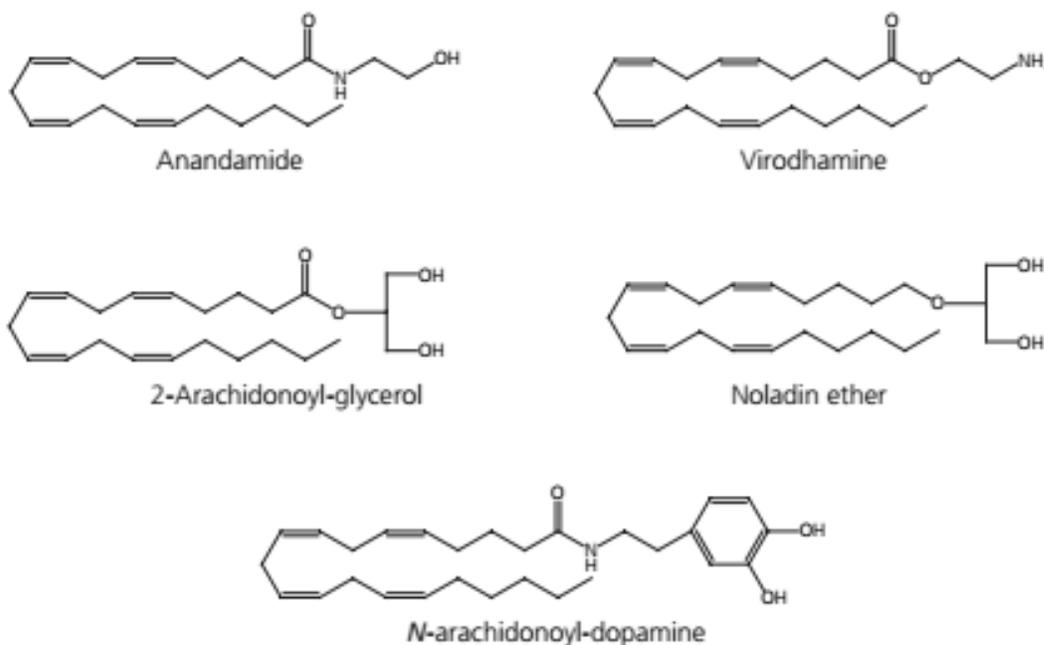
### **Section 3: Cannabinoid Systems**

#### **3.1 Endogenous Cannabinoid System (eCB)**

The discovery of specific binding sites for THC led to the discovery of the endocannabinoid system (eCB). (Bisogno, 2008). The eCB is an array of biosynthetic and signaling pathways which consists of endogenous cannabinoids which act on endogenous cannabinoid receptors. Widely distributed throughout body in both the central as well as the peripheral nervous system, manipulation of the eCB exerts influence on many aspects of human metabolism and function. As such, Cannabinoid medicine provides the opportunity for new drug therapies aimed at mediating cannabis tone in the eCB system.

##### **3.1.1 eCB System Overview**

Cannabinoid medicines work thru interaction with G-coupled protein receptors (GPCR) of the endocannabinoid system (eCB). Two cannabinoid receptors have been cloned from mammalian tissues, CB1 & CB2, often mislabeled as the central & peripheral receptors (Matusda 1990, Munro, 1993). CB1 and CB2 are the two most prevalent and understood GPCR's of the eCB system. Yet, increasing bodies of evidence indicate that cannabinoids may exert their biological effects in pathways beyond the CB1 & CB2 pathways. (Di Marzo, 2000, Kunos, 2000, & Maccarrone, 2000) However, the CB1 receptors are, to date, the most dominant receptor form. The putative endocannabinoid ligands, arachidonylethanolamide (anandamide, AEA) and 2-arachidonylglycerol (2-AG), have been identified as major endogenous transmitters of the eCB. Known endogenous cannabinoids are presented in Figure X below. In addition to the endocannabinoid ligands, there are several other component of the eCB system, presented in Table X below.



**Figure X:** Structure of the five identified endogenous cannabinoids (Bisogno, 2008)



Table X: Main Components of the Endocannabinoid System (eCB) in	
Member	Function
TRPV1	Target of AEA
CB3	Primary Target of 2-AG & PEA
CB2	Primary Targets of AEA & 2-AG
CB1	
MAGL	Hydrolytic Enzyme Responsible for AEA catabolism
NAAA	Hydrolytic Enzyme Responsible for 2-AG catabolism
FAAH	
FAAH2	
DAGL	Biosynthetic enzyme involved in synthesis of 2-AG
NAT	Biosynthetic enzymes involved in synthesis of AEA
NAPE-PLD	
EMT	Responsible for transport of AEA and possibly 2-AG
2-AG	Prototype members of MAGs (2-AG) or FAAs (AEA) which act on CB receptors in periphery and central nervous systems.
AEA	
Adapted from Battista 2008	

The CB1 & CB2 receptors encode a seven-transmembrane-domain protein belonging to the Gai protein coupled receptor families. Signal transduction pathways, downstream of the cannabinoid receptors, includes adenylate cyclase, mitogen activated protein kinase, and in the case of CB1, ion channels. (Munro, 1993, Howlett, 1986, Bouaboula, 1005, Mackie & Hille, 1992) Some evidence indicates CB2 is the predominant form in the peripheral immune cells (Munro, 1993 & Galiege, 1995). CB1 has been demonstrated to be preferentially expressed in the central nervous system (Matsuda, 1990)

The endocannabinoids that work in the endocannabinoid receptors are lipid molecules consisting of long-chain polyunsaturated fatty acids, ethers, amides, esters; with varying degrees of selectivity for the receptor types. AEA & 2-AG, and other arachidonate derivatives are the best known cannabimimetic. Also, N-stearoylethanolamine (SEA), N-oleoylethanolamine (OEA), and N-palmitoylethanolamine (PEA), compounds present in the human brain, are said to be endocannabinoid like. (Demario, 1998, Maccarone & Finazzi-Agro 2002). It has been suggested that these compounds inhibit the degradation of AEA or 2-AG, increasing their activity.

Endocannabinoids, in the central nervous system, act as neuromodulators and retrograde messengers, inhibiting the release of various other neurotransmitters. As paracrine or autocrine mediators, in the peripheral and neural tissues, endocannabinoids modulate the effects of nuclear factors and proteins involved in cell proliferation, differentiation, and apoptosis, suggesting cannabinoids role in the control of cell fate. (McDonald & Vaughn, 2001, Schlicker & Kathmann, 2001, Guzman 2001b)



AEA, and 2-AG are, respectively, prototype members of the fatty acid amides (FAAs) and the monoglycerols (MAGs), primary actors on the CB1 and CB2 pathways... Although endocannabinoids activate the CB1 and CB2 receptors, they also interact with other G-coupled proteins, ion channels, and receptors. Some of the other interactions they are known to have; several types of potassium channels, GPR55, alpha7 nicotinic and 5-HT<sub>3</sub> receptors, and others. Conversely, exocannabinoids, synthetics and phyto, can be expected to have interactions beyond the CB1 and CB2 receptors. (Mackie, 2008) Additionally, AEA binds vanillin receptor, TRPV1, a cationic channel which capsaicin also activates. Endocannabinoids are not stored in the body, but rather, synthesized on demand and may be transported across cell membranes by a yet unidentified endocannabinoid membrane transporter. Altogether, AEA, 2-AG, their congeners, metabolic enzymes, molecular targets, and possible transporters make up the eCB.

Cannabinoids may act as a full agonist, partial agonist, neutral agonist, inverse agonists, and antagonists. Additionally, evidence indicates that some cannabinoids exhibit functional selectivity, preferentially activating one signal pathway over another. (Mackie, 2008)

The eCB is widely distributed throughout the human body. The following is a summary of known eCB distribution, effects, and in some cases, insight into the possibility of new cannabinoid therapies.

### **3.1.2 eCB System Specifics**

#### **3.1.2.1 Bone Metabolism**

CB1 receptors are present in the sympathetic nerve terminals near osteoblasts, bone forming cells, as well as osteoclasts, bone resorbing cells. Cells of the osteoblastic and clastic lineages synthesize endocannabinoids 2-AG and AEA. Excitation of the CB1 receptors by 2-AG communicates brain to bone formations and linkage is reinforced by traumatic brain injury induced brain formation. In a retrograde CB1 signaling process, noradrenaline release is inhibited removing tonic sympathetic restraint of bone formation. CB2 receptors are also expressed by osteoblasts and osteoclasts. CB2 excitation stimulates bone formation and prohibits resorption. In mice models, CB2 deficiency marked accelerated bone loss. It has been shown that Ovariectomy-induced bone loss can be prevented and rescued by CB2 specific agonists. Therefore CB2 ligands should be explored for novel anti-osteoporotic therapies. (Bab, 2008)

#### **3.1.2.2 Reproduction**

The majority of human reproductive tissues and cells; testis, uterus, spermatozoa, and blastocysts, possess the ability to synthesize and degrade AEA, and in fact, several studies highlight the possibility of FAAH as a checkpoint in the tonal regulation of AEA and signaling in human reproduction. Also some components of the eCB modulate the journey of the oocyte from the ovary to implantation, systems known to participate are, NAPE-PLD, NAPE, FAAH, and CB receptors. Evidence indicates that the eCB along with a network of sex hormones, cytokines, and leptin are involved in successful human pregnancy. In particular, FAAH activity and expression in T-lymphocytes is involved with successful implantation. This activity is known to be modulated by CB1 receptors. Targeting FAAH expression through CB receptor activation or inhibition may prove to be of therapeutic value for the treatment of male and female infertility.

#### **3.1.2.3 Adipose Tissue**

The eCB system has been demonstrated to be an important mediator of several adipose tissue functions. CB1 activation/inhibition in adipocytes causes changes in cell proliferation, differentiation and secretion. Specifically, evidence indicates that CB1 over activation, accumulation of AEA, and increases in CB1 density correlate with obesity, whereas inhibition through a cannabinoid antagonists, such as rimonabant, has the opposite effect. Targeting the development of CB1 antagonists may prove of therapeutic value for treating obesity. On the other hand, it is the effect of CB1 agonists that seem to be of therapeutic value in treating cachexia and other syndromes related to wasting to include anorexia nervosa (although there is a psychological component to anorexia that must also be addressed). (Bellocchio, 2008) (Engeli, 2008)

#### **3.1.2.4 Brain & Nerve Tissue**



Detectable in the cortex, cerebellum, hippocampus, basal ganglia, the eCB systems are dispersed throughout the body and brain, regulating synaptic release of excitatory and inhibitory neurotransmitters. A key role of this system is the activation of the CB1 receptors, which show a 10 fold greater distribution level in comparison with opioid receptors. AEA and 2-AG, act together with these receptors and are post synaptically synthesized signaling molecules, not being stored in the vesicles, seeming instead to be produced on demand and liberated to act in retrograde fashion on presynaptically localized CB1 receptors. Research has revealed the eCB system is homeostatic, preventing extreme cortical excitation and inhibition that in some mental disorders, may be dysfunctional. eCB signaling is widely dispersed throughout corticolimbic circuits that are linked to the stress response. The level of cortical excitability is determined by the neurotransmitter system's glutamate & GABA. Stress, linked to severe psychiatric disorders like PTSD, comorbid with a great many other disorders, may produce imbalance in the eCB system. Serving as a modulator, the eCB system is comparable to a dimmer switch, helping to prevent excessive excitatory and inhibitory activity. Since its discovery the eCB system has been investigated for its potential role in disorders like schizophrenia, bipolar disorder, major depression, and anxiety. (Passie, 2012, Matsuda, 1990, Munro, 1993, Felder & Glass 1998, Straker, 199, Liu, 2000, Pertwee 2000, Cota, 2003)

While studies have suggested the stimulating effect of marijuana and its derivatives on the hypothalamic-pituitary-adrenal axis (HPA), evidence now indicates the presence of endocannabinoid tone which inhibits the release of glucocorticoid and adrenocorticotropic hormone. Studies in mice lacking CB1 receptors have demonstrated that CB1 receptors are essential for the management of the HPA. These findings indicate that alterations in endocannabinoid tone are associated with the development of stress related disorder and disease like anxiety, depression, obesity, and PTSD. Therefore cannabinoids which affect this tone should be investigated for possible therapeutics. (Cota, 2008)

### **3.1.2.5 Immune System**

The CB2 receptor, normally expressed in areas enriched in B lymphocytes such as the spleen marginal zone, the lymph node cortex, the nodular corona of Peyer patches, the mantle zones of secondary follicles in tonsils, is typically expressed in the immune system and generally believed to be unrelated to the psychoactive effects of Cannabinoids. CB2 receptors have also been found in skin tumor cells & glioma, in the microglial cells. It has also been found to play a role in B-cell differentiation and migration of splenic B lymphocytes. (Galiege, 1995, Carayon, 1998)

### **3.1.2.6 Gastrointestinal Regulation of Food**

Evidence indicates AEA, as well as acylethanolamide oleoylethanolamide are produced in the intestine and seem to regulate feeding behaviors thru engagement of sensory afferent neurons. Intestinal levels of acylethanolamide are inversely correlated to feeding, and anandamide levels are positively correlated with food deprivation (hunger signal) and simultaneous reductions in oleoylethanolamide. Furthermore, evidence indicates that gastric levels of acylethanolamide change in response to diet induced obesity, altering gastrointestinal motility, and may contribute effect on nutrient absorption and food intake.

### **3.1.2.7 Liver**

The expression of CB1 and CB2 receptors is low and often absent in a healthy liver. However, evidence demonstrates the eCB system is a primary actor in the pathophysiology of various liver diseases. The eCB system is highly upregulated during chronic liver disease, implicated in the pathogenesis of non-alcoholic fatty liver disease, the development of the cardiovascular abnormalities of cirrhosis; hyper dynamic circulatory syndrome and cirrhotic cardiomyopathy, and the progression of fibrosis to cirrhosis. Additionally, the eCB system has been shown to influence the mechanisms responsible for inflammatory responses and cell damage as a result of acute liver injury. Cannabinoids targeting CB1 and CB2 receptors may provide therapeutics for the agents of liver disease. CB1 antagonists present a possible tool to resolve fat accumulation in patients with non-alcoholic fatty liver disease, as well as slow the progression of fibrosis and attenuate cardiovascular disorder related to later stages of the disease. (Caraceni, 2008)

### **3.1.2.8 Skin**



Much evidence supports the protective anti-inflammatory role of AEA and N-palmitoyl ethanolamine. Additionally, the endogenous cannabinoid like, N-palmitoyl ethanolamine, has been found to downregulate inflammation in the skin. This effect has been mimicked by synthetic nonselective CB1/CB2 receptor agonists such as WIN55, 212-2. Therefore, cannabinoids which are nonselective eCB agonists may prove useful in the treatment of skin inflammation, and are targets for the development of therapeutics. (Carbonare, 2008)

**3.1.2.9 Mast Cells**

Mast cells are immune competent and regulate a variety of immune responses including inflammation. Consequences of dysregulation of this system are believed to occur in arthritis, atherosclerosis, asthma, and inflammatory bowel syndrome. Cannabinoids have been shown to regulate mast cell behavior, specifically degranulation. Due to their ability to regulate mast cells, cannabinoids hold promise as therapeutics for a variety of chronic inflammatory disorders. (De Fillipis, 2008)

**3.1.2.9 Cardiovascular System**

Evidence indicates endocannabinoid signaling plays a role in the pathogenesis of atherogenesis. Inhibiting CB1 receptors has been shown to mediate weight reduction while producing several cardiometabolic effects in both rodents and humans. In mice, excitation of CB2 receptors by THC has been demonstrated to block the progression of atherosclerotic plaque through the inhibition of macrophage recruitment. Furthermore, endocannabinoids released from platelets, macrophages, and endothelial cells have been shown to reduce hypertension in rodents. AEA inhibits inflammatory gene expression in endothelial cells, inhibiting monocyte adhesion. And while it is not clear if endocannabinoid signaling also contributes to the progression of the disease, cannabinoids may offer potential therapeutic targets. (Mach, 2008) Additionally, the pathological over activation of the endocannabinoid system is indicated in a variety of heart failures and shocks. Tonic activation of CB1 receptors has also been indicated in a variety of cardiovascular risk factors to include, diabetes, obesity, hepatic steatosis, insulin and leptin resistance, and inflammation. (Pacher, 2009)

**3.1.2.10 Glucose Homeostasis**

Selective CB1 antagonists have demonstrated success in clinical trials leading to sustained weight loss and reductions in waist circumference. Also significant changes to levels lipoprotein cholesterol, triglyceride levels and insulin resistances were demonstrated. The eCB system has been demonstrated to have an effect on glucose homeostasis and insulin sensitivity. Therefore, cannabinoids may offer potential therapeutics in treating a variety of metabolic syndromes. (Nogueiras, 2008)

There are a variety of Cannabinoids, natural and synthetic see table X below, that have been developed to further explore the eCB system as well as hopeful development for therapeutics, with some being licensed for various purposes. Synthetics are known to have side effects and patients often report increased efficacy when using natural products. This may be due in part to differences in synthetic isomeric structure and possible non-understood entourage effects.

Compound	Target	Potential as Therapeutic
BML190	Non selective against (CB2>>CB1)	Tumor growth inhibitor (in glioma, skin carcinoma, leukemia, lymphoma), multiple sclerosis, peripheral analgesia, immune diseases.
JWH-015	Selective CB2 agonists	
JWH-113		
HU-308		
AM-1241		



Noladin Ether	Selective CB1 agonist	Analgesic
O-1269	Partial CB1 agonist	Analgesic, antiemetic, appetite stimulant, tumor growth inhibitor
2-AG	Non selective agonist (CB1>CB2)	
(R)- methandamie	Non selective agonist (CB1>> CB2)	Analgesic, antiemetic, appetite stimulant, tumor growth inhibitor
Anandamide		
$\Delta^9$ -THC	Non selective agonist (CB1>CB2)	
HU-210	Non selective agonist (CB1= CB2)	Analgesic, multiple sclerosis, neuroprotective
CP-55,940		Analgesic, antiemetic, appetite stimulant, tumor growth inhibitor, multiple sclerosis
WIN 55,21 2-2		

The number of synthetic cannabinoids pale in comparison to the variety of natural cannabinoids that marijuana produces, which are unique to its biochemistry, dubbed phytocannabinoids. Some 66 unique phytocannabinoids have been described, some 100-120 are estimated to exist. In addition to the phytocannabinoids, Marijuana also produces a great variety of terpenes, hundreds are believed to exist. While not unique to Cannabis, terpenes are central to the aroma, flavor, and in some cases, the possible therapeutic value of the natural product and its derivatives.

Despite our understanding of the composition and distribution of the eCB system, further research is needed to fully understand its physiological meaning, structure and function. In addition to the complexities of the eCB there is a great variety of possible exogenous cannabinoids, available in singularity or plurality, further expanding research needs, and therapeutic potential. (Bisogno, 2008)

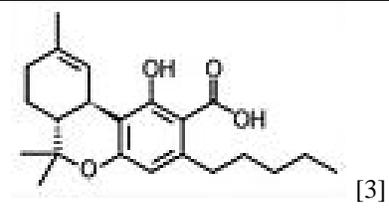
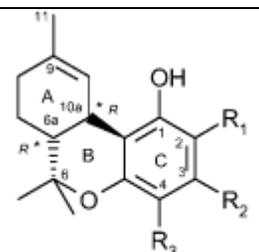
### **3.2 Marijuana Cannabinoid System**

#### **3.2.1 Phytocannabinoids**

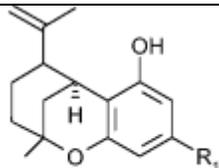
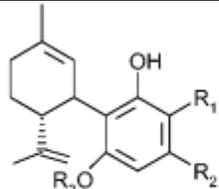
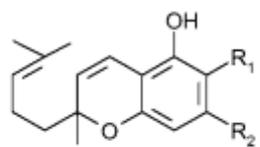
Three major cannabinoids are typically present in marijuana to varying degrees, THC, CBD, & CBN. THC is the primary active ingredient found in the vast majority of marijuana & its derivatives, it is psychoactive and is reported to exhibit anxiolytic affects, although these are inconsistent, and in some patients anoxigenic affects are generated. CBD, another prevalent cannabinoid which recently gained much publicity in its dramatic effect on sufferers of seizure and other forms of epilepsy, including Dravet's, has anxiolytic, anti-psychotic, and anticonvulsant effects, antagonizing the intoxicating and psychomimetic actions of THC. CBD also has opposite effects on the regional cerebral blood flow when compared to THC. Reviews indicate that CBD is a promising candidate for the treatment of neuropathic disorders. Furthermore, CBD also facilitates extinction in a contextual aversive conditioning model following intracerebral ventricular administration. (Passie, 2012)

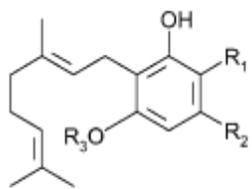
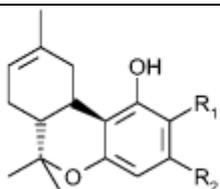
Other than these well-known Cannabinoids, the Marijuana plant contains a vast variety of chemicals with varied pharmacological effects and possible medicinal value. Approximately 483 compounds have been identified, and some are unique to the plant. Marijuana and its products contain any number of cannabinoids, terpenes, fatty acids, nitrogenous compounds including spermidine type alkaloids, various sugars, flavonoids, non-cannabinoid phenols, simple alcohols, aldehydes, ketones, acids, esters, and lactones. Cannabinoids represent a class of C21 terpenophenolic compounds, are unique to the Marijuana plant, and are of the most immediate medical, these compounds are typically referred to as phytocannabinoids to distinguish them from the synthetically & endogenously

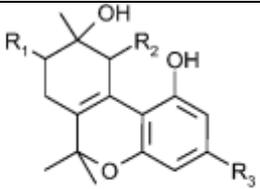
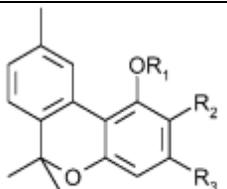
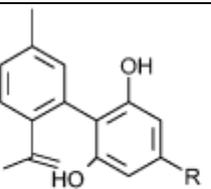
produced cannabinoids. See Table 1 for a review of the so far identified phytocannabinoids, their structure, and their so far understood pharmacological effects. (ElShohly 2007)

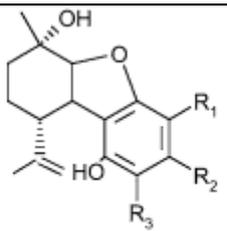
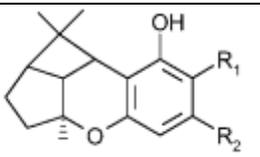
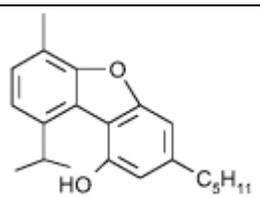
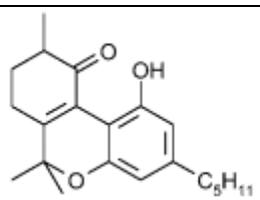
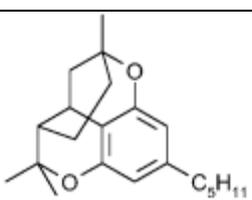
Table 1: Phytocannabinoids of the Marijuana Plant		
Compound	Structure	Primary Pharmacological Characteristics
Delta-9-tetrahydrocannabinol Class		
Delta-9-tetrahydrocannabinolic ( $\Delta^9$ -THC)	 <p>[3]</p> <p><math>R_1=H, R_2= C_5H_{11}, R_3=H</math></p>	Euphoria, Analgesic, Anti-Inflammatory, Antioxidant, Antiemetic
Delta-9-tetrahydrocannabinolic acid B ( $\Delta^9$ -THCA-B)	$R_1= COOH, R_2 =C_5H_{11}, R_3=H$	
Delta-9-tetrahydrocannabinolic acid A ( $\Delta^9$ -THCA-A)	 <p><math>R_1 = COOH, R_2 = C_5H_{11}, R_3 = H</math></p>	
Delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC-C <sub>1</sub> )	$R_1= H, R_2= CH_3, R_3= H$	
Delta-9-tetrahydrocannabinolic acid ( $\Delta^9$ -THCA-C <sub>1</sub> )	$R_1= COOH, R_2= CH_3, R_3=H$ or $R_1= H, R_2= CH_3, R_3=COOH$	
Delta-9-tetrahydrocannabivarin ( $\Delta^9$ -THCV)	$R_1= H, R_2=C_3H_7, R_3=H$	Analgesic, Euphoria ( <i>more to add here?</i> )
Delta-9-tetrahydrocannabivarinic acid ( $\Delta^9$ -THCVA)	$R_1=COOH, R_2=C_3H_7, R_3=H$	

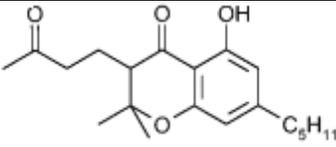
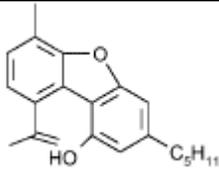
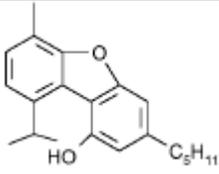
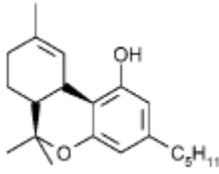
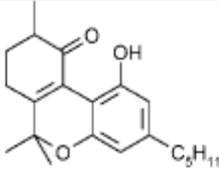
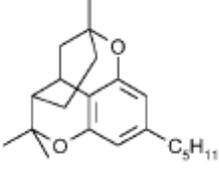
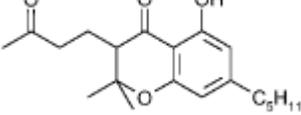
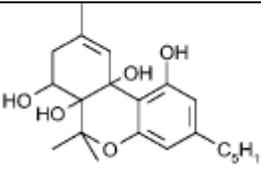
<sup>1</sup> Adapted from ElShohly 2007

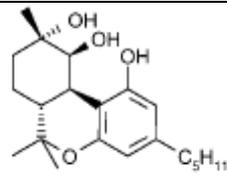
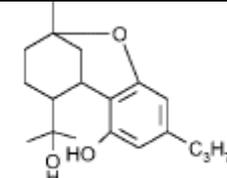
Delta-9-tetrahydrocannabinol-C <sub>4</sub> ( $\Delta^9$ -THC-C <sub>4</sub> )	R <sub>1</sub> =H , R <sub>2</sub> =C <sub>4</sub> H <sub>9</sub> , R <sub>3</sub> =H	
Delta-9-tetrahydrocannabinolic acid-C <sub>4</sub> ( $\Delta^9$ -THCA-C <sub>4</sub> )	R <sub>1</sub> =COOH, R <sub>2</sub> =C <sub>4</sub> H <sub>9</sub> , R <sub>3</sub> =H or R <sub>1</sub> =H , R <sub>2</sub> =C <sub>4</sub> H <sub>9</sub> , R <sub>3</sub> =COOH	
Delta-7-cis-iso-tetrahydrocannabivarin ( $\Delta^7$ -cis-iso-THCV)	 <p>R<sub>1</sub> = C<sub>3</sub>H<sub>7</sub></p>	
Cannabidiol Class		
Cannabinolic Acid (CBDA)	 <p>R<sub>1</sub> = COOH, R<sub>2</sub> = C<sub>5</sub>H<sub>11</sub>, R<sub>3</sub> = H</p>	Antibiotic
Cannabidiol (CBD)	R <sub>1</sub> =H , R <sub>2</sub> =C <sub>5</sub> H <sub>11</sub> , R <sub>3</sub> =H	Antispasmodic, Antioxidant, Anti-inflammatory, Analgesic, Antipsychotic, Anxiolytic
Cannabidiolcol (CBD-C <sub>1</sub> )	R <sub>1</sub> = H, R <sub>2</sub> = CH <sub>3</sub> , R <sub>3</sub> =H	
Cannabidivarian (CBDV)	R <sub>1</sub> =H , R <sub>2</sub> =C <sub>3</sub> H <sub>7</sub> , R <sub>3</sub> =H	
Cannabidivarinic acid (CBDVA)	R <sub>1</sub> =H , R <sub>2</sub> =C <sub>3</sub> H <sub>7</sub> , R <sub>3</sub> =H	
Cannabidiol- C <sub>4</sub> (CBD-C <sub>4</sub> )	R <sub>1</sub> =H, R <sub>2</sub> =C <sub>4</sub> H <sub>9</sub> , R <sub>3</sub> =H	
Cannabidiol monomethylether (CBDM)	R <sub>1</sub> =H , R <sub>2</sub> =C <sub>5</sub> H <sub>11</sub> , R <sub>3</sub> =CH <sub>3</sub>	
Cannabichromene Class		
Cannabichromenic acid (CBCA)	 <p>R<sub>1</sub> = COOH, R<sub>2</sub> = C<sub>5</sub>H<sub>11</sub></p>	

Cannabichromene (CBC)	$R_1=H, R_2=C_5H_{11}$	Analgesic, Antifungal, Antibiotic, Anti-Inflammatory
Cannabichromevarinic acid (CBCVA)	$R_1=COOH, R_2=C_3H_7$	
Cannabichromevarin (CBCV)	$R_1=H, R_2=C_3H_7$	
Cannabigerol Class		
Cannabigerolic Acid (CBGA)	 $R_1 = COOH, R_2 = C_5H_{11}, R_3 = H$	Antibiotic
Cannabigerolic monomethylether (CBGAM)	$R_1=COOH, R_2=C_5H_{11}, R_3=CH_3$	
Cannabigerol (CBG)	$R_1=H, R_2=C_5H_{11}, R_3=H$	Antibiotic, Analgesic, Antifungal, Anti-inflammatory
Cannabigerovarinic acid (CBGVA)	$R_1=COOH, R_2=C_3H_7, R_3=H$	
Cannabigerovarin (CBGV)	$R_1=H, R_2=C_3H_7, R_3=H$	
Cannabigerol monomethylether (CBGM)	$R_1=H, R_2=C_3H_7, R_3=H$	
Delta-8-tetrahydrocannabinol class		
Delta-8-tetrahydrocannabinolic acid ( $\Delta^8$ -THCA)	 $R_1 = COOH, R_2 = C_5H_{11}$	
Delta-8-tetrahydrocannabinol ( $\Delta^8$ -THC)	$R_1=H, R_2=C_5H_{11}$	Similar, but less potent than $\Delta^9$ -THC
Cannabitriol Class		

Cannabitrinol (CBT)	 <p><math>R_1 = H, R_2 = OH, R_3 = C_5H_{11}</math></p>	
10-Ethoxy-9-hydroxy-delta6a-tetrahydrocannabinol	$R_1 = H, R_2 = OC_2H_5, R_3 = C_5H_{11}$	
Cannabitrinolvarin (CBTV)	$R_1 = H, R_2 = OH, R_3 = C_3H_7$	
Ethoxy-cannabitrinolvarin (CBTVE)	$R_1 = H, R_2 = OC_2H_5, R_3 = C_3H_7$	
8,9 Dihydroxy-delta-6a-tetrahydrocannabinol	$R_1 = OH, R_2 = H, R_3 = C_3H_7$	
Cannabinol & Cannabinodiol Classes		
Cannabinolic Acid (CBNA)	 <p><math>R_1 = H, R_2 = COOH, R_3 = C_5H_{11}</math></p>	
Cannabinol (CBN)	$R_1 = H, R_2 = H, R_3 = C_5H_{11}$	Anti-Inflammatory, Antibiotic, Anticonvulsant, Sedative
Cannabinol methylether (CBNM)	$R_1 = CH_3, R_2 = H, R_3 = C_5H_{11}$	
Cannabiorcol (CBN-C <sub>1</sub> )	$R_1 = H, R_2 = H, R_3 = CH_3$	
Cannabiorcol (CBN-C <sub>2</sub> )	$R_1 = H, R_2 = H, R_3 = C_2H_5$	
Cannabivarin (CBV)	$R_1 = H, R_2 = H, R_3 = C_3H_7$	
Cannabinol-C <sub>4</sub> (CBN-C <sub>4</sub> )	$R_1 = H, R_2 = H, R_3 = C_4H_9$	
Cannabinodiol (CBND)	 <p><math>R = C_5H_{11}</math></p>	
Cannabinodivarin (CBVD)	$R = C_3H_7$	

Cannabielsoin Class		
Cannabielsoic Acid A (CBEA-A)	 <p><math>R_1 = \text{COOH}, R_2 = \text{C}_5\text{H}_{11}, R_3 = \text{H}</math></p>	
Cannabielsoic Acid B (CBEA-B)	$R_1 = \text{H}, R_2 = \text{C}_5\text{H}_{11}, R_3 = \text{COOH}$	
Cannabielsoin (CBE)	$R_1 = \text{H}, R_2 = \text{C}_5\text{H}_{11}, R_3 = \text{H}$	
Cannabicyclol Class		
Cannabicyclic Acid (CBLA)	 <p><math>R_1 = \text{COOH}, R_2 = \text{C}_5\text{H}_{11}</math></p>	
Cannabicyclol (CBL)	$R_1 = \text{H}, R_2 = \text{C}_5\text{H}_{11}$	
Cannabicyclovarin (CBLV)	$R_1 = \text{H}, R_2 = \text{C}_3\text{H}_7$	
Miscellaneous Cannabinoids		
Cannabifuran (CBF)		
10-Oxo-delta-6a-tetrahydrocannabinol (OTHC)		
Cannabicitran (CBT)		

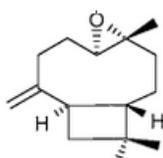
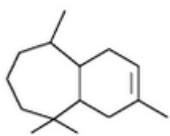
Cannabichromanon (CBCN)		
Miscellaneous Cannabinoids Class		
Dehydrocannabifuran (DCBF)		
Cannabifuran (CBF)		
Delta-9- <i>cis</i> -tetrahydrocannabinol ( <i>cis</i> -THC)		
10-Oxo-delta-6a-tetrahydrocannabinol (OTHC)		
Cannabicitran (CBT)		
Cannabichromanon (CBCN)		
Trihydroxy-delta-9-tetrahydrocannabinol (triOH-THC)		

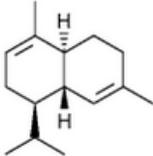
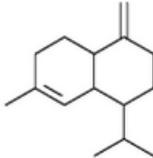
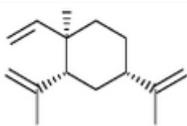
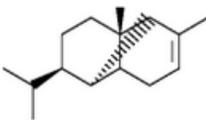
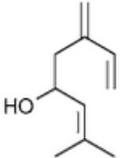
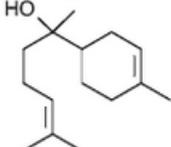
Cannabiripsol (CBR)		
3,4,5,6-Tetrahydro-7-hydroxy-alpha-alpha-2-trimethyl-9-n-propyl-2,6-methano-2H-1-benzoxocin-5-methanol (triOH-THC)		

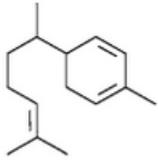
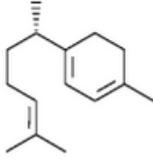
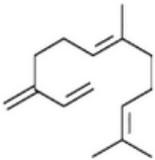
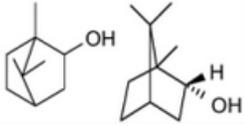
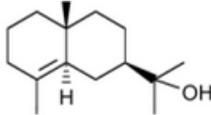
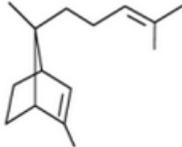
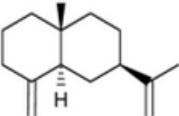
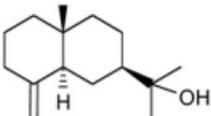
As evidenced by the great variety of cannabinoids, marijuana is a complex plant. However, when considering the terpenes produced by Cannabis, the story becomes even more complex.

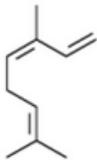
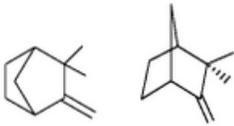
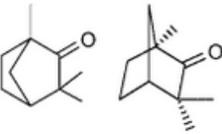
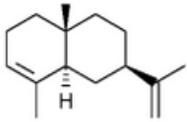
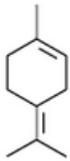
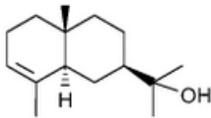
### 3.2.2 Terpenes

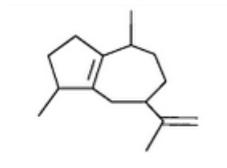
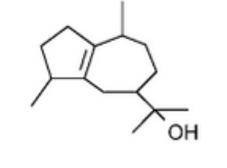
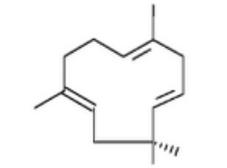
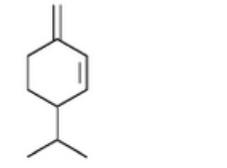
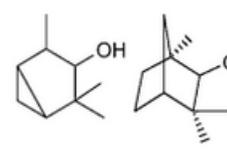
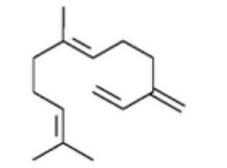
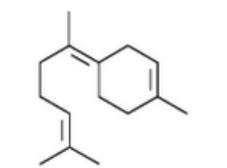
Marijuana scents are comprised of approximately 140 terpenes, however some estimates place this variety closer to 600. See Table X below for a summary of terpenes known to exist in Cannabis. Isoprene units form monoterpenoids, sesquiterpenoids, diterpenoids, and triterpenoids. Terpenoids may be acyclic, monocyclic, or polycyclic hydrocarbons with substitution patterns involving esters, ketones, aldehydes, ethers, and alcohols. The composition and yield depend on the cultivar type, cultivation conditions, harvest time, curing conditions, and storage conditions. Due to their volatility terpenes will evaporate at different rates given the molecular class. In addition to the scents and aromas that terpenes add to the Marijuana plant, some are evidenced to have some therapeutic potential.

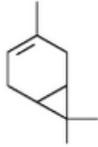
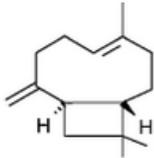
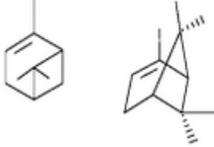
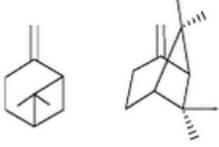
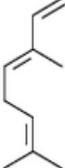
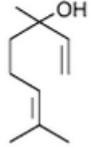
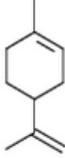
Table X: Terpenes in Cannabis, their effects and their therapeutic potential			
Compound	Structure	Effect	Therapeutic Application
Caryophyllene oxide			
Alpha-Longipinene			

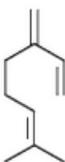
Alpha-Cadinene			
Gamma-Muurolene			
Alpha- <i>cis</i> -Bergamotene			
Beta-Elemene			
Alpha-Ylangene			
Ipsdienol			
Epi-alpha-Bisabolol			
Alpha-Thujene			

Cis-gamma-bisabolene			
Gamma-curcumene			
Cis-beta-Farnesene			
Borneol		Sedative	Fatigue, Stress
Gamma-Eudesmol			
Alpha-trans-bergamotene			
Beta-Selinene			
Beta-Eudsemol			

Cis-Ocimene			
Cis-Sabinene hydrate			
Camphene			
Fenchone			
Alpha-Terpineol			
Alpha-selinene			
Terpinolene			
Alpha-Eudesmol			

Alpha-Gualene			
Guajol			
Alpha-Caryophyllene		Anti-Inflammatory, analgesic	Potassium Ion Channel Disorders
Bet-Phellandrene			
Beta-Fenchol			
<i>Trans</i> -alpha-Farnesene			
<i>Trans</i> -gamma-Bisabolene			

Delta-3-Carene		Dehydration of mucus membranes, reduced menstrual flow rate	Otolaryngological & menstrual disorders
Beta-Caryophyllene			
Alpha-pinene		Mental Focus, Expectorant, bronchodilator, antiseptic	ADHD, Asthma
Beta-pinene			
<i>Trans</i> -Ocimene			
Linalool		Anti-anxiety, sedative	Anxiety disorders, insomnia
Limonene		Anti-bacterial, anti-fungal, anti-depressant, anti-carcinogen	Infection, depression, cancer

Myrcene		Antimicrobial, antiseptic, analgesic, antioxidant, anti-carcinogen, anti-depressant, anti-inflammatory, muscle relaxant	Infection, heart conditions, depression, muscle and joint issues.
Cineole		Brain Stimulation	Neurological Deficiencies
Pulegone		Acetylcholinesterase Inhibitor	Alzheimer's
Terpineol		Sedative	Insomnia, anxiety, stress
Adapted from El Sohly 2007, Russo 2011			

Terpenes such as limonene, Myrcene, a-pinene, linalool, B-Caryophyllene, Caryophyllene oxide, nerolidol, and phytol, may contribute to entourage effects of cannabis-based therapeutics. This phytocannabinoid –terpenoid synergy opens the door to an extensive pipeline of therapeutic possibilities. (Russo, 2011)

### 3.3 Entourage Effects & Variability in Individual Outcomes

#### Section 4: Therapeutic Marijuana Product Manufacturing

Marijuana Products come in a variety of forms. Marijuana flower is by far the most well-known and oldest product. However there has been a growing interest in the production of extract concentrates which are used by themselves or to develop infused products. Extraction methodologies include; hydrocarbon extraction, typically butane and/or a mix of propane, alcohol, supercritical CO<sub>2</sub>, lipid extractions using things like butter, coconut oil etc., live resin which involves freezing at -70C within hours of harvest followed by a hydrocarbon extraction, rosin, a type of melt based extraction, and finally traditional hash making which involves actual mechanical sieving. While all methods extract cannabinoids, and to some degree terpenoids, extraction efficiencies vary based on the extraction solvent and its implementation.

Concentrates are used to produce a wide variety of infused products to include; edible perishables such as various baked goods, candies, and beverages, transdermal patches, sublingual applications, inhalers, gel caps, pressed tablets, vaporizers & suppositories. The specific chemo metric profiles of cannabinoids and terpenoids is dependent on a variety of factors to include; cultivar type, spatial location of flower on plant, cultivation conditions, harvest time, curing methods, extraction methods, heat activation steps, infusion methodology, and storage conditions. The complexity of human & marijuana chemistries, with their multiple & distributed receptors & active ingredients, as well as the multitude of manufacturing methods, exert various degrees of influences over the content of marijuana products and its treatment outcomes.

Marijuana use as a medicine has not been an exact science. In fact, complications with standardization and effect, plagued early western adoption of medicinal cannabis. In some ways contributing to its initial decline. In order to achieve the best possible therapeutic potential of Cannabis, in light of the complexity of the plant and the confounding



variables which affect final product composition, it is necessary to more completely understand the products chemical composition.

Given advancements in analytical chemistry and the influx of attention to the field, the Marijuana Industry is well positioned to develop consistent, standardized products. In order to achieve true content uniformity, improving product standards and eliminating uncontrolled unknowns, a higher resolution of chemo metric analytics will be required. The use of an HPLC-DAD, and a GC-FID/MS, or other comparable technologies, for quantifying cannabinoid and terpenoid content, respectively, running multi compound panels, are necessary to achieve a better understanding of chemical composition of Marijuana Products, improving product standardization, making effects more predictable, and improving the foundation for therapeutic research.

Currently, Marijuana and their products are categorized by strain name and/or the concepts Sativa, Indica, or Hybrid. Sativa's are typically associated with energetic cerebral highs, Indicas are associated with relaxed sedative highs, and hybrids are something in-between. While there is morphological and genotypic basis for the classifications of Sativa, Indica, Kush, and Hemp, there is little to no oversight in the industry to ensure a product is the type of strain it is being called, or that the strain is in fact a Sativa, Indica, or some percentage of hybrid. Furthermore, other than colloquial, anecdotal evidence, there is no clinical evidence to support the effects associated with any of these categories, as such the categories assigned, which may be wrong in the first place, are often poor predictors of treatment outcomes.

Now that industry has begun in Colorado and other states, a quality control industry is developing to support. However, while the tools are familiar to science, the methodologies are new and the teams are often tyros in the field of quality control laboratory development. Nonetheless, cannabinoid profiling is beginning and the content of THCA/THC and CBDA/CBD is becoming a staple piece of information in dispensaries. Additionally, CBG, & CBN panels are also typically run. However, further cannabinoid analysis is lacking and no terpene measurements have taken hold in a meaningful way. Without this information it is impossible to know what a patient is actually getting.

To advance Marijuana medicine, it is critical to move away from strain name or Indica/Sativa based categorization, or if we are too keep this method of classification we will have to adopt some amount of chemo metric and possibly genotypic validation to ensure products meet specifications for a given strain and/or product category. Regarding concentrates and infused products, strain name and Indica/Sativa based classifications really break down, as many factors that chemical composition outcomes come into play through the production pipeline. In these instances a chemo metric profile is the only classification approach that will take us closer to standardized, predictable products. In addition to considering the various chemistries involved, modern efforts will have to grapple with the fact that marijuana& its derivatives affect different people differently, and that the plant's chemistry can in some cases, only, operates in concert with one another, the entourage effect.

When developing Marijuana based therapeutics, it would prove useful to manufacture products of varying cannabinoid and terpenoid ratios in all categories of administration. Currently, popular ratios focus primarily on THC/CBD ratios. Of this product category, ratios typically seen in the market at 1:1, 1:2, 1:23, THC: CBD. Additionally, products exist which are solely THC or solely CBD. Manufacturing products that are singular or plural in cannabinoids other than THC and CBD, like CBN, CBG, and THCV are targets for manufacture. Additionally, developing products with varying concentrations of terpenoids which are known to possess therapeutic and/or synergistic properties are worth considering.

## References

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## Attachment 5.2

# Education

We are committed to educating the consumer and general public on the deep medicinal benefits of Cannabis. This brochure is a detailed introduction to the many facets of this versatile plant. We look forward to continuing this path by keeping the medical cannabis community well informed on the latest news and research through our own efforts and by relaying the advancements made in the global medical community.

Cannabis is a dynamic plant with many uses. People have used this beneficial plant for thousands of years, yet the complex chemistry of this plant are only beginning to be understood. To help educate the consumer on the deeper medicinal benefits of cannabis, this brochure lists the common cannabinoids, terpenes and flavonoids found in cannabis plants, along with some of their known effects and a spectrum analysis of the plant for better understanding.

Cannabis plants produce a complex blend of bioactive compounds, primarily cannabinoids and terpenes or terpenoids, and also flavonoids. The cannabinoids and terpenes are concentrated in the sticky flowering tops, also known as colas, whereas the flavonoids are spread throughout the plant.

The spectrum of cannabinoids in a specific cannabis strain is known as its cannabinoid profile. Most of these compounds are not psychoactive, yet they synergize together in complex ways. For example, the psychoactivity of THC is modified by interactions with other cannabinoids such as CBD and THCV. These cannabinoids bind to the CB1 and CB2 receptor sites on cells in the human body, and there may be other receptor sites that we are only now discovering. The CB1 receptor sites are found especially in the nervous system and also in the reproductive system, and the CB2 receptor sites are found mostly in the immune system, especially in the spleen.

THC and other cannabinoids found in cannabis are called phytocannabinoids, or cannabinoids from plants. Our bodies also produce their own cannabinoids, called endocannabinoids, such as anandamide, also known as AEA, short for N-arachidonylethanolamine. Another endocannabinoid is 2-AG or 2-arachidonoyl glycerol. 2-AG is present in human mothers' milk. The endocannabinoids function as intercellular messengers, but their mode of action tends to be more localized, and they are lipid-soluble, unlike neurotransmitters such as serotonin.

In addition, the complex set of interactions between the cannabinoids is further affected by the presence of a wide spectrum of terpenes found in cannabis plants.

Terpenes, also referred to as terpenoids, are a class of chemical compounds that are present in many of the plants we eat, and which contribute to their scent or taste. Large quantities of terpenes are present in cannabis flowering tops. For example, the smells of citrus fruits are from terpenes like limonene, a common terpene in cannabis, which has anti-cancer properties, and helpful against depression. Pine trees have a piney smell due to terpenes such as alpha-pinene, also present in cannabis. Alpha-pinene helps memory, and acts as a bronchodilator. Mangoes contain beta-myrcene, a terpene also found in cannabis in large quantities, which synergizes with THC and is analgesic, anti-inflammatory and antibiotic. For example, eating a mango an hour before consuming cannabis, may improve the vibrancy of the effects one experiences, due to the beta-myrcene in the mango interacting with the THC and other cannabinoids.

Flavonoids are polyphenols found in plants and constituents of many foods we eat. “Preliminary research indicates that flavonoids may modigy allergens, viruses, and carcinogens, and so may be biological “response modifiers.” In vitro studies show that flavonoids also may have anti-allergic, anti-inflammatory, anti-microbial, and anti-cancer activities.” (Wikipedia)

Flavonoids act as antioxidants in the human body, and they may help in the prevention of certain cancers and cardiovascular diseases.

## SPECIES OF CANNABIS PLANTS

There are three primary species of cannabis: indica, sativa and ruderalis.

Cannabis indica tends to have wider leaves and denser flowering tops, a shorter, bushy appearance, as well as often having more sedative effects.

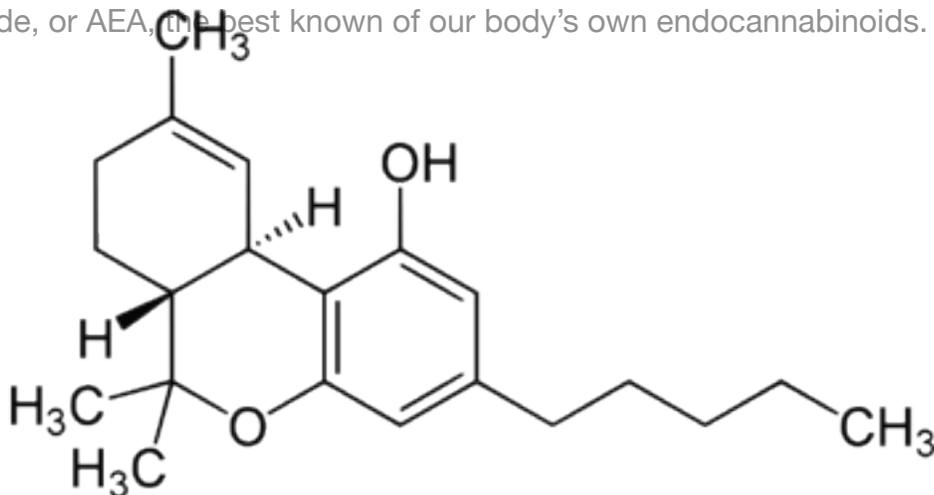
Cannabis sativa generally has more slender leaves, airy flowering tops, often a tall, gangly appearance, and provides a more active, cerebral, and energetic high. Most indicas take less time for their flowering tops, known as colas, to mature. Indicas and sativas have been hybridized to produce strains that blend characteristics of both species.

A third species, Cannabis ruderalis, is a small plant native to Russia, and is a short-season cannabis plant that begins flowering dependent on the age of the plant. Cannabis indica and Cannabis sativa are photoperiod species, in that the length of the day determines the onset of flowering. Cannabis ruderalis is very low in THC, and is only used in some hybrids designed for cultivation in northern areas with a short growing season.

## PRIMARY CANNABINOIDS:

Over 85 cannabinoids have been isolated from *Cannabis indica* and *Cannabis sativa*. The following cannabinoids are the most common, and are the focus of intensive research at this time. Also listed here is anandamide, or AEA, the best known of our body's own endocannabinoids.

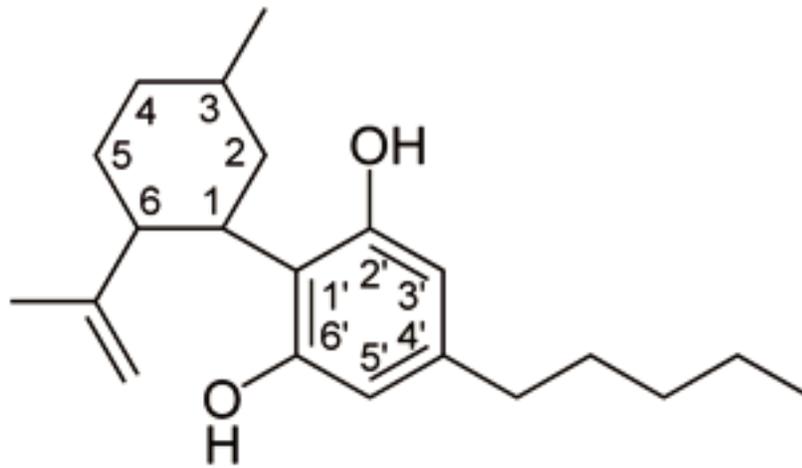
### THC



THC is well known for its psychoactivity. THC or tetrahydrocannabinol has many effects including elevation of mood, alteration of awareness, and increasing appetite. THC is the predominant cannabinoid in the majority of strains of medical cannabis, and is primarily responsible for the common euphoric element of cannabis via the CB1 receptor sites in the nervous system. THC binds equally to CB1 and CB2 receptor sites in the body.

Benefits and effects of THC: psychoactive, sensory enhancement, euphoria, elevation of mood, anti-cancer, anti-nausea, anti-viral, pain relief, improves appetite, help for glaucoma, mitigates spasms, muscle relaxant, antimicrobial, neuroprotective, help for autoimmune disorders such as Crohn's disease, anti-inflammatory, and antioxidant.

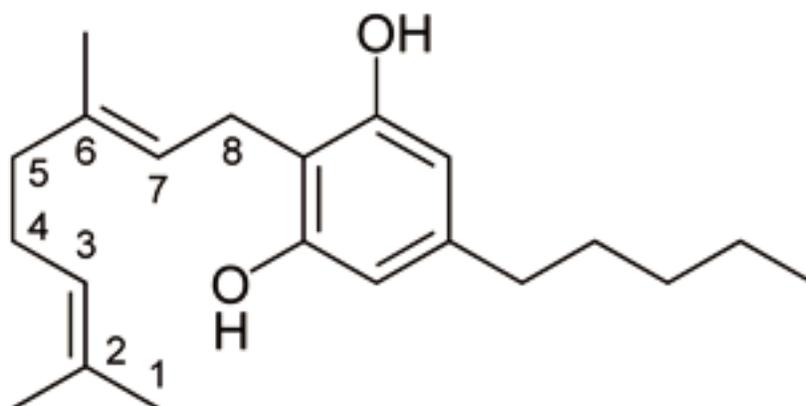
CBD



Although not psychoactive, CBD or cannabidiol modifies the effects of THC. CBD has great medical potential, with numerous effects including anti-cancer, anti-nausea, and pain reduction. CBD binds more to the CB2 receptor site than to the CB1 receptor site, and it also has been found to be a 5-HT 1A receptor agonist, giving CBD anti-depressant, anxiolytic, and neuroprotective effects. CBD also binds to the vanilloid receptor TRPV1, which regulates sensations of pain, and this helps to explain how CBD acts as an analgesic in the human body. Strains with lower THC may have higher levels of CBD.

Benefits and effects of CBD: non-psychoactive, extensive effects include anti-cancer, anti-nausea, pain relief, causes drowsiness or sedation, mitigates spasms, mitigates seizures, anxiolytic, muscle relaxant, antibacterial, neuroprotective, anti-diabetic, improves blood circulation, help for autoimmune disorders such as Crohn's disease and psoriasis, bone growth stimulant, help for rheumatoid arthritis, and a neuroprotective antioxidant.

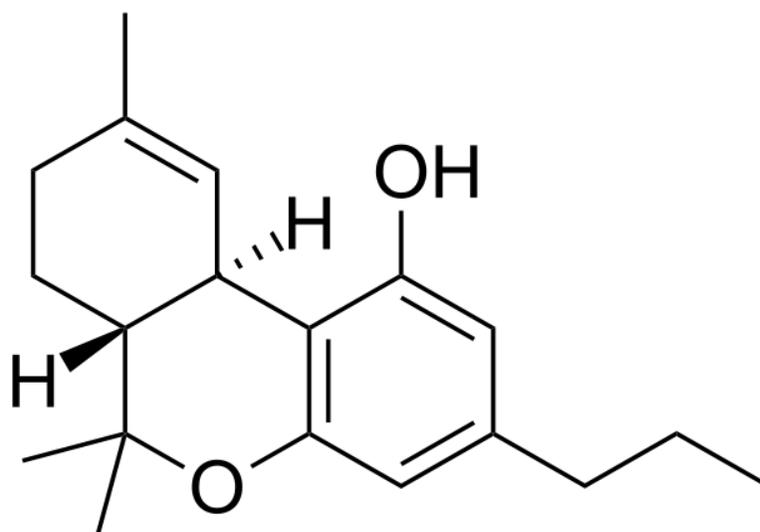
## CBG



Not psychoactive, CBG or cannabigerol is commonly found in large quantities in fiber hemp. Certain medical strains have considerable CBG, which has promise for its anti-tumor qualities. CBG binds to the CB2 receptor site, as well as being a CB1 receptor antagonist. It also is an alpha-2 adrenergic receptor agonist and a 5-HT 1A receptor antagonist.

Benefits and effects of CBG: non-psychoactive, promising as an anti-cancer agent, antibacterial, lowering of blood pressure, anti-inflammatory, and as a bone growth stimulant.

## THCV

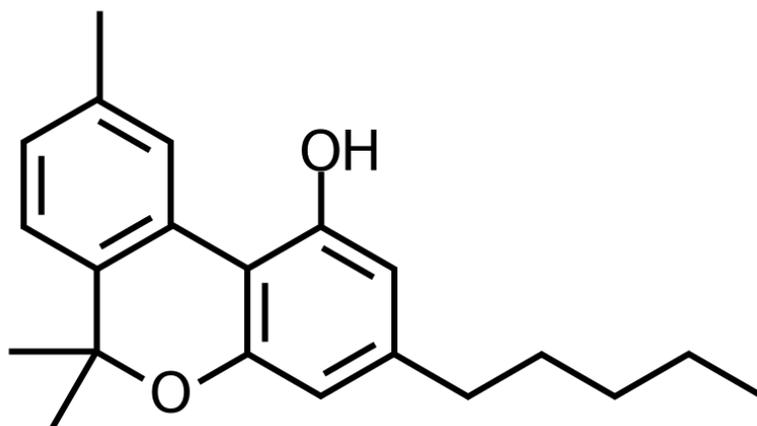


Closely related to THC, THCV or tetrahydrocannabivarin has a shorter 'tail' in its chemical structure,

and it is not psychoactive. THCV is an antagonist at the CB1 and CB2 receptor sites, and tends to moderate some of the effects of THC. THCV is present in certain strains of cannabis, notably ones originating from Southeast Asia or South Africa. THCV has potential as an appetite suppressant and may also help with diabetes.

Benefits and effects of THCV: modifies the high from THC as it is a CB1 receptor site antagonist, decreases appetite, mitigates seizures, and as a bone growth stimulant.

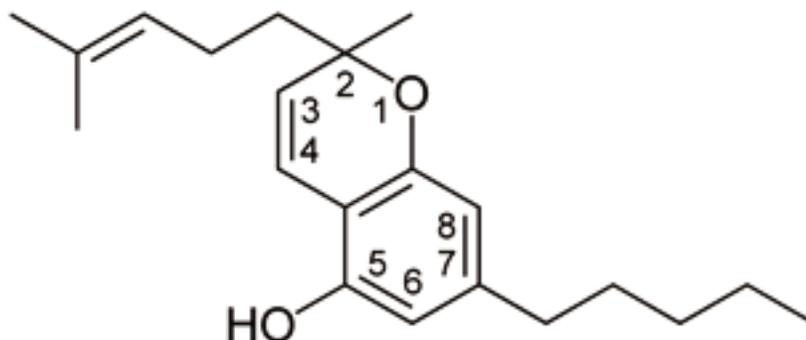
## CBN



Cannabinol (CBN) is primarily a decomposition product of THC from exposure to heat or light, very little CBN is found in fresh plants. CBN or cannabinol has only mild psychoactivity, and may cause drowsiness, as well as being antispasmodic. This is why freshly harvested cannabis buds may be more vibrant and awake than buds with higher levels of CBN that have been sitting around for a while.

Benefits and effects of CBN: somewhat psychoactive, relief for pain, causes drowsiness, mitigates spasms, help for glaucoma, neuroprotective, anti-inflammatory, and antioxidant.

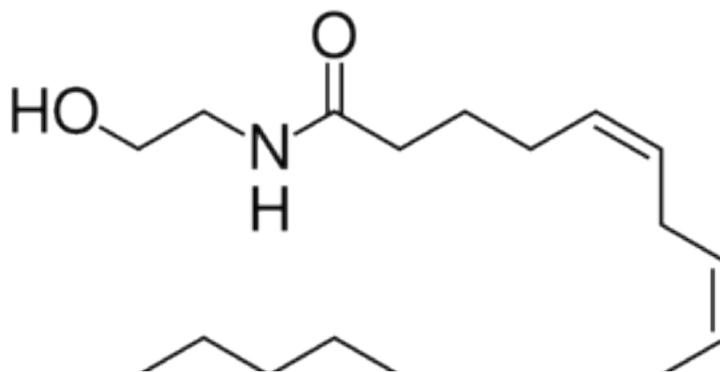
## CBC



Cannabichromene or CBC is not psychoactive.

Benefits and effects of CBC: anti-cancer, antibacterial, antifungal, anti-inflammatory, analgesic, and bone growth stimulant.

## AEA (Anandamide)



Your Body already knows and produces its own type of cannabis called an EndoCannabinoid. Endocannabinoids are substances produced from within the body that activate cannabinoid receptors. After the discovery of the first cannabinoid receptor in 1988, scientists began searching for an endogenous ligand for the receptor. Here's the most recognized of that group:

Anandamide literally means, “bliss amide,” according to Wikipedia, and it is one of the endocannabinoids found in the human body. Amazingly, anandamide is also present in chocolate from the tropical cacao tree, *Theobroma cacao*. This may be the reason that chocolate is sometimes called the “love drug.” Anandamide, also known as AEA, short for N-arachidonylethanolamine, has a chemical structure unlike the phytocannabinoids found in cannabis, and binds equally to the CB1 and CB2 receptor sites.

Benefits and effects of AEA: Anandamide regulates the function of our central nervous system and our immune system, via the CB1 and CB2 receptors. AEA also regulates appetite, memory, sensations of pleasure and pain, and sleep patterns. It also inhibits certain cancers, such as breast cancer in humans. In women, levels of anandamide are highest at ovulation. Like CBD, AEA also attaches to the vanilloid receptors TRPV1, which are involved with the sensation of pain. Levels of anandamide in the brain may be increased by dietary essential fatty acids, especially arachidonic acid.

## TERPENES IN CANNABIS

Terpenes are the main components of the essential oils and resins found in most plants, and especially in cannabis plants. Their functions include limiting insect feeding, attracting pollinating insects, protecting plants from external agents like animals and environmental conditions, and as construction materials for other molecules. They have distinctive scents and, even more important, they synergize with and modify the effects of THC and other cannabinoids. The following are some of the common terpenes in cannabis:

**Beta-myrcene:** a monoterpene found also in large amounts in West Indian bay tree, mango, myrcia, verbena, cannabis and hops. Not found in fiber hemp plants. Used in the perfume industry, beta-myrcene smells like cloves, earthy, green vegetation, citrus, fruity, with mango and minty undertones. Ed Rosenthal, in *The Big Book of Buds*, states that eating a mango an hour before smoking cannabis can add “zing” to the quality of the high, due to the beta-myrcene in the mango. Beta-myrcene is found especially in tropical sativas. Analgesic, anti-inflammatory, muscle relaxing, anti-depressant and uplifting, antibiotic, blocks certain carcinogens such as aflatoxin B. Enhances absorption of cannabinoids, allowing more THC to reach cells in the brain, and probably synergizes with THC. Extremely high levels of beta-myrcene have been found in White Widow and probably Neville’s Haze.

**Limonene:** has the strong smell of oranges, and gives citrus fruits their distinctive scents. Relaxation effects, plus enhances alertness and focused attention, anti-depressant, anti-cancer, antibiotic and anti-fungal. Found in high amounts in lemons and other citrus, especially in citrus rind; also in rosemary, juniper, peppermint; and abundant in cannabis. Helps with absorption of other terpenes such as cannabinoids. Cannabis strains high in limonene are Lemon Skunk and Big Bang.

**Caryophyllene:** one variation, beta-caryophyllene, also known as BCP, binds to the CB2 receptor site, and it is the first known cannabinoid found in food. Most cannabis essential oil contains large amounts of beta-caryophylline. Beta-caryophylline is analgesic and anti-inflammatory; it is non-psychoactive. A major component of cloves and black pepper, it is also found in cinnamon, limes, carrots, celery, hops and many other food plants. Smells and tastes peppery, spicy, sweet, and woody, with elements of cloves and camphor.

**Pinene:** One form, beta-pinene, can increase mental focus and energy, and feelings of self-satisfaction; it inhibits acetylcholinesterase in the brain, and hence enhances memory. This explains why rosemary and sage, both high in beta-pinene, are considered “memory plants.” Beta-pinene also acts as an expectorant and bronchodilator. Beta-pinene is common in cannabis, and also eucalyptus oil, dill, parsley, rosemary, basil, yarrow, rose, hops, and sage; it has the familiar pine tree odor. Alpha-pinene is found in pine trees and pine needles, essential oil of rosemary, and eucalyptus oil; high levels have been found in Super Silver Haze and possibly Great White Shark; it also smells like

pine trees.

**Terpineol:** Terpineol has the scents of floral, lilac, apple and orange blossoms, limes. Terpineol reduces physical motility by nearly half in lab rats, possibly the source of couchlock in humans after smoking cannabis, and is present in some Afghan indica strains. Terpineol is a sedative, and its presence is often masked by pinene. Helpful for insomnia.

**Borneol:** smells like menthol or camphor, pine or woody; borneol is found in cinnamon and wormwood or artemisia. This is calming, sedative and relaxing, used for fatigue, and recovery from stress or illness. Probably abundant in Silver Haze, which is calming, as well as psychoactive.

**Delta-3-Carene:** sweet, pine, cedar, woody, pungent. May contribute to dry eyes and mouth in cannabis smokers, as cedar oil, which has abundant delta-3-carene, has a drying effect on bodily fluids and secretions. Found in pine and cedar resin, and also in rosemary.

**Linalool:** has a sweet, floral scent like lily of the valley, with hints of spice. Found in lavender, neroli and other essential oils. Linalool is strongly sedative, especially when inhaled, and may lead a person into sleep. May be anti-cancer. The floral scent of linalool can be masked under the citrus scents of limonene.

**1,8-Cineole:** spicy, camphor, minty, refreshing. Found in eucalyptus and rosemary, 1,8-cineole is good for circulation and pain relief; effects are also thought-provoking and stimulating.

**Sabinene:** a monoterpene found in juniper berries, marjoram and black pepper, and is a major constituent of carrot seed oil. Sabinene has a spicy scent, and may act as an anti-depressant. Sabinene is found in high amounts in Super Silver Haze and in Arjan's Ultra Haze #1.

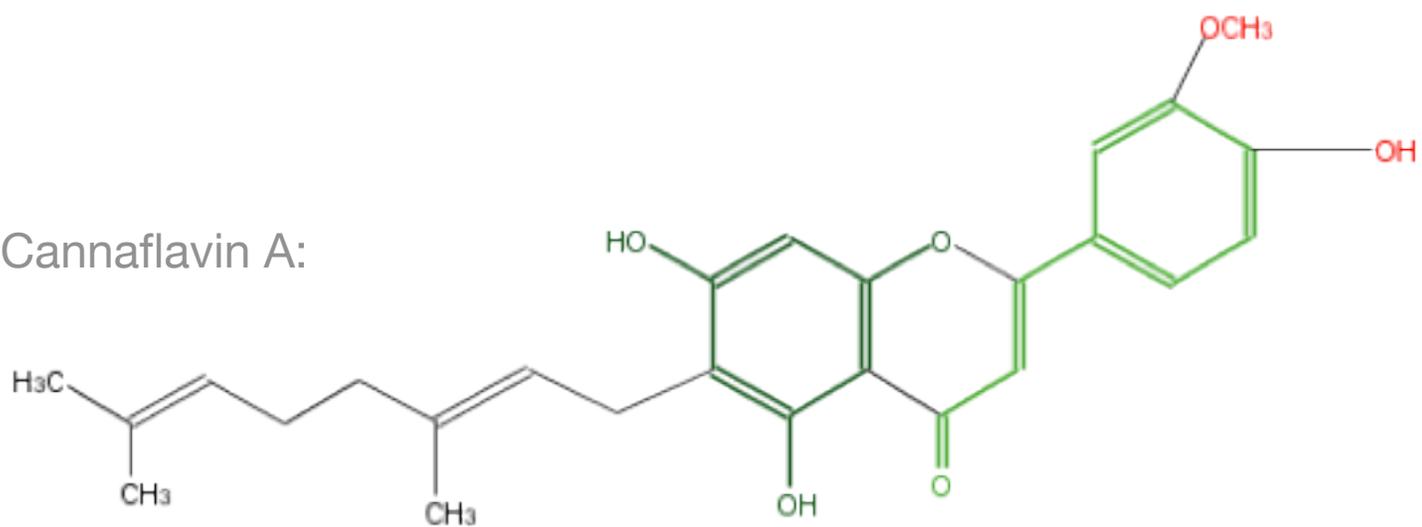
There are many other terpenes found in cannabis. We are only beginning to understand their effects and interactions with the phytocannabinoids of cannabis and the endocannabinoids in our bodies.

## FLAVONOIDS

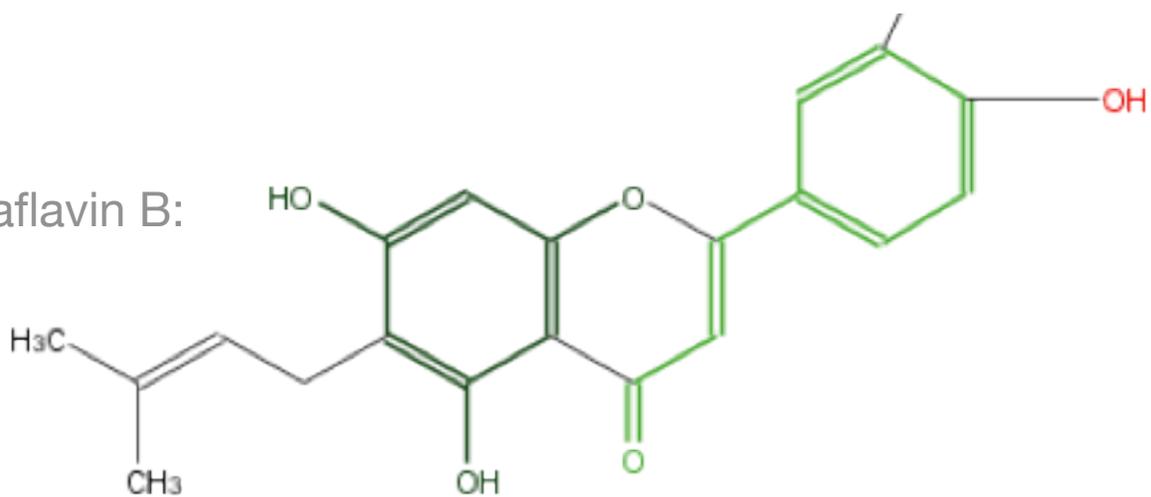
Flavonoids in cannabis have now come under scrutiny for their various effects. The following are the most common flavonoids in *Cannabis sativa*.

**Cannflavin A and B:** COX-2 inhibitor (anti-inflammatory and pain relief, as well as potentially anti-cancer), and Lipoxygenase (LO) inhibitor (anti-inflammatory). Cannflavin A and B appear to be the prevalent flavonoids in cannabis. Both cannflavin A and B inhibit prostaglandin E2 production.

Cannaflavin A:



Cannaflavin B:

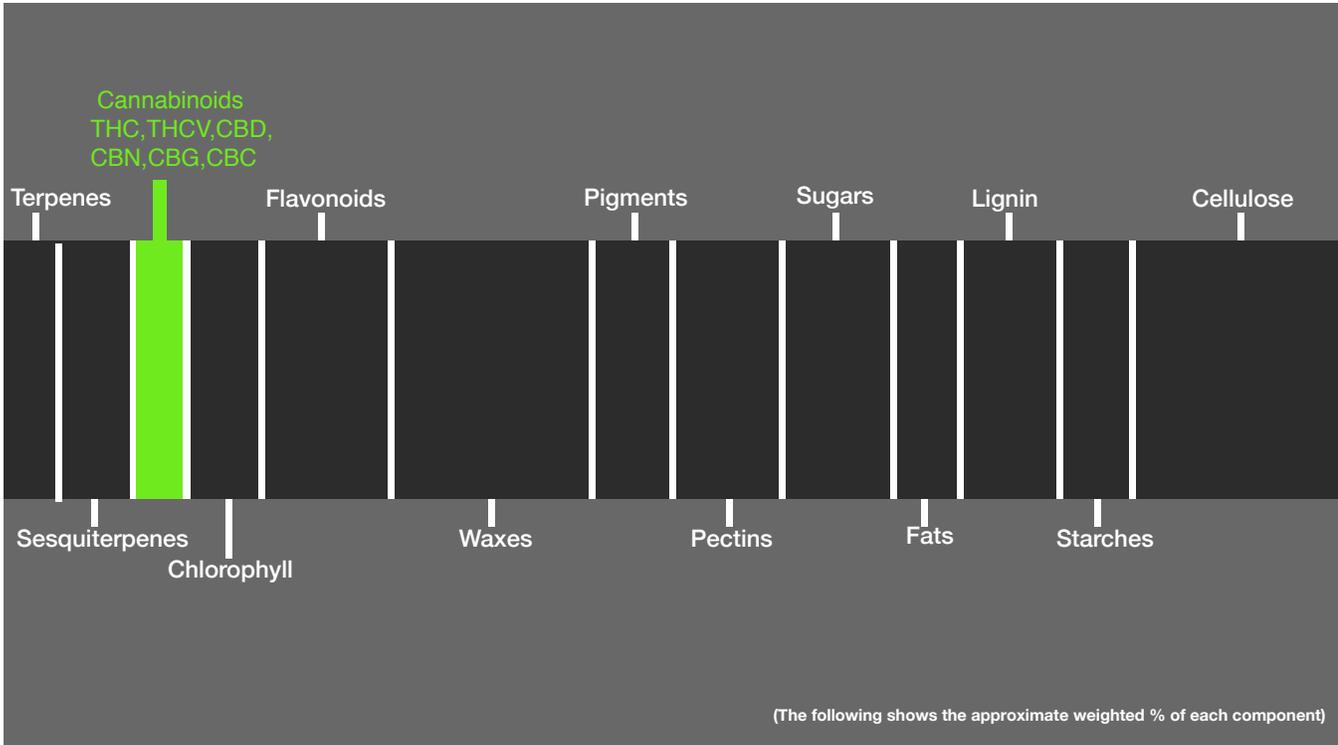


Apigenin: Anxiolytic (anti-anxiety anti-panic), anti-tumor, anti-depressant, and anti-inflammatory. Apigenin also facilitates the transport of monoamines within the body. It is a citrus flavonoid, and is found in parsley and celery.

Quercetin: Antioxidant, antimutagenic, antiviral, antihistamine, and antineoplastic (anti-cancer/tumor). One in-vitro study indicated that the combination of quercetin and resveratrol (binds to CB1 as a reverse agonist) inhibited the production of fat cells.

## NON-CANNABIS PHYTOCANNABINOIDS

Recently a number of phytocannabinoids have been discovered and researched. The first one discovered was beta-caryophylline, a terpene that binds to the CB2 receptor site. In addition, trans-resveratrol (a polyphenol found in red grapes) and curcumin (a polyphenol found in turmeric, a plant in the ginger family) have been found to bind to the CB1 receptor site. Both trans-resveratrol and curcumin act as inverse agonists at the CB1 site, which means that they modulate effects of agonists that occupy that receptor site. Both trans-resveratrol and curcumin are anti-inflammatory and COX2 inhibitors, and may help prevent cancer. In addition, recent research indicates that these nontoxic polyphenols or derivatives thereof may be effective for weight loss therapy.



Terpenes: Terpenes and terpenoids are the primary constituents of the essential oils of many types of plants and flowers. Essential oils are used widely as natural flavor additives for food, as fragrances in perfumery, and in traditional and alternative medicines such as aromatherapy. Synthetic variations and derivatives of natural terpenes and terpenoids also greatly expand the variety of aromas used in perfumery and flavors used in food additives. Vitamin A is a terpene.

Terpenes are released by trees more actively in warmer weather, acting as a natural form of cloud seeding. The clouds reflect sunlight, allowing the forest to regulate its temperature.

The aroma and flavor of hops, highly desirable in some beers, comes from terpenes. Of the terpenes in hops myrcene,  $\beta$ -pinene,  $\beta$ -caryophyllene, and  $\alpha$ -humulene are found in the largest quantities

Sesquiterpenes: A class of terpenes that consist of three isoprene units and have the molecular formula  $C_{15}H_{24}$ . Like monoterpenes, sesquiterpenes may be acyclic or contain rings, including many unique combinations. Biochemical modifications such as oxidation or rearrangement produce

the related sesquiterpenoids.

Sesquiterpenes are found naturally in plants and insects, as semiochemicals, e.g. defensive agents or pheromones.

**Cannabinoids (THC,THCV,CBD,CBN,CBG,CBC):** A class of diverse chemical compounds that act on cannabinoid receptors on cells that repress neurotransmitter release in the brain. These receptor proteins include the endocannabinoids (produced naturally in the body by humans and animals), the phytocannabinoids (found in cannabis and some other plants), and synthetic cannabinoids (manufactured chemically). The most notable cannabinoid is the phytocannabinoid  $\Delta^9$ -tetrahydrocannabinol (THC), the primary psychoactive compound of cannabis. Cannabidiol (CBD) is another major constituent of the plant, representing up to 40% of the extracted plant resin. There are at least 85 different cannabinoids isolated from cannabis, exhibiting varied effects

**Chlorophyll:** A green pigment found in cyanobacteria and the chloroplasts of algae and plants. Its name is derived from the Greek words  $\chi\lambda\omega\rho\acute{o}\varsigma$ , chloros ("green") and  $\phi\acute{\upsilon}\lambda\lambda\omicron\nu$ , phyllon ("leaf"). Chlorophyll is an extremely important biomolecule, critical in photosynthesis, which allows plants to absorb energy from light

**Flavonoids:** Flavonoids (or bioflavonoids) (from the Latin word flavus meaning yellow, their color in nature) are a class of plant secondary metabolites. Flavonoids have been shown to have a wide range of biological and pharmacological activities in in vitro studies. Examples include anti-allergic, anti-inflammatory, antioxidant, anti-microbial (antibacterial, antifungal, and antiviral, anti-cancer, and anti-diarrheal activities

**Waxes:** Especially in warm climates, plants secrete waxes as a way to control evaporation and hydration.

**Pigments:** The primary function of pigments in plants is photosynthesis, which uses the green pigment chlorophyll along with several red and yellow pigments that help to capture as much light energy as possible.

**Pectins:** In plant biology, pectin consists of a complex set of polysaccharides (see below) that are present in most primary cell walls and are particularly abundant in the non-woody parts of terrestrial plants. Pectin is a major component of the middle lamella, where it helps to bind cells together, but is also found in primary cell walls.

The amount, structure and chemical composition of pectin differs among plants, within a plant over time, and in various parts of a plant. Pectin is an important cell wall polysaccharide that allows primary cell wall extension and plant growth. During fruit ripening, pectin is broken down by the enzymes pectinase and pectinesterase, in which process the fruit becomes softer as the middle lamellae break down and cells become separated from each other. A similar process of cell separation caused by the breakdown of pectin occurs in the abscission zone of the petioles of deciduous plants at leaf fall.

Pectin is a natural part of the human diet, but does not contribute significantly to nutrition. The daily intake of pectin from fruits and vegetables can be estimated to be around 5 g (assuming consumption of approximately 500 g fruits and vegetables per day).

In human digestion, pectin binds to cholesterol in the gastrointestinal tract and slows glucose

absorption by trapping carbohydrates. Pectin is thus a soluble dietary fiber.

Consumption of pectin has been shown to reduce blood cholesterol levels. The mechanism appears to be an increase of viscosity in the intestinal tract, leading to a reduced absorption of cholesterol from bile or food. In the large intestine and colon, microorganisms degrade pectin and liberate short-chain fatty acids that have positive influence on health (prebiotic effect)

Sugars: A short-chain, soluble carbohydrates, many of which are used in food. They are carbohydrates, composed of carbon, hydrogen, and oxygen. There are various types of sugar derived from different sources. Simple sugars are called monosaccharides and include glucose (also known as dextrose), fructose and galactose.

Fats: Plant fats/oils or vegetable oils are oils derived from plant sources, as opposed to animal fats or petroleum. There are three primary types of plant oil, differing both the means of extracting the relevant parts of the plant, and in the nature of the resulting oil:

1. Vegetable fats and oils were historically extracted by putting part of the plant under pressure, squeezing out the oil.

2. Macerated oils consist of a base oil to which parts of plants are added.

Essential oils are composed of volatile aromatic compounds, extracted from plants by distillation.

Lignin: A complex polymer of aromatic alcohols known as monolignols. It is most commonly derived from wood, and is an integral part of the secondary cell walls of plants and some algae. The term was introduced in 1819 by de Candolle and is derived from the Latin word lignum, meaning wood. It is one of the most abundant organic polymers on Earth, exceeded only by cellulose. Lignin constitutes 30% of non-fossil organic carbon and a quarter to a third of the dry mass of wood.

Starches: A carbohydrate consisting of a large number of glucose units joined by glycosidic bonds. This polysaccharide is produced by most green plants as an energy store. It is the most common carbohydrate in human diets and is contained in large amounts in such staple foods as potatoes, wheat, maize (corn), rice, and cassava.

Cellulose: An organic compound with the formula  $(C_6H_{10}O_5)_n$ , a polysaccharide consisting of a linear chain of several hundred to over ten thousand  $\beta(1 \rightarrow 4)$  linked D-glucose units. Cellulose is an important structural component of the primary cell wall of green plants

(Source for Glossary definitions, Wikipedia and private research)

# Cannabinoid Use Chart

## THC Δ9

Reduces vomiting and nausea  
Pain relief  
Stimulate appetite  
Suppresses muscle spasms  
Cachexia  
Glaucoma  
Fatigue  
ADD/ADHD

## THC Δ8

Pain relief  
Appetite -Stimulating  
Analgesic

## THCA Δ9

Aids sleep  
Inhibits cancer cell growth  
Suppresses muscle spasms

## THCV

Reduces convulsions and seizures  
Bone growth stimulant  
Diabetes

## CBDA

Reduces inflammation  
Inhibits cancer cell growth

## CBDV

Bone growth stimulant

## CBG

Aids sleep  
Inhibits cancer cell growth  
Bone growth stimulant  
Slows bacterial growth

## CBD

Antibacterial  
Anxiety  
Inhibits cancer cell growth  
Neuro-protective  
Bone growth stimulant  
Seizures and convulsions  
Blood sugar levels  
Immune system support  
Inflammation  
Risk of artery blockage  
Nausea  
Pain relief  
Slows bacterial growth  
Suppresses muscle spasms  
Tranquilizing  
Treats psoriasis  
Vasorelaxant  
Cramps

## CBGA

Reduces inflammation  
Pain relief  
Slows bacterial growth

## CBC

Inhibits cancer cell growth  
Bone growth stimulant  
Reduces inflammation  
Pain relief

## CBCA

Reduces inflammation  
Treats fungal infection

## CBN

Anti-spasmodic  
Anti-insomnia  
Analgesic

The Cannabis plant contains on average 70 types of cannabinoids. These are the chemical compounds created by the cannabis plant that are used to treat conditions from pain and epilepsy to cancer and nausea. They mirror the endocannabinoids that our bodies naturally produce illustrating our close relationship with the cannabis plant. There are three types of cannabinoids: phytocannabinoids (found in plants), synthetic cannabinoids (produced in the lab) and endocannabinoids (produced in the human body). Simply, they modulate communication between cells, and also help when a deficiency or problem with our endocannabinoid system exist. These cannabinoids bind to receptor sites throughout our brain (CB1 Receptors) and body (CB2 Receptors). Different cannabinoids have different effects depending on which receptors they bind to. For example, THC binds to receptors in the brain whereas CBD (cannbidiol) has a strong affinity for CB-2 receptors located throughout the body.

### THC Δ9

THC delta 9 or tetrahydrocannabinol is well known for its psychoactivity. Effects include: psychoactive, euphoria, sensory enhancement, anti-cancer, anti-nausea, pain relief, improves appetite, help for glaucoma, muscle relaxant, help for autoimmune disorders, and anti-inflammatory.

### THC Δ8

THC delta 8 is an analogue of THC Δ9 with antiemetic, anxiolytic, appetite-stimulating, analgesic, and neuroprotective properties and binds to the cannabinoid G-protein coupled CB1 receptor.

### THCA Δ9

Tetrahydrocannabinolic Acid is the acidic precursor to THC, which actually exists in only minute quantities in the living plant. In the live plant THCa is the most abundant cannabinoid. After harvest THCA begins to naturally convert to THC.

### THCV

THCV or tetrahydrocannabivarin is not psychoactive, but moderates some of the effects of THC. THCV is present in certain strains of cannabis, notably ones originating from Southeast Asia or South Africa. Effects include: decreases appetite, mitigates seizures, bone growth stimulant, and may help with diabetes.

### CBDA

Cannabidiolic Acid is not psychoactive. Initial research suggest that CBDA offers anti-emetic and anti-proliferative effects, making it ideal for fighting cancer. It also offers anti-inflammatory and anti-bacterial properties.

### CBDV

Cannabidivarin is similar to cannabidiol (CBD) and has anticonvulsant effects. Plants with relatively high levels of CBDV have been reported in feral populations of *C. indica* (= *C. sativa* ssp. *indica* var. *kafiristanica*) from northwest India, and in hashish from Nepal.

### CBG

Cannabigerol is not psychoactive. It is commonly found in large quantities in fiber hemp. Certain medical strains have considerable CBG, which has promise for its anti-tumor qualities. Effects include: promising as an anti-cancer agent, lowers blood pressure, anti-inflammatory, and bone growth stimulant.

### CBD

Cannabidiol is not psychoactive, yet it modifies the effects of THC. CBD has great medical potential, and effects include: anti-depressant, anti-cancer, anti-nausea, anxiolytic, pain relief, mitigates spasms, improves blood circulation, help for autoimmune disorders, and bone growth stimulant.

### CBGA

Through different forms of biosynthesis, Cannabigerolic acid (CBGA) becomes THCA, THC, CBDA, CBD, CBCA, CBC and CBG providing many of the medicinal elements of cannabis.

### CBC

Cannabichromene is not psychoactive. Effects include: anti-cancer, antibacterial, antifungal, anti-inflammatory, analgesic, and bone growth stimulant. It bears structural similarity to the other natural cannabinoids, including THC, THCV, CBD and CBN Evidence has suggested that it may play a role in the anti-inflammatory and anti-viral effects of cannabis, and may contribute to the overall analgesic effects of the plant.

### CBCA

Cannabichrome carboxylic acid (CBC-A) In this case of CBC-A, it obviously passes through the CBC synthase, or the enzymes that get the specific process underway. Over time, or quickly if exposed to heat, the CBC-A will lose a molecule of CO<sub>2</sub>; at this point it is considered CBC.

### CBN

Cannabinol is primarily a decomposition product of THC from exposure to heat or light, and very little CBN is found in fresh plants. CBN has only mild psychoactivity, and effects include pain relief, causes drowsiness, mitigates spasms, help for glaucoma, and anti-inflammatory.

### Anandamide (AEA)

AEA, is one of the endocannabinoids found in the human body, and has a chemical structure unlike the phytocannabinoids found in cannabis. Anandamide regulates the functions of our central nervous system and our immune system. AEA regulates appetite, memory, sensations of pleasure and pain, our immune system, and sleep patterns. It also inhibits certain cancers, such as breast cancer in humans.

## The Receptors

CB1 receptors are found primarily in the brain. They are also present in both the male and female reproductive systems. CB1 receptors are absent in the medulla oblongata, the part of the brain stem responsible for respiratory and cardiovascular functions. Thus, there is not the risk of respiratory or cardiovascular failure that can be induced by some drugs. CB1 receptors appear to be responsible for the euphoric and anticonvulsive effects of cannabis

CB2 receptors are predominantly found in the immune system, with the greatest density in the spleen. CB2 receptors appear to be responsible for the anti-inflammatory and other therapeutic effects of cannabis.

# SAMPLE PACKAGE SAFETY INSERT

## (1) MEDICAL MARIJUANA PRODUCT:

Each insert will be specific to each product identifying and defining the medical marijuana product. Once approved, information with regard to state approved brands will be inserted here.

## (2) LIST OF EXCIPIENTS USED:

The following is a list excipient ingredients other than marijuana contained in this product: The Department will work with each registered organization to create a list of ingredients approved for use by the registered organization in its manufacturing process. A registered organization need only obtain prior approval of an additive one time prior to approval of the brand. Once approved, information with regard to excipients used will be inserted here.

## (3) SPECIFIC DOSAGE DIRECTIONS AND INSTRUCTIONS FOR ADMINISTRATION:

This product contains X mg per dose of THC, with specific dosing instructions for administration described below. Use as directed by your medical practitioner and do not exceed your prescribed dose without further consultation. Once approved, include specific directions by product. Example: "Shake well before dispensing. Hold dispenser up right and press firmly down on the atomizer to fully dispense a measured 2.5 mg dose under tongue.

## (4) ALLERGENS WARNING:

This product is produced in a dedicated gluten free, wheat free, dairy free, peanut free, and tree nut free facility. This product contains lecithin and fractionated coconut oil. This product contains marijuana. A recent study written by a team of allergy researchers at the University of Antwerp in Belgium entitled "Emerging Allergens: Cannabis" finds that Cannabis sativa has the ability to trigger allergic rhinitis (hay fever), conjunctivitis (pink eye), as well as skin irritation and asthmatic symptoms when it is inhaled or ingested. Those interested in determining whether they have a marijuana allergy can do so by submitting to a skin allergy test. Any adverse reactions should be reported to your practitioner.

## (5) CONTRAINDICATIONS:

**Major Interaction** Do not take in combination with:  
Sedative medications (Barbiturates and CNS depressants) interact with marijuana. Marijuana might cause sleepiness and drowsiness. Medications that cause sleepiness are called sedatives. Taking marijuana along with sedative medications might cause too much sleepiness. Some sedative medications include but are not limited to clonazepam (Klonopin), lorazepam (Ativan), phenobarbital (Donnatal), zolpidem (Ambien), and others.  
Theophylline interacts with marijuana. Taking marijuana might decrease the effects of theophylline. Information is limited on this contraindication.  
Alcohol is also a depressant. Do not consume marijuana with alcohol.

**Moderate Interaction** Be cautious with this combination  
Disulfiram (Antabuse) might interact with marijuana. Taking marijuana along with Disulfiram can cause agitation, trouble sleeping, and irritability.  
Fluoxetine (Prozac) interacts with marijuana. Taking marijuana with fluoxetine (Prozac) might cause you to feel irritated, nervous, jittery, and excited, ie: hypomania.

**Minor Interaction** Be watchful with this combination  
Warfarin (Coumadin) interacts with marijuana.  
Using marijuana might increase the effects of warfarin (Coumadin). Using marijuana while taking warfarin (Coumadin) might increase the chance of bruising and bleeding.

## (6) WARNING OF ADVERSE EFFECTS AND/OR POTENTIAL DANGERS STEMMING FROM THE USE OF MEDICAL MARIJUANA:

Marijuana contains chemicals that work by binding to specific sites in the brain and on the nerves. Use of marijuana can cause dry mouth, nausea, vomiting, dry or red eyes, heart and blood pressure problems, lung problems, impaired mental functioning, headache, dizziness, numbness, panic reactions, hallucinations, flashbacks, depression, and sexual problems.

### Special Precautions & Warnings:

**Pregnancy:** Marijuana is unsafe when taken by mouth or inhalation during pregnancy.

**Breast-feeding:** Using marijuana, either by mouth or by inhalation is likely unsafe during breast-feeding. The THC in marijuana passes into breast milk.

**Heart disease:** For those with an existing heart condition, marijuana might cause rapid heartbeat, short-term high blood pressure and may increase the risk of a having heart attack.

**Seizure disorders:** For those with an existing seizure disorder, marijuana might increase the severity of seizure disorders in some people; in other people it might help to control seizures.

**Surgery:** Marijuana affects the central nervous system. It might slow the central nervous system too much when combined with anesthesia and other medications during and after surgery. Stop using marijuana at least 2 weeks before a scheduled surgery.

## (7) INSTRUCTIONS FOR REPORTING ADVERSE EFFECTS:

Any adverse effects should be reported to your practitioner. A practitioner shall report patient adverse events to the department of health, in a manner determined by the department, not more than five business days after the practitioner becomes aware of such adverse event, except that serious adverse events shall be reported not more than one business day after the practitioner becomes aware of such adverse event.

## (8) WARNING ABOUT DRIVING, OPERATION OF MECHANICAL EQUIPMENT, CHILD CARE, OR MAKING IMPORTANT DECISIONS WHILE UNDER THE INFLUENCE OF MEDICAL MARIJUANA:

The following are effects of marijuana that may impair driving and piloting skills:

- Slowed complex reaction time
- Poor detection of peripheral light stimuli
- Poor oculomotor tracking
- Space and time distortion
- Impaired coordination
- Brake and accelerator errors, poor speed control
- Poor judgment, increased risks in over medicating
- Impaired attention especially for divided attention tasks
- Impaired short-term memory
- Additive effects with alcohol and other drugs

Do not drive or operate mechanical equipment, perform child-care, or make important decisions while under the influence of medical marijuana.

## (9) INFORMATION ON TOLERANCE, DEPENDENCE AND WITHDRAWAL, AND SUBSTANCE ABUSE:

**Tolerance:** The specified dosage on this package allows an individual to consistently measure consumption. The state specifies a maximum dose of 10 mg of THC. However, levels of tolerance to marijuana vary greatly and it is difficult to predict the degree of tolerance in an individual or the extent to which a particular task is impaired by a given dose of marijuana or THC. It is important for each individual to establish a safe and preferable amount of marijuana that can be consumed in each form. Once a true level of tolerance is determined then the level and frequency can safely be adjusted by your practitioner to meet your needs.

Since Delta 9 THC (activated) is the commonly accepted active ingredient creating the euphoria experienced when consuming marijuana this is used as the testing point. For purposes of safely determining the level of tolerance, it is recommended that the patient start with low levels of THC until tolerance is established. Patients are encouraged to discuss this with their practitioner during the process of determining a prescribed dose. For example, the practitioner may prescribe limiting usage to no more than 2-5 MG of THC within a 24 hour period when introducing marijuana to a new user.

The following are suggested amounts of THC over a 24-hour period that might be discussed with your practitioner. Initial use:

First time user:  
THC over a 24 hour period: 2-5 MG  
Occasional user:  
Frequency of use: once a month  
THC over a 24 hour period: 6-10 MG  
Experienced user:  
Frequency of use: once a week  
THC over a 24 hour period: 11-20 MG  
Advanced user:  
Frequency of use: once a day  
THC over a 24 hour period: 21+ MG

# SAMPLE PACKAGE SAFETY INSERT

## Dependence

A physically dependent person demonstrates a specific set of withdrawal symptoms when levels of THC are drastically reduced or stopped completely. On the other hand, a psychologically addicted person will oftentimes lose self-control if s/he risks drug deficit.

The following may indicate a person has developed a physical dependence on marijuana:

- Disorientation
- Dizziness
- Drowsiness
- Forgetfulness
- Impaired learning
- Mood changes
- Red, bloodshot eyes

The following may indicate a person is psychologically addicted to marijuana:

- Compulsive behavior
- Continuous use even when knowing the negative consequences
- Cravings and urges when off the drug
- Feeling in danger when the supplies are low
- Feeling indifferent about work, home, school etc
- Inability to quit
- Obsessive thinking about how to get marijuana

If you recognize these symptoms in yourself talk about it. If you are having a hard time and suspect a physical and/or psychological dependence which would indicate problematic usage of medical marijuana discuss this with your medical practitioner and obtain appropriate services or treatment.

## Withdrawal symptoms and signs

That a degree of physical and psychological dependence to marijuana develops is suggested by the advent of a withdrawal syndrome on cessation of use after chronic use. A physically dependent person will manifest withdrawal symptoms when they stop smoking marijuana completely, or drastically reduce intake. Withdrawal symptoms associated with acute marijuana detox include:

- Anxiety
- Depression
- Drug craving
- Headache
- Increased aggression
- Irritability
- Sleeping difficulties

## (10) HOW TO KEEP MEDICAL MARIJUANA SECURE:

If you have marijuana in your home, take the below precautions to ensure the safety of your children, including young visitors to your home and your pets.

Keep marijuana up and away, and out of sight from curious children and pets. Pick a place your children cannot reach. Any kind of medicine or vitamin can cause harm if taken in the wrong way, even medicine you can buy without a prescription. Walk around your house and find a storage place too high for a child to reach or see. This is also important to remember when families are away from home and staying in hotels, or as guests in others' homes. Put marijuana away every time. Never leave it out on a kitchen counter or at a bedside, even if you anticipate using it again in a few hours. Always put every marijuana product and other medicine away every time you use it, including those you use every day.

Consider purchasing a medication lock box or safe. A lock box or safe provides a safe, convenient and affordable method for securing marijuana products in the home or while traveling. Everyone has a responsibility to safeguard their medicines and marijuana products, and protect children from gaining access to potentially harmful substances.

Talk to your children about marijuana. As with all medicines and marijuana products, teach your children about medicine safety. Tell your children what medicine is and why you must be the one to handle it. Tell guests about marijuana safety. Ask houseguests and visitors to keep purses, bags, or coats that have marijuana products in them up and away and out of sight when they are in your home. If you use a babysitter, choose those who are mature, trained and responsible, and are recommended by someone you trust.

Ask other parents if they have marijuana products in their home before sending your child to play a neighbor or classmate's house. If the answer is yes, make sure that all products are stored up and away and out of children's sight. Because it can be difficult to ask people about this, try including the question along with other things you might normally discuss before sending your child to someone's home, such as seat belts, animals, or allergies.

Be prepared in case of an emergency. Call the Poison Help Center at (800) 222-1222 right away if you think your child might have consumed marijuana products. Program the number into your home and cell phones so you will have it when you need it.

## (11) UNLAWFUL DISTRIBUTION:

No person, except for a certified patient or designated caregiver, or an approved laboratorian shall open or break the seal placed on an approved medical marijuana product packaged by a registered organization and provided to the certified patient. The certified patient may not distribute any medical marijuana product to anyone else.

No certified patient or designated caregiver shall be in possession of approved medical marijuana products without having in his or her possession his or her registry identification card. The certified patient or designated caregiver, upon request by the department or law enforcement, shall present such card to verify that the certified patient or designated caregiver is authorized to possess approved medical marijuana products.

## (12) DISPOSAL OF UNWANTED, EXCESS OR CONTAMINATED MARIJUANA:

A certified patient or designated caregiver shall dispose of all approved medical marijuana product in the certified patient's or designated caregiver's possession no later than ten calendar days after the expiration of the patient's certification, if such certification is not renewed, or sooner should the patient no longer wish to possess medical marijuana or if it is determined that the marijuana has been contaminated.

A certified patient or designated caregiver shall complete disposal of approved medical marijuana product by one of the following methods:

1. Rendering the approved medical marijuana product non-recoverable in accordance with the department's proper disposal instructions, which are available on the department's Internet web site; [https://www.health.ny.gov/regulations/medical\\_marijuana/](https://www.health.ny.gov/regulations/medical_marijuana/)
2. Disposing of the approved medical marijuana product at a department-recognized drug take-back program located in New York.

## (13) FDA DISCLAIMER:

This product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks.

The information contained in this package insert is meant to supplement, not replace advice from your doctor or healthcare provider and is not meant to cover all possible uses, precautions, interactions or adverse effects. This information may not fit your specific health circumstances. Never delay or disregard seeking professional medical advice from your doctor or other qualified health care provider if any adverse effects are noticed. You should always speak with your doctor or health care professional before you start, stop, or change any prescribed part of your health care plan or treatment and to determine what course of therapy is right for you.

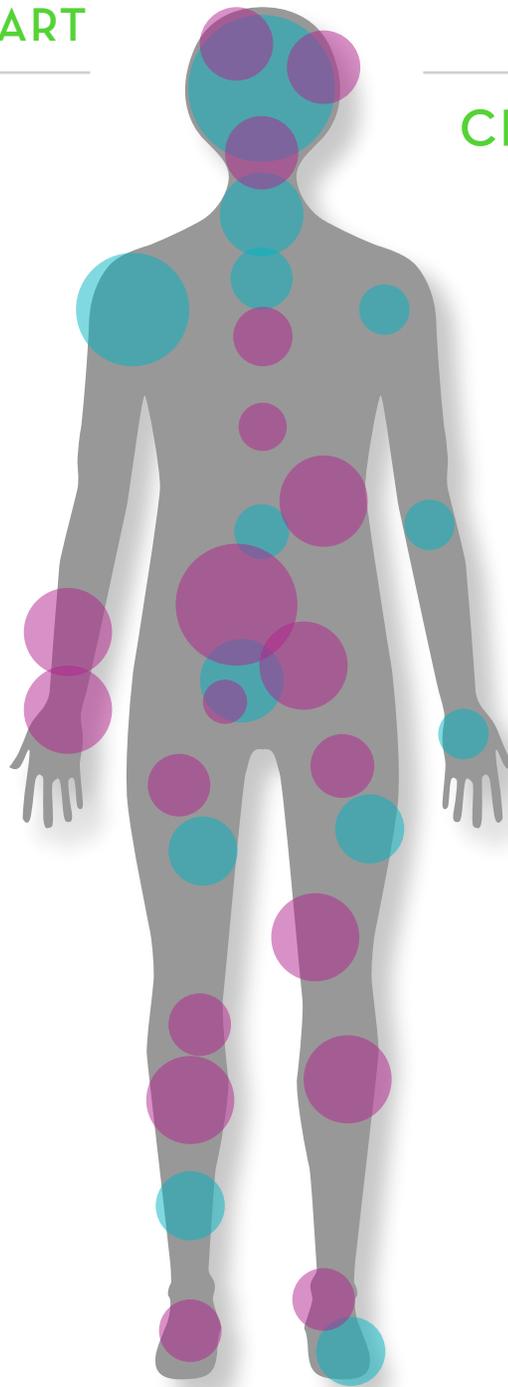
# CB RECEPTOR REFERENCE CHART

## CB<sub>1</sub>

**receptors** are found primarily in the brain. They are also present in both the male and female reproductive systems. CB<sub>1</sub> receptors are absent in the medulla oblongata, the part of the brain stem responsible for respiratory and cardiovascular functions. Thus, there is not the risk of respiratory or cardiovascular failure that can be induced by some drugs. CB<sub>1</sub> receptors appear to be responsible for the euphoric and anticonvulsive effects of cannabis.

## CB<sub>2</sub>

**receptors** are predominantly found in the immune system, with the greatest density in the spleen. CB<sub>2</sub> receptors appear to be responsible for the anti-inflammatory and other therapeutic effects of cannabis.



## CB<sub>1</sub> Receptor Sites in the Brain (concentrated)

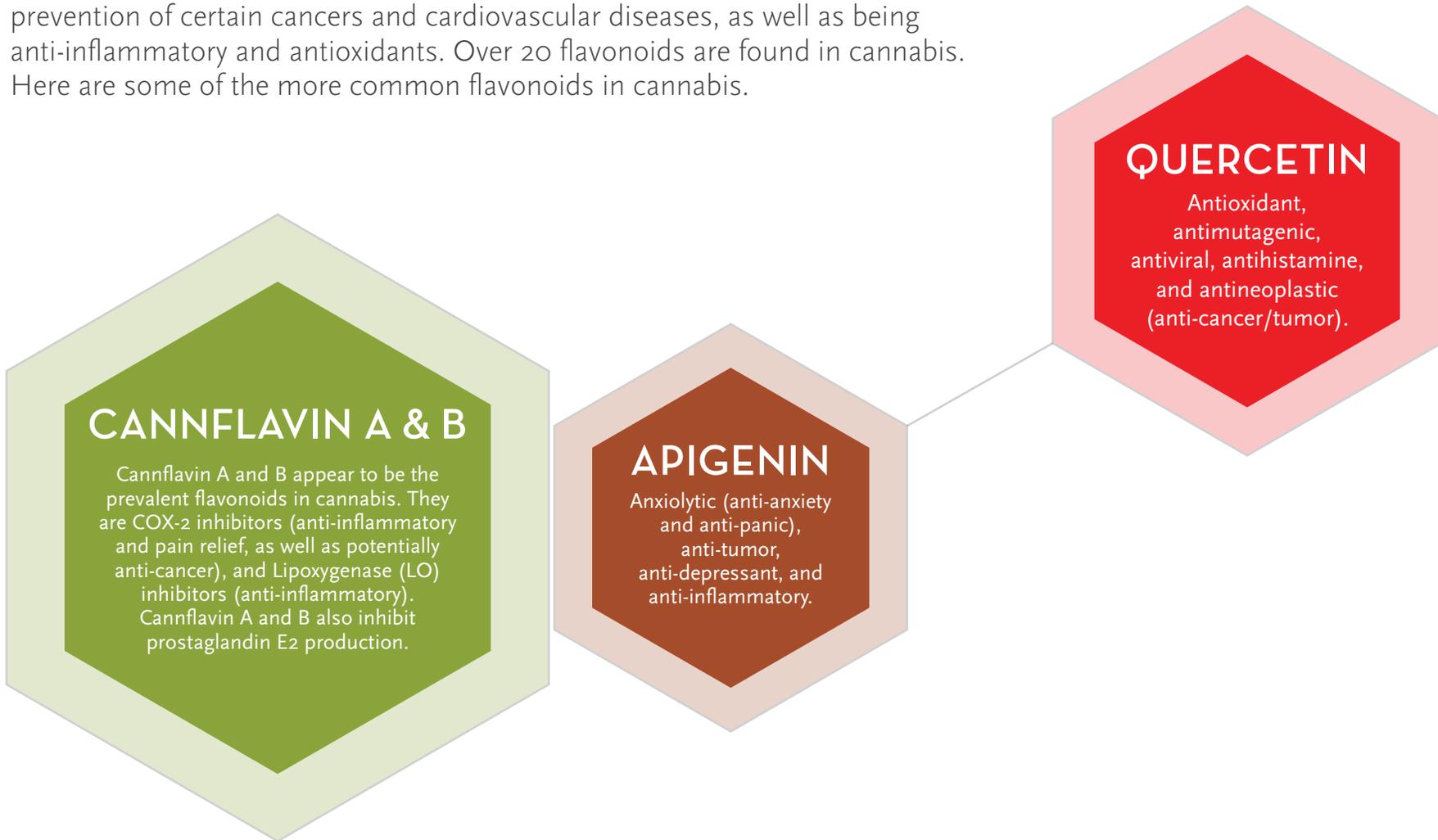


- |                 |   |              |   |
|-----------------|---|--------------|---|
| Medulla         | ● | Hypothalamus | ● |
| Cerebellum      | ● | Hippocampus  | ● |
| Basal Ganglia   | ● | Spinal Cord  | ● |
| Cerebral Cortex | ● |              |   |

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# FLAVONOID REFERENCE CHART

**Flavonoids** are polyphenols ubiquitous in plants and constituents of many foods that we eat. They may modify the way our bodies respond to allergens, viruses, and carcinogens, and studies indicate that flavonoids may help in the prevention of certain cancers and cardiovascular diseases, as well as being anti-inflammatory and antioxidants. Over 20 flavonoids are found in cannabis. Here are some of the more common flavonoids in cannabis.



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# TERPENE REFERENCE CHART

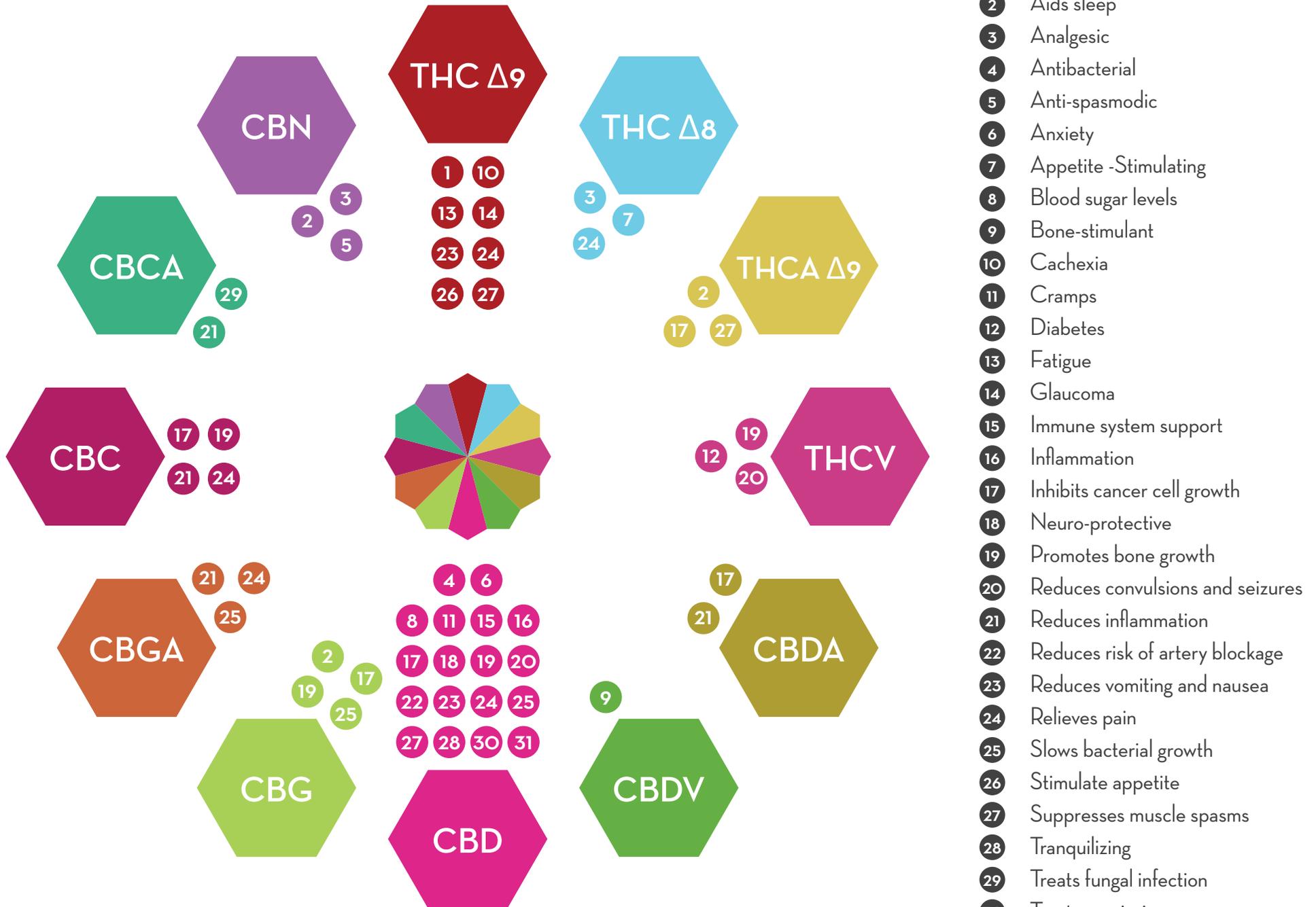
**Terpenes** (terpenoids) are components of the essential oils and resins found in many plants, and especially in cannabis plants. Terpenes synergize with and modify the effects of THC and other cannabinoids. We are only beginning to understand their effects and interactions with the phytocannabinoids in cannabis and the endocannabinoids in our bodies.

From **over 100 terpenes possible in the cannabis plant**, here are some of the more common terpenes present in cannabis.



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# CANNABINOID REFERENCE CHART



- 1 ADD/ADHD
- 2 Aids sleep
- 3 Analgesic
- 4 Antibacterial
- 5 Anti-spasmodic
- 6 Anxiety
- 7 Appetite -Stimulating
- 8 Blood sugar levels
- 9 Bone-stimulant
- 10 Cachexia
- 11 Cramps
- 12 Diabetes
- 13 Fatigue
- 14 Glaucoma
- 15 Immune system support
- 16 Inflammation
- 17 Inhibits cancer cell growth
- 18 Neuro-protective
- 19 Promotes bone growth
- 20 Reduces convulsions and seizures
- 21 Reduces inflammation
- 22 Reduces risk of artery blockage
- 23 Reduces vomiting and nausea
- 24 Relieves pain
- 25 Slows bacterial growth
- 26 Stimulate appetite
- 27 Suppresses muscle spasms
- 28 Tranquilizing
- 29 Treats fungal infection
- 30 Treats psoriasis
- 31 Vasorelaxant

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# CANNABINOID REFERENCE CHART (page 2)

The Cannabis plant contains on average 70 types of cannabinoids. These are the chemical compounds created by the cannabis plant that are used to treat conditions from pain and epilepsy to cancer and nausea. They mirror the endocannabinoids that our bodies naturally produce illustrating our close relationship with the cannabis plant. There are three types of cannabinoids: phytocannabinoids (found in plants), synthetic cannabinoids (produced in the lab) and endocannabinoids (produced in the human body). Simply, they modulate communication between cells, and also help when a deficiency or problem with our endocannabinoid system exists. These cannabinoids bind to receptor sites throughout our brain (CB1 Receptors) and body (CB2 Receptors). Different cannabinoids have different effects depending on which receptors they bind to. For example, THC binds to receptors in the brain whereas CBD (cannabidiol) has a strong affinity for CB-2 receptors located throughout the body.



THC delta 9 or tetrahydrocannabinol is well known for its psychoactivity. Effects include: psychoactive, euphoria, sensory enhancement, anti-cancer, anti-nausea, pain relief, improves appetite, help for glaucoma, muscle relaxant, help for autoimmune disorders, and anti-inflammatory.



THC delta 8 is an analogue of THC Δ9 with antiemetic, anxiolytic, appetite-stimulating, analgesic, and neuroprotective properties and binds to the cannabinoid G-protein coupled CB1 receptor.



Tetrahydrocannabinolic Acid is the acidic precursor to THC, which actually exists in only minute quantities in the living plant. In the live plant THCA is the most abundant cannabinoid. After harvest THCA begins to naturally convert to THC.



THCV or tetrahydrocannabivarin is not psychoactive, but moderates some of the effects of THC. THCV is present in certain strains of cannabis, notably ones originating from Southeast Asia or South Africa. Effects include: decreases appetite, mitigates seizures, bone stimulant, and may help with diabetes.



Cannabichrome carboxylic acid (CBC-A), passes through the CBC synthase, or the enzymes that get the specific process underway. Over time, or quickly if exposed to heat, the CBC-A will lose a molecule of CO<sub>2</sub>; at this point it is considered CBC.



Cannabinol is primarily a decomposition product of THC from exposure to heat or light, and very little CBN is found in fresh plants. CBN has only mild psychoactivity, and effects include relief from pain, causes drowsiness, mitigates spasms, help for glaucoma, and is anti-inflammatory.



AEA, is one of the endocannabinoids found in the human body, and has a chemical structure unlike the phytocannabinoids found in cannabis. Anandamide regulates the functions of our central nervous system and our immune system. AEA regulates appetite, memory, sensations of pleasure and pain, our immune system, and sleep patterns. It also inhibits certain cancers, such as breast cancer in humans.



Cannabidiol is not psychoactive, yet it modifies the effects of THC. CBD has great medical potential, and effects include: anti-depressant, anti-cancer, anti-nausea, anxiolytic, pain relief, mitigates spasms, improves blood circulation, help for autoimmune disorders, and bone stimulant.



Cannabigerol is not psychoactive. It is commonly found in large quantities in fiber hemp. Certain medical strains have considerable CBG, which has promise for its anti-tumor qualities. Effects include: promising as an anti-cancer agent, lowers blood pressure, anti-inflammatory, and bone stimulant.



Through different forms of biosynthesis, Cannabigerolic acid (CBGA) becomes THCA, THC, CBDA, CBD, CBCA, CBC and CBG providing many of the medicinal elements of cannabis.



Cannabichromene is not psychoactive. Effects include: anti-cancer, antibacterial, antifungal, anti-inflammatory, analgesic, and bone stimulant. It bears structural similarity to the other natural cannabinoids, including THC, THCV. CBD and CBN Evidence has suggested that it may play a role in the anti-inflammatory and anti-viral effects of cannabis, and may contribute to the overall analgesic effects of the plant.



Cannabidiolic Acid is not psychoactive. Initial research suggest that CBDA offers anti-emetic and anti-proliferative effects, making it ideal for fighting cancer. It also offers anti-inflammatory and anti-bacterial properties.



Cannabidivarin is similar to cannabidiol (CBD) and has anticonvulsant effects. Plants with relatively high levels of CBDV have been reported in feral populations of *C. indica* (= *C. sativa* ssp. *indica* var. *kafiristanica*) from northwest India, and in hashish from Nepal.

## Attachment 5.3



## High Country Healing (“HCH”) Company Profile

### High Country Healing Overview

- Medical Cannabis Cultivation and Dispensing since 2009
- Opened 2 of Colorado's first 20 recreational cannabis dispensaries on 1/1/2014
- Corporate mission statement is to sustainably grow some of the world's premier pharmaceutical grade cannabis for the connoisseur. Compassion, Caring, and Education are core values of High Country Healing (HCH)... as highlighted by the HCH's Free CBD oil program for those with a dire medical need, Sommelier ("Interpening") and Compliance training for all staff.
- Currently operating 3 medical and 3 recreational dispensaries: Vail, Silverthorne, Alma, and CO Springs (multiple locations)
- Currently operating 4 cultivation facilities, the largest is 22,000 square feet (organic soil and various hydroponic techniques)
- Grows over 60+ varieties of high quality pharmaceutical grade cannabis, including rare CBD-rich genetics
- CBD oil program provides free CBD-oil to cancer patients and those suffering from various forms of epilepsy, auto-immune diseases, chronic pain syndrome, PTSD etc.
- *High Times* Magazine's (leading cannabis culture magazine) most featured dispensary brand of all time (known for exceptional flower quality).
- As featured in *The Cannabist*, MSNBC's *Pot Barons*, *The Denver Post*, *The Guardian* (UK), *Skiing*, *Powder*, and *Ski Magazines*, *Yo Beat*, *Dope Directory*
- Perfect record of compliance spanning 6-years of constant and significant regulatory change with zero security issues. Certificate of good standing.
- One of Colorado's first dispensary chains to formally train staff and receive RVT (Responsible Vendor Training) Status
- Rigorously complies and exceeds all security protocol required by the state of Colorado.

### Andrew J. Salini – Chief Operating Officer - Operations, Finance, & Strategy

- COO & Chief Strategist at High Country Healing’s Retail & Cultivation Facilities, 2014-Present
- *Management*: HCH operations, retail/cultivation/financial strategy & analytics, brand, and business development
- Formerly, Vice President, Strategist & Portfolio Management at EMF Fixed Income Fund, \$500mm AUM, 2011-2014
- Associate, Credit Suisse Fixed Income Strategy & Research, 2010-2011
- Associate, Deutsche Bank Securities, Global Finance & Foreign Exchange, Proprietary Trader & Portfolio Manager, 2006-2009
- Received a A.B. in Economics, Princeton University, 2002-2006



## Attachment 5.3

- Received Certificates in both Finance and French Language & Culture from Princeton University, 2002-2006
- Academic All-American in Baseball, Princeton Baseball's All-time hits leader, & 3-time Ivy League Champion
- Graduated, Phillips Academy Andover, 2002

### Andrew Salini Narrative Resume

Mr. Salini graduated Princeton University in 2006 with a degree in Economics, with certificates in Finance and French Language & Culture in 2006. He was also a 4-year letterman and starter for the Varsity Baseball team, where he was part of 3 Ivy-League Championship teams ('03, '04, '06) making 3 College World Series Tournament appearances. Mr. Salini also holds the all-time record for most hits in a career in Princeton baseball history.

Following graduation, Mr. Salini started his career in investment banking as an Associate at Deutsche Bank in the Global Finance and Foreign Exchange division where he worked until 2009. His responsibilities included portfolio management and proprietary trading of fixed income derivatives and currencies. From 2010 to 2011, Mr. Salini joined the Credit Suisse Fixed Income team in their investment bank before transitioning to the hedge fund business as the lead Strategist for EMF, a fixed income relative value fund with as much as \$500 AUM where he worked until 2014 before joining High Country Healing.

Mr. Salini developed a niche in finance through his ability to distill the quantitative nuances of the fixed income markets. His professional experience has thus always focused on the details and intricacies of a highly complex and highly regulated market place. This detail-orientation and meticulous approach to work made him a natural fit to step into the COO role at High Country Healing. His role has included overseeing and optimizing all operations and compliance functions and offering market analysis and strategy to help steer HCH through the tumultuous waters of ever-changing regulatory landscape of this blossoming new cannabis industry.

As a researcher by training, Mr. Salini took a deep dive into the medicinal benefits of cannabis following conversations with Mr. Brown in 2009. His resulting conviction sparked a desire to be a part of the movement to share the wonderful healing powers of this giving plant with the world to help end suffering. After losing his mother to breast cancer in 2009 after a 10 year battle, and seeing the deleterious and lingering effects of cancer on his father, he joined the HCH team in 2014 and has not looked back since.



# Attachment 5.4



## American Cannabis Company, Inc. (“ACC”) Company Profile

### Executive Summary

- Based in Denver, Colorado
- Consult, advise, & provide equipment and supplies to businesses entering or currently operating in *regulated* cannabis industries
- Currently serve clients in 14 states & Canada
- Have assisted clients in winning 10+ licenses in 5 five states
  - Business & operational plans, pro-forma, market study, & application
  - Facility design, equipment selection, & construction management
  - Facility roll-out, employee training, & on-going cultivation management
  - On-going retail, operational, & compliance monitoring

### Industry Successes

American Cannabis Company					
Year	State	W	L	Total	Cumulative Client W %
2013	Connecticut	1	0	1	100%
2013	Massachusetts	1	2	3	50%
2014	Nevada	6	1	7	73%
2014	Minnesota	1	0	1	75%
2014	Illinois	2	4	6	61%
<b>Total</b>		<b>11</b>	<b>7</b>	<b>17</b>	<b>61%</b>

### Vision

We are redefining society’s relationship with cannabis through responsible stewardship.

### Mission Statement

With our expert teams we establish and service regulated cannabis markets globally providing best in industry solutions that continue to exceed the requirements of the evolving cannabis industry thus ensuring our client’s success through superior service and deep industry knowledge.

### Core Values

1. Accountability & Professionalism
2. Integrity
3. Open, Transparent, & Respectful Communication
4. Passionate Teamwork
5. Sustainability

### About The American Cannabis Company

American Cannabis Company (ACC) was founded to meet the needs of the rapidly developing cannabis industry, including: medical, commercial and industrial hemp operators. We are experienced in cultivation, infused products and retail operations within regulated cannabis markets, as well as, establishing successful companies within the emerging limited licenses markets. From merit based applications, to facility design and deployment, to managing ongoing operations ACC has the experience and expertise to guide your business in the competitive cannabis space. Currently, we’ve operated in nine states and in the country of Canada. Our company focuses on providing services and products to the cannabis industry through our two operating divisions:



## Attachment 5.4



### **Company Ownership & Legal Entity**

American Cannabis Company, Inc. is a Delaware corporation with its headquarters in Denver, Colorado. ACC Inc. is a public company and trades under the stock ticker AMMJ on the OTCQB stock exchange. Services, Equipment & Supplies

Through its two divisions American Cannabis Consulting and The Trade Winds, American Cannabis Company provides its customers a full solution for success. From bringing your idea to a reality to ensuring it performs beyond expectation, ACC has the people, partners and products to ensure success.

### **Services**

American Cannabis Consulting is the premier advisory agency for those seeking to achieve success in the highly competitive and rapidly expanding commercial cannabis industry.

Whether you're preparing to enter the market or already have a footprint, our team of industry leaders can help your business reach its potential while meeting the necessary regulatory framework. With first-hand experience in regulated commercial Cannabis cultivation since 2009 and backed by accomplishments in related industries such as healthcare and horticulture, we have the knowledge and resources to guide you through every aspect of growing your Cannabis business.

### **Cannabis Industry Research & Design**

Our knowledgeable team identifies needs in the marketplace and develops next generation products to fill those needs. Our in-house products include:



- The Cultivation Cube™: The foundation for a complete, commercial-scale grow operation, the Cultivation Cube provides exceptional environmental control, speed-to-market, production, space efficiency, lean manufacturing and security.



## Attachment 5.4



- SoHum Living Soil™: A 100% organic growing medium, SoHum Soil prevents an improper balance of nutrients, improves plant immunity, and is more cost-effective than traditional soil and fertilizer growth methods.

- The Satchel™: The Satchel is a pouch-like case for Cannabis and Cannabis-infused products that was designed to meet regulatory compliance with laws that require child-resistant exit packaging for licensed medicinal and recreational Cannabis businesses.

### Equipment & Supplies

From cultivation necessities to retail goods to ancillary products like office supplies and cleaning agents, The Trade Winds can address your business' needs quickly and cost-effectively. The products we carry are carefully selected by our professionals and represent best-in-class solutions for the developing commercial cannabis markets. We continue to strive to realize solutions that improve our Client's business operations.



The Trade Winds group purchasing organization (GPO) provides clients with a comprehensive supply chain. Membership in the GPO gives your business significant buying power with substantial savings over retail costs, and it concentrates all your needs into a single outlet to save you time as well as money.



American Cannabis Company is proud to offer compliant, solution-based products and services to commercial cannabis cultivation and cannabis retail businesses.

### Management Consulting

With hands-on experience in commercial cannabis cultivation, the team at American Cannabis Company has the knowledge and resources to help your crop and your business realize their potential. From Cultivation, through processing and into retail sales, our team has firsthand knowledge and experience.

Our goal is to lead you through a successful development and launch process, and to work with you to help your cultivation business grow into the future. As part of the design and build out of your business, our advisory services will focus on key elements that include:

- Business and operational plan
- Pro-forma financials
- Business plan writing
- Standard operating procedures
- Protocol based workflow
- Retail Strategies
- Retail Operations
- Regulatory compliance
- Market modeling and forecasting
- Security and safety measures
- Equipment and technology purchasing
- Quality control



## Attachment 5.4

- Direct staffing and/or recruitment and training
- Facility design and build-out
- Construction Management
- Patient centric strain selection
- Methodology selection
- Perpetual harvest and workflow requirements to meet patient demand
- Environmental controls
- Integrated pest management

### **Management Team & Client Advisors**

#### ***Corey Hollister, Co-Founder & Chief Executive Officer***

In March 2013, Mr. Hollister co-founded ACC, and from March 2013 to May 2014, Mr. Hollister served as a Managing Director of ACC. From September 2009 to July 2013, Mr. Hollister co-owned and was director of The Village Green Society, a Colorado-based Medical Marijuana Center. From September 2009 to June 2010, Mr. Hollister served as the Director of Operations of Colorado Kind Care LLC, where he oversaw all aspects of operations, including legal, accounting, regulatory compliance, seed-to-sale tracking, security, staff management and production. From October 2007 to September 2009, Mr. Hollister owned and operated Built-to-Last Fitness, a private health and wellness company focused on exercise and nutritional guidance for individuals, companies and schools. Prior to this, Mr. Hollister was based in Boston, MA and worked in Marketing and Advertising.

#### ***Ellis Smith, Co-Founder & Chief Development Officer***

In March 2013, Mr. Smith co-founded ACC, and from March 2013 to May 2014, Mr. Smith served as a Managing Director of ACC. From September 2010 to July 2013, Mr. Smith co-owned The Village Green Society, a Colorado-based Medical Marijuana Center, where he was responsible for managing the operations and protocols supporting the growth and production of medical marijuana. From 2008 to 2010, Mr. Smith founded and operated The Happy Camper Organics Inc., a medical marijuana company focused on the growth of wholesale cannabis for sale to medical marijuana businesses. From 2005 to 2010, Mr. Smith founded and operated Bluebird Productions, a video production company. Mr. Smith has been published and recognized for his horticultural experience and organic gardening in the cannabis industry, and he is known for assisting in identifying the Hemp Russet Mite and working with SKUNK magazine to educate the industry.

### **Key Client Advisors**

#### ***Brett Eaton, Director of Horticulture***

Mr. Eaton graduated from Colorado State University with honors and a bachelor's degree in Horticulture in 2003 during which time he researched an array of plants and food crops at the campus University Plant Environment Research Center during his time there. Mr. Eaton brings over 12 years of horticulture experience to ACC, primarily from the commercial fresh cut flower industry. This led to the development of his expertise in facility design and maintenance, organic cultivation, greenhouse and indoor production and cultivation of cannabis. Furthermore, Mr. Eaton has experience in a variety of cannabis cultivation methods including; organics, inorganics and hydroponics with an understanding of a wide range of grow systems associated with these processes.

#### ***Sam Leuschen, VP of Operations***

Sam holds a Bachelor's degree in Restaurant and Resort management with a minor in business administration and a Master's degree in Management Practices from Colorado State University. Sam is a new generation of college graduates, transitioning from the university into his professional career within the legal and regulated cannabis industry. Sam is one of the first young professionals to take this approach using his degrees and college experience to help bring the regulated cannabis industry into the forefront of the consumer goods industry. Upon completion of his Master's program, Sam began working at a local dispensary as a budtender and quickly worked his way up the ladder becoming the operation's master grower and later transitioned to the position of General Manager, highlighting his work ethic and higher education. While in the position of General Manager, Sam managed the growth from one retail location with one cultivation license to two retail locations and three cultivation licenses. Sam was responsible for



## Attachment 5.4

everything from obtaining state and local licensing, regulatory compliance, cultivation activities including being the head grower, staff recruitment and training, inventory monitoring and reconciliation, order purchasing, and all daily operations of the business.

### ***Brent DeArmond, Cultivation Project Manager***

Brent attended the College of Charleston where he obtained degrees in both Biology and Geology. Upon completion, Brent worked as a fish research technician for the State of South Carolina. He then went on to become a fish farmer for a leading global provider of caviar where he was tasked with utilizing environmentally responsible fish farming practices focused on fish sustainability. Brent leveraged his experience gained as a fish farmer to transition into the position of Head Grower at one of the original medicinal and recreational dispensaries in Denver, CO. He held this position for the last three years prior to joining ACC. As the Head Grower Brent was tasked with designing organic fertilizer programs, yield and quality maximization, managing cultivation and processing teams, diagnosing and treating pest and disease, establishing and implementing Integrated Pest management, ensuring compliance with laws and regulations with regard to inventory through development of monitoring processes and procedures, and developing operating processes and procedures to ensure the tracking of plants and products from clone to final sale to ensure compliance. Brent brings a wealth of knowledge to our clients to ensure they are always operating as efficiently as possible through best practices around cultivation methodologies and operating procedures.

### ***Tyler Schloesser, Operations Manager and Regulatory Compliance Advisor***

Tyler graduated from the University of Colorado at Boulder receiving double majors with honors in Psychology and Philosophy. He then went on to work in Denver, Colorado at two national banks followed by a local credit union gaining experience as a banker, senior banker, sr. bank compliance auditor and lastly management. Working in the Colorado banking industry has provided Tyler with the first-hand experience of understanding the issues that cannabis businesses face with banking. Tyler assists our clients with developing policies, procedures, processes, and risk mitigation best practices to ensure our clients are compliant with the evolving cannabis industry regulatory regulations.



## **Attachment 5.5**

### **Dr. Kenneth Leonhardt, Ph.D.—Chief Horticulture Advisor**

Dr. Kenneth Leonhardt, Ph.D., also a UH affiliated scientist, will act as the Company's Chief Horticultural Advisor ("CH") and provide BPH with guidance regarding the best horticultural practices necessary to economically produce quality pharmaceutical grade MM for Hawai'i's patients. Dr. Leonhardt will work closely with BPH's Cultivation Manager.

Ken has considerable experience in plant breeding, having created and introduced over 100 new varieties to Hawai'i growers. Ken's professional research focus is on polyploidy induction and creating sterility (seedless clones). Tetraploid forms of 22 species have been created. Only 2 other labs in the US focus on this kind of research (Dr. Ranney at North Carolina State U, and Dr. Contrearras at Oregon State U). Tetraploid forms of Marijuana will have higher concentrations of CBDs and THCs.

Ken has familiarity with all sectors of agribusiness in Hawai'i for 43 years and has acted as a crop science educator for the past 39 years. He was the owner/operator of a commercial ornamental plant nursery for 13 years (1975-1988).

As Chairman of the undergraduate program at the UH department of Tropical Plant and Soil Sciences, Ken is familiar with the top graduates, thus when BPH is looking to hire technicians with a crop science background, Ken will be able to source the top candidates. Ken also sits on the board of advisors for Medical & Product Testing – Hawai'i MDs.



## **Attachment 5.6**

### **Forecasts: BPH Cannabis Flower Production**

<b>Cannabis Flower Demand (pounds)</b>	<b>2016*</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>
Total Market	948	3,988	8,044	12,744	14,560
BPH	316	1,329	2,468	3,019	3,386
Market Share (%)	33%	33%	30.6%	24%	23.2%

### **Required to Meet Demand of All Cannabis Products**

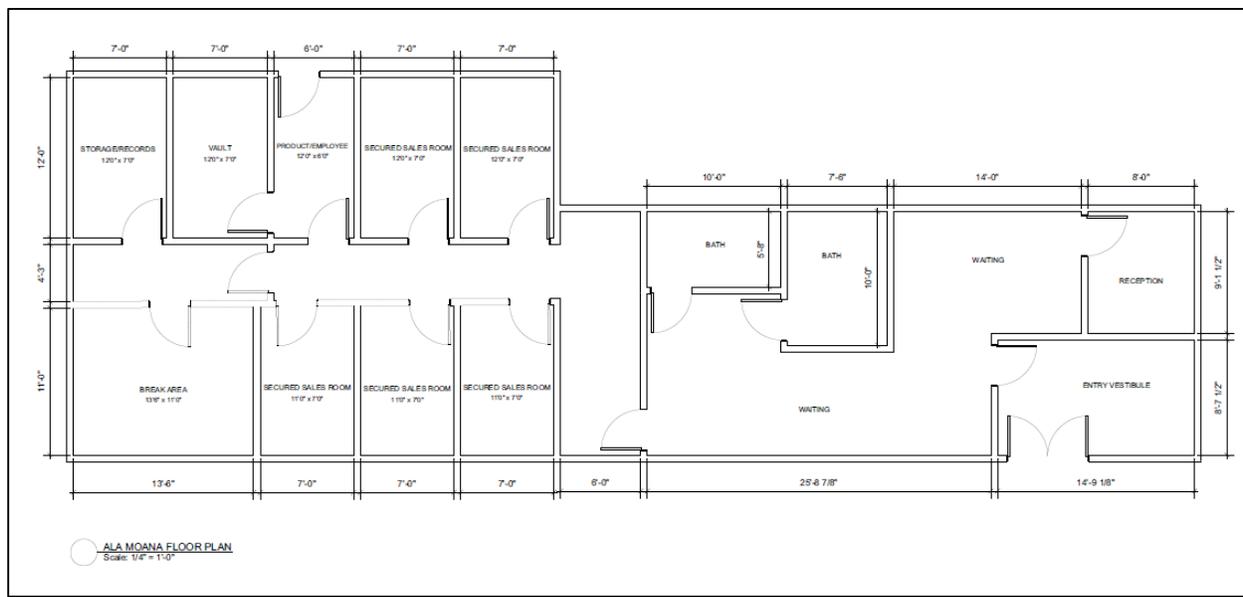
*(Based on adoption rates, consumption patterns, and market share)*

\* 2016 Demand data is theoretical based on the adoption rate and consumption patterns. BPH is seeking a speed-to-market strategy to open its doors in 2016, but our conservative approach, with a focus on sustainability, is targeting a Jan-2017 launch, and therefore production data for 2016 is hypothetical and reflects the full market demand as if stores were open in 2016 and able to serve the demand contemplated by our assumptions of consumption and adoption.



# Attachment 5.7

## Blue Planet Healing LLC Retail Dispensary Location Floor Plan



# Attachment 5.8



## Patient Feedback Evaluation Form

*The purpose of this form is to evaluate data on patient's reactions to the marijuana and/or manufactured marijuana products dispensed. Patient feedback is critical in order to supply patients with needed and required medications to treat specific ailments.*

### **Patient Information**

Qualified Patient Name:

DOB:

Patient State Registry Number:

Expiration Date:

Marijuana Product(s) Dispensed:

Date Marijuana Products  
Dispensed:

Quantity Dispensed:

Route of Administration/Consumption Method:

Smoke/Vaporize/Inhalation    Ingestion--Tincture/Capsule/Pill    Topical Product    Other

### **Patient Qualifying Condition**

Cachexia    Wasting syndrome    Severe nausea    Severe or Persistent Muscle Spasms    PTSD    Other  
 Anorexia    Severe or chronic pain    Seizures    Glaucoma    Hospice Care

**Patient Ailments, etc.** *(please write any ailments or side effects, etc. that you may be suffering from or noticed in relation to your medical condition)*

### **General Questions**

Did patient experience relief after using the marijuana product?    YES    NO

*(please describe your reactions (positive or negative) you may have experienced with the marijuana product.)*

Did patient experience any unforeseen side effects from the marijuana product?    YES    NO

*(please describe any unforeseen side effects (positive or negative) you may have experienced with the marijuana product.)*

Will patient continue using the marijuana product to treat your medical condition?    YES    NO    Undecided

*(do you have any additional comments or thoughts about marijuana products as a treatment option?)*

### **Additional Comments:**

Fourth edition  
2008-11-15

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## Quality management systems — Requirements

*Systèmes de management de la qualité — Exigences*



Reference number  
ISO 9001:2008(E)

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This fourth edition cancels and replaces the third edition (ISO 9001:2000), which has been amended to clarify points in the text and to enhance compatibility with ISO 14001:2004.

Details of the changes between the third edition and this fourth edition are given in Annex B.

## Introduction

### 0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

- a) its organizational environment, changes in that environment, and the risks associated with that environment,
- b) its varying needs,
- c) its particular objectives,
- d) the products it provides,
- e) the processes it employs,
- f) its size and organizational structure.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

### 0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value,

- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

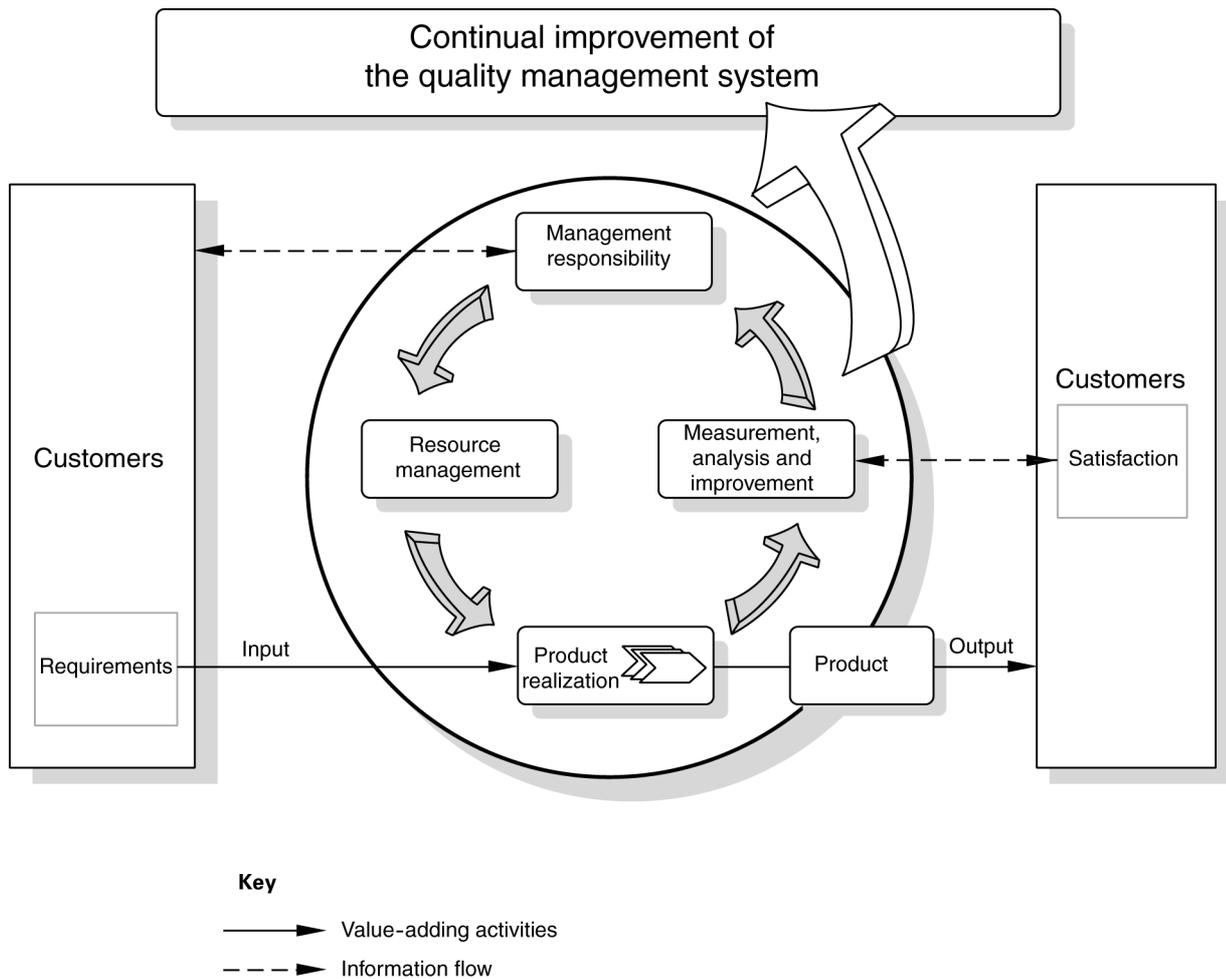
NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.



**Figure 1 — Model of a process-based quality management system**

### 0.3 Relationship with ISO 9004

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

### 0.4 Compatibility with other management systems

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.



# Quality management systems — Requirements

## 1 Scope

### 1.1 General

This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term “product” only applies to

- a) product intended for, or required by, a customer,
- b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

### 1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

## 4 Quality management system

### 4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable, and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the application of 7.4.

### 4.2 Documentation requirements

#### 4.2.1 General

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures and records required by this International Standard, and
- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

#### **4.2.2 Quality manual**

The organization shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

#### **4.2.3 Control of documents**

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

#### **4.2.4 Control of records**

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

## **5 Management responsibility**

### **5.1 Management commitment**

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

## **ISO 9001:2008(E)**

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

### **5.2 Customer focus**

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

### **5.3 Quality policy**

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

### **5.4 Planning**

#### **5.4.1 Quality objectives**

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

#### **5.4.2 Quality management system planning**

Top management shall ensure that

- a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

### **5.5 Responsibility, authority and communication**

#### **5.5.1 Responsibility and authority**

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

### 5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) reporting to top management on the performance of the quality management system and any need for improvement, and
- c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

### 5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

## 5.6 Management review

### 5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

### 5.6.2 Review input

The input to management review shall include information on

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement.

### 5.6.3 Review output

The output from the management review shall include any decisions and actions related to

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs.

## 6 Resource management

### 6.1 Provision of resources

The organization shall determine and provide the resources needed

- a) to implement and maintain the quality management system and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

### 6.2 Human resources

#### 6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

#### 6.2.2 Competence, training and awareness

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

### 6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport, communication or information systems).

### 6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

## 7 Product realization

### 7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents, and to provide resources specific to the product;
- c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

### 7.2 Customer-related processes

#### 7.2.1 Determination of requirements related to the product

The organization shall determine

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known,
- c) statutory and regulatory requirements applicable to the product, and
- d) any additional requirements considered necessary by the organization.

NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

#### 7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

### 7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

- a) product information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

## 7.3 Design and development

### 7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

- a) the design and development stages,
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

### 7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

### 7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

- a) meet the input requirements for design and development,
- b) provide appropriate information for purchasing, production and service provision,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

NOTE Information for production and service provision can include details for the preservation of product.

#### **7.3.4 Design and development review**

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

- a) to evaluate the ability of the results of design and development to meet requirements, and
- b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

#### **7.3.5 Design and development verification**

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

#### **7.3.6 Design and development validation**

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

#### **7.3.7 Control of design and development changes**

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

### **7.4 Purchasing**

#### **7.4.1 Purchasing process**

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

### 7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including, where appropriate,

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

### 7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

## 7.5 Production and service provision

### 7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring equipment,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product release, delivery and post-delivery activities.

### 7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable,

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,

- d) requirements for records (see 4.2.4), and
- e) revalidation.

### 7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

### 7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

### 7.5.5 Preservation of product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

## 7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

- a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
- b) be adjusted or re-adjusted as necessary;
- c) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

## **8 Measurement, analysis and improvement**

### **8.1 General**

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity to product requirements,
- b) to ensure conformity of the quality management system, and
- c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

### **8.2 Monitoring and measurement**

#### **8.2.1 Customer satisfaction**

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

#### **8.2.2 Internal audit**

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

### 8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

### 8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

## 8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application;
- d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

## 8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

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The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1),
- b) conformity to product requirements (see 8.2.4),
- c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) suppliers (see 7.4).

### 8.5 Improvement

#### 8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

#### 8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken (see 4.2.4), and
- f) reviewing the effectiveness of the corrective action taken.

#### 8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of results of action taken (see 4.2.4), and
- e) reviewing the effectiveness of the preventive action taken.

## Annex A (informative)

### Correspondence between ISO 9001:2008 and ISO 14001:2004

**Table A.1 — Correspondence between ISO 9001:2008 and ISO 14001:2004**

ISO 9001:2008		ISO 14001:2004	
Introduction (title only)			Introduction
General	0.1		
Process approach	0.2		
Relationship with ISO 9004	0.3		
Compatibility with other management systems	0.4		
Scope (title only)	1	1	Scope
General	1.1		
Application	1.2		
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
Quality management system (title only)	4	4	Environmental management system requirements (title only)
General requirements	4.1	4.1	General requirements
Documentation requirements (title only)	4.2		
General	4.2.1	4.4.4	Documentation
Quality manual	4.2.2		
Control of documents	4.2.3	4.4.5	Control of documents
Control of records	4.2.4	4.5.4	Control of records
Management responsibility (title only)	5		
Management commitment	5.1	4.2 4.4.1	Environmental policy Resources, roles, responsibility and authority
Customer focus	5.2	4.3.1 4.3.2 4.6	Environmental aspects Legal and other requirements Management review
Quality policy	5.3	4.2	Environmental policy
Planning (title only)	5.4	4.3	Planning (title only)
Quality objectives	5.4.1	4.3.3	Objectives, targets and programme(s)
Quality management system planning	5.4.2	4.3.3	Objectives, targets and programme(s)
Responsibility, authority and communication (title only)	5.5		
Responsibility and authority	5.5.1	4.1 4.4.1	General requirements Resources, roles, responsibility and authority
Management representative	5.5.2	4.4.1	Resources, roles, responsibility and authority
Internal communication	5.5.3	4.4.3	Communication
Management review (title only)	5.6	4.6	Management review
General	5.6.1	4.6	Management review
Review input	5.6.2	4.6	Management review
Review output	5.6.3	4.6	Management review

Table A.1 — Correspondence between ISO 9001:2008 and ISO 14001:2004 (continued)

ISO 9001:2008		ISO 14001:2004	
Resource management (title only)	6		
Provision of resources	6.1	4.4.1	Resources, roles, responsibility and authority
Human resources (title only)	6.2		
General	6.2.1	4.4.2	Competence, training and awareness
Competence, training and awareness	6.2.2	4.4.2	Competence, training and awareness
Infrastructure	6.3	4.4.1	Resources, roles, responsibility and authority
Work environment	6.4		
Product realization (title only)	7	4.4	Implementation and operation (title only)
Planning of product realization	7.1	4.4.6	Operational control
Customer-related processes (title only)	7.2		
Determination of requirements related to the product	7.2.1	4.3.1	Environmental aspects
		4.3.2	Legal and other requirements
		4.4.6	Operational control
Review of requirements related to the product	7.2.2	4.3.1	Environmental aspects
		4.4.6	Operational control
Customer communication	7.2.3	4.4.3	Communication
Design and development (title only)	7.3		
Design and development planning	7.3.1	4.4.6	Operational control
Design and development inputs	7.3.2	4.4.6	Operational control
Design and development outputs	7.3.3	4.4.6	Operational control
Design and development review	7.3.4	4.4.6	Operational control
Design and development verification	7.3.5	4.4.6	Operational control
Design and development validation	7.3.6	4.4.6	Operational control
Control of design and development changes	7.3.7	4.4.6	Operational control
Purchasing (title only)	7.4		
Purchasing process	7.4.1	4.4.6	Operational control
Purchasing information	7.4.2	4.4.6	Operational control
Verification of purchased product	7.4.3	4.4.6	Operational control
Production and service provision (title only)	7.5		
Control of production and service provision	7.5.1	4.4.6	Operational control
Validation of processes for production and service provision	7.5.2	4.4.6	Operational control
Identification and traceability	7.5.3		
Customer property	7.5.4		
Preservation of product	7.5.5	4.4.6	Operational control
Control of monitoring and measuring equipment	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement (title only)	8	4.5	Checking (title only)
General	8.1	4.5.1	Monitoring and measurement
Monitoring and measurement (title only)	8.2		
Customer satisfaction	8.2.1		
Internal audit	8.2.2	4.5.5	Internal audit
Monitoring and measurement of processes	8.2.3	4.5.1	Monitoring and measurement
		4.5.2	Evaluation of compliance

Table A.1 — Correspondence between ISO 9001:2008 and ISO 14001:2004 (continued)

ISO 9001:2008		ISO 14001:2004	
Monitoring and measurement of product	8.2.4	4.5.1 4.5.2	Monitoring and measurement Evaluation of compliance
Control of nonconforming product	8.3	4.4.7 4.5.3	Emergency preparedness and response Nonconformity, corrective action and preventive action
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement (title only)	8.5		
Continual improvement	8.5.1	4.2 4.3.3 4.6	Environmental policy Objectives, targets and programme(s) Management review
Corrective action	8.5.2	4.5.3	Nonconformity, corrective action and preventive action
Preventive action	8.5.3	4.5.3	Nonconformity, corrective action and preventive action

**Table A.2 — Correspondence between ISO 14001:2004 and ISO 9001:2008**

ISO 14001:2004		ISO 9001:2008	
Introduction		0.1	Introduction (title only)
		0.2	General
		0.3	Process approach
		0.4	Relationship with ISO 9004
		0.4	Compatibility with other management systems
Scope	1	1	Scope (title only)
		1.1	General
		1.2	Application
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
Environmental management system requirements (title only)	4	4	Quality management system (title only)
General requirements	4.1	4.1	General requirements
		5.5	Responsibility, authority and communication (title only)
		5.5.1	Responsibility and authority
Environmental policy	4.2	5.1	Management commitment
		5.3	Quality policy
		8.5.1	Continual improvement
Planning (title only)	4.3	5.4	Planning (title only)
Environmental aspects	4.3.1	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
Legal and other requirements	4.3.2	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
Objectives, targets and programme(s)	4.3.3	5.4.1	Quality objectives
		5.4.2	Quality management system planning
		8.5.1	Continual improvement
Implementation and operation (title only)	4.4	7	Product realization (title only)
Resources, roles, responsibility and authority	4.4.1	5.1	Management commitment
		5.5.1	Responsibility and authority
		5.5.2	Management representative
		6.1	Provision of resources
		6.3	Infrastructure
Competence, training and awareness	4.4.2	6.2.1	(Human resources) General
		6.2.2	Competence, training and awareness
Communication	4.4.3	5.5.3	Internal communication
		7.2.3	Customer communication
Documentation	4.4.4	4.2.1	(Documentation requirements) General
Control of documents	4.4.5	4.2.3	Control of documents

Table A.2 — Correspondence between ISO 14001:2004 and ISO 9001:2008 (continued)

ISO 14001:2004		ISO 9001:2008	
Operational control	4.4.6	7.1	Planning of product realization
		7.2	Customer-related processes (title only)
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
		7.3.1	Design and development planning
		7.3.2	Design and development inputs
		7.3.3	Design and development outputs
		7.3.4	Design and development review
		7.3.5	Design and development verification
		7.3.6	Design and development validation
		7.3.7	Control of design and development changes
		7.4.1	Purchasing process
		7.4.2	Purchasing information
		7.4.3	Verification of purchased product
		7.5	Production and service provision (title only)
		7.5.1	Control of production and service provision
7.5.2	Validation of processes for production and service provision		
		7.5.5	Preservation of product
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking (title only)	4.5	8	Measurement, analysis and improvement (title only)
Monitoring and measurement	4.5.1	7.6	Control of monitoring and measuring equipment
		8.1	(Measurement, analysis and improvement) General
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
		8.4	Analysis of data
Evaluation of compliance	4.5.2	8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
Nonconformity, corrective action and preventive action	4.5.3	8.3	Control of nonconforming product
		8.4	Analysis of data
		8.5.2	Corrective action
		8.5.3	Preventive action
Control of records	4.5.4	4.2.4	Control of records
Internal audit	4.5.5	8.2.2	Internal audit
Management review	4.6	5.1	Management commitment
		5.6	Management review (title only)
		5.6.1	General
		5.6.2	Review input
		5.6.3	Review output
		8.5.1	Continual improvement

## Annex B (informative)

### Changes between ISO 9001:2000 and ISO 9001:2008

**Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008**

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
Foreword	Para 2	D + A	International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, <del>Part 3</del> <u>Part 2</u> .
Foreword	Para 3, Sentence 1	A	<u>The main task of technical committees is to prepare International Standards.</u>
Foreword	Para 4, Sentence 1	D + A	Attention is drawn to the possibility that some of the elements of this International Standard document may be the subject of patent rights.
Foreword	Para 5	D	<del>International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 2, Quality systems.</del>
Foreword	Para 6	D	<del>This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.</del>
		A	<u>This fourth edition cancels and replaces the third edition (ISO 9001:2000), which has been amended to clarify points in the text and to enhance compatibility with ISO 14001:2004.</u>
Foreword	Para 7	D	<del>The title of ISO 9001 has been revised in this edition and no longer includes the term "Quality assurance". This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.</del>
Foreword	Para 8	D	<del>Annexes A and B of this International Standard are for information only.</del>
Foreword	New para 7	A	<u>Details of the changes between the third edition and this fourth edition are given in Annex B.</u>
0.1	Para 1, Sentence 2	D	<del>The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization.</del>
		A	<u>The design and implementation of an organization's quality management system is influenced by</u> a) <u>its organizational environment, change in that environment, and the risks associated with that environment;</u> b) <u>its varying needs;</u> c) <u>its particular objectives;</u> d) <u>the products it provides;</u> e) <u>the processes it employs;</u> f) <u>its size and organizational structure.</u>
	Sentence 3	Now a new para	It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.
0.1	Para 4	A	This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, <u>statutory and</u> regulatory requirements <u>applicable to the product</u> , and the organization's own requirements.
0.2	Para 2	D + A	For an organization to function effectively, it has to <del>identify</del> <u>determine</u> and manage numerous linked activities. An activity <u>or set of activities</u> using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
0.2	Para 3	A	The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management <u>to produce the desired outcome</u> , can be referred to as the “process approach”.
0.3	Para 1	D + A	<del>The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.</del>
0.3	Para 3	D + A	<del>ISO 9004 gives a guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.</del>  <u>At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.</u>
0.4	Para 1	D + A	<del>This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.</del>  <u>During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.</u>
1.1	Bullet a) Bullet b) Note  New Note 2	A A D A A	a) needs to demonstrate its ability to consistently provide product that meets customer and applicable <u>statutory and</u> regulatory requirements, and  b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable <u>statutory and</u> regulatory requirements.  <del>NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.</del>  <u>NOTE 1 In this International Standard, the term “product” only applies to</u> a) <u>a product intended for, or required by, a customer,</u> b) <u>any intended output resulting from the product realization processes.</u>  <u>NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.</u>
1.2	Para 3	A	Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable <u>statutory and</u> regulatory requirements.
2	Para 1	D + A  A  D + A	<del>The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.</del>  <u>The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.</u>  ISO 9000:20002005, <i>Quality management systems — Fundamentals and vocabulary</i>

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
3	Para 1	D + A	For the purposes of this <del>document</del> International Standard, the terms and definitions given in ISO 9000 apply.
3	Paras 2, 3	D	The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used: <b>supplier → organization → customer</b> The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.
4.1	Bullet a)	D + A	a) <del>identify</del> <u>determine</u> the processes needed for the quality management system and their application throughout the organization (see 1.2),
4.1	Bullet e)	A	e) monitor, measure <del>where applicable</del> , and analyse these processes, and
4.1	Para 4	D + A	Where an organization chooses to outsource any process that affects product conformity <del>with</del> <u>to</u> requirements, the organization shall ensure control over such processes. <del>The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.</del>
4.1	Note 1	D + A	NOTE 1 Processes needed for the quality management system referred to above <del>should</del> include processes for management activities, provision of resources, product realization, <del>and</del> measurement, <del>analysis and improvement.</del>
4.1	New Notes 2 & 3	A	NOTE 2 An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party. NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) <del>the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,</del> b) <del>the degree to which the control for the process is shared,</del> c) <del>the capability of achieving the necessary control through the application of 7.4.</del>
4.2.1	Bullet c)	A	c) documented procedures <del>and records</del> required by this International Standard, <del>and</del>
4.2.1	Bullet d)	A + D	d) documents, <del>including records,</del> <del>needed</del> <u>determined</u> by the organization <del>to be necessary</del> to ensure the effective planning, operation and control of its processes. <del>and</del>
4.2.1	Bullet e)	D	e) <del>records required by this International Standard (see 4.2.4).</del>
4.2.1	Note 1	A	NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. <del>A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.</del>
4.2.3	Bullet f)	A	f) to ensure that documents of external origin <del>determined by the organization to be necessary for the planning and operation of the quality management system</del> are identified and their distribution controlled, and
4.2.4	Para 1	D + A	Records <del>shall be established and maintained</del> to provide evidence of conformity to requirements and of the effective operation of the quality management system <del>shall be controlled</del> . <del>Records shall remain legible, readily identifiable and retrievable.</del> The organization shall <del>establish</del> a documented procedure <del>shall be established</del> to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. <del>Records shall remain legible, readily identifiable and retrievable.</del>
5.5.2	Para 1	A	Top management shall appoint a member of <del>the organization's</del> management who, irrespective of other responsibilities, shall have responsibility and authority that includes
6.2.1	Para 1	A + D	Personnel performing work affecting <del>conformity to</del> product quality requirements shall be competent on the basis of appropriate education, training, skills and experience.
	New Note	A	NOTE <del>Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.</del>

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
6.2.2	Clause title	A + D	Competence, <del>training and</del> awareness and <del>training</del>
6.2.2	Bullets a) & b)	A + D	a) determine the necessary competence for personnel performing work affecting <del>conformity to product quality requirements,</del> b) <del>where applicable,</del> provide training or take other actions to satisfy these needs <del>achieve the necessary competence,</del>
6.3	Bullet c)	A	c) supporting services (such as transport, communication <del>or information systems</del> ).
6.4	New Note	A	<del>NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).</del>
7.1	Bullet b)	A + D	b) the need to establish processes <del>and</del> documents, and <del>to</del> provide resources specific to the product;
7.1	Bullet c)	A	c) required verification, validation, monitoring, <del>measurement,</del> inspection and test activities specific to the product and the criteria for product acceptance;
7.2.1	Bullet c)	D + A	c) statutory and regulatory requirements related <del>applicable</del> to the product, and
	Bullet d),	D + A	d) any additional requirements <del>determined</del> <del>considered necessary</del> by the organization.
	New Note	A	<del>NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.</del>
7.3.1	New Note	A	<del>NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.</del>
7.3.2	Para 2	D + A	These <del>The</del> inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.
7.3.3	Para 1	D + A	The outputs of design and development shall be <del>provided in a form that enables in a form suitable</del> for verification against the design and development input and shall be approved prior to release.
7.3.3	Bullet b)	D	b) provide appropriate information for purchasing, production and <del>for</del> service provision,
7.3.3	New Note	A	<del>NOTE Information for production and service provision can include details for the preservation of product.</del>
7.3.7	Paras 1 & 2	No text change. Paras now merged	Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).
7.5.1	Bullet d)	D + A	d) the availability and use of monitoring and measuring <del>devices</del> <del>equipment,</del>
7.5.1	Bullet f)	A	f) the implementation of <del>product</del> release, delivery and post-delivery activities.
7.5.2	Para 1	D + A	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement <del>This includes any processes where and, as a consequence,</del> deficiencies become apparent only after the product is in use or the service has been delivered.
7.5.3	Para 2	A	The organization shall identify the product status with respect to monitoring and measurement requirements <del>throughout product realization.</del>
7.5.3	Para 3	D + A	Where traceability is a requirement, the organization shall control <del>and record</del> the unique identification of the product <del>and maintain records</del> (see 4.2.4).
7.5.4	Para 1, Sentence 3	D + A	If any customer property is lost, damaged or otherwise found to be unsuitable for use, <del>this shall be reported to the customer and records maintained</del> <del>the organization shall report this to the customer and maintain records</del> (see 4.2.4).
	Note	A	NOTE Customer property can include intellectual property <del>and personal data.</del>

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
7.5.5	Para 1	D + A	The organization shall preserve the <del>conformity of product</del> during internal processing and delivery to the intended destination <u>in order to maintain conformity to requirements</u> . This <del>As applicable</del> , preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.
7.6	Title	D + A	Control of monitoring and measuring <del>devices</del> <u>equipment</u>
7.6	Para 1	D + A	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring <del>devices</del> <u>equipment</u> needed to provide evidence of conformity of product to determined requirements (see 7.2.4).
7.6	Bullet a)	A	a) be calibrated or verified, <u>or both</u> , at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
7.6	Bullet c)	D + A	<del>e) be identified to enable the calibration status to be determined;</del> c) <u>have identification in order to determine its calibration status;</u>
7.6	Para 4, Sentence 3	Now new para 5, without change.	Records of the results of calibration and verification shall be maintained (see 4.2.4).
7.6	Note	D + A	<del>NOTE See ISO 10012-1 and ISO 10012-2 for guidance</del> <u>NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.</u>
8.1	Bullet a)	D + A	a) to demonstrate conformity <del>of the product</del> <u>to product requirements</u> ,
8.2.1	New Note	A	<u>NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.</u>
8.2.2	Para 2 Sentence 3	A	The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.
8.2.2	New Para 3	A	<u>A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.</u>
8.2.2	Para 3	Now para 4 D + A	<del>The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.</del> <u>Records of the audits and their results shall be maintained (see 4.2.4).</u>
8.2.2	Para 4 Sentence 1	Now para 5 A	The management responsible for the area being audited shall ensure that <u>any necessary corrections and corrective</u> actions are taken without undue delay to eliminate detected nonconformities and their causes.
8.2.2	Note	D + A	<del>NOTE See ISO 10011-1, ISO 10011-1 and ISO 10011-3. See ISO 19011 for guidance.</del>
8.2.3	Para 1 Sentence 3	D	When planned results are not achieved, correction and corrective action shall be taken, as appropriate, <del>to ensure conformity of the product.</del>
8.2.3	New Note	A	<u>NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.</u>
8.2.4	Para 1	A	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). <u>Evidence of conformity with the acceptance criteria shall be maintained.</u>
	Para 2	D + A	<del>Evidence of conformity with the acceptance criteria shall be maintained.</del> Records shall indicate the person(s) authorizing release of product <u>for delivery to the customer</u> (see 4.2.4).
	Para 3	D + A	<del>Product release and service delivery</del> <u>The release of product and delivery of service to the customer</u> shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
8.3	Para 1, Sentence 2	D + A	The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. <del>A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.</del>
8.3	Para 2	A	Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:
8.3	New bullet d) Para 3 Para 4 Para 5	A Moved to be Para 4 Moved to be Para 3 Now new bullet d)	d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. <del>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4)</del> When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). <del>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.</del>
8.4	Bullet b) Bullet c) Bullet d)	D + A A A	b) conformity to product requirements ( <del>see 7.2.1</del> ) (see 8.2.4), c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and d) suppliers (see 7.4).
8.5.2	Para 1	D + A	The organization shall take action to eliminate the cause <del>causes</del> of nonconformities in order to prevent recurrence.
8.5.2	Bullet f)	A	f) reviewing <del>the effectiveness of</del> the corrective action taken.
8.5.3	Bullet e)	A	e) reviewing <del>the effectiveness of</del> the preventive action taken.
Annex A	All	D + A	Updated to reflect ISO 9001:2008 versus ISO 14001:2004
Annex B	All	D + A	Updated to reflect ISO 9001:2008 versus ISO 9001:2000
Bibliography	New and amended references	D + A	Updated to reflect new standards (including ISO 9004, currently under revision), new editions of standards, or withdrawn standards.

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2) Available from website: <http://www.iso.org>.

3) To be updated and aligned with ISO 9001:2008.

[22] *ISO Management Systems* <sup>4)</sup>

[23] Reference web sites:

<http://www.iso.org>

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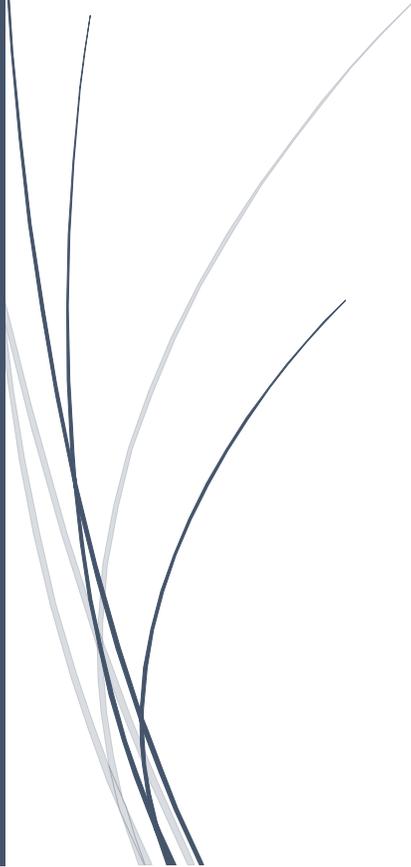
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4) A bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world. Available from ISO Central Secretariat ([sales@iso.org](mailto:sales@iso.org)).





# Quality Management Plan





To ensure employee and public safety, Blue Planet Healing LLC (“BPH”) is committed to establish, document, implement and maintain an appropriate Quality Management System.

To this end, BPH is committed to the following Quality Management Principles:

- Customer Focus
  - Leadership
- Involvement of People
  - Process Approach
- System Approach to Management
  - Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships

To assure adequate establishment, implementation, documentation and maintenance of their Quality Management System, the applicant has taken guidance from ISO 9001 (see below) and has *budgeted to hire a full-time Director of Quality Management who is certified as a Manager of Quality and Organizational Excellence by the American Society of Quality*. The Director of Quality Management shall be responsible for using the guidance from ISO 9001 to develop the appropriate Quality Management System for the applicant in accordance with Hawaii state regulations.

[http://www.iso.org/iso/home/standards/management-standards/iso\\_9000.htm](http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm)

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

**Plan:** establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies

**Do:** implement the processes.

**Check:** monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

**Act:** take actions to continually improve process performance.

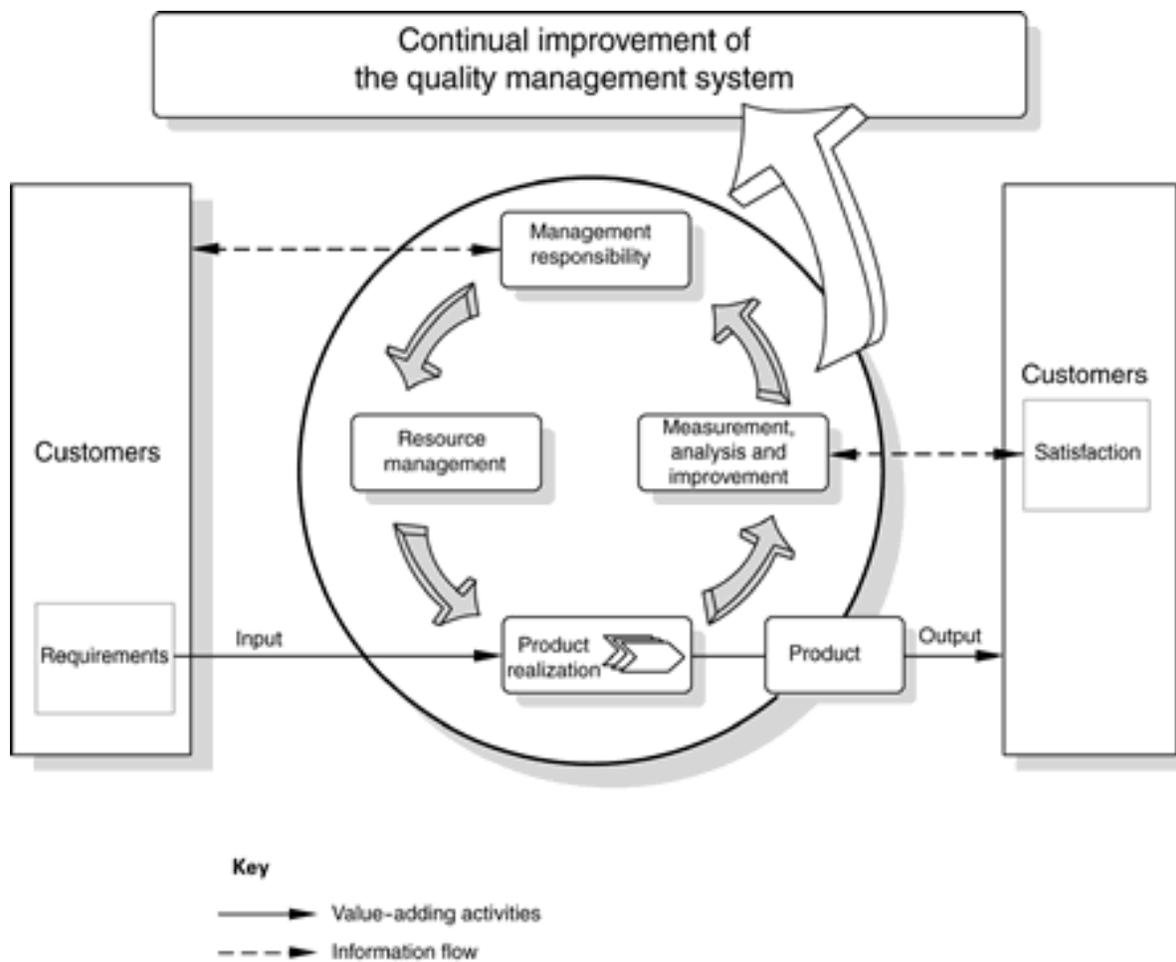




Figure 1 — Model of a process-based quality management system

*NOTE-Sections 1, 2 and 3 are not included because they are not directly pertinent to the establishment, implementation application and maintenance of a Quality Management System.*

## **4. Quality Management System**

### **4.1 General Requirements**

Establish, document, implement, and maintain a quality management system. Continually improve its effectiveness in accordance with ISO 9001 requirements. Implement the system to:

- Determine processes needed for the quality management system (and their application throughout the organization)
- Determine process sequence and interaction
- Determine criteria and methods for process operation and control
- Ensure resources and supporting information are available
- Monitor, measure where applicable, and analyze these processes
- Implement actions to achieve planned results and continual process improvement
- Manage these processes in accordance with ISO 9001 requirements. Define the type and extent of control applied to any outsourced processes that affect product conformity to requirements.

NOTE 1: Processes needed for the quality management system include the processes for management activities (see 5), provision of resources (see 6), product realization (see 7), and measurement, analysis, and improvement (see 8).

NOTE 2: An outsourced process is a process the organization needs for its quality management system, and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve your organization of the responsibility to conform to all customer, statutory, and regulatory requirements. The type and extent of control applied to an outsourced process can be influenced by factors such as:

- Potential impact of the outsourced process on your organization's capability to provide product that conforms to requirements.
- Degree to which the control for the process is shared
- Capability of achieving the necessary control through the application of 7.4

### **4.2 Documentation Requirements**

#### **4.2.1 General Requirements**

Include in the quality management system documentation:



- Documented statements of a quality policy and quality objectives
- A quality manual
- Documented procedures and records required by ISO 9001
- Documents and records determined by the organization to be necessary for the effective planning, operation, and control of its processes

NOTE 1: Where “documented procedure” appears within the Standard, this means that the procedure is established, documented, implemented, and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The extent of the quality management system documentation can differ from one organization to another due to:

- Size of the organization and type of activities
- Complexity of processes and their interactions
- Competence of personnel

NOTE 3: The documentation can be in any form or type of medium.

#### **4.2.2 Quality Manual**

Establish and maintain a quality manual with:

- Scope of the quality management system
- Details and justification for any exclusions
- Procedures or references to the procedures
- Description of interaction between processes

#### **4.2.3 Control of Documents**

Control the documents required by the quality management system. Records are a special type of document and must be controlled as required by clause 4.2.4.

Establish a documented procedure to:

- Approve documents for adequacy prior to issue
- Review, update as necessary, and re-approve documents
- Identify the changes and current document revision status
- Make relevant documents available at points of use
- Ensure the documents remain legible and readily identifiable
- Identify external documents and control their distribution
- Prevent obsolete documents from unintended use



- Apply suitable identification if obsolete documents are retained

#### **4.2.4 Control of Records**

Establish and control records as evidence of conformity to requirements and to demonstrate the effective operation of the quality management system.

Establish a documented procedure to define the controls needed for record:

- Identification
- Storage
- Protection
- Retrieval
- Retention
- Disposition
- Keep records legible, readily identifiable, and retrievable.

### **5. Management Responsibility**

All requirements in clause 5 are the responsibility of top management.

#### **5.1 Management Commitment**

Provide evidence of management commitment to develop and implement the quality management system, as well as, continually improve its effectiveness by:

- Expressing the importance of meeting requirements
- Establishing the quality policy and quality objectives
- Conducting management reviews
- Ensuring the availability of necessary resources

#### **5.2 Customer Focus**

Ensure customer requirements are determined and met in order to improve customer satisfaction.

#### **5.3 Quality Policy**

Ensure the quality policy is:

- Appropriate to the purpose of the organization
- Focused on meeting requirements and continual improvement
- Used as a framework for quality objectives
- Communicated and understood at appropriate levels



- Reviewed for continuing suitability

## **5.4 Planning**

### **5.4.1 Quality Objectives**

Ensure quality objectives, including those needed to meet product requirements, are established at the relevant functions and levels within the organization. Ensure quality objectives are measurable and consistent with the quality policy.

### **5.4.2 Quality Management System Planning**

Ensure that planning for the quality management system:

- Meets the general requirements (4.1), as well as, quality objectives (5.4.1)
- Maintains the system integrity when changes are planned and implemented

## **5.5 Responsibility, Authority, and Communication**

### **5.5.1 Responsibility and Authority**

Ensure responsibilities and authorities are defined and communicated within the organization.

### **5.5.2 Management Representative**

Appoint a member of your management who, irrespective of other duties, has the responsibility and authority to:

- Ensure the needed processes are established, implemented, and maintained
- Report to top management on quality management system performance
- Report to top management on any need for improvement
- Ensuring the promotion of awareness of customer requirements

NOTE: The responsibility of a management representative can include being the liaison with external parties on matters relating to the quality management system.

### **5.5.3 Internal Communication**

Ensure the appropriate communication processes are established and carried out within the organization regarding the effectiveness of the system.

## **5.6 Management Review**



### **5.6.1 General**

Review the quality management system at planned intervals to:

- Ensure a suitable, adequate, and effective system
- Assess possible opportunities for improvement
- Evaluate the need for any changes to the system
- Consider the need for changes to the quality policy and objectives
- Maintain records of the management reviews.

### **5.6.2 Review Input**

Inputs for management review must include information on:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from earlier reviews
- Changes that could affect the quality system
- Recommendations for improvement

### **5.6.3 Review Output**

Outputs from the management review must include any decisions and actions related to:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

## **6. Resource Management**

### **6.1 Provision of Resources**

Determine and provide the resources necessary to:

- Implement and maintain the quality management system
- Continually improve the effectiveness of the system
- Enhance customer satisfaction by meeting customer requirements

### **6.2 Human Resources**

#### **6.2.1 General**



Ensure people performing work affecting conformity to product requirements are competent based on the appropriate education, training, skills, and experience.

NOTE: Conformity to product requirements can be affected directly, or indirectly, by personnel performing any task within the quality management system.

## **6.2.2 Competence, Training, and Awareness**

The organization must:

- Determine the competency needs for personnel
- Provide training (or take other actions) to achieve the necessary competence
- Evaluate the effectiveness of the actions taken
- Inform employees of the relevance and importance of their activities
- Ensure they know their contribution to achieving quality objectives
- Maintain education, training, skill, and experience records

## **6.3 Infrastructure**

Determine, provide, and maintain the necessary infrastructure to achieve product conformity.

Infrastructure includes, as applicable:

- Buildings, workspace, and associated utilities
- Process equipment (both hardware and software)
- Supporting services (such as transport, communication, or information systems)

## **6.4 Work Environment**

Determine and manage the work environment needed to achieve product conformity.

NOTE: The term “work environment” relates to those conditions under which work is performed, including physical, environmental, and other factors such as noise, temperature, humidity, lighting, or weather.

## **7. Product Realization**

### **7.1 Planning of Product Realization**

Plan and develop the processes needed for product realization. Keep the planning consistent with other requirements of the quality management system and document it in a suitable form for the organization. Determine through the planning, as appropriate, the:



- Quality objectives and product requirements
- Need for processes, documents, and resources
- Verification, validation, monitoring, measurement, inspection, and test activities
- Criteria for product acceptance
- Records as evidence the processes and resulting product meet requirements

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes), and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2: The organization can also apply the requirements given in 7.3 to the development of product realization processes.

## **7.2 Customer-Related Processes**

### **7.2.1 Determination of Requirements Related to the Product**

Determine customer requirements:

- Specified for the product (including delivery and post-delivery activities)
- Not specified for the product (but needed for specified or intended use, where known)

Determine:

- Statutory and regulatory requirements applicable to the product
- Any additional requirements considered necessary by the organization

NOTE: Post-delivery activities include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

### **7.2.2 Review of Requirements Related to the Product**

Review the product requirements before committing to supply the product to the customer in order to:

- Ensure product requirements are defined
- Resolve any requirements differing from those previously expressed
- Ensure its ability to meet the requirements
- Maintain the results of the review, and any subsequent follow-up actions. When the requirements are not documented, they must be confirmed before acceptance.
- If product requirements are changed, ensure relevant documents are amended and relevant personnel are made aware of the changed requirements.



NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information such as catalogs or advertising material.

### **7.2.3 Customer Communication**

Determine and implement effective arrangements for communicating with customers on:

- Product information
- Inquiries, contracts, or order handling (including amendments)
- Customer feedback (including customer complaints)

## **7.3 Design and Development**

### **7.3.1 Design and Development Planning**

Plan and control the product design and development. This planning must determine the:

- Stages of design and development
- Appropriate review, verification, and validation activities for each stage
- Responsibility and authority for design and development
- The interfaces between the different involved groups must be managed to ensure effective communication and the clear assignment of responsibility. Update, as appropriate, the planning output during design and development.

NOTE: Design and development review, verification, and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as deemed suitable for the product and the organization.

### **7.3.2 Design and Development Inputs**

Determine product requirement inputs and maintain records. The inputs must include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Applicable information derived from similar designs
- Requirements essential for design and development
- Review these inputs for adequacy. Resolve any incomplete, ambiguous, or conflicting requirements.

### **7.3.3 Design and Development Outputs**

Document the outputs of the design and development process in a form suitable for verification against the inputs to the process. The outputs must:



- Meet design and development input requirements
- Provide information for purchasing, production, and service
- Contain or reference product acceptance criteria
- Define essential characteristics for safe and proper use
- Be approved before their release

NOTE: Information for production and service can include details for product preservation.

#### **7.3.4 Design and Development Review**

Perform systematic reviews of design and development at suitable stages in accordance with planned arrangements (see 7.3.1) to:

- Evaluate the ability of the results to meet requirements
- Identify problems and propose any necessary actions

The reviews must include representatives of the functions concerned with the stage being reviewed. Maintain the results of reviews and subsequent follow-up actions.

#### **7.3.5 Design and Development Verification**

Perform design and development verification in accordance with planned arrangements (see 7.3.1) to ensure the output meets the design and development input requirements. Maintain the results of the verification and subsequent follow-up actions.

#### **7.3.6 Design and Development Validation**

Perform validation in accordance with planned arrangements (see 7.3.1) to confirm the resulting product is capable of meeting the requirements for its specified application or intended use, where known. When practical, complete the validation before delivery or implementation of the product. Maintain the results of the validation and subsequent follow-up actions.

#### **7.3.7 Control of Design and Development Changes**

Identify design and development changes and maintain records. Review, verify, and validate (as appropriate) the changes and approve them before implementation. Evaluate the changes in terms of their effect on constituent parts and products already delivered. Maintain the results of the change review and subsequent follow-up actions.

### **7.4 Purchasing**

#### **7.4.1 Purchasing Process**



Ensure that purchased product conforms to its specified purchase requirements. The type and extent of control applied to the supplier and purchased product depends upon the effect of the product on the subsequent realization processes or the final product. Evaluate and select suppliers based on their ability to supply product in accordance with the requirements. Establish the criteria for selection, evaluation, and re-evaluation. Maintain the results of the evaluations and subsequent follow-up actions.

#### **7.4.2 Purchasing Information**

Ensure the purchasing information contains information describing the product to be purchased, including the requirements for:

- Approval of product, procedures, processes, and equipment
- Qualification of personnel

(Also include quality management system requirements in the purchasing information)

Ensure the adequacy of the specified requirements before communicating the information to the supplier.

#### **7.4.3 Verification of Purchased Product**

Establish and implement the inspection or other necessary activities for ensuring the purchased products meet the specified purchase requirements. If the organization or its customer proposes to verify the product at the supplier location, state the intended verification arrangements and method of product release in the purchasing information.

### **7.5 Production and Service Provision**

#### **7.5.1 Control of Production and Service Provision**

Plan and carry out production and service provision under controlled conditions to include, as applicable:

- Availability of product characteristics information
- Availability of work instructions, as necessary
- Use of suitable equipment
- Availability and use of monitoring and measuring equipment
- Implementation of monitoring and measurement activities
- Implementation of product release, delivery, and post-delivery activities

#### **7.5.2 Validation of Processes for Production and Service Provision**

Validate any production or service provision where subsequent monitoring or measurement cannot verify the output. This validation includes processes where deficiencies may become apparent only after product



use or service delivery. Demonstrate through the validation the ability of processes to achieve the planned results.

Establish validation arrangements including, as applicable:

- Criteria for process review and approval
- Approval of equipment
- Qualification of personnel
- Use of defined methods and procedures
- Requirements for records
- Re-validation

### **7.5.3 Identification and Traceability**

Identify, where appropriate, the product by suitable means during product realization. Identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, control the unique identification of the product and maintain records.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.

### **7.5.4 Customer Property**

Exercise care with any customer property while it is under the control of, or being used by, the organization. Identify, verify, protect, and safeguard customer property provided for use, or for incorporation into the product. Record and report any lost, damaged, or unsuitable property to the customer.

NOTE: Customer property can include intellectual property and personal data.

### **7.5.5 Preservation of Product**

Preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes:

- Identification
- Handling
- Packaging
- Storage
- Protection
- Also apply preservation to the constituent parts of the product.

## **7.6 Control of Measuring and Monitoring Equipment**



Determine the monitoring and measurements to be made, and the required equipment, to provide evidence of product conformity. Use and control the monitoring and measuring devices to ensure that measurement capability is consistent with monitoring and measurement requirements.

- Where necessary to ensure valid results:
- Calibrate and/or verify the measuring equipment at specified intervals or prior to use
- Calibrate the equipment to national or international standards (or record other basis)
- Adjust or re-adjust as necessary
- Identify the measuring equipment in order to determine its calibration status
- Safeguard them from improper adjustments
- Protect them from damage and deterioration
- Assess and record the validity of prior results if the device is found to not conform to requirements. Maintain records of the calibration and verification results.
- Confirm the ability of software used for monitoring and measuring for the intended application before its initial use (and reconfirmed as necessary).
- NOTE: Confirming the ability of software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

## **8. Measurement, Analysis, and Improvement**

### **8.1 General**

Plan and implement the monitoring, measurement, analysis, and improvement processes needed to:

- Demonstrate conformity to product requirements
- Ensure conformity of the system
- Continually improve effectiveness
- Determine through planning the need for, and use of, applicable methods, including statistical techniques, as well as, the extent of their use.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

Monitor information on customer perception as to whether the organization is meeting requirements (as one of the performance measurements of the quality management system).

Define the methods for obtaining and using this information.

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and dealer reports.



### **8.2.2 Internal Audit**

Conduct internal audits at planned intervals to determine if the quality management system:

- Conforms to planned arrangements (see 7.1)
- Conforms to requirements of ISO 9001
- Is effectively implemented and maintained

The organization must:

- Plan the audit program
- Consider the status and importance of the audited areas
- Consider the results of prior audits
- Define the audit criteria, scope, frequency, and methods
- Select and use impartial and objective auditors (not audit their own work)

Establish a documented procedure to address responsibilities and requirements to:

- Plan audits and conduct audits
- Establish records and report results
- Maintain records of the audits and their results.
- Ensure management of the audited areas takes actions without undue delay to eliminate detected nonconformities and their causes. Verify through follow-up actions the implementation of the action and report the results.

NOTE: See ISO 19011 for audit guidance.

### **8.2.3 Monitoring and Measurement of Processes**

Apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. Confirm through these methods the continuing ability of each process to satisfy its intended purpose. When the planned results are not achieved, take correction and corrective action, as appropriate.

NOTE: When determining “suitable” methods, consider the type and extent of monitoring or measurement for each process in relation to its impact on product conformity and on the effectiveness of the quality management system.

### **8.2.4 Monitoring and Measurement of Product**

Monitor and measure product characteristics to verify product requirements are being met. Carry out the monitoring and measuring at the appropriate stages of product realization in accordance with planned arrangements (see 7.1). Maintain evidence of conformity with the acceptance criteria.



Record the person responsible for authorizing release of product for delivery to the customer. Product release and service delivery cannot proceed until all planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, the customer.

### **8.3 Control of Nonconforming Product**

Ensure any nonconforming product is identified and controlled to prevent its unintended use or delivery. Establish a documented procedure to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, deal with the nonconforming product by one or more of the following ways:

- Take action to eliminate the detected nonconformity
- Authorize its use, release, or acceptance by concession
- Take action to preclude its original intended use or application
- Take action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started
- Maintain records of the nature of the nonconformity, and any subsequent actions, (including any concessions). When the nonconformity is corrected, re-verify it to show conformity.

### **8.4 Analysis of Data**

Determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system, as well as, evaluate where continual improvement of the effectiveness of the quality management system can be made. Include in the analysis the data generated by monitoring and measuring activities and from other relevant sources. Analyze this data to provide information on:

- Customer satisfaction (see 8.2.1)
- Conformity to product requirements (see 8.2.4)
- Characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3, 8.2.4, and 8.5.3)
- Suppliers (see 7.4)

### **8.5 Improvement**

#### **8.5.1 Continual Improvement**

Continually improve the effectiveness of the quality management system through:

- Quality policy
- Quality objectives



- Audit results
- Analysis of data
- Corrective and preventive action
- Management review

### **8.5.2 Corrective Action**

Take corrective action to eliminate the causes of nonconformities and prevent recurrence.

Corrective action must be appropriate to effects of the problem.

Establish a documented procedure for corrective action that defines requirements to:

- Review nonconformities (including customer complaints)
- Determine the causes of nonconformities
- Evaluate the need for actions to prevent recurrence
- Determine and implementing the needed action
- Maintain records of the results of the action taken
- Review the effectiveness of corrective action taken

### **8.5.3 Preventive Action**

Determine the action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Ensure preventive actions are appropriate to the anticipated effects of the potential problem.

Establish a documented procedure for preventive action to define requirements to:

- Determine potential nonconformities and their causes
- Evaluate the need for actions to prevent occurrence
- Determine and implementing the needed action
- Maintain records of the results of the action taken
- Review the effectiveness of preventive action taken



### Application Response: Question 6

Blue Planet Healing LLC (“BPH”) understands that the purpose of this chapter and sections HRS §§329D-7, 329D-12, and 846-2.7, is to ensure that BPH’s license applicants, licensees, employees, contractors and their employees, all prospective employees of BPH and any and all individuals permitted to enter and remain in a BPH dispensary facility, as provided in HRS §§329D-15(a)(4) and 329D-16(a)(3) are reputable and possess a responsible and trustworthy character and are otherwise fit and capable of following all applicable laws and regulations and all instruction of BPH in connection with the operation of BPH’s dispensary facilities. (See HRS §326D-7)(8)). BPH’s principal owners have an unblemished background free of any criminal activity. (See eCrim reports attached as “6.1”.)

BPH will carry this standard of excellence into all of BPH’s operations by ensuring that all individuals retained by BPH will have reputable, responsible characters and will be capable of implementing all of BPH’s policies and procedures in accordance with applicable law. These policies will be strictly enforced to ensure that no person will be allowed to enter any BPH dispensary facility or medical marijuana transportation vehicle if they have been convicted of a felony and/or the other offenses described in HAR §11-850-17(b)(2)-(5). In addition, BPH will pre-screen all of its employees, other workers and contractors and any other persons that may require access to any BPH dispensary facility to ensure they will not pose a risk to the health, safety or welfare of the public, any BPH customer or other BPH employee or worker. BPH will ensure that all personnel required to do so will agree to submit to fingerprinting and a background check as required by HRS §329D-12 and HAR §11-850-17. To accomplish this, all BPH license applicants, licensees, employees, contractors, and prospective employees, and individuals permitted to enter and remain in BPH dispensary facilities, as provided under HRS §329D-15(a)(4) and 329D-16(a)(3) will be required to review and execute an Advisory Letter and Consent Form



### Application Response: Question 6

in substance and form as that attached as “6.2”. The Advisory Letter puts all such individuals on notice regarding important legal considerations involving participation in BPH’s operations. The Consent Form documents said person’s representations regarding their age and criminal history and their consent to fingerprinting and background checks as required by applicable law. The Consent Form will be provided to Department of Health, State of Hawai‘i (“DOH”) and no person will be allowed into any BPH dispensary facility unless said person appears on DOH’s list of individuals allowed to enter a BPH dispensary facility.

Finally, BPH’s written Standard Operating Procedures will ensure that no individual licensee or registered employee of BPH with control over or responsibility for a production center (“PC) or retail dispensing location (“RDL”) shall intentionally or knowingly allow another to enter or remain upon the premises of the PC or RDL, unless the other is permitted to enter and remain therein as specified in HRS §§329D-15(a) and 329D-16(a).

**Access to BPH Production Centers.** BPH will ensure that no person will enter or remain upon the premises of any BPH PC unless said person is: (1) An individual licensee or registered employee of a BPH PC; (2) A government employee or official acting in the person's official capacity; or (3) Previously included on a current DOH-approved list provided to the DOH by BPH of those persons who are allowed into that PC for a specific purpose, including but not limited to construction, maintenance, repairs, legal counsel, or investors; provided that: (A) The person has been individually approved by the DOH to be included on the list; (B) The person is at least twenty-one years of age, as verified by a valid government-issued identification card; (C) The DOH has confirmed that the person has no felony convictions; (D) The person is escorted by an individual licensee or registered employee of BPH at all times while in the PC; (E) The person is only permitted within those portions of the PC as necessary to fulfill the person's purpose for



Application Response: Question 6

entering; (F) The person is only permitted within the PC during the times and for the duration necessary to fulfill the person's purpose for entering.

In addition, each PC shall keep an accurate record of: each person's identity, including first and last name; the date and times upon entering and exiting said PC; the purpose for entering; and the identity of the person's escort.

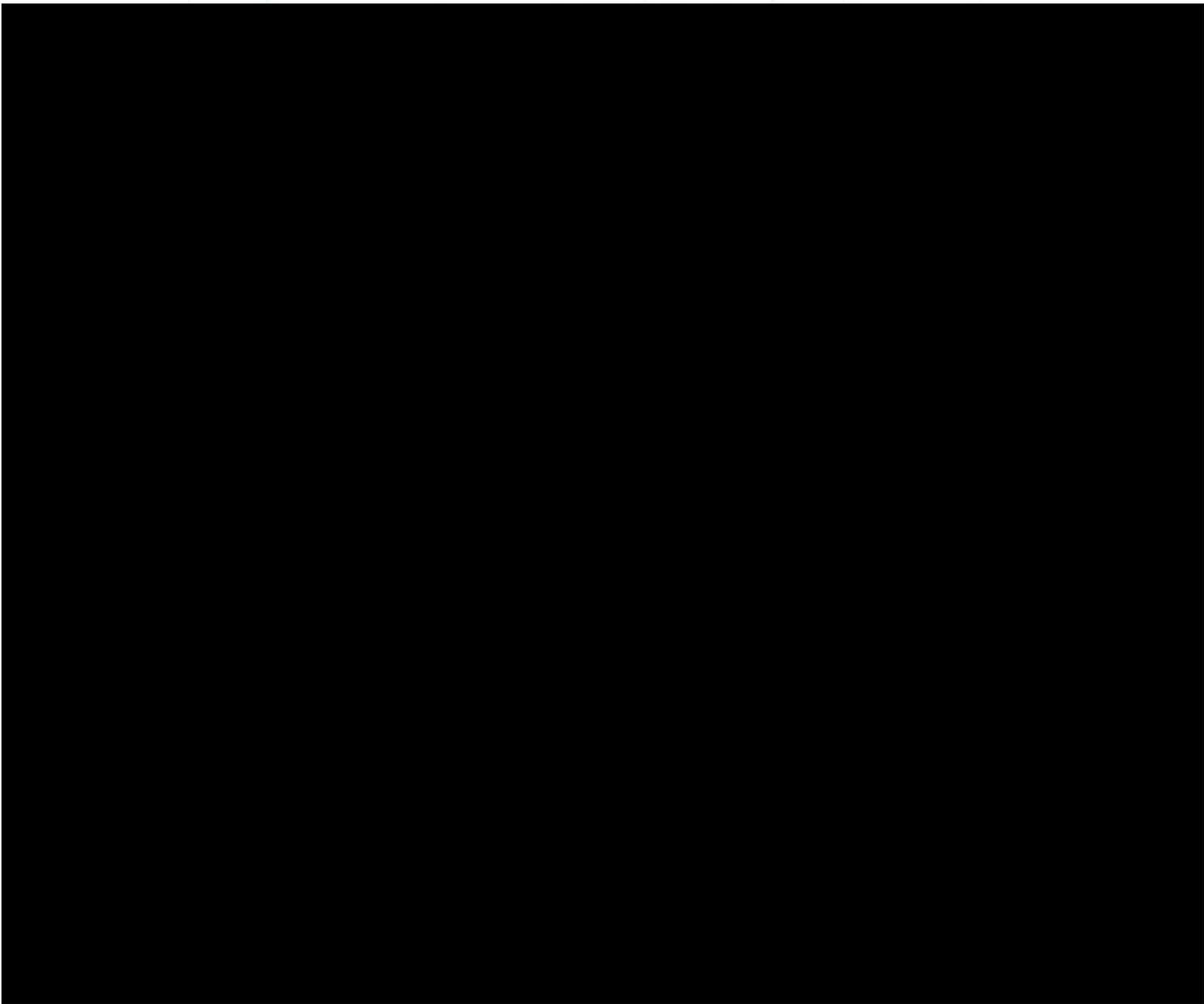
**Access to Retail Dispensary Locations.** BPH will ensure that no person will enter or remain upon the premises of any BPH RDL unless said person is: (1) An individual licensee or registered employee of a BPH RDL; (2) A qualifying patient or primary caregiver of a qualifying patient; (3) A government employee or official acting in the person's official capacity; or (4) Previously included on a current DOH-approved list provided to DOH by BPH of those persons who are allowed into that RDL for a specific purpose for that dispensary, including but not limited to construction, maintenance, repairs, legal counsel, or investors; provided that: (A) The person has been individually approved by DOH to be included on the list; (B) The person is at least twenty-one years of age, as verified by a valid government-issued identification card; (C) DOH has confirmed that the person has no felony convictions; (D) The person is escorted by an individual licensee or registered employee of the RDL at all times while in the RDL; (E) The person is only permitted within those portions of the RDL as necessary to fulfill the person's purpose for entering; (F) The person is only permitted within the RDL during the times and for the duration necessary to fulfill the person's purpose for entering.

In addition, each RDL shall keep an accurate record of: each person's identity, including first and last name; the date and times upon entering and exiting said RDL; the purpose for entering; and the identity of the person's escort and shall maintain records in locked, secure document storage.

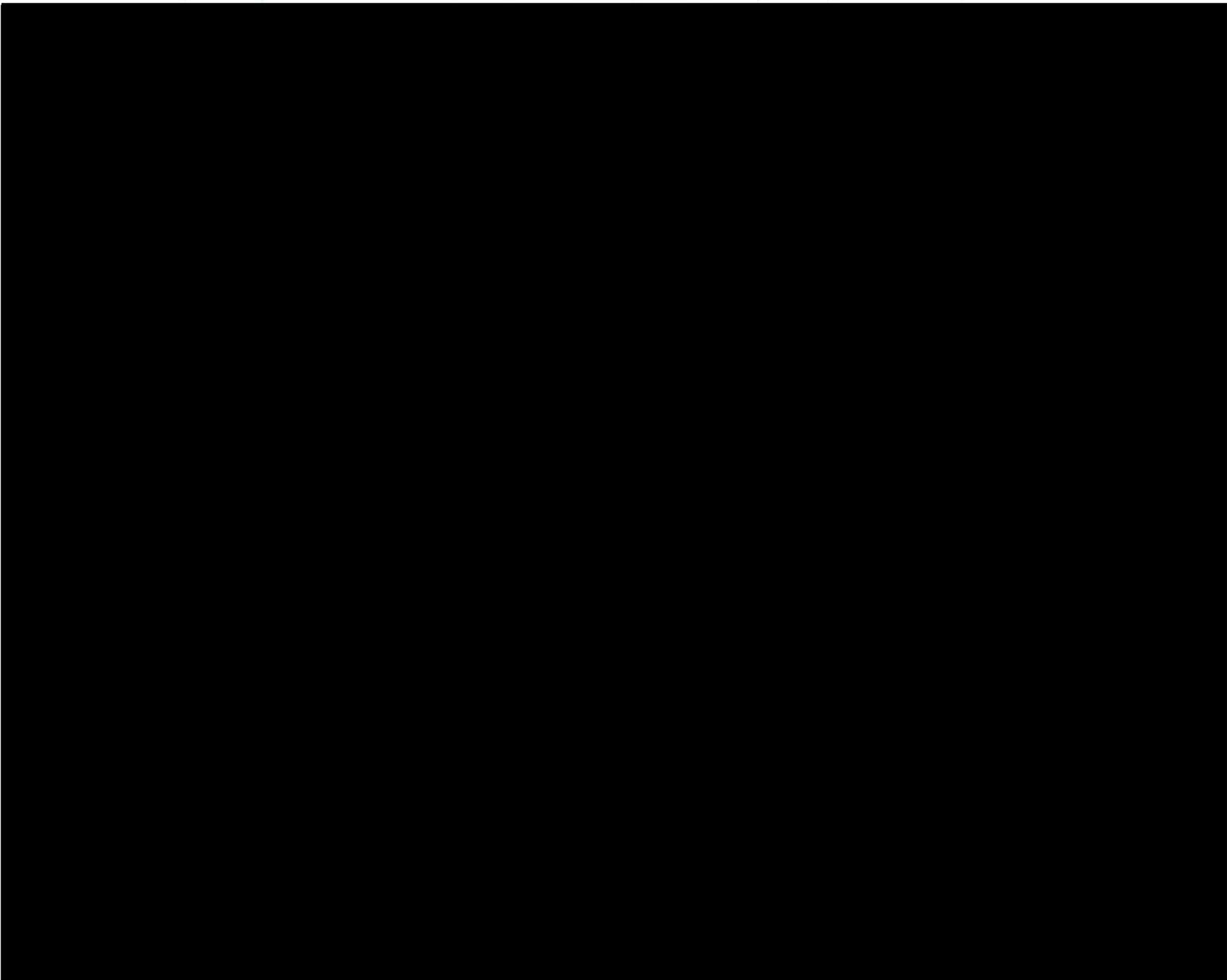
**Attachment 6.1**



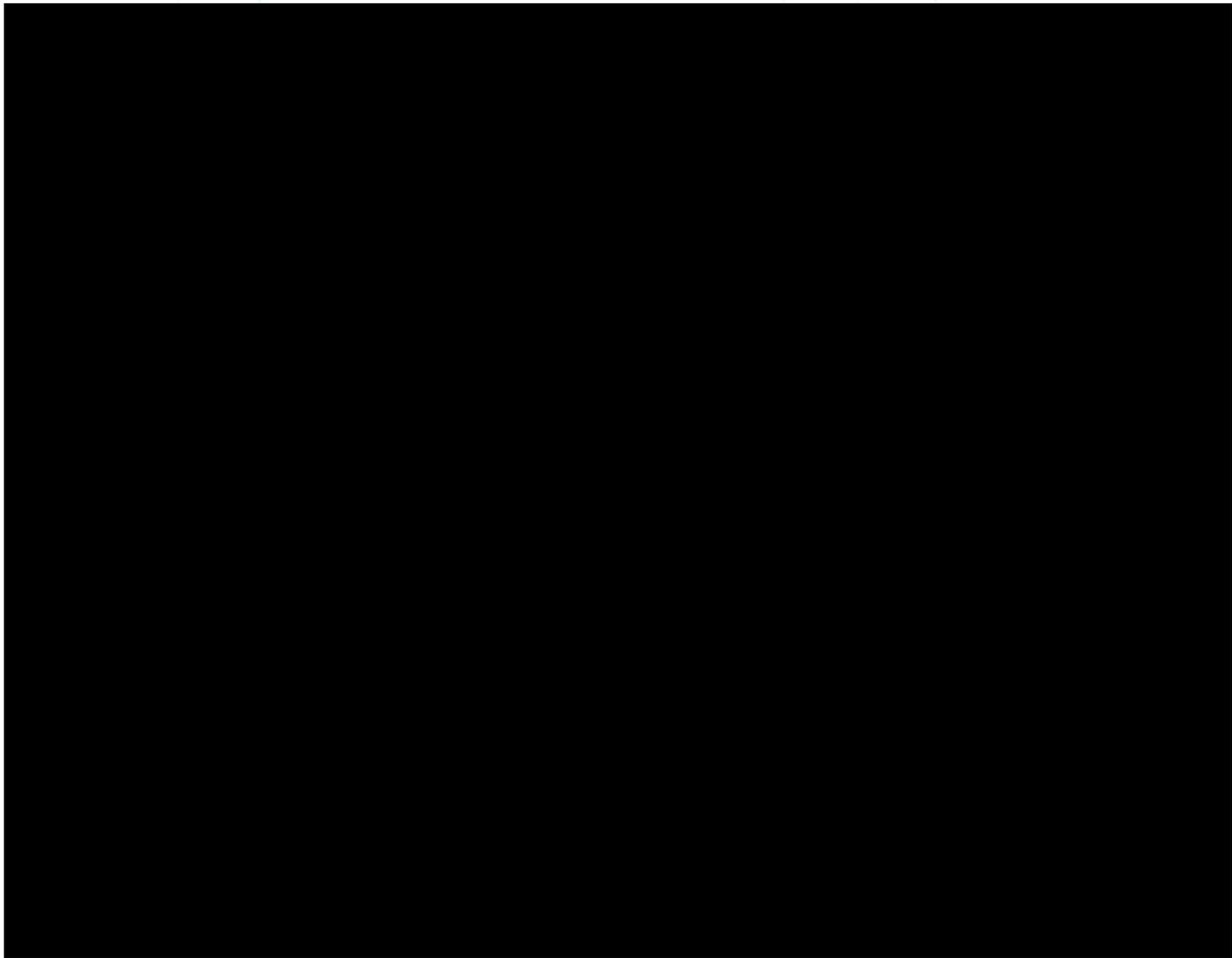
**Attachment 6.1**



**Attachment 6.1**

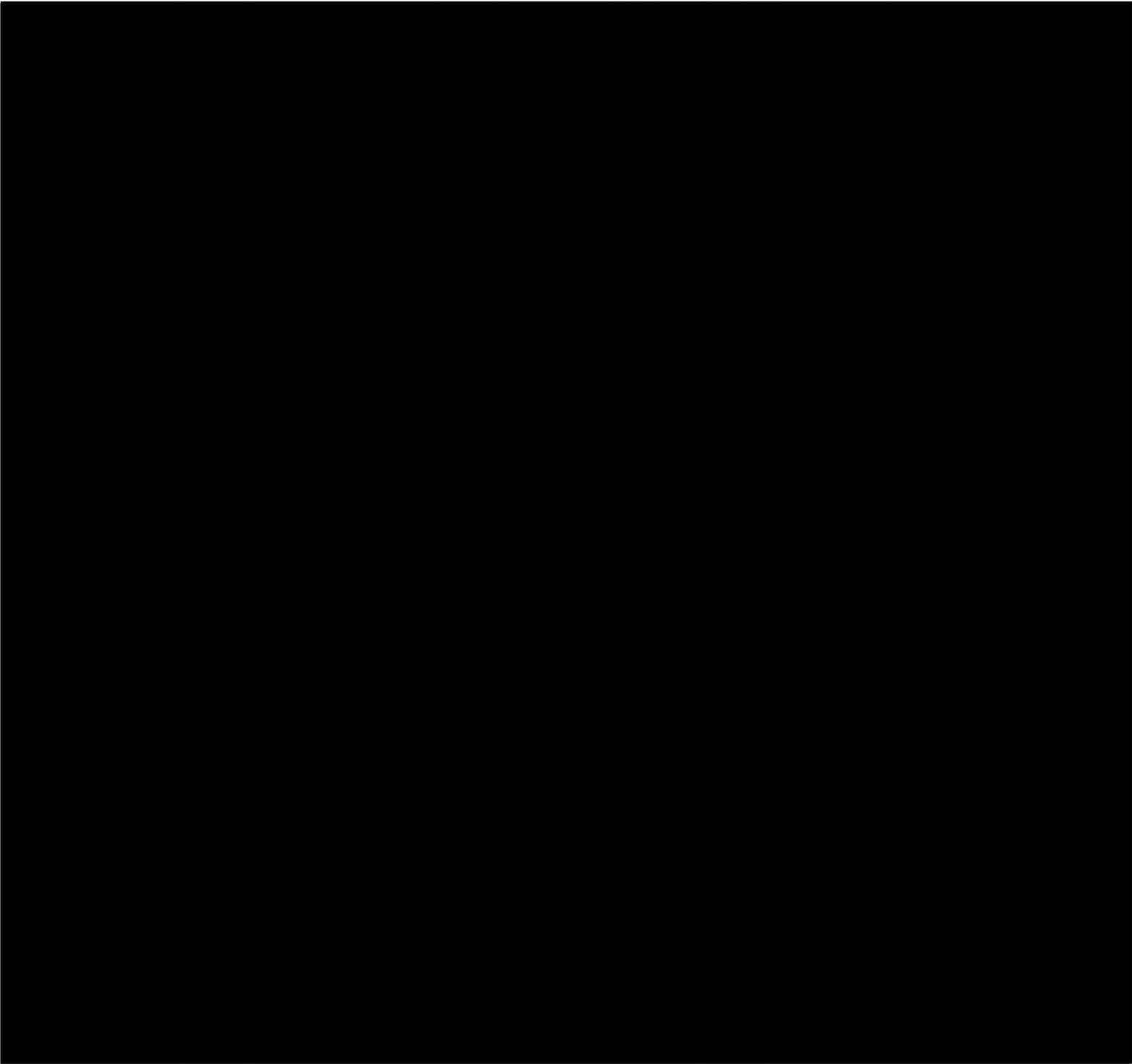


**Attachment 6.1**











## Attachment 6.2

Dear Prospective Participant of Blue Planet Healing, LLC,

As a condition of Blue Planet Healing, LLC (the, "Company") considering: you to provide services to the Company; and in connection therewith providing you access to its Medical Marijuana Production Centers or Retail Dispensing Locations (as those terms are defined in Section 329 D-1 of the Hawaii Revised Statutes) you must acknowledge, represent, and agree to the following:

1) I understand and acknowledge that the Company will be engaged in the manufacture and sale of marijuana and marijuana products and that this activity is illegal under the federal Controlled Substances Act (21 U.S.C. § 801 et. Seq.), and under the laws of the State of Hawaii, except as provided under the Hawaii Revised Statutes § 329-D and Hawaii Administrative Rules § 11-850 and that the violation of these laws can result in the imposition of severe penalties including possible incarceration in a State or Federal facility.

2) I have been advised by the Company, and have been given a full opportunity, to seek the advice and representation of independent legal counsel of my choice regarding the legal ramifications of signing this form, and the attached consent form, and participating in the activities of the Company.

3) I assume all risk associated with my involvement in the activities of the Company and I agree to indemnify, defend and hold harmless the Company, its members, principals, partners, clients, associates, supervisors, employees, directors, shareholders, agents, attorneys, successors and/or assigns from and against any and all losses, costs, fees, liabilities, damages, or injuries suffered by me and arising from my participation in the activities of the Company.

Very Truly Yours,

Blue Planet Healing, LLC

I, the undersigned, hereby acknowledge, represent, agree and consent to all of the above terms.

\_\_\_\_\_  
Name: \_\_\_\_\_

\_\_\_\_\_  
Address: \_\_\_\_\_

\_\_\_\_\_  
Date: \_\_\_\_\_

{00245418.8}

Blue Planet Healing, LLC  
55 Merchant Street, 17th Floor  
Honolulu, Hawaii 96813



# Attachment 6.2

## CONSENT FORM

I, the undersigned, hereby acknowledge, represent, and agree to the following:

1) I am at least twenty-one (21) years old.

2) I have never been convicted of a felony or any other crimes specified in Section 11-850-17(b) of the Hawaii Administrative Rules, including crimes related to the use, possession or distribution of drugs or intoxicating compounds, crimes involving violence or firearms, crimes involving theft, or business or commercial fraud, nor do I have any other background history that would pose a risk to the health, safety or welfare of the public or a qualifying medical marijuana patient.

3) Check one: I  have never been convicted of a crime.

I have been convicted of a crime (provide a detailed explanation below. If needed, attach additional pages hereto).

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4) I hereby consent to any and all background checks, including, but not limited to, eCrim reports and criminal history record checks pursuant to Hawaii Revised Statutes (“HRS”) § 846-2.7, participation in the Rap Back Program, if applicable, and fingerprinting required of me by the Company and/or by the State of Hawaii Department of Health (“Department”) and I agree to pay all applicable processing fees to the Department or its designee to conduct the required background check. I acknowledge that my fingerprints shall be retained by the Hawaii criminal justice data center and the Federal Bureau of Investigation for all purposes and uses authorized for fingerprint submissions.

5) The following identification information is required by the Federal Bureau of Investigations pursuant to HRS § 846-2.7(d)(2);

Date of Birth: \_\_\_\_\_ Place of Birth: \_\_\_\_\_  
Height: \_\_\_\_\_ Hair Color: \_\_\_\_\_  
Weight: \_\_\_\_\_ Gender: \_\_\_\_\_  
Eye Color: \_\_\_\_\_ Race: \_\_\_\_\_

I, the undersigned, hereby acknowledge, represent, agree and consent to all of the above terms.

\_\_\_\_\_  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
Date: \_\_\_\_\_

{00245418.8}

Blue Planet Healing, LLC  
55 Merchant Street, 17th Floor  
Honolulu, Hawaii 96813



### Application Response: Question 7

**Inventory Tracking.** Blue Planet Healing LLC (“BPH”) will ensure compliance with HRS Chapters 329 and 329D and HAR §11-850-61 by utilizing a secure computer system for inventory control, tracking, and as a Point-of-Sale control (“POS”) within each facility. This system will be the control point for “seed-to-sale” tracking, inventory control, monitoring sales limits for qualifying patients, record documentation and retention, and for other various daily activities. BPH intends to deploy BioTrackTHC™ (See “7.7”), Hawai‘i’s state-implemented seed-to-sale tracking solution, which will provide seamless integration and system communication. BioTrackTHC™ is also the system used in five (5) of BPH’s consultant, High Country Healing’s facilities, as well as in many of American Cannabis Company’s client facilities. Deep familiarity with the system will further ensure BPH’s successful deployment and adherence to best-practice procedures.

BioTrackTHC™ will enable BPH to track all marijuana plants, products, and manufactured marijuana products at every stage in all dispensary facilities within the supply chain, which is defined as: the cultivation/manufacturing facility; transportation to third-party labs; and to BPH’s retail dispensary locations. As a redundancy, in the event the electronic system malfunctions, fails to operate or loses records, registered BPH employees will complete physical documentation templates and log sheets for all medical marijuana at every stage of the process. BPH will utilize over 20 different physical documentation log sheets in its operations. BPH’s written SOPs set out every situation that requires a physical log sheet. The log sheets serve as an additional reference point for key points in the chain of custody. (The said Standard Operating Procedures (“SOPs”) and documentation log sheets are attached as “7.1”; “7.2”; “7.3” and “7.4”.)

All marijuana plants and marijuana product tracking will begin when a seed sprouts or a part of a parent plant is removed and a clone is created. At this point, a unique plant Radio-frequency identification (“RFID”) number will be assigned, labeled, and recorded. This RFID



### Application Response: Question 7

number will be used to track the history and data throughout the plant's lifecycle: propagation, vegetation, flower, harvest, dry/cure, processing, and final packaged inventory through retail dispensing to registered patients. At the time of planting, all plants will be accounted for as a batch and assigned a unique batch number that will remain with the batch through final packaging. Each batch number will be a unique numeric or alphanumeric identifier assigned at the cultivation facility when the batch is first planted. All batch numbers will contain the cultivation facility number and a sequence to allow for inventory and traceability. Any removal of plants from the batch will be recorded in the BioTrackTHC™ inventory control system, and the record will be maintained at the cultivation facility. For traceability purposes in the event of a return, adverse event, or product recall, the batch number will be displayed on all approved labels of marijuana product designated for distribution.

Each batch that is cultivated, manufactured, packaged, and labeled during a specified time period according to a single cultivation, manufacturing, packaging, and labeling batch will have a specific, uniform quantity intended to meet specifications for identity, consistency, purity and composition. Batches will consist of plants of the same variety and strain, grown in the same contiguous area, and on the same cultivation time frame. Batches will be used to create BPH's cultivated medical marijuana and manufactured marijuana products. Each plant will be tracked by its physical grid location in the cultivation facility at all times. All significant dates and observations will be recorded in BioTrackTHC™ during the plant's life cycle. These key data points will be available for future reference. This information can be used to easily recall any contaminated marijuana plant, product, material, medium, nutrient, or manufactured marijuana product for any issue or non-compliance that may occur during the stages listed above. During the cultivation process, the physical location of all batches will be separated into a zone/room system.



### Application Response: Question 7

Zones/rooms will have a designated number of cultivation lights and plants and will be planted on a perpetual cycle basis (harvesting equal amounts at equal intervals) to create a consistent, easily managed workflow. In addition, this protocol reduces the amount of on-hand finished product and mitigates diversion risk that can occur with a bumper crop workflow. Finally, this protocol allows for production levels to be adjusted based on market demand. Auditing the inventory of all plants will be effectively and efficiently accomplished with daily spot checks to mitigate diversion during cultivation, processing and/or packaging, and to detect any human error that may have occurred while entering information during the plant's life cycle.

After the flowering cycle has been completed and the plant is harvested, inventory will be transitioned from the flowering zone/room to the processing/manufacturing operations area to create manufactured marijuana products. During this transfer, all products will be scanned, tracked and logged in the electronic BioTrackTHC™ system and on physical log sheets. After being weighed and logged, all flowers will be cleaned, trimmed, and prepared for drying in the secured vault and restricted access area. After drying and curing, each batch will be placed in segregated secure storage and tested per State regulations. Once a batch has passed all regulated testing protocol and the standards set forth by management, it will be released for packaging, labeling and distribution or further manufacturing. Before being transferred, the entire batch will again be weighed, scanned and logged into the POS via a RFID scanner. If the batch is transferred to packaging, it will be packaged into unit sizes and each individual package weighed and reconciled against the total batch weight. Once packaged, all products will be scanned, logged and transferred into the second secure vault designated for any/all approved and packaged products awaiting transfer. If the batch is transferred for further manufacturing it will be retested at two additional points: first after the CO<sub>2</sub> extraction process and again prior to packaging. At each point in the



### Application Response: Question 7

supply chain, any product requiring future testing will be stored in a secure segregated area and not in the finished product vault.

Immediately before transfer to a retail dispensary location, all tested and approved marijuana products and manufactured marijuana products will be scanned and logged into the POS and additionally physically documented on the travel manifest, signed by the initiating employee and his/her manager or individual with equivalent authority. Once arriving at the retail dispensary location, all delivered marijuana products will be inventoried and received by a registered employee; all information will be logged into the POS computer system and store inventory. This process will be witnessed by both the delivering registered employee and the receiving registered employee, with each signing a physical transportation manifest, as well as updating the electronic system. The addition of this physical component is intended to further mitigate diversion risk and create a paper trail that can be reconciled against the BioTrackTHC™ system in case a diversion event does occur or is suspected. The entire process from seed to sale will be recorded on facility security surveillance system and high definition cameras, and all recordings will be stored and retained by BPH.

**Security.** BPH will ensure compliance with all requirements set forth in: HRS Chapter 329D and HAR §11-850-51 relating to required security in all dispensary facilities; HAR §11-850-52 relating to required security in production centers; and HAR §11-850-53 relating to required security in all retail dispensary locations. Detailed security requirements and protocols can be found in BPH's Security Plan, which is attached as "7.5". The security plan details the various security and video alarm equipment and specifications to be utilized in BPH operations.

**Sales Limits for Qualifying Patients.** BPH will ensure compliance with HAR §11-850-42 by utilizing BioTrackTHC™, an inventory tracking system that will ensure registered employees do



Application Response: Question 7

not dispense any marijuana or manufactured marijuana products to registered patients in excess of the limits allowed pursuant to HAR §11-850-42(a). BPH will educate and train all registered employees to ensure the mandatory sales limits are strictly enforced. To wit: BPH may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four (4) ounces of marijuana or its dry weight equivalent during a period of fifteen (15) consecutive days, and shall not exceed eight (8) ounces of marijuana or its dry weight equivalent during a period of thirty (30) consecutive days.

BPH's inventory control system will have the capability to interface with the State inventory control system and other dispensary licensee control systems in order to determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver. BPH will ensure no dispensing of marijuana or manufactured marijuana products to a qualifying patient or primary caregiver of a qualifying patient that exceeds the legal sales limits for qualified patients. Sales limits for qualifying patients are detailed in BPH's written SOPs, which are attached to this application as "7.6".

BPH's consultant, High Country Healing (HCH), has conducted compliant operations under the Colorado regulatory framework for six years without any mishaps or infractions. During this time numerous regulatory adjustments and enhancements have been made which HCH has successfully adapted. Further, BPH's vendor, American Cannabis Company, has significant experience in developing compliant operational practices for clients in new medical marijuana markets and has done so in six US markets and Canada. This combined experience will be critical in ensuring that BPH establishes and follows best practices in compliance with applicable law.



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# STANDARD OPERATING PROCEDURES

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*State Of Hawai'i Production Center—Cultivation Operations*





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**-----STATE REGULATORY COMPLIANCE DISCLOSURE-----**

*Medical cannabis facilities operate in a highly regulated industry, as such adherence to all applicable state and local laws pertaining to the cultivation, production, manufacturing, possessing and dispensing of cannabis and/or cannabis-infused products within the facility is of utmost importance. State and local laws and regulations will vary among states; it is recommended to read and have good understanding of the state and local laws and regulations in which you operate. Having a good understanding of the state and local laws is the first step in being educated on how to operate within regulations, the records and documents needed to be maintained to be in full compliance and to continue operating a cannabis business within a regulated market.*

**-----CONFIDENTIALITY DISCLOSURE-----**

“Confidential Information and Intellectual Properties” means and includes any tangible or intangible information or material that is confidential or proprietary to Consultant that Client may obtain knowledge of through, or as a result of, its relationship with Consultant. Such information shall be deemed Consultant’s Confidential Information and Intellectual Properties whether or not owned or developed by Consultant. Confidential Information and Intellectual Properties shall also include, but is not limited to, any inventions, processes, designs, formulae, trade secrets, Standard Operating Procedures, know-how, confidential information, trademarks, copyrights, service marks, domain names, computer software, data and documentation, and all similar intellectual property.

Ownership. All Confidential Information and Intellectual Properties owned, developed or acquired by Consultant or Confidential Information and Intellectual Properties developed or acquired (hereafter, "Existing Consultant IP") shall be owned by the Consultant.

Client understands that all such Existing Consultant IP, including all Standard Operating Procedures shall remain the sole property of Consultant, and Client agrees that neither it, nor any of its officers, directors, employees, consultants, affiliates or anyone acting in concert with Client will: (i) acquire any ownership interest in any Existing Consultant IP; and (ii) will not, convey, sell, publicize, use, trade, distribute any Existing Consultant IP to any other person or business, or take or modify Existing Consultant IP in order to convey, sell or distribute to any other individual or business not a party to this Agreement, that results in competition with the consulting services offered by Consultant, or interferes with any existing or prospective business advantage Consultant may have. No other license to any Existing Consultant IP is granted or implied by this Agreement.



<b>Standard Operating Procedure:</b> Standard Operating Procedures
<b>Purpose:</b> To explain the standard operating procedures needed to be adhered to within the Licensed Premise
<b>Scope:</b> To cover the education and training required pertaining to the standard operating procedures utilized within the Licensed Premise.
<b>Initial Training:</b> TBD

**Definitions**

**Standard Operating Procedure (SOP)**—a set of step-by-step instructions to achieve a predictable, standardized, desired result often within the context of a longer overall process. At its simplest, an SOP is a repeated application of unchanged processes and procedures and its documentation. These SOP’s are to be followed as directed and not deviated for the cultivation of marijuana within any Blue Planet Healing LLC (BPH) registered production centers.

**Material Change**—a material change is defined as a major deviation from the standard procedure, or changing the procedure or methodology drastically enough to notice a change. The material change is important enough to notice or to have an effect on the standard operating procedure.

**Principles of Standard Operating Procedures**

The cultivation of marijuana can be difficult for the rudimentary gardener. American Cannabis Company’s (ACC) Standard Operating Procedures (SOP’s) insure consistent production of high quality medical marijuana. BPH will utilize said SOP’s for all marijuana cultivation methodologies and operations. Understanding and abiding by the following SOP’s is mandatory for all registered employees working within BPH’s registered dispensary facilities.

The standard operating procedures must be practiced and utilized to cultivate each plant and to produce each batch of marijuana. The strict adherence to the written SOP’s will aid in BPH’s quality control program and measures. The written SOP’s have been developed within a regulated marijuana industry with the purpose of creating systems and procedures that result in a consistent and reproducible marijuana product. The cultivation process is broken down into each week of the plant’s lifecycle. Apply the following SOP instructions to the lifecycle of each plant in the facility. Do not deviate from exact instruction within these standard operating procedures.

- Failure to practice and utilize BPH’s written standard operating procedures is grounds for disciplinary action and possible job termination.

Written standard operating procedures will be utilized for all cultivation activities and operations, for the cultivation of all marijuana plants to ensure consistency of the batch with the variety and for accuracy of the day-to-day production. The written standard operating procedures will ensure consistency of batch and accuracy of day-to-day production if utilized properly and not deviated from.

- Registered employees will be required to record and maintain documentation log sheets and forms to record the cultivation process
  - Required documentation and record keeping is highlighted throughout the SOP’s and indicates which documentation log sheets and records are to be taken and maintained.
    - Registered employees will need to pay careful attention to each standard operating procedure to ensure proper documentation and record keeping
      - The documentation should demonstrate consistency of batch with the medical marijuana variety being cultivated
      - The documentation should also demonstrate the accuracy of the day-to-day production within the Licensed Premise.
- Any major deviation from the standard operating procedure defined as a material change that could impact the quality of batch must be documented, recorded and maintained on the Licensed Premise
  - Registered employees are required to document any major deviation in production of a batch from the standard operating procedure



**Deviation/Material Change to Standard Operating Procedures**

Upon recognizing the need for or making a material change to a standard operating procedure, registered employees will be required to document the material change within the *Material Change to SOP's* log sheet and update the current SOP to reflect the material change.

<b><u>Deviation/Material Change to SOP's</u></b>		
<b>Date:</b>	<b>Registered Employee:</b>	<b>Deviation in Production:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Reason for the deviation</b> ( <i>identify and describe in detail the deviation from the SOP</i> ):		
<b>SOP requiring material change:</b>		
<b>Material Change made to the SOP</b> ( <i>please describe in detail</i> ):		
<b>SOP Updated?</b> <input type="checkbox"/> YES	<b>Date Updated:</b>	<b>Update By:</b>
<b>Manager/Supervisor Awareness and Approval:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Manager/Supervisor Signature:</b>	
<b>Sample of production batch with deviation sent to independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO		<b>Sample of production batch with deviation determined to meet specifications for the variety by BPH and the independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Medical Cannabis Batch Released for Distribution?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO		<b>Additional Notes/Comments:</b>
<i>After documentation of a material change to a standard operating procedure, registered employees will be required to maintain the record of material change within a limit-access and secured area of the Licensed Premise.</i>		

**Deviations in Production—Independent Laboratory Testing**

Per State of Hawai'i regulations, BPH will not release any batch of marijuana or manufactured marijuana products if there was any deviation in production from the batch from the standard operating procedure. All medical marijuana will need to be securely held and stored until:

- The sample from the batch of marijuana and/or manufactured marijuana product with any deviation in production is sent to an independent testing laboratory for testing
  - The marijuana will not be released for distribution until after an independent testing laboratory and BPH determines, as a result of testing, that the batch meets the specifications for the variety and the determination is recorded.
- Follow *Samples for Laboratory Testing* and the *Transferring/Transporting and Shipping Medical Marijuana* standard operating procedures for procedures and requirements pertaining to laboratory testing and transport.
  - Ensure to follow Sampled for Laboratory Testing
    - Fill out and record all required documentation log sheets
      - Fill out *Material Change Samples for Laboratory Testing* log sheet (*can be seen below*)

<b><u>Material Change Samples for Laboratory Testing</u></b>					
<b>Date:</b>	<b>Employee:</b>	<b>Attribute ID #/Product Batch #/Strain:</b>	<b>Sample Quantity:</b>	<b>Sample Attribute ID # (NEW):</b>	<b>Receiving Laboratory:</b>



State Regulatory Compliance

<b>Standard Operating Procedure:</b> State Regulatory Compliance Training
<b>Purpose:</b> To explain the regulatory compliance needed to be adhered to in the State of Hawai'i.
<b>Scope:</b> To cover the regulations enacted within Hawaii pertaining to legally operating a marijuana business.
<b>Initial Training:</b> training done on individual time

**Required Documents**

- 1) State Regulations
- 2) Local/City Regulations (*if applicable*)

**The Principles of State Regulatory Compliance Training**

BPH will require all registered employees to read and become familiar with the State and Local/City regulations that have been enacted pertaining to operating a legal, licensed marijuana business.

BPH will keep a physical, up-to-date copy of any and all laws and regulation in which you must operate under at every licensed facility. Every registered employee will receive a hard copy of the laws and regulation which they can read and become familiar with.

Key State Regulations Employees Should be Familiar With:

- Who can have access to the facility
  - Visitor process
- Packaging and labeling compliances and requirements
- Allowed purchase amounts (quantities and distribution timeframe)
- Hours of allowed operation
- Inventory tracking and required record keeping
- Security procedures and protocols
- Laboratory testing requirements
- Transportation of marijuana products
- Etc.

**State of Hawaii**

- <http://health.hawaii.gov/medicalmarijuana/>



Record Keeping and Documentation

**Standard Operating Procedure: Record Keeping and Documentation**

**Purpose:** To ensure that all required marijuana cultivation records and data are properly recorded and documented. Including zone/room environments, transplant logs, IPM applications, inventory, etc.

**Scope:** Procedures covering record keeping and documentation for activities within the production center

**Initial Training:** 4-8 hours

**What is the Purpose of Record Keeping and Documentation?**

Marijuana cultivation facilities operate in a highly regulated industry, as such proper record keeping and documentation are essential within the cultivation facility. Having records of crop inputs such as growing media records and pesticide applications will aid during the cultivation process to ensure proper feedings occur and that plants are not treated with chemicals more than absolutely necessary.

**Equipment/Tools Required**

- 1) Pen or pencil
- 2) Clipboard
- 3) Log Sheets

**Principles of Record Keeping and Documentation**

Adherence to all applicable state and local laws pertaining to the cultivation of marijuana within the production center facility is of utmost importance. State and local laws and regulations will vary among states; having a good understanding of the state and local laws is the first step in being educated on the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within Hawai'i's regulated market.

Required records and documentation are noted throughout the written Standard Operating Procedures; BPH's registered employees will be required to make such records and documentation as part of their job responsibilities. Registered employees will be required to make two sets of all records and documentation; one set of records and documentation will be made within the BioTrackTHC™ inventory control system, and a second set of records and documentation will be made using physical log sheets and templates. The physical records and documentation will be maintained on at the production center within a limited access area. Failure to create and maintain records and documentation will be grounds for disciplinary action and/or job termination.

Record Keeping and documentation are noted within other SOP's where documentation is required. The SOP's will also reference which documentation records and log sheets are required to be filled out and maintained.

**Cultivation Licensed Premise Records:**

- Propagation Log
- Transplant Log
- Nutrients, Supplements and Growth Additives
- Daily Environment Documentation
- Plant Monitoring—inventory
- POS Inventory
- Inventory Reconciliation
- Daily Marijuana Products Transfer/Shipping Log
- Pest and Disease Identification
- Pesticide/Fungicide Application
- Harvested Marijuana Log
- Marijuana Waste Log
- Finished Marijuana Log

- Cleaning and Sanitation Log
- Product Recall Log
- Returned Marijuana Log
- Employee List
- Visitor Documentation Log
- Etc.

### **Secondary Records**

BPH will maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution. BPH will require registered employees to maintain secondary records on the Licensed Premise. The physical records and documentation log sheets will serve as secondary, back-up records and documentation that will be maintained independent of the inventory control system.

Per Hawaii regulations, records required to be maintained separate of the inventory control system:

- **Records of Each Distribution**
  - Records of distribution must include:
    - The name and address of the recipient retail dispensary location
    - The quantity delivered
    - The name, strength, batch number of the product
    - The date and time of distribution

### **Requirements of Secondary Records:**

- Records must be maintained independent of the inventory control system
  - Physical records will be maintained within a file cabinet, separate from the inventory control system
- Records must be searchable
  - Records will be organized and filed alphabetically according to recipient name
- Records must be secure
  - Records will be maintained within the Licensed Premise, located within a limited-access area inside a manager office equipped with an independent security alarm system. The records will be held within a lockable filing cabinet inside the secure office.
- Records must be tamper-evident
  - The file cabinet where secondary records are to be maintained will have a secure, tamper-evident locking mechanism on it.

**Records and Documents Storage Retention**—Unless otherwise specified, BPH will retain and maintain all records and duplicate sets of records for a minimum of six (6) years.

### **Duplicate Records and Off-Site Storage**

BPH will maintain duplicate sets of all records required by regulation. These duplicate copies of BPH records will be maintained at a secure, off-site location. This location will only be disclosed to personnel with proper security clearance. The off-site record storage will be secured with a security alarm and surveillance system to ensure access is limited to authorized personnel only. BPH will maintain duplicate copies of all records at a secure storage facility within Hawaii.

**Reports**—BPH can generate a list of the products and their specifications that have been offered for distribution. These reports are to be provided to the Department upon request.

- Reports can be created through the BioTrackTHC™ inventory control system
  - Within the inventory control system, BPH will be able to generate a list of all the products along with their specifications that were offered for distribution
  - This list can be generated for all products offered within specific date ranges



General Security/Diversion Prevention Training

<b>Standard Operating Procedure:</b> General Security/Diversion Prevention Training
<b>Purpose:</b> To explain the general security and diversion prevention training needed to be adhered to.
<b>Scope:</b> To understand security and diversion prevention training requirements.
<b>Initial Training:</b> 4-8 hours

**Diversion and Trafficking Prevention Training**

Diversion and trafficking prevention will primarily be done using the various security alarm and surveillance equipment installed and utilized at BPH’s production facility. The various security alarm and surveillance equipment utilized is explained in more detail within the Security Plan which is a separate, additional document that can be viewed upon request. All BPH registered employees will be trained on all security equipment, measures and policies prior to commencing work within the production center.

BPH will utilize BioTrackTHC’s inventory control system and industry best practices and policies to reduce the risk of diversion and theft of marijuana products. All marijuana plants will be tagged, recorded and tracked through the inventory control system from seed-to-sale.

The use of professional security systems from Securitas that will be installed at all of organization facilities will also help to reduce the risk to diversion, loss, theft or unauthorized access.

If any marijuana or manufactured marijuana product loss or discrepancy noticed by a registered employee, management shall be made aware of the loss immediately. Inventory discrepancies should be easily noticeable with the use of the inventory control system. The diversion or product loss must be documented on the **Product Loss** log sheet which can be seen below.

<b><u>Product Loss Log Sheet</u></b>				
<b><u>Date:</u></b>	<b><u>Product Name/Category</u></b>	<b><u>Product Attribute # or Unique ID #</u></b>	<b><u>Total Quantity</u></b> <b><u>Loss:</u></b>	<b><u>Product Loss</u></b> <b><u>Valuation:</u></b>
				\$
<b><u>Reporting</u></b> <b><u>Employee:</u></b>	<b><u>Manager/Supervisor:</u></b>	<b><u>Product Loss Due To:</u></b>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<b><u>Internal</u></b> <b><u>Investigation:</u></b>	<b><u>Required Authorities</u></b> <b><u>Notified:</u></b>	<b><u>Authorities Notified (list all) :</u></b>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<b><u>Note/Comments:</u></b>				

### **Video Surveillance System.**

Securitas will design video surveillance systems at BPH's retail dispensary facilities that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

### **Alarm System.**

Each retail dispensary location operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

### **System Failure.**

In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

### **Other Security Measures.**

All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH- approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

### **Production Center Specific Security Measures.**

In addition to all the above mentioned and all other security measures required by HRS Chapter 329D and HAR Chapter 11-850, BPH will utilize a perimeter security fence around each PC that surrounds the entire premise sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any marijuana in any form as required by HAR §1185052 (1). In addition, BPH will secure all marijuana and manufactured marijuana products in a locked room, vault or container which is securely fixed to a wall or the floor to ensure product safety and to prevent theft.

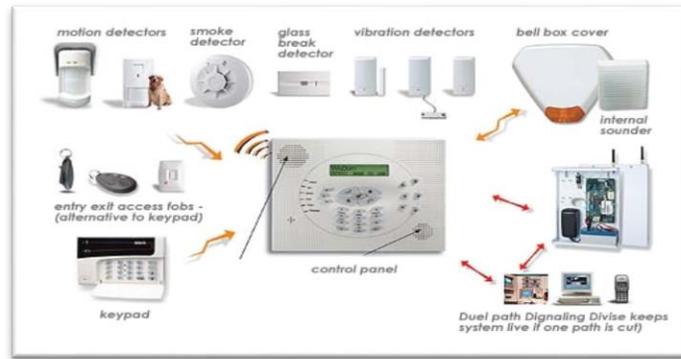
### **Transportation Security.**

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees. 3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH's tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be



packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

**Alarm Surveillance**—a primary alarm system will be installed at all BPH registered dispensary facilities by Securitas, a licensed alarm company, with an advanced security alarm system on all perimeter entry points, perimeter windows, and secured interior rooms. Motion detection equipment and camera equipment will be used to ensure the entire facility(s) is continuously safe from intrusion and product diversion.



**Video Surveillance**—an advanced video surveillance and recording system at all BPH facilities. All cameras will record in digital format and be maintained to meet the requirements outlined by State and local regulations. Video cameras will be maintained in each room and be used to identify any activity occurring within the room and be capable of recording and viewing in low light conditions. An onsite DVR and an additional offsite DVR will be utilized to store all footage; all video surveillance recording will be stored for a minimum of one year.



**Security Lighting**—security lighting around the entire perimeter of the production center to allow surveillance in low light conditions and deter potential intrusion.





**Motion Detector Alarms**—the professional security alarm system will utilize motion detectors that will detect intrusion and will automatically notify the proper authorities.



**Duress Alarms**—the security and alarm systems will utilize a duress alarm button on the alarm panels that can be pushed by employees in the case of an emergency. Different duress alarm buttons can be pushed to automatically notify the proper authority; police, fire or emergency services.



**On-Site Electronic Monitoring**—facility security rooms will have a large screen call-up monitor (at least 19”) and a video printer capable of immediately producing a clear still photo from all video cameras.



**Commercial Grade Door Locks**—commercial-grade, non-residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas. Key-card access door locks may also be utilized to further limit access at facilities.



**Safes and Product Storage**—Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana products and cash.



<b>Standard Operating Procedure:</b> Perpetual Inventory Control System
<b>Purpose:</b> To explain the principles and concepts of the perpetual inventory control system
<b>Scope:</b> To educate and train registered employees and licensed premise employees on the perpetual inventory control system
<b>Initial Training:</b> TBD

**Principles of the Perpetual Inventory Control System**

BPH will utilize a perpetual inventory system from a regulated marijuana industry-specific inventory system provider, BioTrackTHC™. This inventory control system has been developed specifically for the regulated marijuana industry and has been customized to include all marijuana business operational needs. The systems have been designed to be user friendly, the ability to be mobile, and with inventory control capabilities to track every medical marijuana plant and product from seed to sale.

The inventory control system will be designed to have the ability to promptly identify a discrepancy in stocks of marijuana plants and products. BPH administrators of the system will be notified of a substantial reduction in an inventory stock level and be prompted to investigate the inventory levels to ensure no theft, diversion or discrepancies occurred. Administrators and users can run inventory reports from the inventory control system to check inventory stock levels that have been recorded in the inventory control system against a physical inventory audit to further determine inventory discrepancies.

**Inventory Control /POS System**—the tracking of all medical marijuana products from seed to sale will be done through inventory management through the use of template log sheets, computer systems, Secure Information Systems (SIS) and selected Point-of-Sale systems (POS). All medical marijuana plants and products are to be tagged, recorded and tracked through the inventory control system. Failure to do so can result in disciplinary action and/or job termination.



*\*Inventory control system and/or Point-of-Sale (POS) system training will be provided by an expert or consultant from the inventory control system supplier, BioTrackTHC™. This 3<sup>rd</sup> party training will be required for all BPH registered employees prior to working within the production center.*

Registered employees will be required to utilize the inventory control system to identify, record, monitor and track all medical marijuana plants and products from the time the medical marijuana is propagated from seed or cutting to the time it is delivered to a licensed dispensary, licensed processor or a qualifying patient or caregiver. The standard operating procedures detail multiple situations when plant tagging, monitoring and recording activities are required by registered employees within the production center.



Marijuana plants will be given a unique attribute number, assigned to a production batch and recorded in the inventory control system. The plant will then be given a new and unique plant tag with the plants identification and specifications and be recorded in the inventory control system, the tag will remain with the plant throughout the plants lifecycle enabling the plant to be identified and tracked.

The inventory control system intended to be utilized within BPH's production center will in the event of a serious adverse event have the ability to track any marijuana plant or product back to the originating source, including the ability of tracking marijuana from a qualifying patient back to the source of the marijuana. The marijuana believed to have caused a serious adverse event should have a product label with product information and specifications such as the product name, unique attribute number, batch number and originating entity. With this information, the marijuana product will be able to be traced back to the originating source of the medical marijuana.



OSHA Compliance

<b>Standard Operating Procedure:</b> OSHA Compliance and Training
<b>Purpose:</b> To explain the principles and concepts of OSHA regulations.
<b>Scope:</b> To understand OSHA requirements to create a safe work environment.
<b>Initial Training:</b> 4-6 hours

### OSHA Training

Registered employees have the right to a safe workplace, and BPH intends to provide a safe work environment for all registered employees at all BPH facilities. The Occupational Safety and Health Act of 1970 (OSH Act) was passed into law as a preventative measure for workers from being killed or seriously harmed while at work. The law requires employers to provide employees with working conditions that are free from known dangers.

The OSH Act created the Occupational Safety and Health Administration (OSHA). This regulatory agency sets and enforces protective workplace safety and health standards. OSHA is also charged with providing information, training and assistance to workers and employers to educate and train individuals on workplace safety. Employees may file a complaint if they feel necessary which will result in OSHA to inspect the workplace if they feel OSHA standards are not being met or that there may be serious hazards or danger. More information on the Occupational Safety and Health Administration can be found online at the website: <https://www.osha.gov/>.

**OSHA's Mission**—With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

**OSHA Training**—The OSHA Outreach Training Program for General Industry provides training for workers and employers on the recognition, avoidance, abatement, and prevention of safety and health hazards and dangers in workplaces in general industry. This program also provides information regarding workers' rights, employer responsibilities, and how to file a complaint. Employees can attend a 10-hour or 30-hour class delivered by OSHA-authorized trainers. The 10-hour class is intended for entry level workers, while the 30-hour class is more appropriate for supervisors or workers with some safety responsibility. OSHA training helps to ensure that workers are more knowledgeable about workplace hazards, dangers and their rights.

Under the OSH Law, employers have a responsibility to provide a safe workplace free from known hazards or dangers. The OSHA website provides a short summary of employer responsibilities with which BPH will ensure compliance.

- Provide a workplace free from serious recognized hazards and comply with standards, rules and regulations issued under the OSH Act.
- Examine workplace conditions to make sure they conform to applicable OSHA standards.
- Make sure employees have and use safe tools and equipment and properly maintain this equipment.
- Use color codes, posters, labels or signs to warn employees of potential hazards.
- Establish or update operating procedures and communicate them so that employees follow safety and health requirements.
- Employers must provide safety training in a language and vocabulary workers can understand.
- Employers with hazardous chemicals in the workplace must develop and implement a written hazard communication program and train employees on the hazards they are exposed to and proper precautions (and a copy of safety data sheets must be readily available). See the OSHA page on Hazard Communication.
- Provide medical examinations and training when required by OSHA standards.
- Post, at a prominent location within the workplace, the OSHA poster (or the state-plan equivalent) informing employees of their rights and responsibilities.
- Report to the nearest OSHA office all work-related fatalities within 8 hours, and all work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours. Call our toll-free number: 1-800-321-OSHA (6742); TTY 1-877-889-5627. [Employers under federal OSHA's jurisdiction were required to



begin reporting by Jan. 1, 2015. Establishments in a state with a state-run OSHA program should contact their state plan for the implementation date].

- Keep records of work-related injuries and illnesses. (Note: Employers with 10 or fewer employees and employers in certain low-hazard industries are exempt from this requirement.)
- Provide employees, former employees and their representative's access to the Log of Work-Related Injuries and Illnesses (OSHA Form 300). On February 1, and for three months, covered employers must post the summary of the OSHA log of injuries and illnesses (OSHA Form 300A).
- Provide access to employee medical records and exposure records to employees or their authorized representatives.
- Provide to the OSHA compliance officer the names of authorized employee representatives who may be asked to accompany the compliance officer during an inspection.
- Not discriminate against employees who exercise their rights under the Act. See our "Whistleblower Protection" webpage.
- Post OSHA citations at or near the work area involved. Each citation must remain posted until the violation has been corrected, or for three working days, whichever is longer. Post abatement verification documents or tags.
- Correct cited violations by the deadline set in the OSHA citation and submit required abatement verification documentation.
- OSHA encourages all employers to adopt an Injury and Illness Prevention Program. Injury and Illness Prevention Programs, known by a variety of names, are universal interventions that can substantially reduce the number and severity of workplace injuries and alleviate the associated financial burdens on U.S. workplaces. Many states have requirements or voluntary guidelines for workplace Injury and Illness Prevention Programs. Also, numerous employers in the United States already manage safety using Injury and Illness Prevention Programs, and we believe that all employers can and should do the same. Most successful Injury and Illness Prevention Programs are based on a common set of key elements. These include: management leadership, worker participation, hazard identification, hazard prevention and control, education and training, and program evaluation and improvement. OSHA's Injury and Illness Prevention Programs topics page contains more information including examples of programs and systems that have reduced workplace injuries and illnesses.

### **Plan for OSHA Compliance**

Below details BPH's plan for compliance with OSHA will begin by ensuring that all organizational facilities are free from known hazards and/or dangers. Although OSHA is a federal organization and we are not currently held to OSHA standards, BPH feels it is best practices to be aware of OSHA guidelines and adhere to said guideline within our operations.

All registered employees will be provided basic training covering workplace safety pertaining to identifying and preventing potential hazards and or dangers such as trip hazards. This basic training will begin with training all new employees on policies and procedures. Proper and adequate training can help to reduce workplace accidents through educating and training employees on operations, policies and procedures. Employees will be given a tour of the facility property and areas in which the employee will have access to (limited or restricted). Other training to be included in BPH's plan for OSHA compliance will include:

- Training on SOP's
- Regulatory compliance training (laws and regulations pertaining to medical marijuana cultivation, processing or dispensing)
- Basic training on workplace safety
- Recognition of potential workplace hazards or dangers



Cultivation Methodology

<b>Standard Operating Procedure:</b> Cultivation Methodology
<b>Purpose:</b> To determine and understand the cultivation techniques and methodologies to be implemented in the production center.
<b>Scope:</b> To determine the growing methodology ( <i>soil, hydro, coco, etc.</i> ) and types of equipment and systems to be implemented and utilized
<b>Initial Training:</b> TBD

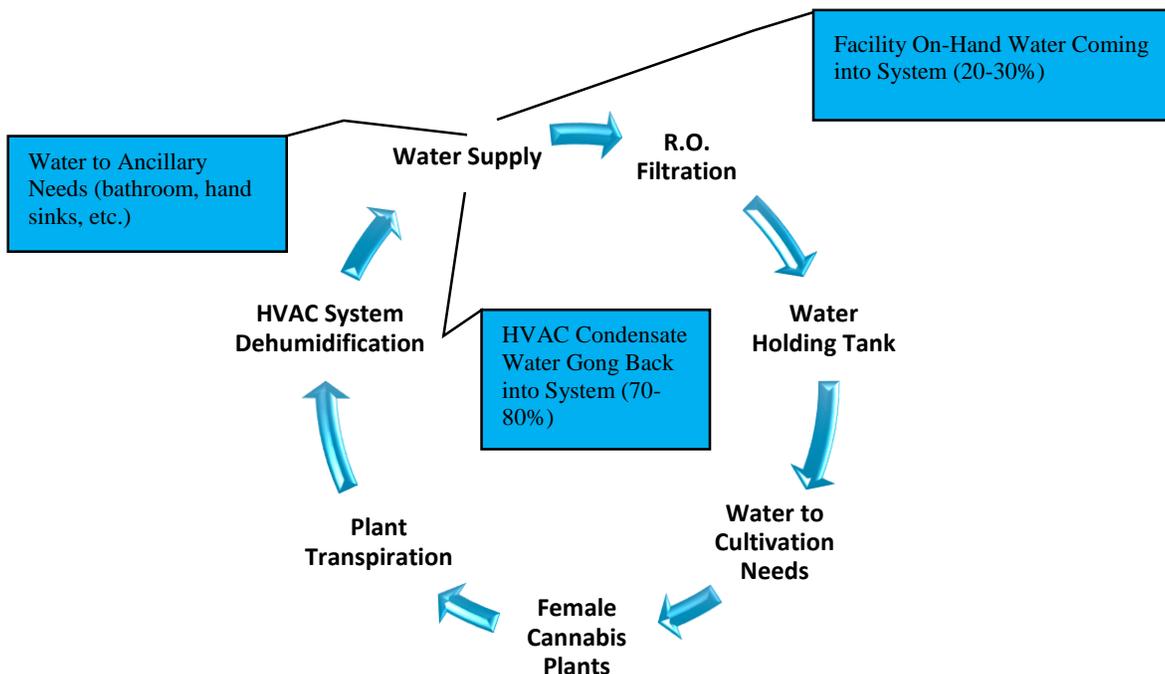
### The Principles of Cultivation Methodology

There are multiple cultivation techniques and methodologies pertaining to marijuana cultivation; ACC utilizes organic cultivation techniques and methodologies encompassing a bio-dynamic super soil, SoHum Living Soil, automated, gravity-fed watering systems from AutoPot, and roll-top benches or moveable palletized racking for increased production capacity and increased efficiency.

### Water Quality

**Water Quality Test(s)**—BPH will perform water quality tests on facility water every six (6) months at a minimum. A water sample from the cultivation facility will be sent to a water testing laboratory where an analysis of the water will be performed to determine what, if any, substances are in the water. A record of all water quality tests will be maintained on-site at the licensed premise within a file labeled “Water Quality Tests”. Water quality tests and records will be made available for inspection to the Commission upon request.

**Reverse Osmosis of Water (RO System)**—all water utilized for cultivation operations will be run through a state-of-the-art Reverse Osmosis (RO) water filtration system to ensure all contaminants have been removed from the water. The RO system will be designed according to the water quality test that will be performed at the facility as well as the RO system being designed to be able to adequately purify and supply the proper amounts of water for daily operations.





### **Growing Medium**—biodynamic soil

SoHum Living Soil is a fully-amended bio-dynamic potting mix which simplifies the growing process while maximizing yields and producing consistent quality. SoHum is a growing medium that is biodynamic, a potting mix developed to optimize the marijuana plants’ maximum genetic potential. In marijuana cultivation, the term “biodynamic” applies to the understanding that soil directly impacts plant development and emphasizes a natural approach to growing that focuses on the micro life in the soil.



- *More information on SoHum Living Soils can be viewed within the **Growing Media SOP***

### **Growing Containers/Watering System**

ACC utilizes an automated watering system and plant containers from AutoPot Automated Irrigation System. The AutoPot systems use a gravity-based irrigation network that stems from a refillable water reservoir to the individual pots. The system prevents over-watering and operator error, and requires no power supplies, water pumps or timers. AutoPots were designed to maximize the crop and save water.

The system is expandable to grow with operational needs; pot modules and additional tanks can be easily added to the watering network. When used in conjunction with complementary products like SoHum Living Soil, AutoPot Automated Irrigation System can be one of the building blocks of a completely organic grow system.

#### **Benefits of AutoPot Automated Irrigation System:**

- An energy-efficient component of a lean manufacturing system, the AutoPot system offers a number of advantages over other irrigation products:
- Delivers exactly the amount of water your plants need
- Eliminates the need for daily moisture monitoring
- Eliminates the need to manually water multiple times per week
- Requires no electricity
- Produces no leaking, runoff or other water waste
- Is readily scalable to your grow operation
- Increases plant growth by 40%

*\*Please see the **AutoPot SOP** for more information on set-up and maintenance on AutoPots.*

### **Roll-Top Benches**

Roll-top benches are utilized as a way to maximize facility cubic footage working space and allows the plants to be elevated off the ground increasing workflow efficiency and effectiveness.



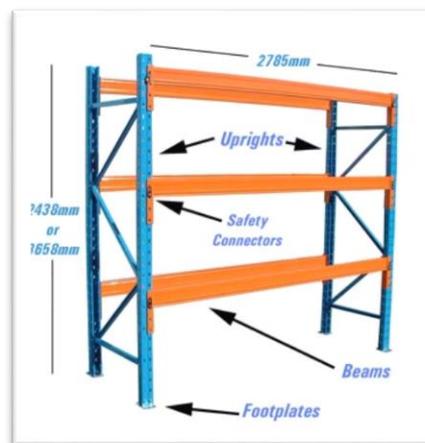
### **Tiered Two-Level Cultivation**

BPH will use a cultivation system utilizing stackable pallet racking creating 2-level cultivation rooms. The pallet racking will be stationary and secured to the floor, maximizing the facility's cubic footage. This system will allow users to maximize their facilities cubic footage resulting in increased production capacity.

Advantages to utilizing the tiered 2-level cultivation include:

- Maximizes plant canopy cubic footage
- Lights within rack footprint so no susceptibility to damage
- Easy to reach plants for maintenance purposes
- Very limited light wasted due to direct concentration above plants
- Less water consumption due to use of Auto Pots (no waste water runoff)
- Lower labor costs due to easier cleaning of lights and system
- Able to use CO<sub>2</sub>

The system will utilize standard pallet racking such as the pallet racking pictured below.





Environmental Control System

<b>Standard Operating Procedure:</b> Environmental Control System
<b>Purpose:</b> To explain the environmental control system
<b>Scope:</b> To educate and train registered employees and licensed premise personnel on the environmental control system and cultivation environmental parameters.
<b>Initial Training:</b> TBD

**Environmental Control System**

Temperature will be monitored by a computer based environmental control system. Multiple temperature sensors will be strategically situated around each cultivation room, these sensors will send data to a central computer. The environmental control system will then log this data for future reference, as well as allow the user to make adjustments, set alarms, and monitor the system from any location. Temperature will be controlled using a HVAC system sized correctly for each growing area. The environmental control system’s main computer will regulate the HVAC system. Maintaining temperatures between 72 and 78 degrees is paramount to plant health and Integrated Pest Management. High temperatures encourage the rapid growth of pests as well as increase stress to the plant. All rooms will have back up HVAC systems for redundancy.

Humidity control is the most important aspect of Integrated Pest Management in the indoor horticulture environment. High levels of humidity encourage molds and mildews, as well as create an environment perfect for the growth of insects. Multiple sensors placed in each cultivation room will monitor humidity. These sensors send data to the environmental control systems computer to be logged, trigger dehumidifiers, or set off an alarm. Humidity is controlled by either dehumidification, or ventilation. During standard operation humidity will be removed from the room using horticultural grade dehumidifiers. In the event of a high humidity alarm, a ventilation system will exhaust the room to rapidly lower humidity. Plant transpiration varies greatly between the light and dark periods in a grow room; anticipating this fluctuation is critical. Maintaining a humidity level between 20%-45% is the best defense against mold and mildew issues.

In the sterile cultivation environment, ventilation is used mainly as an emergency means to clear the air from a room. In place of typical ventilation, supplemental CO2 will be introduced to the room at strictly regulated levels. The environmental system will be tied to several sensors that can trigger the ventilation system in the event of a high reading. When the computer system senses levels of CO2, temperature, or humidity above certain set points, it will initiate the ventilation system, and clear the air out of the room. This air will be replaced by HEPA filtered air from outside of the grow room. This ventilation system will initiate at the following set points which will be adjusted seasonally according to outdoor conditions: Temperature On: 92\* Off: 84\*, Humidity On: 70% Off: 45%, CO2 On: 2000ppm Off: 800ppm.

In the indoor horticulture environment lighting control allows us to manipulate the season the plant perceives it is in. Providing 18 or more hours of light will cause vegetative growth indefinitely, this is simulating spring and summer. When the plants are provided 12 hours of light, the flowering cycle begins; this is simulating the transition from summer to autumn. An environmental control system will control the lighting system from a central computer. This system will not only control the lights according to the desired growth period, but will also reduce the amount of operating lights in the event of a high temperature alarm.

**Facility Ventilation Protection**

All intake and exhaust points on the exterior of the facility are to be screened with 350 micron insect cloth. This cloth will be supported by aluminum frames, and sealed to prevent any risk of infestation. This screen is adequate in size to control insects from entering the facility including thrips, aphids, and mites, which are the most common pests associated with marijuana. Registered employees will be required to inspect all facility ventilation protection barriers on a six (6) month basis. Registered employees may need to remove the filter in order to properly clean the filter to ensure the filter is functioning properly. Filters may need to be replaced all together. All Licensed Premise facility ventilation protection (filters/screens) inspection, cleaning, maintenance and repairs or replacements will need to be documented on the **Facility Ventilation Protection (filters/screens)** log sheet as seen below.



<b>Standard Operating Procedure:</b> Employee Dress Code and Personal Hygiene
<b>Purpose:</b> To explain the employee dress code required.
<b>Scope:</b> Covers the dress code requirements for employees.
<b>Initial Training:</b> 30 minutes

**Principles of Employee Dress Code**

The cultivation facility is considered a “clean” room type setting and as such employees of the cultivation facility will be required to change out of street clothes and into provided work wear to be worn during all scheduled work shifts. The work wear will consist of medical-type scrubs and garden shoes.

Employees are expected to arrive at facilities and enter the locker rooms immediately after entering the facility to shower and change into provided work wear. This will reduce the cultivation areas from exposure to outside contaminants such as pests and diseases.

**Registered employees**—BPH registered employees working will be required to wear approved attire while working within the production center.

- Registered employees will be provided work attire to be worn while working within the Licensed Premise.
  - Work uniform such as scrubs
  - Closed-toe garden shoes such as Crocks
  - Hat (*optional*)

**Transportation Agents**— BPH registered employees working will be required to wear approved attire while on duty. Transportation agent work attire will differ from that of registered employees due to State regulations mandating transportation agents must not have any identifying logos or markings that could indicate ownership or possession of marijuana.

- Transportation agents will be required to wear un-identifying work attire
  - Plain jeans or khakis pants
  - Plain polo or button-up shirt
  - Closed-toe shoe

**Personal Hygiene Policy**

This policy has been set forth in order to ensure that all employees are practicing good personal hygiene to ensure that are products are produced in safest and most sanitary means possible. The personal hygiene policy includes but is not limited to the following:

- A. Maintaining adequate personal hygiene
  - a. Arrive to work clean in appearance/clean clothes.
  - b. Showering every day is essential
  - c. Deodorant and a clean personal smell is required
  
- B. Men must be neatly groomed/shaven
  - a. Mustaches or beards allowed if maintained
  - b. We reserve the right to ask you to wear a beard cover if we deem it necessary
  
- C. Long hair must be constrained in a neat manner to avoid hair coming into contact with food items
  - a. A hat or hairnet is preferred
  - b. Jewelry of any kind is not permitted

- i. This includes earrings, rings, bracelets, watches, etc.
- D. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and
  - E. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

### **General Sanitary Requirements**

BPH will take all reasonable measures and precautions to ensure that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for medical marijuana products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.

BPH will have hand-washing facilities that are convenient and furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

That all registered employees working in direct contact with processing, preparation, weighing or repackaging of medical marijuana products shall conform to hygienic practices while on duty, including but not limited to:

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the processing, preparation, weighing or repackaging of medical marijuana products and at any other time when the hands may have become soiled or contaminated; and
- Refraining from having direct contact with preparation of medical marijuana products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical marijuana products.

Registered employees are required to ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical marijuana products are exposed. Registered employees are required to ensure that floors, walls, and ceilings are adequately cleaned and kept clean and kept in good repair.

The facility will provide adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests. Registered employees must ensure that all contact surfaces, including utensils and equipment used for the preparation of medical marijuana products shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used with medical marijuana and used in accordance with labeled instructions;

BPH requires all toxic cleaning compounds, sanitizing agents, solvents used in the production of medical marijuana and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of medical marijuana products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. That medical marijuana products that can support the rapid growth of undesirable microorganisms will be held in a manner that prevents the growth of these microorganisms; and the storage and transport of finished medical marijuana products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.



**Standard Operating Procedure:** Facility Entry Protocol and Good Growing and Handling Practices

**Purpose:** To explain how employees should enter the production center, preventative IPM measures, and procedures to follow to gain access to Limited Access Area(s).

**Scope:** Covers the steps involved for properly entering the Licensed Premise as well as good growing and handling practices

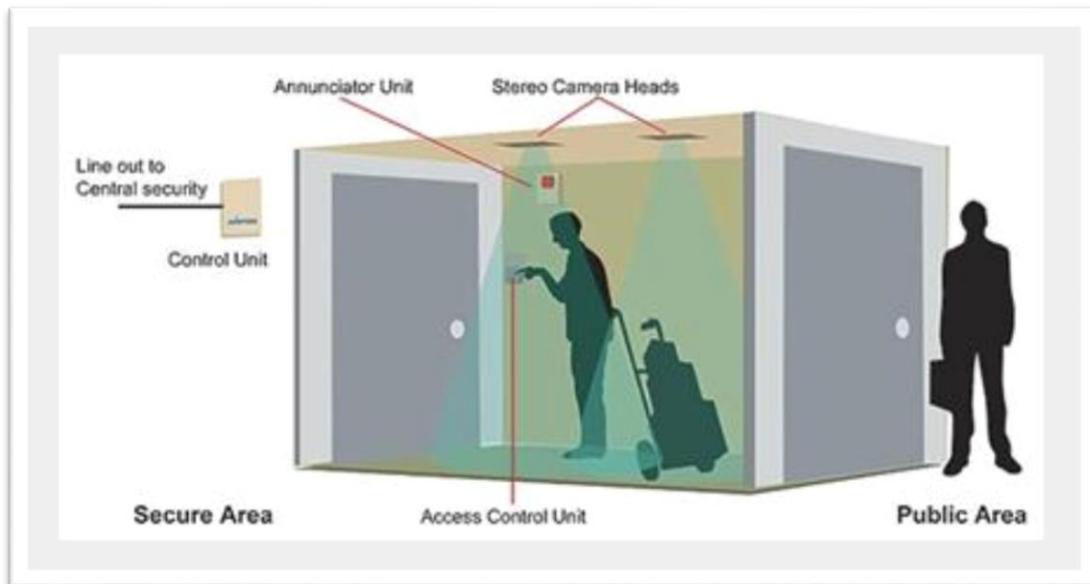
**Initial Training:** 2-4 hours

**Principles of Facility Entry Protocol**

The primary objective of having a specific facility entry protocol is to try to reduce the exposure and risk to outside contaminants from entering the facility. Containments can be anything from pests such as insects and diseases such as powdery mildew. It will be of utmost importance for employees to be mindful of where they have been immediately before arriving at the cultivation facility as this can determine the likelihood and types of contaminants possible.

Upon arriving at the cultivation facility, registered employees will enter the facility using their issued key/keycard or the like, enter the facility’s ‘entry vestibule’. This area is designed as a security measure against unwanted intruders. There will be a magnetic door that can only be opened by personnel with the proper security clearance. This door will be opened through the use of an access control unit.

***Example of a “Entry Vestibule”:***



Upon exiting the “Entry Vestibule” employees will head directly for the locker rooms where they will change out of all street clothes, take showers and change into provided work attire/uniform prior to entering the “clean” area of the cultivation facility.

**Locker Room Steps for Employees to Follow:**

1. Enter locker room
2. Remove **ALL** street clothes and place them in your locker
  - a. *ALL* clothes
  - i. Hats



- ii. Socks
  - iii. Shoes
3. Take a shower
  - a. This is done as another preventative measure to ensure the cultivation facility is not exposed to any outside contaminants
4. Change into provide work attire/uniform
  - a. Scrubs
  - b. Hair nets
  - c. Hat (optional)
  - d. Garden shoes

Upon successfully showering and changing into the provided work wear, employees will be ready to begin their work shift within the “clean” area of the cultivation facility.

Upon exiting the locker room, employees will go through an “air-lock” chamber to remove any remaining potential contaminants prior to entering the clean cultivation area. Upon exiting the Air-Lock chamber, the employee will be in the “clean” area of the cultivation facility.

***Example of an Air-Lock Chamber:***



**Good Growing and Handling Practices**

The indoor cultivation environment offers little help to registered employees in terms of biosecurity, so preventative maintenance and clean protocols are essential in operations. Plants are typically cultivated and arranged in close proximity and as such plants in close proximity to each other spread diseases, molds, mildews, and insects with ease in comparison to the natural growing conditions found outside. Due to this, very strict clean entry protocols, as well as quarantine, and biosecurity procedures are necessary.

The facility will be divided into a “clean zone” and a “dirty zone”.

- The clean zone represents any area where marijuana products will be whether in plant form, flower form, concentrate, or infused product.
  - All “clean zones” in the facility will require registered employees to follow the clean entry protocol to enter.
- The dirty zone represents any area where no marijuana product will ever be (excluding marijuana waiting destruction and disposal), including soil receiving, and administration offices.

**Cultivation Areas**—each cultivation chamber in the facility will have separate entry protocols, to keep from cross contaminating any possible pests from room to room. Upon entry into a cultivation room, each grower agent will put on a pair of nitrile gloves, as well as step in a disinfecting footbath. The disinfecting footbath is filled with a plant

and animal safe disinfecting solution, typically used in the animal care, and commercial greenhouse industry. This will control any contaminants on the bottom of grower agent’s feet, where the biggest risk of disease lies. Now in a cultivation chamber, it is the grower agent’s responsibility to be observant for any signs of issues. Upon exiting a cultivation room, the grower agent is required to remove gloves, and step in the disinfecting footbath upon exit.

**Example of Disinfecting Foot Mat/Bath:**



In the event that a disease, mold, mildew, or pest is found, the facility will enter quarantine protocols; refer to the **Integrated Pest management SOP**.

**Foliar Spray Applications**—during the application of foliar sprays, registered employees will be required to wear certain protective clothing depending of type of material being applied. Foliar sprays applied to plants are non-harmful in nature, and do not require protection clothing to be worn. Despite these materials being nonhazardous to plants and animals, the procedure will be to wear protective eyewear, an organic oil capable respirator, and nitrile gloves. This will protect the applicator from breathing any small particles emitted by atomizing sprayers. Sterilizing sprays applied to rooms when plants are not present will require an increased amount of protective clothing. During empty room cleaning and spraying, the applicator will wear a full body chemical suit, protective eyewear, organic chemical respirator, and nitrile gloves. This will protect the applicator from any potential hazardous materials entering eyes, touching skin, or being inhaled.

**Propagation Room(s)**—one of the most important areas of cultivation to assure strict cleanliness protocols are followed is the propagation area. In this area, very specific steps must be taken to not cross contaminate diseases. The propagation room will have a higher temperature and humidity, therefore encouraging insects, molds, and mildews to grow at an increased rate. The first procedure to assuring a clean propagation room is daily inspection of mother plants. These plants will typically be much older and larger than an average cultivation plant, and tend to have more space, and foliage to inspect. Assuring stock plants are not affected will allow you to be sure you are not starting any new clones with a pest. When propagating plants, the first step is to sterilize the work area. Wiping down all work surfaces with a 3% hydrogen peroxide solution will clean any lingering pests. All cloning equipment including clone domes, trays, scissors, and razor blades must be sterilized with hydrogen peroxide solution also. During the cloning process, scissors and razor blades will be sterilized between each strain propagated. Once cloning is completed, the work area is to be sterilized, and remain clean for the next time propagation is done. Protocols for inspecting, and maintaining clone domes are very important. Naturally all clones taken will not survive, and this unhealthy clone presents a food source for molds and mildews. During the time clones are given to grow roots, daily inspections of each dome will be required. Any mold will be removed, as well as dead leaves and clones. If a dome is found to have mold, it will be misted with 3% hydrogen peroxide solution before being closed. During these inspections it is important to clean tools between each dome to reduce the risk of spreading disease.

*\*During daily cultivation tasks, strict procedures are set to minimize risk of pest introduction, or spread. It is the responsibility of each grower agent to read and know these procedures and how they relate to their position. It will be the grower agent’s responsibility to monitor these procedures to assure they are being completed in entirety.*

**Processing/trimming**—the processing/trimming area of the facility will have procedures set in place to reduce the risk of pest and disease issues post-harvest. Post-harvest, it is very important to have strict procedures, and the plants natural resistance to pests is diminished. This wet plant material is very susceptible to mold contamination, and must be handle properly. All processing registered employees will undergo the same entry protocol including mandatory shower, and wearing medical scrubs, hairnet, beard cover if necessary, garden shoes, and clean nitrile gloves. When entering the processing room agents will first step in a sterilizing footbath to mitigate tracking pests between



areas. Prior to harvest the processing team will clean and sterilize all surfaces in the processing room with 3% hydrogen peroxide solution. Once all surfaces are sterilized, harvested plants may enter the room. During all stages of processing registered employees are required to wear nitrile gloves, hairnets, and beard covers. If harvesting more than one cultivation room, the processing room will be sterilized again prior to the next room's plants entering.

When the processing stage is complete, the registered employees responsible for monitoring the drying process will be required to follow cleanliness procedures. Prior to entering the drying room, agent will step in sterilizing footbath to stop the spread of pests on feet. When inspecting drying product, agent will wear clean nitrile gloves, hairnet, beard cover if necessary, medical scrubs and garden shoes. Product will be inspected for issues procedurally, required inventory management forms will be kept with product to monitor progress.



Limited Access Areas

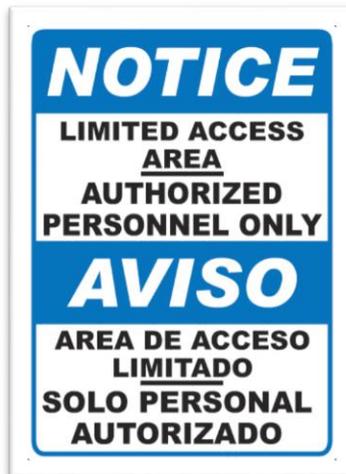
<b>Standard Operating Procedure:</b> Limited Access Areas
<b>Purpose:</b> To explain Limited Access Areas, who is allowed in these areas, and procedures to follow within the Limited Access Area.
<b>Scope:</b> Covers the steps involved in escorting visitors in limited access areas.
<b>Initial Training:</b> 1 hour

### The Principles of Limited Access Areas

A Limited Access Area is a building, room, or other contiguous area upon the Licensed Premises where medical marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee. Limited Access Areas are areas within the licensee's facility where only certain people will have the required permission to access.

Limited Access Areas may have people in them without the proper permission as long as the Visitor SOPs and state regulatory required protocols are followed. Registered employees will follow the *Visitor SOP*; with allowed visitors being escorted by a registered employee at all times while in the facility and Limited Access Areas.

Limited access areas should be limited to State licensed, facility employees only. If a visitor needs to access the limited access areas, registered employees will be required to follow the written *Visitor SOP*.





Visitors

<b>Standard Operating Procedure: Visitors</b>
<b>Purpose:</b> To explain the processes involved to accept/allow visitors into the retail dispensary.
<b>Scope:</b> Covers the required steps to follow to allow visitors into the facility.
<b>Initial Training:</b> 1 hour

**Requirements**

- 1) Visitor Log Sheet
- 2) Visitor pass

Pursuant to 329D-15 and 329D-16, unauthorized access to retail dispensing locations and/or a production center is a Class C felony. Due to the strict penalties for infractions, BPH will take steps to identify all potential subcontractors, maintenance workers, and any other individual identified as needing to visit one of BPH retail dispensing locations or our production center. Such steps will allow said individuals to submit proactively to fingerprint cards and background checks and be aware of the information submitted to the Department. In order to obtain Department approval, BPH also intends to identify secondary, back-up individuals who can be utilized as resources if the primary resource is unavailable; these secondary subcontractors and resources will also be required to submit fingerprint cards and authorize consent for background investigations to ensure the individual does not have any felony convictions or other offenses listed in §11-850-17.

**The Principles of Visitor Protocol**

BPH’s visitor protocol will follow industry best practices and current regulations. There will be situations that arise that will require someone to enter the registered dispensary facility premises who is not a State-licensed industry worker or not a State-registered patient or caregiver but they will need access to the facility. Common visitors typically will be support-type businesses such as HVAC, electric and plumbing, general contractors, etc.

All visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

Approved visitors will be required to provide a BPH registered employee with a current, valid government-issued identification. The registered employee will confirm the individual is on the BPH’s Department-approved list, make a photocopy of the visitor’s ID and maintain the photocopy with the visitor log book; visitors will be required to sign in and out with a registered employee and provide a written reason for the visit (e.g. maintenance work, HVAC, repairs, etc.). Upon completing these requirements, the registered employee will issue a ‘visitor badge’ for the visitor to wear and display while at any BPH registered dispensary facility. BPH will also require a registered employee to remain with the visitor for the duration of the visit to ensure the visitor does not interact with or handle any marijuana plant, material, product, or manufactured marijuana product.

- **Government-Issued ID**—all visitors must have a current and valid government-issued ID (passport, Driver’s License, military ID)
  - Ensure that the government-issued ID is current (check expiration date on ID)
- **Verification**—Verify the validity of the government-issued ID and that the visitor is on the current Department-approved list
- **Photocopy**— Make photocopy of visitor’s government-issued ID
  - Make a photocopy of visitor’s ID; Photocopy is to remain with *Visitor Log Sheet*

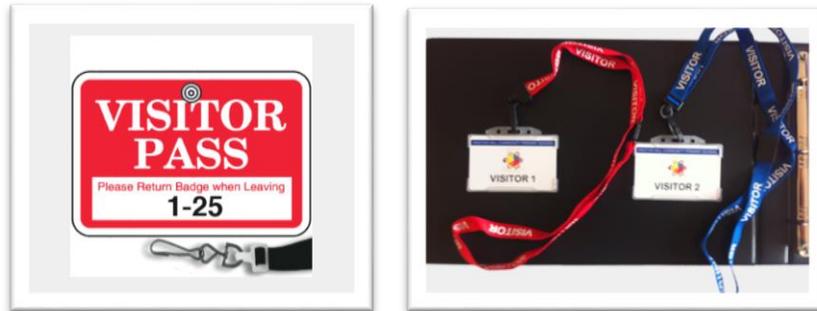


- **Access**—Allow or deny access to the facility
  - Allow entry to dispensary if the visitor has a valid government-issued ID.
  - Deny entry to the facility if the visitor does not have a valid government-issued ID.
- **Record/Documentation**—Have visitor fill out the *Visitor Log Sheet*
  - *Visitor Log Sheet* will document visitors name, company, date, time-in, time-out, signature, reason for the visit
  - Maintain photocopy of visitor ID with the *Visitor Log Sheet*
  - This record of visit must be retained and maintain on the licensed premise for a minimum of two (2) years.

**Visitor Access Process:**

- 1) Check visitors ID and credentials at the check-in station
  - a. Make photocopy of Visitor’s ID
- 2) Verify with management that visitors are expected and on the current Department-approved list
- 3) Fill out *Visitor Log Sheet*
- 4) Have said visitor sign-in and date the *Visitor Log Sheet*
- 5) Give visitor a ‘*Visitor Pass*’
- 6) When visitor is finished at the licensed premises:
  - a. Have visitor sign-out on *Visitor Log Sheet*
  - b. Collect the ‘*Visitor Pass*’ from said visitor

*Example of a Visitor Pass can be seen below:*



*Example of Visitor Sign-In Documentation Log Sheet:*

<u>Visitor Sign-In Documentation Log Sheet</u>							
<u>Date</u>	<u>Time In</u>	<u>Time Out</u>	<u>Visitor Name</u>	<u>Visitor's Company</u>	<u>Visitor Signature</u>	<u>Reason for Visit</u>	<u>Registered Employee Escort</u>



Daily Facility Evaluation

**Standard Operating Procedure: Daily Facility Evaluation**

**Purpose:** To train employees on the production center daily evaluation prior to conducting any cultivation and/or processing daily operations.

**Scope:** Explain what items, equipment and processes need to be evaluated on a daily basis prior to commencing any daily operations.

**Initial Training:** 4-6 hours

**Principles of Daily Facility Evaluation**

Adhering to a daily facility evaluation is paramount within a cultivation facility. Registered employees will be required to inspect the cultivation facility/operations on a daily bases to ensure the facility is operating optimally. The facility evaluation is done to ensure that the various cultivation room environments are optimal, to ensure no lighting or equipment is malfunctioning, and to assess the overall health of the marijuana plants.

If performed routinely on a daily bases, registered employees will become in-tune with the cultivation facility and realize potential problems and be able to address those potential problems before they become issues. The facility evaluation will be the first task completed by registered employees after completing the facility entry and clean protocols.

**Items to Evaluate:**

1. Room environment
  - a. Temperature
  - b. Humidity
  - c. CO2 level (*if applicable*)
2. Plant medium moisture
3. Lights functioning properly
4. Growing equipment functioning properly
  - a. Autopots
  - b. CO2 system(s)
  - c. Fans
  - d. HVAC system(s)
5. Signs of disease/pests
  - a. Type of disease/pest
6. Additional notes/details

***Cultivation Facility Evaluation form can be seen below:***



### Cultivation Facility Evaluation

<b>Date:</b>		<b>Time:</b>		<b>Registered Employee:</b>	
<b>Mother Room</b>					
Temp.:		Humidity:		Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO	
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO		Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO			
Overall Plant Health:					
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO		What type of disease/pest infestation?			
Notes/Details:					
Number of Plants:		POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO		Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Action Items ( <i>if any</i> ):					
Additional Notes/Details:					
<b>Propagation/Clone Room</b>					
Temp.:		Humidity:		Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO	
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO		Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO			
Overall Plant Health:					
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO		What type of disease/pest infestation?			
Notes/Details:					
Number of Plants:		POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO		Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Action Items ( <i>if any</i> ):					
Additional Notes/Details:					



Vegetative Room(s)		
Temp.:	Humidity:	Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO
Plant Vegetative Lifecycle Week:		
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO	Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Overall Plant Health:		
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO	What type of disease/pest infestation?	
Notes/Details:		
Number of Plants:	POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO	Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO
Action Items ( <i>if any</i> ):		
Additional Notes/Details:		
Flowering Room(s)		
Temp.:	Humidity:	Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO
CO2 Level:	Plant Flowering Lifecycle Week:	
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO	Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Overall Plant Health:		
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO	What type of disease/pest infestation?	
Notes/Details:		
Number of Plants:	POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO	Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO
Action Items ( <i>if any</i> ):		
Additional Notes/Details:		



Receipt of Material

<b>Standard Operating Procedure: Receipt of Materials</b>
<b>Purpose:</b> Explain procedure and requirements for receiving raw materials
<b>Scope:</b> To educate and train licensed premise employees on the procedures and requirements involved with receipt of materials.
<b>Initial Training:</b> 1-2 hours

**Principles of Receipt of Material**

The process of receipt of material or receiving raw materials is not as simple as just taking the raw materials into the licensed premise. There are regulations, guidelines and procedures to follow when receiving raw materials or other inventory into the cultivation facility licensed premise.

Upon receiving any raw materials, inventory or other items used in operations said items will be placed in a quarantine storage area within the receiving area of the licensed premise. Employees will need to quarantine any materials received to be used to produce marijuana. These items will include but not be limited to:

- Medical marijuana seeds
- Medical marijuana cutting/clones
- Medical marijuana plants
- Soil/potting mix
- Fertilizers
- Pesticides, insecticides and fungicides
- Growing containers

**Receipt of Materials**—upon receiving materials into the licensed premise, registered employees and/or licensed premise employees will need to document the receipt of materials on the *Receipt of Materials* log sheet.

*Example of Receipt of Materials Log Sheet can be seen below:*

<b>Receipt of Materials</b>							
<u>Date of Receipt:</u>	<u>Receiving Employee #1:</u>	<u>Receiving Employee #2:</u>	<u>Product/Strain/Attribute ID #:</u>	<u>Quantity Received:</u>	<u>Received From:</u>	<u>Materials Placed in Quarantine:</u>	<u>Materials Pass Visual Inspection:</u>
						YES NO	YES NO
<i>Describe why Materials did not pass visual inspection:</i>				<i>Corrective action to be taken:</i>			
<u>Materials Pass Visual Inspection after Corrective Action:</u>		<i>Describe why Materials did not pass visual inspection after corrective action:</i>		<i>Next corrective action to be taken:</i>			
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>If materials passed visual inspection, and are determined to be acceptable for use as intended, said materials may be released from the quarantine areas and used as intended.</i>							
<u>Date of Release of Materials:</u>	<u>Employee(s)/Supervisor Releasing Materials:</u>		<u>Product/Strain/Attribute ID # of Released Material(s):</u>		<u>Quantity Released:</u>		
<u>Record of Receipt of Materials Made in Perpetual Inventory Control System (POS)?</u>		<u>Required POS Records:</u> <i>date of receipt, quantity of material, types/variety of material date of release</i>		<u>Employee Making POS Record Entry:</u>		<u>Employee Witnessing POS Record Entry:</u>	
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>Notes/Comments:</i>							



**Quarantine Storage Area**—the quarantine storage area will be within the licensed premise and clearly identified on the facility floor plan diagram. The quarantine area will be classified as a “dirty” zone within the cultivation facility. Materials will be held within the quarantine area where they will be segregated from the rest of the cultivation licensed premise and/or “clean” areas of the facility.

**Inspection**—after received inventory items/materials are placed in quarantine, the items will need to be inspected to ensure there are no defects or contamination. All received items/materials will remain in the quarantined area until said material pass inspection and is determined to be acceptable for use as intended.

- Registered employees will be required to inspect all materials for visible defects and contamination
- Inspecting materials for contamination is essential for the facilities clean protocols and IPM measures
  - If a contamination is identified proper cleaning and/or segregation procedures will be implemented.
    - Cleaning and sanitizing the contamination: if the contamination is deemed reasonable to clean and sanitize you will need to clean and sanitize all surface areas of the material if possible. This should be done using a cleaning/sterilizing agent such as bleach.
    - If cleaning and sanitizing is not an option, the materials will be segregated within the quarantine area until they are properly destroyed and disposed of.
    - If contaminated with pests, insects or disease; immediately segregate the material while trying to identify the contamination.
      - Refer to the *IPM SOP* for proper identification and treatment of material (plants)
  - Once the materials are properly cleaned and sanitized and believed to be free from contamination they will need to be inspected a second time.
    - Materials will need to pass this second inspection prior to being released for their intended use.

**Release**—upon the received materials passing inspection and being determined to be acceptable for use as intended, the materials will be released from the quarantine receiving/storage area. At this time the materials can be used within the licensed premise for their intended use.

- Release materials if they pass initial inspection
- Release materials once they are cleaned and sanitized and pass secondary inspection

**Documentation and Record**—upon the materials being released from quarantine and determined to be acceptable for use as intended BPH registered employees and/or licensed premise employees will be required to log the materials into the inventory control system.

- Document and record new materials released from quarantine in the inventory control system (POS system)
- Ensure record is accurate with physical inventory on hand
- Ensure the *Receipt of Material* log sheet is filled out properly and completed



**Standard Operating Procedure:** Growing Containers—AutoPots Automated Watering System(s)

**Purpose:** To understand the set-up and operation of AutoPots automated watering system

**Scope:** To understand how to properly assemble and trouble shoot AutoPot systems. *AutoPot Set-Up Instructions can be found at:* <http://www.autopot.co.uk/autopot-1pot-xl-system?download=92>

**Initial Training:** 2-4 hours

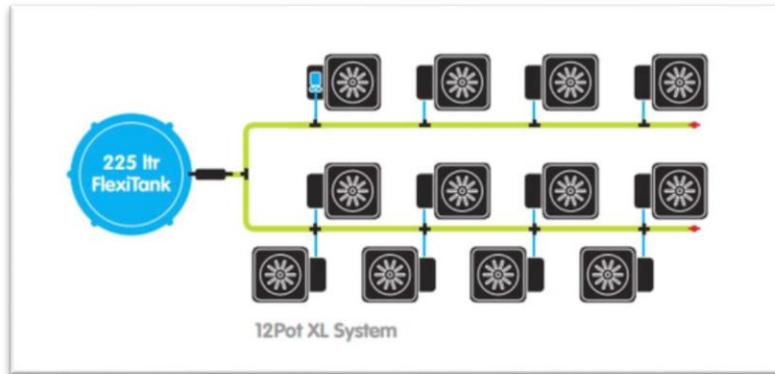
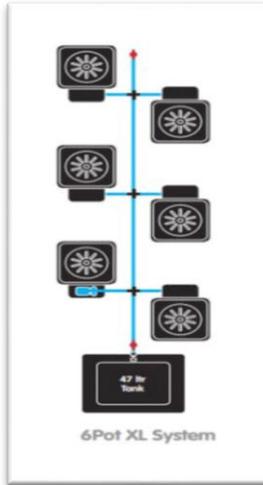
**The Principles of AutoPot Automated Watering System(s)**

ACC utilizes AutoPot automated watering systems as the container and watering system for marijuana plants. The AutoPot watering system is a gravity-fed system utilizing a large main reservoir supplying water and/or nutrients to the marijuana plants in their own, individual AutoPot container. The individual AutoPot containers will vary depending on the plants growth stage. During the vegetative growth stage marijuana plants will be housed in 1 gallon pot/container and/or a 2.2 gallon AutoPot; and during the flowering growth stage marijuana plants will be transplanted into a 6.6 gallon AutoPot.





*AutoPot Systems are scalable to meet cultivation demand requirements*



### AutoPot Set-Up:

1. The AutoPot system should be used with Reverse Osmosis water or de-chlorinated water and this water can be stored in any size reservoir.
2. The reservoir should have a pressurized line (*coming from the RO system if applicable*), attached to a float valve that regulates the water level based on the usage of water by the plants. This design and install should be set up by a licensed plumber or an Autopot representative
3. Located near the bottom of the reservoir, there is a connector that is installed, again by a licensed plumber or Autopot representative that will attached to the main line that feeds the AutoPots.
4. Follow set-up instructions found in the AutoPot manual with the addition of adding two inches (2") of perlite at step 1.5

*AutoPot set up instructions that can be found at <http://www.autopot.co.uk/autopot-1pot-xl-system?download=92> can be seen below:*



# AQUAvalve™

## Simple care guidelines



### Ensuring that the AQUAvalve floods and drains correctly

- 1** Making sure your AQUAvalve floods and drains correctly is simply achieved and only takes a few seconds.
- 2** Hold the AQUAvalve at eye level so that you can see the yellow silicon fitted to the top float resting on the hole below it
- 3** The yellow silicon must create a tight seal when touching the hole.
- 4** If it looks like it is not sitting parallel on the hole below, simply lift the top float and apply pressure to one side of the yellow silicon, drop the float and hold at eye level again. Repeat the procedure if necessary.

### Care and maintenance

- 1** At the end of your growing season, clean the AQUAvalve using warm soapy water. Using an old tooth brush will help.  
  
The AQUAvalve is easily disassembled. The top float will slide all the way across and the bottom float is unclipped from its pivoting position. The circular discs fitted to the top float can also be removed by using pliers to grip the raised point.  
  
At this point it is advisable to remove the yellow silicones to avoid them being lost.
- 2** It is also handy to have a paper clip or pipe cleaner to hand so that you can push it through the AQUAvalve nozzle, this will remove any lime scale build up that may have occurred during the growing season.  
  
Blowing through the AQUAvalve nozzle will also help to remove any build up. Do not under any circumstances use a drill & drill bit to clear the AQUAvalve nozzle.  
  
This will potentially damage the AQUAvalve beyond repair.



## Your 1Pot XL module set-up guidelines



Allow your  
**plants**  
to establish  
before turning your  
system ON.

Trays & Pots  
available in  
black



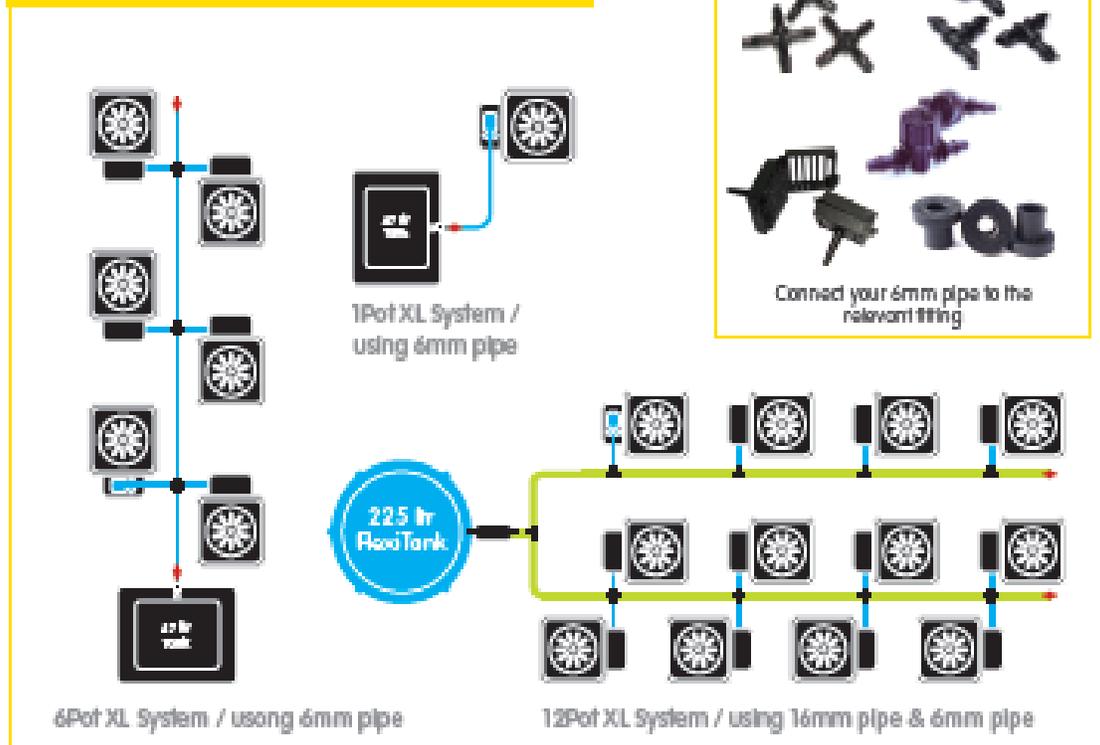
mail@autopot.co.uk | www.autopot.co.uk | +44 (0)844 8581520

### 1Pot XL module contents

- 1x 1Pot XL tray & lid
- 1x 25ltr pot
- 1x AQUAvalve
- 1x 1.0 metres of 6mm pipe
- 1x root control disc
- 1x 6mm tee connector
- 1x 16/6mm tee connector

### Plan views and options

### Suggested layouts

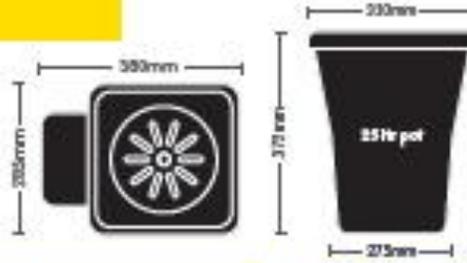


### Advice

- Pot up your plants, water through, then allow your plants to establish in the pots for a period of 7 to 10 days before turning your system on. This will encourage a stronger and healthier root system.
- Always raise your tank to a minimum of 150mm above the highest AQUAvalve and re-fill the tank when there is approximately a 1/3 of the solution left - NEVER ALLOW THE TANK TO RUN EMPTY.
- For best results, we recommend mineral fertilisers. Do not use organic fertilisers, as they have a tendency to block small pipe work.
- Clean all substrate from the bottom and sides of the pots before placing in each tray. This will ensure your system is clean from the start.
- Always use free draining substrates, for example: soil/perlite, coco/perlite, soil/day pebbles, coco/day pebbles, rockwool/day pebbles.

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### 1Pot XL dimensions



### 1Pot XL setup instructions

- 

**1** Place circular root control disc gold face down in the pot.
- 

**2** Fill pot with medium and pot up plants.  
Water through pot and allow to drain outside the tray.
- 

**3** Remove collar.  
Push 6mm pipe through collar and attach to AQUAvalve nozzle.  
Rescrew collar - **DONT** overturn... when you feel it grip **STOP**.
- 

**4** Connect AQUAvalve so 'half moon' is on T section in the tray.
- 

**5** Position tray so it is level.
- 

**6** Cut 6mm/16mm pipe to appropriate length
- 

**7** According to the size of your system connect your 6mm/16mm pipe to relevant fitting or tank...
- 

**8** Place pot in the tray, make sure it is **CLEAN!**  
Place lid over valve onto tray.

Using your front instruction sheet, repeat the module set up instructions for the number of trays.

**Allow your plants to establish for 7-10 days before turning system on**

**Advice**

If you require any guidance email - [mail@autopot.co.uk](mailto:mail@autopot.co.uk)



Quality Control

<b>Standard Operating Procedure: Quality Control</b>
<b>Purpose:</b> To describe the quality control
<b>Scope:</b> To train registered employees on quality control measures to be utilized within the cultivation operations
<b>Initial Training:</b> TBD

Quality control measures will primarily be in the form of adherence to the written standard operating procedures to ensure quality and consistency of products produced within the facility. BPH will utilize the established and proven SOP's for all cultivation operations. BPH will use standard operating procedures (SOP's) to promote good growing and handling practices including:

- All aspects of the:
  - Irrigation, propagation, cultivation, fertilization;
  - Harvesting, drying, curing;
  - Rework or reprocessing;
  - Packaging, labeling, and handling of medical marijuana products, byproduct; and
  - Waste products, and the control thereof, to promote good growing and handling practices.

BPH will require that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical marijuana has received the training, education, or experience necessary to perform assigned functions; and will also require that all registered employees practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

BPH will require grower agents to follow the protocol for Receipt of Material including:

- BPH shall quarantine received material that will be used to produce marijuana and/or manufactured marijuana products
- BPH shall inspect materials for defects and contamination.
- Material may not be released from quarantine by a BPH until the material:
  - Passes inspection; and
  - Is determined to be acceptable for use as intended.



<b>Standard Operating Procedure:</b> Growing Media and Nutrients, Supplements and Growth Additives
<b>Purpose:</b> To describe the growing media and nutrients, supplements and growth additives used
<b>Scope:</b> To train licensed premise employees on the type of growing media and nutrients, supplements and growth additives to be utilized within the cultivation operations
<b>Initial Training:</b> 1 hour

### **Principles of Growing Media**

SoHum Living Soil (SoHum) is fully amended biodynamic potting mix which simplifies the growing process while maximizing yields and producing a consistent quality product. SoHum is a growing medium that is biodynamic, a soil developed to optimize the marijuana plants' maximum genetic potential. In marijuana cultivation, the term "biodynamic" applies to the understanding that soil directly impacts plant development and emphasizes a natural approach to growing that focuses on the micro life in the soil.



The SoHum medium is a fully amended potting mix that contains none of the artificial components found in other soils and requires no chemical additives to spur growth. The potting mix is perfectly balanced with the proper mixture of nutrients and fertilizers promoting strong terpenoid and flavonoid development to enhance the medicinal benefits of the marijuana. SoHum is a fully amended biodynamic potting medium having nutritional amendments of a type and formulation required for optimal marijuana plant growth.

The potting mix consists of coconut coir, perlite, worm castings, biochar, 0-15-1 bat guano, 12-11-2 bat guano, greensand, lime, glacial rockdust, azomite, alfalfa meal, kelp meal, langbeinite, fossilized, bone meal, feather meal, rock phosphate, neem seed meal and crab meal.

### **The Benefits of SoHum Living Soil:**

- Compared with traditional soil and fertilizer growing programs, SoHum potting mix offers a number of advantages:
  - Consistent high grade quality
  - Improved plant immunity to disease
  - Reduced operator error
  - No need for expensive nutrient or additives

SoHum has been specifically formulated for optimal marijuana plant health and growth and can be used as a stand-alone nutrient/fertilizer regime for marijuana plants, eliminating the need for additional nutrients, fertilizers, additives, supplements, growth regulators or boosters.

**Soil Storage**—SoHum Living Soil has living microbes within the potting mix which require certain storage requirements.

- Potting mix should be stored on the pallets that they arrive on in the storage area.
- The soil storage area should be climate controlled between 68F-78F optimally but can withstand temperatures between 58F-88F.

- Pallets should be used and rotated according to date of arrival; using a First-In-First-Out (FIFO) inventory rotation system.
- For optimal bio-security, bags should be sanitized by wiping them down with a cleaning solution prior to transporting them to the transplant area.

**Nutrients, Supplements and Growth Additives**

There should be no need for additional nutrients, supplements or growth additives required when utilizing SoHum Living Soils. The potting mix contains all nutritional requirements for the entire lifecycle of the plant.

If a situation arises where nutritional deficiencies are identified, the use of natural, protein-chelated liquid nutrients and fertilizers is recommended. If using additional nutrients, supplements and/or growth additives follow manufacturer recommendations for mixing ratios and directions for use.

Upon using additional nutrients, supplements and/or growth additives outside of SoHum Living Soil, BPH registered employees will be required to document said application on the *Nutrients, Supplement and/or Growth Additive* log sheet. This log will need to be maintained with the Production Center cultivation records. Registered employees will place each monthly log in the appropriate folder within the cultivation operations file cabinet.

The documentation will detail which nutrients, supplements and/or growth additives were applied as well as the dosage rates and amounts applied to medical marijuana plants being cultivated.

<b><u>Nutrients, Supplements and/or Growth Additives</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Grow Room:</u>	<u>Plant Attribute # and Batch #</u>	<u>Lifecycle Stage:</u>	<u>Week:</u>
				<input checked="" type="checkbox"/> Vegetative <input type="checkbox"/> Flowering	
<b>Nutritional Deficiency Identified?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>What is the nutritional deficiency (reason for application)?</b>		<b>Nutrient, Supplement and/or Growth Additive Applied:</b>	<b>Amount Applied:</b>	<b>Applied By:</b>
Note/Comments:					



Plant Tagging

**Standard Operating Procedure: Plant Tagging**

**Purpose:** To explain the principles and concepts of plant tagging

**Scope:** To educate and train registered employees and licensed premise employees on plant tagging for inventory control

**State of Hawaii Regulations**

The State of Hawaii requires that as soon as practical, each plant to be tagged with materials that are indelible and tamper-evident. Indelible is defined as something that is not able to be removed, and tamper-evident means that if the tag is removed or tampered with it will be visibly noticeable.

**Medical Marijuana Plant Tag Requirements:**

- Indelible
- Tamper-evident
- Temperature resistant
- Moisture resistant

Medical marijuana plant tags to be utilized by BPH will be indelible and tamper-evident. The tags will also be water and temperature resistant to ensure tags will not be destroyed during cultivation operations. Tags will be secured to medical marijuana plants using tamper-evident zip-ties. Plants tags should be made of plastic of a variation that will meet all regulatory requirements. *\*Medical marijuana plants are to be tagged once they are planted in a growing contained of 1-gallon or larger. This will ensure the marijuana plant will be large enough to support the plant tag.*

**Tagging**—after each marijuana clone/cutting is received into the licensed premise, created through propagation/cloning or sprouted from seed, the employee will record required plant information within the perpetual inventory control system, create, assign and securely attach a new plant tag to the plant’s container or to the plant itself.

- All transplants and harvests are to be recorded into inventory control system the day of transplant and/or harvest.
  - One employee will enter the record into the inventory control system with another employee witnessing the record; double check data inputs to insure there are no mistakes.
- Keep a hard copy on the licensed premise of every change that occurs pertaining to medical marijuana plant cultivation in the facility.

For every medical marijuana plant in the licensed premise BPH will:

- create a unique identifier for each plant (*attribute #*)
- assign each plant to a batch (*production batch #*)
- enter information regarding the plant (*attribute # and batch #*) into the inventory control system (*POS system*)
- create a tag with the unique identifier and batch number
  - enter information regarding the plant tag (*plant tag #*) into the inventory control system (*POS system*)
- securely attach the tag to a plant container or plant.

**Example of Marijuana Plant Tag:**





Mother Plants

<b>Standard Operating Procedure: Mother Plants</b>
<b>Purpose:</b> Demonstrate the correct technique used to maintain a mother plant as a marijuana genetic/strain bank.
<b>Scope:</b> Explains the principles of mother plants and how to maintain said plants.
<b>Plant Environment:</b> 75-85 <sup>o</sup> Fahrenheit; ~30-50% humidity
<b>Plant Light/Photo Cycle:</b> Minimum for 18 hours of continuous light and up to 24 hours of continuous light.
<b>Initial Training:</b> 4-6 hours

### **Principles of Mother Plants**

A “mother” plant is a female marijuana plant that is held in reserve in the vegetative state in which cutting or clones are taken from the mother plant to create, identical female marijuana plant. The idea behind keeping “mother” plants is to ensure marijuana genetics and strains are maintained for future crop production.

Any female marijuana plant can be turned into a mother plant to preserve marijuana genetics and strains. Mothers can be grown from seed or clone. Mother plants should be selected only if they are disease and pest free.

In order to maintain a mother plant you will need to maintain the proper vegetative growth light cycle of a minimum of 18 hours of lights on with 6 hours of lights off or 24 hours of continuous lights on.

Mother plants should be given minimal nutrients as you are not trying to grow the plant for vigorous growth but rather as a “genetics bank”; in this scenario the mother plant should be given enough nutrients to maintain healthy growth but you are not preparing the plant for the flowering growth stage.

### **ACC Recommendations for Mother Plants:**

1. Mothers should be held as mother plants for a maximum of six (6) months
2. Maintain mothers under 24-hours of continuous lights on
3. Keep mother plants “clean” through pruning
  - a. Maintain mother plant branch growth; plants will become bushy and thick with vegetation
  - b. Proper pruning and “thinning” out of the plant will ensure proper airflow and reduce the risk of pests and/or disease
4. Adhere to IPM protocols (*IPM SOP is discussed later*)
5. When a mother plant has reached the end of its lifecycle (6 months) the plant will be cloned from to take the final round of cuttings/clones
  - a. Upon taking the final cuttings from the mother plant, the plant will be killed off and discarded
    - i. Follow the marijuana waste disposal SOP (*SOP discussed later*)



Propagation and Cloning

<b>Standard Operating Procedure: Propagation and Cloning</b>
<b>Purpose:</b> Demonstrate the correct technique used to propagate (clone) a new plant and to facilitate new root development in cuttings.
<b>Scope:</b> Covers the propagation and cloning process within the cultivation facility. Approximately a 5-14 day process.
<b>Plant Environment:</b> 75-85 <sup>o</sup> Fahrenheit; ~50-80% humidity
<b>Plant Light/Photo Cycle:</b> Minimum for 18 hours of continuous light and up to 24 hours of continuous light.
<b>Initial Training:</b> 4-8 hours

### Documentation Log Sheets Required

#### 1) Propagation Log

#### Equipment/Tools Required

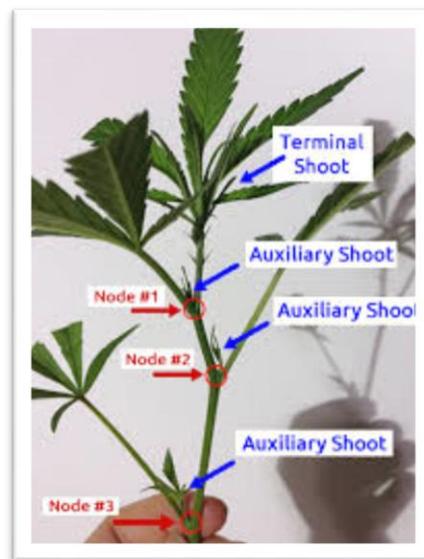
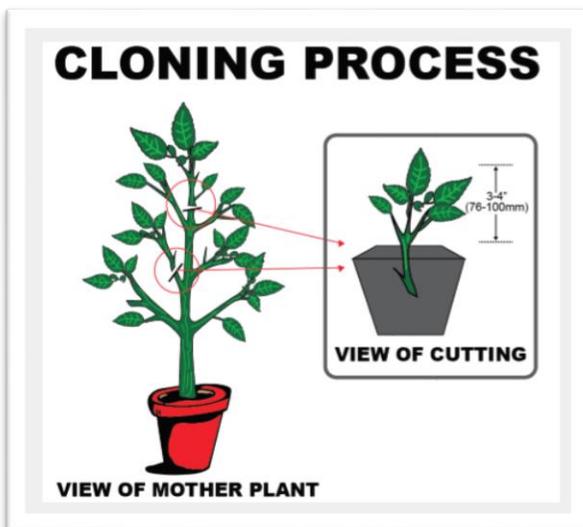
- Scissors, scalpel, razor blade
- Rooting hormone/stimulant
- Humidity dome
- Root cubes
- Plant tags

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### <WEEK 1>

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The cultivation process will begin in week one with the propagation/cloning of medical marijuana plants. Propagation/cloning is the process of producing a genetically identical plant. Every strand of DNA in a clone is exactly like the plant from which it was propagated; propagation/cloning allows for identical genetic reproduction ensuring marijuana genetics and strains can be cultivated infinitely.



Cannabis Cutting



### The Principles of Cloning a Plant

- 1) It is imperative to clone from a healthy mother plant; this is key to achieving quick root development during the cloning process. The stem of the area you select to cut should appear green with no signs of deficiency. A healthy clone will produce roots within 7-14 days.
- 2) Cuttings should be taken from a healthy mother plant and from an area of said mother plant that appears to have new growth and have at least 3 node sites (*see picture of marijuana cutting shown above*).

*Example of a healthy mother plant(s):*



- 3) The vegetation of the mother plant should show little to no sign of deficiency. Signs of nitrogen deficiency (yellowing) within the mother plant indicate a clone becoming phosphorous, calcium, and magnesium deficiency during the cloning process.
- 4) Mother plants must be examined for any contaminants to assure a clean clone, as clone environments are ideal for pest and fungus proliferate.

### Documentation Log Sheets Required

- 1) Propagation Log Sheet
- 2) Daily Environment Documentation

### Supplies/Tools Required

- 1) 5-gallon Bucket
- 2) Rooting Stimulant
- 3) Small cup
- 4) Scissors (clean/sharp)
- 5) Razor blade (new)
- 6) Large Cup
- 7) Root Cubes
- 8) Clone Dome
- 9) Clone tray

### Preparation

- 1) Fill 5-gallon bucket with 3 gallons of filtered water.
- 2) Adjust the water to 5.8 pH.
- 3) Pour some of the adjusted water over the pre-soaked Root Cube trays
- 4) Soak Root Cube (medium) in solution for 5 minutes *\*See below (if applicable; if root cubes are not pre-soaked with nutrients).*



**Selecting Samples (Mother Plants)**

1) Select the branches that allow for ideal clone, leaf and stem structure.

**1. Mother Plant**

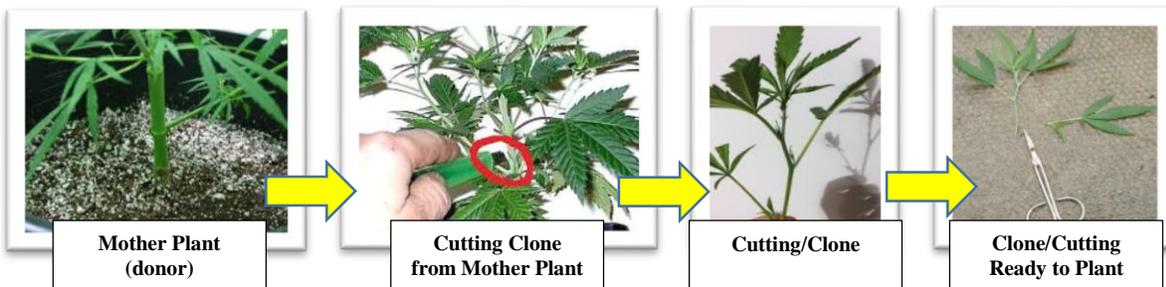
**2. Clone (cutting) to Take**

**3. Mother Plant after Cutting**

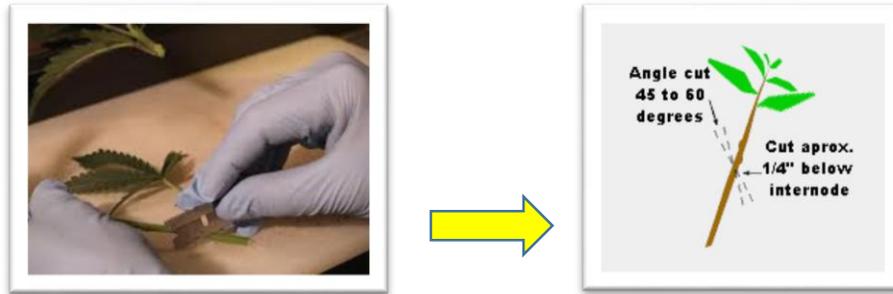


- 2) The samples should be 6-12 inches long.
- 3) 1” inch above the last node make a perpendicular (flat) laceration with a pair of scissors. Making the cut 1” above the node induces minimal stress and lowers risk of the Mother plant acquiring disease.
- 4) Trim all nodes except the 3-5 closest to the tip of the clone.
- 5) Form a loose fist with your hands to cup the leaves of the clone upward. Cut the tip of each major leaf off in a single motion.
- 6) Put the branch into a cup of water.
- 7) Repeat until you have finished taking samples of selected strain.
- 8) Only cut clones from one mother plant at a time.
- 9) Clean scissors with 91% rubbing alcohol between taking samples from each mother plant.

**Cutting Clones**



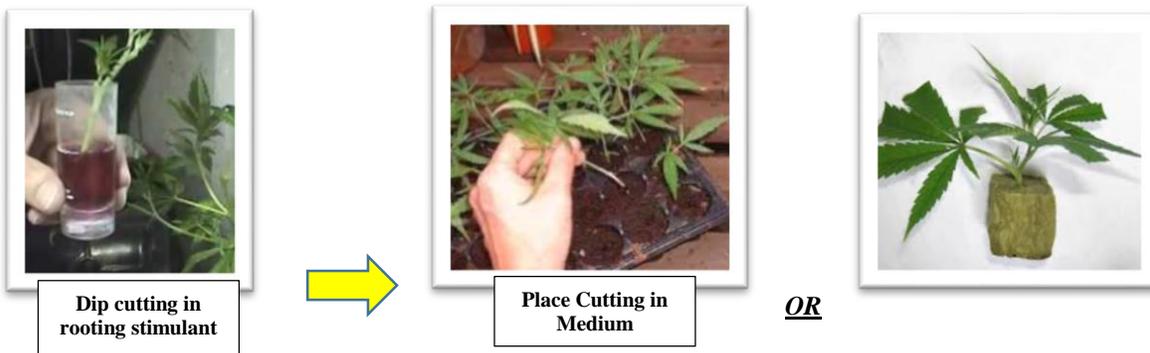
- 1) Using a clean razor or scissors for each mother, make a laceration or cut segmenting the stem at a 45°-60° angle.



- 2) Cut each branch to be 5-8 inches long.
- 3) Make three (3) delicate length-wise lacerations to the exterior plant tissue immediately above the base of the cutting to increase the exposed surface area of the cutting.
- 4) Dip the finalized portion of the clone into the rooting stimulant/hormone. Submerge the base of the cuttings stem 0.5" to 1" inches into the rooting solution/hormone.



- 5) Firmly bracing the stem insert the sample into the roter cube or into the clone hydroponic machine. Avoid bending or breaking the stalk while forcing the clone into a secure position.



- 6) Place 30-50 clones into each humidity dome or into the hydroponic cloning machine.

**Examples of Humidity Domes:**



**Examples of Hydroponic Clone Machines:**



- 7) Keep the domes covered while taking each clone to maintain required humidity levels; this is not required for the hydroponic clone machines.
- 8) Place the clones into their position in each humidity dome or clone machine and put the humidity dome/clone machine under the T-5 light on the clone rack or in the clone room/area.



- 9) Record and document all clones taken and all relative information required and document on the propagation log sheet.
- 10) Store equipment and clean work area

**Clone Moisture Regulation**

- 1) During this process the employee must analyze the moisture levels of all clones in each humidity dome and/or hydroponic/aeroponic cloning machines.
  - a. As the employee encounters clones that appear to be dry, they will be watered with a cloning nutrient solution or 5.8 pH water solution.
- 2) If a humidity dome/plant is determined to need to be watered said plant or humidity dome will be watered with a cloning nutrient solution or 5.8 pH water
  - a. Let water sit in the humidity dome for approximately 3-5 minutes to allow the root cubes to absorb the water and/or cloning nutrient solution
  - b. After 3-5 minutes pour remaining/excess water out of humidity dome.



- 3) Repeat individually for each humidity dome that needs water.
- 4) Do not spray plants with water directly or leave standing/stagnant water in the humidity domes/clone trays
  - a. This will help prevent disease such as powdery mildew
- 5) Store equipment and clean work area.

**Clones with Health Root Development (ready for transplant and vegetative growth stage)**

- 1) Allow the clone root system 5-14 days to develop before transplanting into a larger, vegetative Autopot and/or pot/container.



- **Tagging**
  - After each marijuana clone/cutting is transplanted the employee will record:
    - The number of plants.
    - The number of each tag used for every plant.
    - The new location each plant.
    - The date of transplant.
  - Once the data is captured an employee will place the tags selected for that plant into each pot.
  - All transplants are to be recorded into POS software day of transplant.
    - Double check data inputs to insure there are no mistakes.
  - Keep a hard copy of every change that occurs in the facility.
    - Plant moves, transplants, harvests, and waste will be the most frequent and important data inputs.
      - Place plant on rack to be transported to new location.
        - Recordkeeping/Documentation required:
          - Record:
            - New location
            - Date of transplant
          - All changes are to be recorded in POS tracking software day of activity(s).

**Example of Marijuana Plant Tag:**





Example of the Propagation Log sheet:

<b><u>Propagation Log</u></b>					
<u>Date:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Plant ID#/Strain that Clone was Taken From:</u>	<u>Quantity of Cuttings Taken:</u>	<u>POS Record Made/Notes:</u>
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
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-----<WEEK 2>-----

After two (2) weeks in the propagation/cloning growth stages the medical marijuana plants will transition into the vegetative growth stage. Prior to transferring plants into the vegetative growth stage, registered employees will perform a preventative Integrated Pest Management (IPM) measure by spraying and/or dunking/dipping the plants in an insecticide and/or fungicide. The various IPM steps and processes are the next SOP discussed followed by the vegetative growth.



Integrated Pest Management (IPM)

<b>Standard Operating Procedure:</b> Integrated Pest Management (IPM)
<b>Purpose:</b> To ensure that cultivation facility employees are properly trained in the identification of pest and diseases, preventative maintenance measures, eradication techniques, and documentation of all relevant information for IPM.
<b>Scope:</b> Procedures covering preventative maintenance and IPM activities within the cultivation facility.
<b>Initial Training:</b> 4-8 hours

**The Principles of Integrated Pest Management (IPM)**

IPM takes advantage of all appropriate pest management options including, but not limited to, the use of pesticides. In contrast, organic food crop cultivation applies many of the same concepts as IPM but limits the use of pesticides to those that are produced from natural sources, as opposed to synthetic chemicals.

IPM is not a single pest control method but, rather, a series of pest management evaluations, decisions, and controls. When practicing IPM, growers who are aware of the potential for pest infestation *utilize a four-tiered approach*:

- 1) **Set Action Thresholds**—before taking any pest control action, IPM first sets an action threshold, which is where you determine the level of pest and/or disease infestation that are acceptable and levels of infestation requiring control measures.
- 2) **Monitor and Identify Pests**—this is the stage in where pests and/or disease should be identified. IPM programs work to monitor for pests and identify them accurately, so that appropriate control decisions can be made in conjunction with action thresholds. Proper identification of pests and disease is of utmost importance in order to select the proper action and control measures to implement.

<b><u>Pest and Disease Identification Documentation</u></b>		
Date of 1st Sign of Infestation:	Type of Issue: <input type="checkbox"/> Pest/Insect Infestation <input type="checkbox"/> Mold/Fungal Infestation <input type="checkbox"/> Bacterial Infestation <input type="checkbox"/> Other	
Name of Pest or Disease (if known):	Zone/Room of Infestation:	
Corrective Action to be Taken:		
Notes:		

- 3) **Prevention**—as a first line of pest control, IPM programs work to manage the crop or cultivation area to prevent pests from becoming a threat. Preventative measures are practiced prior to entering a cultivation facility and through proper ‘clean’ protocols, preventative plant measures such as disease-fighting and disease-preventing nutrients and organic compost teas, and proper/optimal growing environments (*temperature, humidity, CO2 level, etc.*).
- 4) **Control**—once monitoring, identification, and action thresholds indicate that pest control is required, and preventive methods are no longer effective, the IPM program then evaluates the proper control method both for effectiveness and risk. Control measures will include the use of organic compost teas to help fight pest and/or disease. Predatory insects can also be used as a control measure to fight invasive insects. As a last

resort, control measures will include the use of approved insecticides, fungicides and other chemicals. Any control measure utilized will be approved for use of crops intended for human consumption. Upon the need for control employees will begin a process of disease/pest eradication by using select insecticides, fungicides or other measures. Employees will utilize three (3) different pesticides and three (3) different fungicides to properly combat the disease(s)/pest(s). These measures will be applied to the marijuana plants on a 3-day rotation to effectively combat the intrusion.

### **Documentation Log Sheets Required**

- 2) Pest and Disease Identification Documentation
- 3) Pesticide/Fungicide Application Log Sheet

### **Equipment/Tools Required**

- Personal Protective Equipment
  - a. Eye Protection
  - b. Tyvek protective coveralls
  - c. Respirator
  - d. Rubber gloves
- Tools
  - a. Atomizer/Sprayer
  - b. Scissors
  - c. Sticky Traps

### **Pesticides, Fungicides and Herbicides**

ACC limits the use of pesticides, fungicides and herbicides to a minimum. Producing medicinal grade medicine that is free of unwanted contaminants is at the core of ACC's mission. Especially when the products are being concentrated into oil forms further increasing the potential harmful effects of contaminants. The cultivation methodology to be implemented by ACC will utilize organic cultivation techniques in a biodynamic super soil medium. A biodynamic soil will have an active ecosystem of beneficial bacteria, these beneficial bacteria not only improve the expression of the plants genetic potential but also improve the plants natural immunity reducing the need for reliance on pesticides. ACC will only utilize organic pesticide, fungicides and herbicides that are approved for use on crops for human consumption and are not harmful to humans, animals or the environment.

### **Potential Pesticides, Fungicides, Herbicides or Other Chemicals:**

1. Actinovate
2. Azamax
3. Organocide
4. BotaniguardES
5. Pyganic
6. GreenCure
7. Green Clean
8. Neem Oil
9. Compost Teas
10. ProKureV
11. Clorox Bleach
12. Hydrogen Peroxide
13. Isopropyl Alcohol

### **Fungicides:**

- 1) **Actinovate**—beneficial bacterium *Streptomyces lydicus*, the product is OMRI listed and is sprayed as a preventative measure, or as a combative measure. It is applied on both root pests, as well as molds and mildews on the foliage.
- 2) **GreenCure**— Green cure is a fungicide comprised of potassium bicarbonate and is OMRI listed. Green cure raises the pH of the leaf surface to a level where mildew cannot survive



- 3) **Organocide**—organocide if a fungicide.

#### **Pesticides:**

- 1) **Azamax** — the active ingredient in Azamax is Azadirachtin. The product is OMRI listed, and is used as a broad spectrum pesticide, it is applied as a foliar as well as a root drench.
- 2) **BotaniguardES**— Organic product; the active ingredient in BotaniguardES is Beauveria bassiana. This beneficial bacteria acts as a growth inhibitor to soft bodied insects.
- 3) **Pyganic**— the active ingredient in Pyganic is Pyrethrin. This is an organic pesticide derived from the chrysanthemum flower. The product is OMRI listed.

#### **Preventative Maintenance:**

- 1) **Neem Oil**— Neem oil is used as a broad range preventative measure. The oil mechanically prevents mildew by protecting foliar surfaces, and also disrupts insect respiration by clogging an insects spiracles, which intake and exhale air. The product is OMRI Listed.
- 2) **Green Clean**— Organic- Green clean is a broad range preventative, a combination of plant based oils, as well an organic emulsifier. Used to disrupt the respiration in molds and mildews
- 3) **Compost Teas**— Organic - fungal dominant compost tea is used to non-chemically prevent powdery mildew, Compost teas also prevent root borne diseases by combating them with an array of microbes. Compost teas also strengthen a plants natural resistance to disease.

#### **Cleaning and Sanitation:**

1. **ProKureV**— Oxidizing agent, general cleaning, room sterilizing
2. **Hydrogen Peroxide**— Oxidizing agent, general cleaning and sterilizing
3. **Isopropyl Alcohol**— general cleaning and sterilization
4. **Clorox Bleach**— general cleaning and sterilization

All four of these are used to sterilize equipment between uses, or between cultivation cycles when cleaning empty cultivation rooms.

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### **<Preventative Measures>**

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Preventing the introduction of insects, molds, mildews, bacteria, and diseases in general is a top priority of the cultivation facility. Preventative measures and procedures will be implemented and utilized within the cultivation facility. All employees working within the facility must adhere to all IPM procedures and preventative measure and procedures.

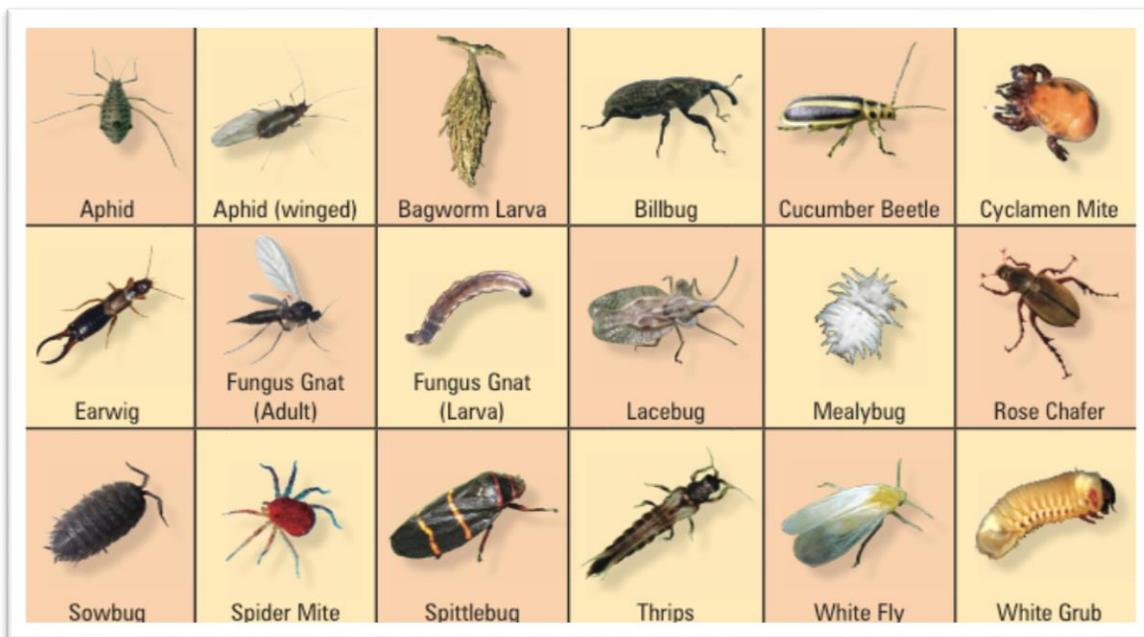
**Facility Entrance**—need to refer to and follow the Facility Entry Protocol SOP which explains the preventative procedures in place for entering the cultivation facility.

- **Cultivation Room(s)/Area(s)**—explains the preventative measures and procedures to follow prior to entering/while working within cultivation areas
  - Before entering the cultivation area all entry protocols for decontamination must be completed.
  - Once decontaminated the employee is to enter the facility through the air shower.
    - Air Shower: Enclosure that removes contaminates via air movement, pressure, and filtration.
  - Cultivation Rooms
    - At the entrance to each room a footbath will be required to decontaminate shoes. This will prevent employees from becoming a vector for spreading contaminates between rooms.
    - Gloves are required to be worn upon entry of each cultivation room.
    - Gloves are to be removed before exiting each cultivation area.
    - DO NOT use the same pair of gloves to manicure plants in two different rooms.
    - Gardeners will be trained in IPM to insure contaminates are located early in development.
  - **Cultivation Room Outbreak Protocol**—explains the procedures to follow once a problem or pest/disease arises.
    - After a room is labeled contaminated it must be kept isolated.

- Footbaths will be placed on both sides of the door.
- Lab coats will be worn in these isolated zones and are always removed before exiting the contamination zone.
- It is critical that the necessary precaution is taken to eliminate the spread of an outbreak.
  - Strict managerial protocol will be necessary during these times.
  - No employee shall enter this room without a Head Grower.
- **Cultivation Room Waste Disposal**—explains the procedures to follow within the cultivation rooms for waste disposal (*random trash and unwanted plant material*)
  - Each room will be equipped with two garbage cans.
    - One can for trash and another can specifically for plant material only.
      - Never mix plant waste with trash.
    - Plant Waste
      - Under state law plant waste must be weighed and recorded before going to the proper disposal unit.
      - A log will be kept at each door to record kilograms of manicure waste.

**<Identifying Pests and Disease(s)>**

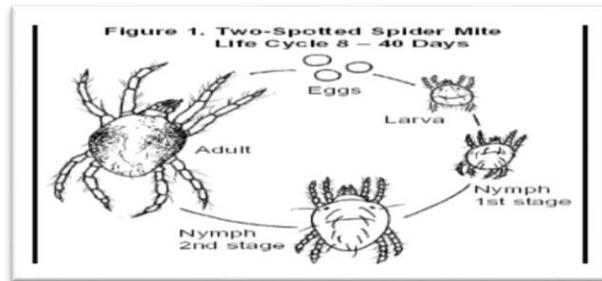
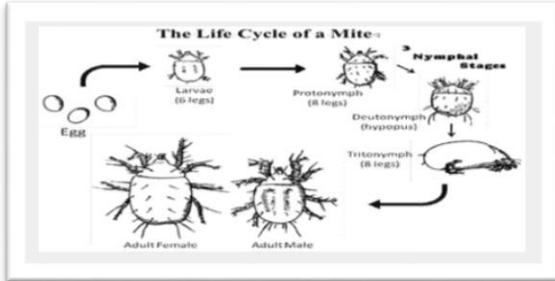
Marijuana plants can be susceptible to a multitude of different pests and insects. Highlighted within this IPM SOP will be the most common pests and insects found within a commercial cultivation facility.

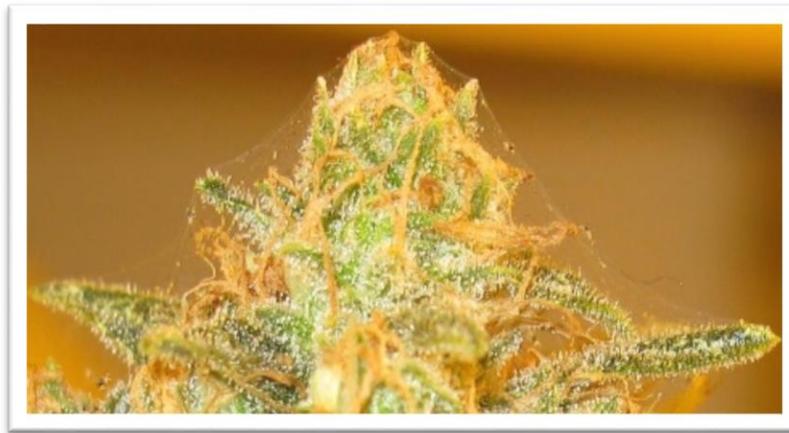


**Spider Mites**—generally live on the undersides of leaves of plants, where they may spin protective silk webs, and they can cause damage by puncturing the plant cells to feed. Spider mites are known to feed on several hundred species of plants, including the marijuana plant. Hot, dry conditions are often associated with population build-up of spider mites. Under optimal conditions (approximately 80 °F or 27 °C), the two-spotted spider mite can hatch in as little as 3 days, and become sexually mature in as little as 5 days. One female can lay up to 20 eggs per day and can live for 2 to 4 weeks, laying hundreds of eggs. This accelerated reproductive rate allows spider mite populations to adapt quickly to resist pesticides, so chemical control methods can become somewhat ineffectual when the same pesticide is used over a prolonged period.

**Action Threshold:** When multiple stages of the insect’s life cycle is identified.

**Monitoring and Identifying:** Keeping an eye out for each stage of the life cycle is key to monitoring plants for mites. There are 4 stages in a mites' life: egg, larvae, nymph, and adult. Eggs are laid on the underside of the leaf and take 3 days to hatch. Larvae and nymphs live in localized areas on the undersides of the leaves and avoid being exposed. Adult mites are mobile and move to areas of the plant where they can reproduce most efficiently. Looking at the bottom side of leaves will expose the egg, larvae, and nymph.





**Prevention:** The consequence of using broad-spectrum chemical pesticide is that the chemicals can be toxic to non-target beneficial or endangered species. The modern concept of biological pest control has been developed primarily by entomologists and in practice is taken to mean the use of living natural enemies to control pest species.

**Control:** In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

**Azamax** (follow manufacture recommendations for mix ratios):

- Fill 5-gallon bucket with 2 gallons of water.
- Add an emulsifier or wetting agent
- Mix 30 mL of Azamax per gallon of water.
- Apply as a foliar spray with pump sprayer and/or atomizer.

**Pyganic** (follow manufacture recommendations for mix ratios):

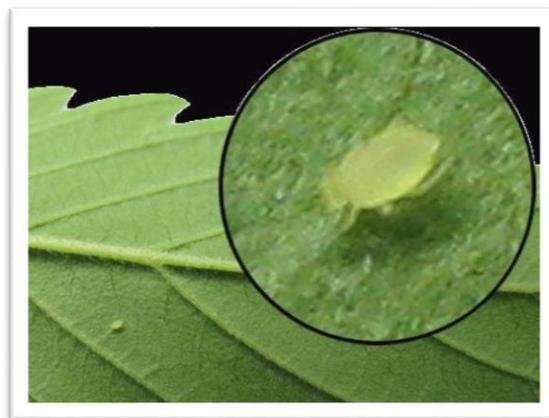
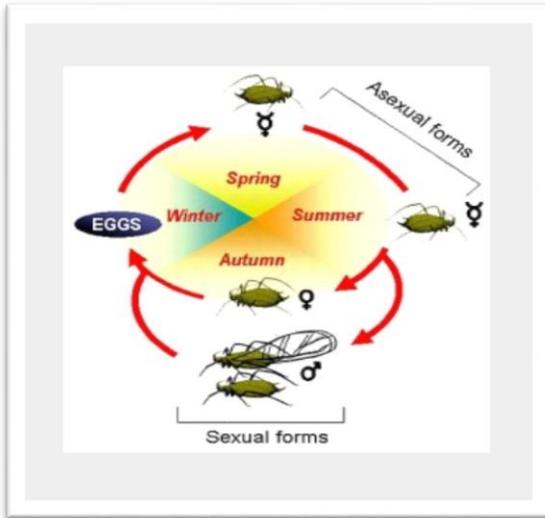
- Fill 5-gallon bucket with 2 gallons of water
- Add an emulsifier or wetting agent
- Mix 30mL of Pyganic per gallon of water
- Apply as a foliar spray with fogger

**<Aphids>**

**Aphids**—are small sap-sucking insects, and members of the superfamily Aphidoidea. Aphids are among the most destructive insect pests on cultivated plants in temperate regions.

**Action Threshold:** When multiple stage of the insect’s life cycle are identified.

**Monitoring and Identifying:** Aphids are visible to the human eye. These insects live together in localized colonies. An Aphids infestation will be obvious to the rudimentary gardener after the insect matures to its adult state. Early signs of an aphid infestation are visible when the tips of the oldest leaves begin to curl under. This is caused when the larvae begin to feed on the tips of roots.



**Control:** In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

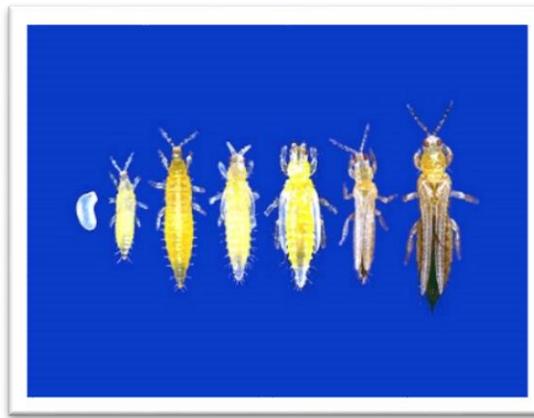
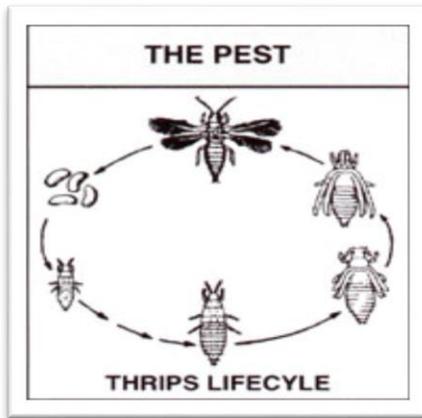
- **Aphid**
  - Spray Azamax at a rate of 30ml/g or use as soil drench
  - Place yellow sticky traps at the base of each plant.
    - Tie the sticky trap to the stalk where the aphids cannot crawl past the trap.
    - Replace sticky trap on each plant weekly for 4 weeks in all infested cultivation areas.

**<Thrips>**

**Thrips**—are tiny, slender insects with fringed wings. Thrips species feed on a large variety of plants and animals by puncturing them and sucking up the contents. A large number of thrips species are considered pests, because they feed on plants with commercial value such as the marijuana plant.

**Action Threshold:** When multiple stage of the insect’s life cycle are diagnosed.

**Monitoring and Identifying:** Daily inspection of the canopy allow the gardener to identify Thrips at the first visible plant indication of an infestation. Thrip larvae feed on the vegetative growth of the plant. Thrips damage the leaf structure leaving behind white scars called “color break,” which is pale or dark discoloring of leaf tissue that was killed.



**Control:** Thrips are typically an easier pest to mitigate, and 1-2 applications is all that is necessary. Apply Azamax and/or Monterey Garden Spray. In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

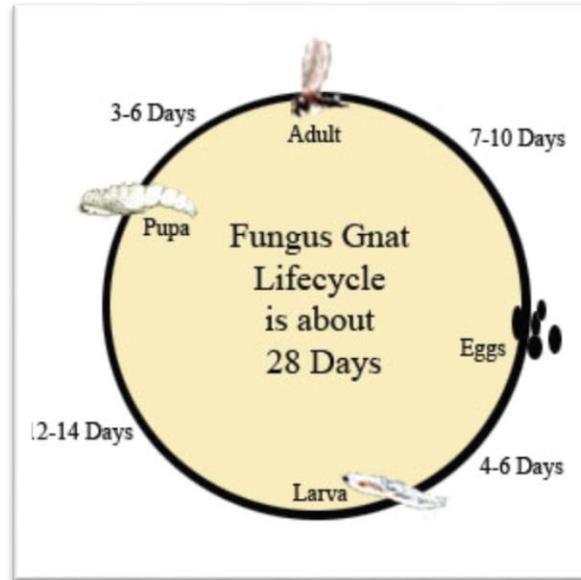
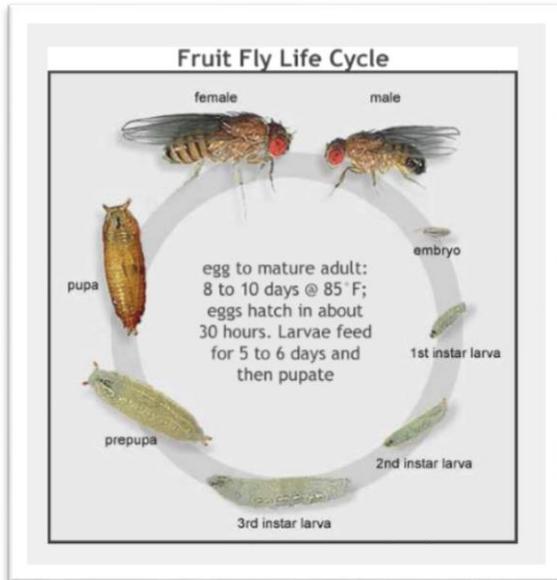
- Mix 30mL/gallon Azamax
- Apply as foliar spray to the canopy of all plants.
- Place yellow sticky traps at the base of each plant.
  - Tie the sticky trap to the stalk where the aphids cannot crawl past the trap.
  - Replace sticky trap on each plant weekly for 4 weeks in all infested cultivation areas.

**<Fungus Gnats>**

**Fungus Gnats**— are small, dark, short-lived flies. The larvae feed on plant roots and fungi, helping in the decomposition of organic matter. The adults are 2–5 mm long can carry diseases such as pythium on their feet.

**Action Threshold:** When multiple stage of the insect’s life cycle are identified.

**Monitoring and Identifying:** Fungus gnat infestations are obvious when the insect has matured to the adult stage. These pest are air born. They will be seen flying around the canopy, lights, and soil.



**Prevention:** Healthy organic soil will produce an array of micro life. Nematodes are predatory roundworms which feed on the larval stage of the fungus gnat. Applying organic cultivation methods will result in a diverse spectrum of natural predators which limit fungus gnat reproduction.

**Control:** In the occurrence of an outbreak chemical pesticides will be used to prevent spreading contaminants between rooms. Pesticides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

- **Fungus Gnat Larvae**
  - Mix 3mL/gallon H2O2 (hydrogen peroxide) in your reservoir.



- Saturate the soil mass completely.
- **Adult Fungus Gnat**
  - Place yellow sticky traps at the base of each plant.
    - Tie the sticky trap to the stalk where the aphids cannot crawl past the trap.
    - Replace sticky trap on each plant weekly for 4 weeks in all infested cultivation areas.

-----<Disease(s); Mold, Mildew and Bacteria>-----

Marijuana plants can be susceptible to a multitude of different diseases. Disease can range from a wide variety of different molds, mildews and bacteria. Highlighted within this IPM SOP will be the most common diseases found within a commercial cultivation facility.

-----<Powdery Mildew>-----

**Powdery Mildew**—is a fungal disease that affects a wide range of plants. Powdery mildew is caused by many different species of fungi. It is one of the easier diseases to spot, as its symptoms are quite distinctive. Infected plants display white powdery spots on the leaves and stems. The lower leaves are the most affected, but the mildew can appear on any above ground part of the plant. As the disease progresses, the spots get larger and denser as large numbers of asexual spores are formed, and the mildew may spread up and down the length of the plant. Powdery mildew grows well in environments with high humidity and moderate temperatures.

**Action Threshold:** First sign of infection.

**Monitoring and Identifying:** Daily inspections of the canopy allow a gardener to identify mildew at its earliest stages. Powdery Mildew begins to grow in the crevices of the leaf and stem. Identifying PM in these areas will keep a gardener ahead of the growth curve.



**Prevention:** Ultra-violet scrubbers will kill spores circulating through the air and will prevent spreading contaminants between rooms and plants.



**Control:** Chemical controls can be applied to prevent mildew from spreading across the vegetation. In the occurrence of an outbreak chemical fungicides will be used to prevent spreading contaminants between rooms. Fungicides will be applied according to manufacturer recommendations. See chemical treatment SOP for further direction on application instructions.

- Powdery Mildew in Veg
  - Mix 30ml/gallon Green Cure.
  - Apply as foliar spray to the canopy of all plants.
    - The active ingredient changes the PH of the surface of the leaves not allowing mold spores to grow.
    - Continue spraying every 30 days or once visible again.
- Powdery Mildew in Flower
  - Mix 10mL/gallon Actinovate fungicide.
  - Apply as foliar spray to the canopy of all plants once first sign of PM.

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**<Pythium>**

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**Pythium**— Commonly referred to as root rot is a fungal disease. To avoid root rot, it is best to only water plants when the soil becomes dry, and to put the plant in a well-drained pot. A plant with root rot will not normally survive, but can often be propagated so it will not be lost completely. Plants with root rot should be removed and destroyed.



**Action Threshold:** At first sign of the parasitic relationship.

**Monitoring and Identifying:** Pythium is a common development of plants that are over-watered. Monitoring the moisture of the soil will help identify an infection. A plant's leaves will droop when it is over saturated with moisture. Stagnant water left in a hydroponic system heightens risk of Pythium colonization.

**Prevention:** Do not allow stagnant water to evaporate anywhere in the cultivation environment.

**Control:** Kill and remove the plant.

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**<Botrytis>**

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**Botrytis (Grey Mold/Bud Rot)** — is commonly known as grey mold or bud rot. Bud rot is the result of consistently wet or humid conditions, and typically results in the loss of the affected flowers.



**Action Threshold:** After first sign of the mold developing.

**Monitoring and Identifying:** When the humidity in a cultivation facility exceeds 50% the plants are at risk of developing Botrytis. Botrytis grows on the inside of the flower where the dense cluster of calyxes supplies adequate moisture and nutrient to the mold. Physically separating the calyxes of each large cola by hand will expose Botrytis for diagnosis.

**Prevention:** Maintain homeostasis of the atmosphere in the cultivation environment. Make sure there is adequate air circulation over the plant canopy.

**Control:** Maintain humidity at or below 45%.

### **Quarantine of Marijuana Plants**

The first step to quarantining a cultivation room is to stop any risk of immediate spread. The room the pest is found in must be immediately closed, and no registered employees may enter or exit. The registered employees in the affected room upon discovery must first line up by the entrance remove gloves, replace gloves, and put on a full body chemical suit with foot covers. The registered employees are then allowed to exit the room while stepping in the footbath, and head to the air shower. After the air shower has cycled, if time allows, registered employees will take a second shower, and change into clean scrubs. These registered employees may now finish the entry protocol, and reenter the “clean” area of the facility.



The contaminated room is now under quarantine protocol, which creates a barrier where the risk of spread can be reduced. During this time, the minimum number of registered employees necessary to complete tasks will enter the room. These registered employees will undergo separate entry protocols designated to the contaminated room. A station of necessary equipment will be placed next to the contaminated room for easy access to body suits, gloves, hairnets, and sterilizing equipment such as hydrogen peroxide. Prior to entry to the contaminated room, registered employees will put on a full body suit, hair net, clean gloves, and shoe covers. During the time in the room, this covering clothing is designed to keep and pests on the suit, and away from the grower agent's hair, and scrubs. When exiting the room, employees will line up by the door to complete the exit protocol. Employees will remove all garments except scrubs, and shoes. The grower agent will place the contaminated clothing into a trash bag for immediate disposal. Upon exiting the room, employees will exit through the air shower, and repeat the entry protocol, to complete work on the rest of the facility. This room will remain on quarantine protocol for 1-week post finding zero sign of pests on daily inspections. It is imperative to inspect each room closely in order assure the quarantine protocol can be halted.



Chemical Treatment

<b>Standard Operating Procedure:</b> Chemical Treatment of Plants
<b>Purpose:</b> To explain how to properly treat a plant with chemicals ( <i>pesticide, insecticide, fungicide, etc.</i> ) and the different methods of treatment.
<b>Scope:</b> To train employees on proper treatment of plants and different methods of treatment. <i>*Refer to IPM SOP and manufacturer directions for chemical usage rates, frequency and amounts.</i>
<b>Training:</b> 4-6 hours

### **The Principles of Chemical Treatment of Plants**

If a pest and/or disease issue is identified within the marijuana crop being cultivated, IPM protocol dictates for a physical chemical application of required pesticides, insecticide, fungicides or other chemicals to eradicate the identified issue.

Facility employees will need to refer to the IPM SOP to determine which pesticide, fungicide, insecticide or other chemical is required to spray on the marijuana crop to rid the infestation/issue. Refer to the instructions on the identified chemical for proper mix/dosage rates.

All pesticide treatment applicators and applications will follow State and federal pesticide requirements for any pesticide applied.

Pesticide applicators/registered employees will undergo required courses and testing to obtain a Private Applicators Certificate, as well as recertification every 3 years, becoming Registered Employees by the State of Hawaii. Applicant's Consultant will complete requirements for Reciprocity. All pesticides applied will be approved by the FDA's National Organic Program, and will be approved on the National List of allowed and prohibited pesticides and OMRI approved.

### **Chemical Treatment of Plants through Dipping/Dunking**

The principle behind dipping/dunking marijuana plants as a chemical application is through dipping/dunking you ensure that the entire surface area of the plant has been treated with the desired chemical. (*When spraying plants with desired chemicals, it is not always ensured that every surface area of the plant has been treated*)

#### **How to Dip/Dunk a Plant:**

1. Get a decent sized container to fill with the desired chemical and water (*follow manufacturer recommended mix rate/dosage instruction*)
  - a. The size of container needed will be determined by the size of plants intended to be dipped/dunked
  - b. Typically a 5-gallon bucket should suffice as you should only dip/dunk smaller plants. However if the need does arise to dip/dunk a larger plant, a plastic trash bin can be utilized to dip/dunk larger plants.
2. Once the container is properly mixed with the desired chemical at the proper rate the plants can be dipped/dunked in the solution
  - a. Ensure that prior to dipping/dunking a plant that you have a hold of the plant medium as you do not want the medium (*dirt, coco, etc.*) to fall into the chemical solution
3. Once the plant has been dipped/dunked, do NOT place it directly under HID lighting as this could result in the plant burning and other negative effects
  - a. Wait until the plant appears to be 75% to 90% dry before placing it back under HID or grow lighting

### **Chemical Treatment of Plants with a Sprayer** (*pump sprayer, automated sprayer or atomizer*)

- Fill the pump sprayer or atomizer sprayer with the proper dilution of the required chemical according to manufacture recommendations.



- Spray applications on marijuana plants should be done while the HID/LED lights are OFF.
  - If the lights are left on, and the plants sprayed/treated it may cause plant burning and damage.
- Spray plants with a gentle action trying not to cause damage to plant stalks, branches and/or leaves.
- Ensure to adequately spray all undersides of plant leaves as this is where a majority of pests live.
- Allow plants to dry completely prior to placing the plants back underneath HID/LED lighting and prior to turning the lights back on.

***Example of Pump Sprayer(s):***



***Examples of Atomizer Sprayer(s):***



**Chemical Treatment of Plants through Root Drench**

Sometimes there is a need to perform a soil/root drench on the plants to eliminate a disease and/or pest. This is done through mixing the desired chemical with the proper mix rates/dosage rates that the manufacturer suggests, once the desired chemical is properly mix at the correct rates the mixture is then evenly poured into the plants container containing the medium (*soil, coco, etc.*).

Pour the mixed chemical all over the plants base and medium as if you were hand watering the plant.

**Documentation**—after an employee of the licensed premise applies any pesticide, insecticide, fungicide or other chemical application to marijuana plants they will be required to document the application on the ***Pesticide/Fungicide Application Documentation*** log sheet.

***Example of Pesticide/Fungicide Application Documentation:***



**Pesticide/Fungicide Application Documentation**

<u>Date/Time Applied</u>	<u>Employee/Signature/License #</u>	<u>EPA Registration #</u>	<u>Name of Pesticide</u>	<u>RFID Tag #/Batch # or Room Applied To</u>	<u>Amount Applied</u>



Transplanting

<b>Standard Operating Procedure:</b> Transplanting Marijuana Plants
<b>Purpose:</b> To explain how to properly transplant marijuana plants into a larger container.
<b>Scope:</b> To train employees how to properly transplant, tag and record/document transplanting activities.
<b>Initial Training:</b> 4-6 hours

### The Principles of Transplanting Plants

Transplanting is the process of staging plant into a larger sized container. Typically transplanting will be done 2-3 times during the plants lifecycle 1) from a clone into a 1 gallon container, 2) from a 1 gallon container into a 2-7 gallon container and 3) from a 2-7 gallon container into the final container of 7-15 gallons.

- **Pre-Transplant**
  - Rooms receiving transplants should be cleaned and ready for cultivation.
  - Water valves on mainlines of plumbing that feed vegetative plants are turned off to allow plants (12-24 hours) to adjust to proper moisture content for transplant.
  
- **Transplant**
  - Remove plants of strains being transplanted from container/AutoPot system onto transport racks.
    - Transport each strain as a group in order to keep our tagging organized.
  - Move plants to transplanting area.
  - Prepare new container/AutoPot for transplant.
    - Copper Screen (*only if using AutoPots*):
      - First, a mesh copper screen will be placed into the bottom of each pot with the copper facing away from the root zone (copper down)
        - Double check your work to be sure the correct equipment is installed
    - Perlite:
      - Second, 2" of Perlite will be placed on the bottom of each pot to insure the root zone is adequately aerated.
  - Fill container/AutoPot with adequate soil/medium to support a 1 gallon sized root zone.
  - Remove the plant from the pot following these steps:
    - Carefully press the sides of the 1 gallon pot inward to loosen the root mass.
    - Place hand on top of soil with stalk between fingers
    - Spread fingers apart to support the inverted root mass
    - Carefully flip plant over with plant between fingers
    - Pull pot upward away from roots
    - Balancing the root mass
    - Aerate dense clusters of roots by gently loosening the growing medium/plant root structure
  - Slowly rotate plant upright and place gently into new container/AutoPot.
  - Fill in empty space with soil/medium.
    - Tamp pot on table/ floor to evenly compact soil/medium
  - Water until soil is thoroughly saturated
  - Place tag into soil/medium; or around plant base or on a branch
  
- **Tagging**
  - After each plant is transplanted the employee will record:
    - The number of plants.
    - The number of each tag used for every plant.
    - The new location each plant.



- The date of transplant.
- Once the data is captured an employee will need to ensure that the plant tag/unique ID tag remains with the plant throughout the plants entire lifecycle.
- All transplants are to be recorded into POS software day of transplant.
  - Double check data inputs to insure there are no mistakes.
- Keep a hard copy of every change that occurs in the facility.
  - Plant moves, transplants, harvests, and waste will be the most frequent and important data inputs.
    - Place plant on rack to be transported to new location.
      - Recordkeeping/Documentation required:
        - Record:
          - New location
          - Date of transplant
  - All changes are to be recorded in POS tracking software day of activity(s).

**Example of Marijuana Plant Tag:**



**Example of Transplant Log Sheet:**

<b><u>Transplant Log</u></b>									
<u>Date:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Plant ID# and Batch #:</u>	<u>Plant Lifecycle Stage:</u>	<u>Original Container Size:</u>	<u>New Container Size:</u>	<u>POS Record Made:</u>		
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	
							<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	



Vegetative Growth Stage

<b>Standard Operating Procedure: Vegetative Growth Stages</b>
<b>Purpose:</b> Demonstrate to proper methods and techniques for healthy marijuana cultivation. Including light cycles, feeding schedules, plant care and maintenance, Integrated Pest Management (IPM), etc.
<b>Scope:</b> These procedures cover marijuana cultivation procedures, methods and techniques in the vegetative and flowering growth stages within the cultivation facility.
<b>Plant Environment:</b> 75-85 <sup>0</sup> Fahrenheit; Humidity ~30-50%
<b>Plant Light/Photoperiod: Vegetative Cycle:</b> Minimum of 18 hours of light ( <i>18 hours lights on; 6 hours light off</i> ) and up to 24 hours of continuous light.
<b>Initial Training:</b> 8-16 hours

### **Documentation Log Sheets Required**

- 1) Daily Environment Documentation
- 2) Daily Plant Monitoring Log Sheet
- 3) Weekly Plant Monitoring Log Sheet
- 4) Daily Products Transfer/Wholesale Log Sheet
- 5) Marijuana Waste Log Sheet

### **Supplies/Tools Required**

- 1) Scissors
- 2) Measuring cups
- 3) Sunglasses
- 4) Personal Protective Equipment (PPE)
  - a. Protective eye gear
  - b. Respirators
  - c. Tyvek protective coveralls
  - d. Etc.
- 5) Watering hoses
- 6) Meters
  - a. TDS pen
  - b. pH Meter
  - c. Light Meter
- 7) Plant Ties
- 8) Trash can(s)

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### **<WEEK 3>**

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Week 3 is the first week of the vegetative growth stage. The purpose of the vegetative growth stage is to prepare the plant for the flowering growth stage. The vegetative stage is very important stage in the marijuana life cycle, a healthy vegetative plant will become a healthy flowering plant producing optimal medicine.

*Examples of Marijuana Plants in the Vegetative Growth Stage (can be seen below):*



**Transplanting**—process of staging plant into larger sized containers during vegetative growth stage.

- Prepare the 1-2 gallon pot to be filled with soil/medium.
- Fill pot to proper height with SoHum soil/medium.
- Lightly press clone into soil/medium.
- Pack the soil around the clone with fingertips.
- Thoroughly water in clone with ½ gallon of filter water.
- Plant 1 strain at a time.
  - This prevents mislabeling of genetics.
- Place each clone/container on rack system to be moved into its vegetative room.

**Foliar Feeding**—the foliar application of plant nutrients is the fastest, most effective method for treating deficiencies. Directly applying the appropriate solution provides nearly immediate results, and can have easily noticeable effects on yield and overall plant health. Foliar sprays can be used to supplement deficient nutrients, introduce beneficial organisms, and also add certain supplements, which, add to flavor and potency. Compost tea foliar applications should be not be applied after the 5<sup>th</sup> week of the flowering cycle.

#### Step 1: Foliar Tea

- Fill tea brewer with de-chlorinated, or RO water, and begin aerating.
- In a large tea bag, combine the ingredients below.

#### Step 2: Preparing Solution

- For foliar application tea will be diluted with water at a ratio of 1:5
- Pour tea through a 70 micron filter or filter floss to remove sediment
- Dilute tea and fill sprayer as close to spraying time as possible

→ **ALL measurements per 5 gallons**

##### **Foliar Tea:**

- 1 Cups Worm castings
- 1 Cups Humisoil
- 1/2 Cup Alfalfa Meal

##### **Directly in Water:**

- 2 Tbsp. Powdered Molasses
- 2 Tbsp. Liquid Kelp
- 1 tsp Glacial Rock Dust
- Aerate tea for 24 hours

#### Step 3: Application

- Approximately 1-2 hours before lights turn on, or immediately after lights turn off, prepare to spray solution
- During application, wear a respirator
- Using pump sprayer or atomizer to apply tea solution to foliage, making sure to coat the underside and top of all leaf surfaces and stems



#### Step 4: Clean Brewer and sprayer

- Immediately after application wash sprayer and rinse with hydrogen peroxide solution
- Clean brewer immediately after brewing is complete. An unsterile brewer can cause breakouts of non-beneficial microbes

\*Note: If compost tea is already being brewed in the facility it can be used for foliar application as long as it does not contain large amounts of guanos.

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### <WEEK 4>

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During the 4<sup>th</sup> week, plants will transition into rapid growth. The root structures will take hold of the soil mass maximizing the plants water absorption. Expect increase water consumption and prepare plants for transplant into large pots by pruning undergrowth. Train plants at the end of this week.

**\*\* NEVER prune a plant prior to taking cuttings/clones from the plant. The material to be pruned from the plant can be used as cuttings to create clones for the future cultivation. \*\***

**Pruning Marijuana Plants**—Pruning marijuana plants is imperative to ensure high yields, as well as a fundamental part of integrated pest management. Without proper pruning, plants will allocate energy to lower-level, light deprived flowers. This will deprive your high yielding canopy, causing light airy flowers. Keeping the plant undergrowth clean of unhealthy and overcrowded branches allows greater airflow and decreases available habitats for pests, molds, and mildews.

Marijuana strains vary greatly in their growth habits creating very different Anatomical Plant Analysis (APA). A strain's APA is defined by its growth characteristics such as, transition period growth, node spacing, flowering period, and flower morphology. These characteristics differ between every strain, and must be documented to create a standardized pruning technique for each one. Transition period growth is particularly important when developing a strain specific pruning procedure. This transition growth is defined by the increased vertical growth during the first stage of the flowering period, followed by increased lateral flower production.

Sativa dominant strains will typically have a longer period of transition growth, and some will still grow vertically into the 4<sup>th</sup> week of the flowering period. These strains with longer transition growth periods will require increased pruning, some sativa strains may need the bottom half of branches to be removed. This increased pruning will also decrease the node spacing during the growth period and form tighter, denser flowers. Indica strains will have a much shorter transition growth period, and will require less pruning. This shorter transition growth period must be taken into consideration in order to ensure maximum yields. In general indica dominant strains should be pruned only 1/3 from the base of the plant, and only very light deprived bud sites should be removed. These strains should also be switched to the flowering period later than sativa strains to ensure maximum yields.

#### Step 1: Preparation

- 1) Clean scissors with isopropyl alcohol
- 2) Assess plants APA's to identify plants requiring pruning

#### Step 2: Pruning Marijuana Plants

- 1) Starting at the lowest point of the plant; begin removing branches on the bottom third of the plant (*keep in mind strains APA and pruning procedure*)
- 2) After bottom third of the plant is clear, remove any undergrown branches and bud sites in the center/core of the plant
- 3) Removing weak bud sites, but not removing the entire branch will cause the plant to concentrate energy into the terminal bud on the branch and increase yields
- 4) Be sure to note what strain you are pruning, and if it is properly pruned according to its APA and designated pruning procedure

#### Step 3: Post-Pruning

- 1) Move plants to designated location



- 2) Clean work area ensuring no plant material remains, and area is free of debris

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<WEEK 5>

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The goal of week 5 is to transplant, relocate, and monitor the growth of plants approaching the flowering cycle. Maintaining the health of plants at this stage will allow for maximum node development during the first 3 weeks of flower.

**Transplant: Vegetative to Flower (1-7 gallon)**

- **Pre-Transplant**
  - Rooms receiving transplants should be cleaned and ready for cultivation.
  - Water valves on mainlines of plumbing that feed vegetative plants are turned off to allow plants (12-24 hours) to adjust to proper moisture content for transplant.
  
- **Transplant**
  - Remove plants of strains being transplanted from container/AutoPot system onto transport racks.
    - Transport each strain as a group in order to keep our tagging organized.
  - Move plants to transplanting area.
  - Prepare new container/AutoPot for transplant.
    - Copper Screen (*only if using AutoPots*):
      - First, a mesh copper screen will be placed into the bottom of each pot with the copper facing away from the root zone (copper down)
        - Double check your work to be sure the correct equipment is installed
    - Perlite:
      - Second, 2" of Perlite will be placed on the bottom of each pot to insure the root zone is adequately aerated.
  - Fill container/AutoPot with adequate soil/medium to support a 1 gallon sized root zone.
  - Remove the plant from the pot following these steps:
    - Carefully press the sides of the 1 gallon pot inward to loosen the root mass.
    - Place hand on top of soil with stalk between fingers
    - Spread fingers apart to support the inverted root mass
    - Carefully flip plant over with plant between fingers
    - Pull pot upward away from roots
    - Balancing the root mass
    - Aerate dense clusters of roots by gentle massaging
  - Slowly rotate plant upright and place gently into new container/AutoPot.
  - Fill in empty space with soil/medium.
    - Tamp pot on table/ floor to evenly compact soil/medium
  - Water until soil is thoroughly saturated
  - Place tag into soil/medium; or around plant base or on a branch
  - Place plant on rack to be transported to new location.
    - Recordkeeping/Documentation required:
      - Record:
        - New location
        - Date of transplant
      - All changes are to be recorded in POS tracking software day of activity(s).

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<WEEK 6>

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Monitoring the plants closely for pests will prevent outbreaks later in the flower cycle. Treat for any visible signs of target species.

- Adhere to IPM protocol; final vegetative spray treatment prior to transitioning into flowering growth stage
- After week six, the medical marijuana plants will be transitioned into the flowering growth stage where the plants' photo cycle will be altered causing them to begin producing flowers. The flowering growth stage is the next SOP discussed.



Flowering Growth Stage

<b>Standard Operating Procedure: Flowering Growth Stage</b>
<b>Purpose:</b> Demonstrate proper methods and techniques for healthy marijuana cultivation, including light cycles, feeding schedules, plant care and maintenance, Integrated Pest Management (IPM), etc.
<b>Scope:</b> These procedures cover marijuana cultivation procedures, methods and techniques in the flowering growth stages within the cultivation facility.
<b>Plant Environment:</b> ~72-78 <sup>0</sup> Fahrenheit; Humidity ~30-50%
<b>Plant Light/Photoperiod: Flowering Cycle:</b> 12 hours of lights on and 12 hours lights off. <i>(must be 12 hours of uninterrupted darkness)</i>
<b>Training:</b> 8 hours

### Documentation Log Sheets Required

- 1) Daily Environment Documentation
- 2) Daily Plant Monitoring Log Sheet
- 3) Weekly Plant Monitoring Log Sheet
- 4) Daily Products Transfer/Wholesale Log Sheet
- 5) Marijuana Waste Log Sheet

### Equipment/Tools Required

- 1) Scissors
- 2) Measuring cups
- 3) Sunglasses
- 4) Personal Protective Equipment (PPE)
  - a. Protective eye gear
  - b. Respirators
  - c. Tyvek protective coveralls
  - d. Etc.
- 5) Watering Pumps, Hoses, Watering Can, etc.
- 6) Meters
  - a. TDS pen
  - b. pH Meter
  - c. Light Meter
- 7) Trellis Netting/plant stakes
- 8) Plant Ties
- 9) Trash can(s)

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### <WEEK 7>

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The 7<sup>th</sup> week is the first week of the flowering growth stage. The flowering growth stage is where your marijuana plants will start to form flowers. This is the stage of the plants life when the majority of weight is gained and oil production occurs. The marijuana plants should be prepared for the flowering growth stage by supporting the plants stock and/or branches through trellising, staking, pruning, and defoliating any excessive canopy.

*Examples of Marijuana Plants in Flowering Growth Stage (can be seen below):*



*Early Flowering Stage*



*Mid Flowering Stage*



*Late Flowering Stage*

**Pruning/Defoliating**—Remove unwanted plant growth. A majority of the required pruning/defoliating will have already occurred during the vegetative stage; so during this time of pruning/defoliating you should only remove new plant growth and foliage that has regrown in previously pruned areas. Pruning/defoliating will allow light to penetrate the plant canopy and result in optimal plant growth and production.

**Trellis Netting**—the use of trellis netting for marijuana cultivation plays several roles in plant health. The main goal in trellising is to provide support for the plant when flower/bud weight increases later in the flowering stage. Providing this support also allows the plant to dedicate energy to flower production, rather than expending energy supporting heavy flowers. Besides physical support, trellising also improves airflow under the canopy, which is an integral aspect of integrated pest management.

→Trellis netting should occur within the first 5-7 days of the flowering cycle.

### **Step 1: Plant Preparation**

- Plants should be previously pruned according to pruning procedures
- Plants should be in final position for completion of round.

### **Step 2: Hanging Trellis**

- In open areas, spread trellis to full extension
- Starting furthest from entry point, attach one short side of trellis to wall, or trellis support
- Stretch the remaining trellis over the canopy, laying ovetop of the plants
- Pull the trellis tight, and attach to wall or trellis support
- The trellis should be uniformly tight, 2”-4” below the top of canopy

### **Step 3: Adjusting Plant Canopy**

- Situate branches evenly in the canopy, concentrating on preventing crowding in any one area
- The tallest branches protruding more than 6” above the canopy should be woven underneath the trellis, or tied to trellis with a plant tie.
- After the Branches are evenly distributed, check underneath the trellis for hanging branches to either be pushed upward into trellis or be removed if they will not reach the canopy.
- All strains have different growth habits, and require different trellising techniques. Sativa strains will require more attention to create adequate support. Indica dominant strains will require little to no time organizing the canopy. Pay close attention to each of your strain’s habits and adjust the canopy accordingly.



#### Step 4: Clean Up

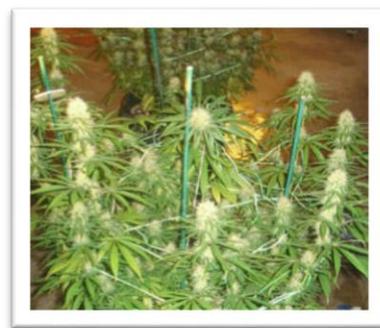
- Clean any remaining plant matter, and trash from the area
- Discard all plant matter into the designated waste bin and discard all trash in the designated trash bin

**Staking/supporting**—The plants will begin producing flowers and gain mass as they approach harvest. Some of the plants stalks and/or branches may need additional support from plant stakes (*bamboo stakes can be seen below*).

- Add support stakes to branches needing support to prevent branches from lying on one another or breaking/snapping.



OR



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#### <WEEK 8-18>

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Over the course of the next several weeks the plant will complete its genetic drive to produce the flowers. The plants will begin to show characteristics of their APA. Pruning, trellising and staking/supporting plants according to this analysis will increase yields and mitigate pest outbreaks. Over the course of weeks 8 through 18 the main objective will be to monitor the marijuana plants, cultivation facility and equipment.

It will be imperative to be aware of all environments and equipment within the facility to be able to locate and identify any potential problems or unforeseen circumstances. Being proactive during the flowering cycle will reduce the risk of equipment malfunction or failure which could have detrimental effects on the plants being cultivated.

Monitor the canopy of each room daily for:

- Pest(s)
- Fungus/disease
- Plant sex; signs of plant hermaphroditism



Performing the proper checks and balances over the next few weeks will determine the quality of the manufactured product. Maintaining ideal growing environments to achieve the plants maximum genetic potential is our goal. Employees must maintain a log of temperature, humidity, and CO2 concentration in the environment of each cultivation area. Records should be maintained daily upon entry of each room.

At this stage in the growth cycle, if there are no visible indications of stress induced on the plants and pests have yet to be identified, the room will require less attention and only inspections are necessary. Check all reservoirs daily to insure plants are receiving adequate hydration.

#### **Determining if Plants are ready for Harvest**

Harvest will occur between the 16<sup>th</sup> and 18<sup>th</sup> week depending on the marijuana strain. Sativa and hybrid genetic lineages should be allowed the full 70 day flowering cycle to reach maturity (*approximately 10 to 14 weeks of flowering growth stage*). Indica strain's flowering growth stage time lengths vary depending on lineage, but most will be harvested around day 60 (*approximately 8 to 10 weeks of flowering growth stage*). \*Refer to ***Harvesting Marijuana*** SOP.

- Monitor the calyxes and the maturity of the trichomes to understand when a strain has reached maturity and is ready to be harvested.
  - Use a microscope to observe the marijuana plants trichomes to determine if the plant is ready to be harvested
    - If a plant is ready to be harvested, the trichomes should appear milky white in color
      - If trichomes are clear, or see-through in color the plant is not ready to be harvested and should be allowed to continue growing in order to reach maturity.
      - If the trichomes appear to be a dark amber or reddish color, the plant may have been allowed to grow too long and over-mature. This will degrade the medicinal properties and benefits of the marijuana.



<b>Standard Operating Procedure:</b> Weights and Measurements and Scale Calibration
<b>Purpose:</b> To explain how to use certified scales for weights and measurements
<b>Scope:</b> To train registered employees on proper use of NTEP certified scales to be used for weights and measures as well as scale calibration/certification
<b>Initial Training:</b> 1 hour

**Types of Scales to be used**

BPH will utilize NTEP-certified scales for the weighing of all medical marijuana, medical marijuana products, medical marijuana waste and all green waste.

**NTEP Certification**— The National Conference on Weights and Measures issues an NTEP Certificate of Conformance following successful completion of an evaluation of a device. It indicates that the device(s) described in the Certificate is/are capable of meeting applicable requirements of the *NIST Handbook 44*.\* <http://www.ncwm.net/ntep/faqs#WhatIsNTEPcertificate>

**Scale Use**

All medical marijuana harvested at BPH’s licensed premise will be weighed and packaged using NTEP-certified scales certified for legal trade and that have been calibrated and certified ISO/IEC 17025 accredited by a Hawaii calibration service supplier.

**Scale Calibration and Frequency**

BPH will ensure that all scales and balances are calibrated by an accredited calibration service supplier. The frequency of having BPH scales calibrated will be on a six (6) month basis. This routine calibration will be documented on the Scale Calibration Log sheet and maintain on the licensed premise.

*Example of the Scale Calibration Log Sheet:*

<b><u>Scale Calibration</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Scale Serial #/ID #:</u>	<u>Calibration Service Supplier:</u>	<u>Scale Calibrated</u>	<u>Notes/Comment:</u>
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
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Harvesting Marijuana

### Standard Operating Procedure: Harvesting Marijuana

**Purpose:** To explain the steps and procedures involved with harvesting marijuana, including: cutting, weighing, processing, trimming, drying, and curing.

**Scope:** Covers the post-cultivation harvest process within the cultivation facility.

**Initial Training:** 8-16 hours

#### Documentation Log Sheets Required

- 1) Harvested Marijuana Log Sheet
- 2) Marijuana Waste Log Sheet

#### Equipment/Tools Required

- 1) Heavy-Duty Sheers
- 2) Certified Scales (hanging scale for wet weight and table scale for trimmed flower/bud and sugar leaf)
- 3) Scissors
- 4) Plant labels/tags
- 5) Drying Racks
- 6) Containers/Jars
- 7) Soil Disposal Carts

#### Principles of Harvesting Marijuana

The harvesting of marijuana is the final process with the plant lifecycle. The harvesting process is when all cultivation activities have come to an end and the marijuana plants flowers are fully ripened and ready to be harvested. The harvest and post-harvest process involves four (4) major steps; 1) harvesting the marijuana plants, 2) trimming the marijuana plants, 3) drying the marijuana and 4) curing the marijuana.

- **Harvesting**
  - Cutting the marijuana plants stock at the point where the stock meets the soil or growing medium. Record the **Plants Attribute #** or **Unique ID #** and strain information on the **Harvested Marijuana Log Sheet**.
  - Once marijuana plant is cut, the plant must be weighed as a whole. This is typically called the marijuana plant **‘Wet Weight’**. Record this weight on the **Harvested Marijuana Log Sheet**.
  - All soil root balls from harvested plants will be placed into the soil disposal cart

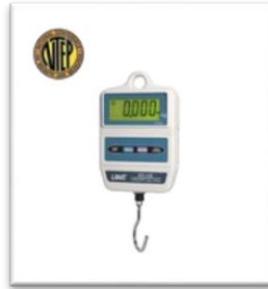


Cut the Plant at Base





Weigh Entire Wet Plant



Documentation

Once the marijuana plant(s) have been chopped and weighed on an NTEP-certified hanging scale, record the wet weight of the plant(s) on the *Harvested Marijuana Log Sheet*.

<b><u>Harvested Marijuana</u></b>						
<b><u>Date:</u></b>	<b><u>Plant Attribute # and Batch#:</u></b>	<b><u>Plant Strain:</u></b>	<b><u>Wet Weight:</u></b>	<b><u>Waste Weight:</u></b>	<b><u>Trim Weight:</u></b>	<b><u>Bud Weight:</u></b>





Processing Operations

<b>Standard Operating Procedure:</b> Processing Operations
<b>Purpose:</b> To explain post-harvest activities, procedures and protocols. Including: trimming, processing, weighing, packaging and labeling.
<b>Scope:</b> Covers the processing activities within the cultivation facility.
<b>Initial Training:</b> 8-16 hours

### What is Included in the Post-Extraction Operations

- 1) Trimming marijuana plants
- 2) Weighing, packaging and labeling finished marijuana medicine
- 3) Marijuana waste disposal

### Documentation Log Sheets Required

- 1) Finished Marijuana Medicine Log Sheet
- 2) Marijuana Waste Disposal Log Sheet

### Equipment/Tools Required

- 1) Nitrile gloves
- 2) Certified Table Scale
- 3) Packaging Materials
- 4) Labeling Materials

### Principles of Processing Operations

Processing operations will consist of the processing/trimming, drying and curing of medical marijuana. Also included in the processing operations if the packaging and labeling of medical marijuana.

- 1) **Processing/trimming** – The marijuana plant will be broken down by removing the larger fan leaves, and hung on drying racks preparing for packaging. Registered employees will be required to wear nitrile gloves during all processing and/or trimming procedures.
  - This is where the marijuana plant will be broken down from the whole plant form into individual branches and grades. This will typically create 3 different ‘grades’ of marijuana from the same plant:
    - **Flower(s)/bud(s)**—this is the portion of the marijuana plants and typically referred to as the ‘kola buds’. This medicine has received all of the optimal growing conditions throughout the plants entire lifecycle (proper light conditions and distribution, optimal CO2 levels, etc.).
    - **Sugar Leaf/trim**—this is typically the lower levels of the plant where the HID lighting cannot fully penetrate resulting in ‘larfy/leafy’ marijuana buds and the sugar leaves that have been trimmed off the plants and flowers. This material is typically used in infused products manufacturing and extraction operations.
    - **Waste**—this is comprised of all the material that will not be used from the plant. This material must be weighed and recorded on the *Harvested Marijuana Log Sheet*. Marijuana waste is typically comprised of:
      - Stalks and stems
      - Fan leaves
      - Roots
      - Other unusable material
  - Make sure that all required information is recorded and transferred with any and all marijuana plant materials. Required information to be transferred with marijuana material:



- Plant strain/name
- Harvest/process date
- Plant Attribute # and Batch #

**Trimming**—this is when the processed marijuana will be trimmed. This process involves trimming all of the leafy material away from the flowers/buds. The trimmed leaf material (sugar leaf) is still usable and typically used in Infused Products Manufacturing or for marijuana extraction. All registered employees are required to “glove-up” prior to commencing any trimming operations. Registered employees will be required to wear and change gloves often throughout the day.

- Trim the leafy material of marijuana flowers; properly weigh the trimmed flowers (buds) as well as weigh all the trim (sugar leaf) and record the weights on the *Harvested Marijuana Log Sheet*. Weights to be recorded (*ensure recording to proper Plant Attribute # or Unique ID #*):
  - Flower/bud weight
  - Trim/sugar leaf weight

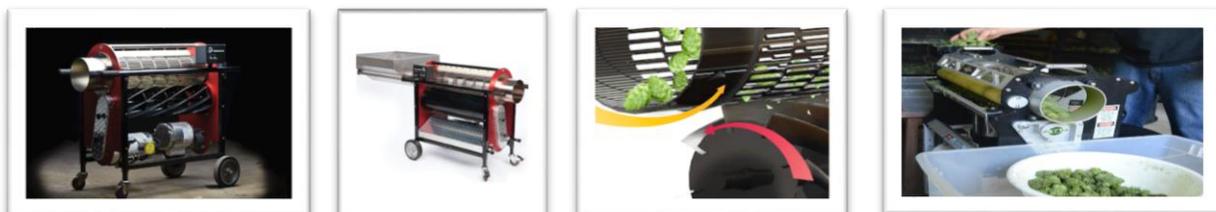


- Once the marijuana material is trimmed it is ready for drying.
- Trimming can be done by using traditional hand-trimming methods or the use of new automated trimming machines such as the TRIMINATOR.
  - If using a trim machine (*ACC recommends the TRIMINATOR*) please refer to the *Trim Machine Operation SOP*.

**Example of Traditional Hand Trimming:**



**Example of a Trim Machine:**





- 2) **Drying**—this is when the marijuana plants will be dried. The drying process is a somewhat delicate process as you do not want to over dry the flowers, but leaving too much moisture in the flowers could result in mold and bud rot.
- Plants will be hung upside down using metal S hooks on a mobile wire shelf
  - Make sure to properly label each plant on the drying racks (ensure all required information is recorded and follows material through drying process to ensure records are not lost.)
    - Required information:
      - Plant Attribute # and Batch #
      - Plant Strain
      - Date flowers (buds) were placed on rack



**Examples of Drying Racks:**



- 3) **Curing**—the curing process begins once the plants have been properly dried.
- Plants can be cured in multiple ways
  - Plants can be cured in place (*within the drying room*) by adjusting the room’s humidity to an equal level as the interior of the flowers. This allows the cannabinoids to fully gain their respective medicinal properties. This process can take 1-2 weeks, depending on desired cannabinoid and terpene values.
  - Plant material (*typically only the plant flowers/buds*) can be placed in a container (*typically a glass jar*) for an extended period of time. During this curing method, the containers will need to be opened periodically to allow air circulation (*this processes is commonly referred to as “burping” the container*).
  - Upon completion of curing, the product will be weighed, tracked, and sent to the vault for storage until extraction.
  - Make sure to properly labels all curing containers with all required information:
    - Plant Attribute # and Batch #
    - Plant Strain
    - Date flowers (buds) were placed in curing container

**Example of Curing in Glass Jars:**



4) **Weighing and Packaging Medical Marijuana**—is the process of accurately weighing the medical marijuana to be put into packages for distribution. Packaging regulations and requirements may vary, so it is essential to reference the state and local laws and regulations pertaining to packaging requirements for medical marijuana business. Use of NTEP certified scales for the weighing of all marijuana products is mandatory.

- All BPH packing will be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
- Packaging must be opaque so that the product cannot be seen from outside the packaging;
- The packaging must be constructed to protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.
- Packages must not contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; providing that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
- Marijuana will be carefully weighed and packaged at the production center. All products will be packaged, recorded into the inventory system, and labeled per Hawai‘i regulations.



- Upon marijuana being weighed and packaged registered employees are required to document the marijuana weight associated to the product with a unique attribute number and batch number. This documentation must be done with two registered employees, one employee to make the record in the inventory control system and a second to witness the record.
- Ensure inventory control system is updated to show the packaged marijuana weights and specifications.

**Examples of Child-Resistant Packaging:**



5) **Labeling**—all packages of medical marijuana will require a label to be conspicuously placed on the package.



- Labels must be made of weather resistant and tamper-evident material
  - As a redundancy, registered employees will be required to recheck each package for a label prior to shipping and package containing medical marijuana from the Licensed Premise.
  - **Hawaii specific labeling requirements:**
    - Labels must use black lettering only on a white background with no pictures or graphics
    - Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
      - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
      - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
    - The dispensary licensee’s license number and the name of the production center where the marijuana in the product was produced;
    - The batch number and date of packaging;
    - A computer tracking inventory identification number barcode generated by tracking software;
    - Date of harvest or manufacture and a “use by date”;
    - Instructions for use;
    - The phrases “For medical use only” and “Not for resale or transfer to another person”;
    - The following warnings:
      - “This product may be unlawful outside of the State of Hawai‘i and is unlawful to possess or use under federal law”;
      - “This product has intoxicating effects and may be habit forming”;
      - “Smoking is hazardous to your health”;
      - “There may be health risks associated with consumption of this product”;
      - “This product is not recommended for use by women who are pregnant or breast feeding”;
      - “Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug”;
      - “When eaten or swallowed, the effects of this drug may be delayed by two or more hours”
    - A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
    - The name of the laboratory that performed the testing
- 6) **Secure, Segregated Storage**—Upon medical marijuana being packaged, BPH registered employees will be required to hold the marijuana in secure, segregated storage until released for distribution
- The secure, segregated storage will be within the production center vault(s).

**Standard Operating Procedure: Inventory Reconciliation Procedure**

**Purpose:** To explain the purpose and processes involved with inventory reconciliation.



**Scope:** Covers the steps involved with inventory reconciliation.

**Initial Training:** 4-6 hours

### **The Principles of Inventory Reconciliation**

It is recommended to perform physical inventory on weekly or monthly basis. At minimum, a monthly inventory reconciliation is to be performed at each facility. This is where every product within the facility will be physically counted, documented and then reconciled (*compared*) against the inventory recorded in the POS system or computer inventory system.

The physical inventory on-hand that is counted should be identical to the inventory that is recorded within the POS system. If there are deviations in these numbers then action must be taken to determine the shortage(s).

- 1) Count **ALL** on-hand inventory at the facility
  - Marijuana plants
    - Mother plants
    - Clones
    - Vegetative plants
    - Flowering plants
    - Hanging/drying plants and material
  - Finished marijuana
    - Flower/bud (*packaged and ready for transport*)
    - Trim/sugar leaf (*packaged and ready for transfer*)
- 2) Document all counted on-hand inventories on the appropriate ***Cultivation Inventory—Marijuana Plants*** (*daily, weekly, or monthly*) log sheet.
- 3) Reconcile counted on-hand inventories against on-hand inventories in the POS system
  - Document discrepancies on the appropriate ***Cultivation Inventory—Marijuana Plants*** and the ***Cultivation POS Inventory Reconciliation*** and ***Product Loss Log Sheet*** between the counted on-hand inventory and POS inventory.
  - Investigate all discrepancies
- 4) Inventory Discrepancies—discrepancies between the inventory stock and the inventory within the inventory control system (*outside of normal weight loss due to moisture loss and handling*)
  - Investigate all discrepancies within one (1) business day
    - Perform inventory audit and reconciliation
    - Review transactions within the inventory control system
    - Review security surveillance footage
  - Report theft or diversion to the Department AND local Police within one business day
    - Contact the Department and local Police in multiple fashions as a redundancy
      1. Contact directly through phone conversation
      2. Contact electronically through email, fax or other electronic means
  - Within 30 days
    - the inventory discrepancy investigation must be conducted and completed
    - the standard operating procedures amended (*if needed*)
    - send an investigation report and audit to the Department

***Example of Cultivation Inventory—Marijuana Plants log sheet:***



### Cultivation Inventory--Marijuana Plants

<u>Date:</u>	<u>Employee:</u>	<u>Grow Room:</u>	<u>Plant ID/Strain:</u>	<u>Quantity:</u>	<u>Lifecycle Stage:</u>

Example of Cultivation POS Inventory log sheet:

<u>Cultivation POS Inventory Reconciliation</u>							
<u>Date:</u>	<u>Product Name:</u>	<u>Product Attribute #/Unique ID #:</u>	<u>Quantity On Hand:</u>	<u>Quantity in POS System:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Notes:</u>

Example of Product Loss log sheet:

<u>Product Loss Log Sheet</u>				
<u>Date:</u>	<u>Product Name/Category</u>	<u>Product Attribute # or Unique ID #</u>	<u>Total Quantity Loss:</u>	<u>Product Loss Valuation:</u>
				\$
<u>Reporting Employee:</u>	<u>Manager/Supervisor:</u>	<u>Product Loss Due To:</u>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<u>Internal Investigation:</u>	<u>Required Authorities Notified:</u>	<u>Authorities Notified (list all):</u>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<u>Note/Comments:</u>				



Trim Machine Operation

**Standard Operating Procedure: Trim Machine Operation**

**Purpose:** To understand how to properly operate the TRIMINATOR trim machine.

**Scope:** To train employees on the proper handling, use and maintenance of the TRIMINATOR. TRIMINATOR user manual can be found online at: <http://thetriminator.com/wet-marijuana-trimmer-machine/>

**Initial Training:** 2-4 hours

**The Principles of the Trim Machine Operation and Maintenance**

Any automated trimming machine being utilized should be used with caution as the machine can cause harm and bodily damage if not used properly. It is recommended to read the user manual and manufacturer instruction prior to use of any automated trim machine.

ACC recommends the use of the TRIMINATOR automated trimming machine for marijuana operations. More information on the TRIMINATOR can be found at the website: <http://thetriminator.com/wet-marijuana-trimmer-machine/>



TRIMINATOR user manual can be found at:

<https://drive.google.com/a/americanmarijuanaconsulting.com/file/d/0B236JzITJeCVaVo1SG5IN1Vna05YU1ZMY3AyR283cGdfUW5J/view>

*TRIMINATOR Spec Sheet can be seen below:*



# TRIMINATOR

## AUTOMATIC CLEANING SYSTEM

eliminates cleaning stops and maximizes production

## COMMERCIAL SIZE

the industry's highest capacity drum allows you to trim up to 2.5X faster

## LOCKING WHEELS

keep the machine in place no matter the slope



## NO BED-KNIFE

no hassles with our bed-knife free design

## WASH DOWN COVER

makes cleaning easy

## TECHNOLOGY

### RESIN REPEL SELF-CLEANING SYSTEM



**WHY** it keeps you trimming long after others have stopped to clean.

**HOW** our patented Resin Repel system uses atomized water to inhibit resin build up, allowing you to trim massive harvests non-stop.

### TRIM LOGIC TECHNOLOGY



**WHY** it cuts closer for hand-trimmed quality results.

**HOW** by eliminating the bed-knife and pushing the cutting blades within .0025" you get a closer trim every time.

## SPECIFICATIONS

### MACHINE

**HEIGHT:** 39 in  
**WIDTH:** 18.5 in  
**LENGTH:** 45 in  
**WEIGHT:** 235 lbs  
**AC VOLTAGE:** 120 V  
**MAX AMPS:** 18 Amps  
**SHIPPING WEIGHT:** 353 lbs

### VACUUM

**HEIGHT:** 92 in (w filter)  
**WIDTH:** 29 in  
**LENGTH:** 37 in  
**WEIGHT:** 140 lbs  
**CFM:** 1300 CFM  
**AC VOLTAGE:** 120 V  
**MAX AMPS:** 16 Amps

**APPLICATION**  
WET TRIM

**WARRANTY**  
2 YEAR

THETRIMINATOR.COM



530.265.4277



INFO@THETRIMINATOR.COM



MADE IN USA



Laboratory Testing

<b>Standard Operating Procedure:</b> Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana and manufactured marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Cultivation Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

### Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

### State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)
  - Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.



- If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the ***Marijuana Waste SOP*** upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

**Preparation of Medical Marijuana Samples to be Tested**

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Flower/bud—ensure adequate quantity from batch for sampling (~7-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# FLW001 → Create new ‘Sample Package’: FLWT101
- Fill out all required documentation/log sheets
  - ***Samples for Laboratory Testing***
  - ***Marijuana Product Shipping Manifest***

<b><u>Marijuana Samples for Laboratory Testing</u></b>					
Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:





- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow ***Transferring/Transporting SOP***

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show medical marijuana potency, cannabinoid profiles, terpene profiles, and contaminants (if any present). The testing laboratory will provide BPH test results from each batch and lot tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meet all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**— there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm$  90-100% of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating

It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.



- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<b><u>Marijuana Batch Samples for Laboratory Testing</u></b>						
Date Sample Prepared:	Grower Agent #1:	Grower Agent #2:	Product Attribute ID #, Batch# and Strain/Variety	Sample Quantity/Weight:	Test Sample ID # (NEW) :	Receiving Laboratory:
Date Sample Shipped:	Sample Pass Testing		Certificate of Analysis Provided w/ Supporting Data?	If sample failed testing, will batch be reprocessed or destroyed?		Licensed Processor to Send Batch to:
	<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed		
Batch Potency	Batch Purity	Batch expiration date data/support:			Notes/Details:	
Date of 6-month interval test:	Sample Pass Testing	Certificate of Analysis Provided w/ Supporting Data?	Batch Potency	Batch Purity	Batch expiration date data/support:	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
Notes/Comments:						

**Release for Distribution**

All batches of marijuana are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH’s registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.

- This process will be completed by two (2) registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

**Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.



Shipping Marijuana Products, Transferring/Transporting

<b>Standard Operating Procedure:</b> Shipping, Transferring/Transporting Marijuana Products,
<b>Purpose:</b> To explain the steps required to be followed to ship marijuana and manufactured marijuana products to BPH retail dispensary locations.
<b>Scope:</b> Covers the training required and procedures for registered employees covering the shipping/transporting of marijuana and manufactured marijuana products.
<b>Initial Training:</b> 2-4 hours

### The Principles of the Shipping Procedure, Transferring/Transporting

The marijuana and manufactured marijuana products will be transported by no less than two registered employees to BPH retail dispensary locations.

#### **The Transportation Process:**

- 1) New Inventory Order
- 2) Fulfillment
- 3) Create Manifest/Trip Plan
- 4) Transportation
- 5) Delivery
- 6) Post-Delivery

#### **1) New Inventory Order**

- 1) Fill out *Marijuana Products Transportation (Outgoing)* log sheet
- 2) Create a new invoice for inventory order
  - a. Date that order is placed
  - b. Products and quantities ordered
  - c. Prices of products
  - d. Estimated delivery date and time

#### **2) Fulfillment**

- 1) Collect products needed for inventory order
- 2) Take ordered/collected products out of the inventory control system
- 3) Package the order of products into a container that is constructed on tamper-evident, opaque material
  - a. The use of tamper-evident cardboard boxes, hard plastic opaque cases that can be locked with tamper-evident seals or locks, or a similar shipping package that will meet Hawaii requirements
  - b. Seal said tamper-evident package with tamper-evident tape.
  - c. If transporting multiple packages to the same dispensary, the packages will need to be shipped within one large opaque tamper-evident container.
- 4) **Repackaging**—if necessary, registered employees may have to repackage the delivery items into a container that is constructed of tamper-evident opaque materials and sealed with tamper-evident tape
  - a. This will typically only happen if the original packaging is defective or gets destroyed.
  - b. Medical marijuana will need to be repackaged if not originally packaged in an opaque container.
  - c. Repackaging may be required if multiple packages are identified as being shipped to the same recipient
    - i. If this is the case, then the packages will need to be repackaged into one large opaque tamper-evident container and sealed with tamper-evident tape
      1. Ensure package is sealed with tamper-evident tape; seal all entry/access points
- 5) Complete the *Marijuana Products Daily Transfer/Shipping* log sheet
  - a. Example of *Marijuana Products Daily Transfer/Shipping* log sheet can be seen below:



### Marijuana Products Daily Transfer

<u>Date:</u>	<u>Employee Preparing Transfer:</u>	<u>Marijuana Product Name/Batch ID #/Strain:</u>	<u>Quantity Shipped:</u>	<u>Receiving Retail Dispensary Location:</u>	<u>Receiving Employee:</u>

- 6) Create new record within the inventory control system for the products being transported—registered employees will need to create a record of the products prior to transportation any marijuana products.
  - a. Information required on record:
    - i. Date and time of the sealing of the package for shipment
    - ii. Name a signature of the registered grower agent who prepared and sealed the package
    - iii. Name and address of BPH
    - iv. Transfer identification number
    - v. A description of the package being transported including the weight of each item
    - vi. The name and address of the party receiving the shipment

### 3) Manifest/Trip Plan Creation—See *Marijuana Product Transfer Manifest SOP*

Prior to the transportation of any marijuana products or marijuana-infused products a facility agent will generate a manifest/trip plan including at a minimum:

- 1) The name of the agents who will be transporting;
- 2) The automobile license plate, make and model;
- 3) The date, start time of the trip and estimated delivery time;
- 4) A description including the exact amount, type and batch of any marijuana products and marijuana-infused products being transported; and
- 5) The intended route of transportation.

Facility management shall maintain a copy of the manifest/trip plan document at the location of departure, record the manifest/trip plan with any needed authorities, and the transporting employees will maintain a copy of the manifest/trip plan during the transportation.

### 4) Transportation

This section covers how to transport the product to the other BPH facilities. All applicable state and local laws/regulations pertaining to transportation of medical marijuana products will need to be strictly adhered to by all organization team members. All transportation/shipping to be done in-house by BPH registered employees and/or transportation agents. BPH does not intend to use a secure transportation company unless deemed absolutely necessary.

**Transportation Vehicle Requirements**—all agents responsible for transporting medical marijuana must:

- 1) Use of an unmarked, unidentifiable vehicle
  - a. Vehicle should not have any BPH markings, logos or identifiers on the vehicle
  - b. Vehicle should not raise awareness that it may be transporting medical marijuana and/or medical marijuana products of any kind



- 2) Ensure the vehicle has current, valid registration from the State
  - a. Registration paperwork should be located in vehicle glovebox
  - b. Vehicle license plate should have current, valid registration sticker
- 3) Ensure the vehicle has current valid proof of insurance
  - a. Proof of insurance paperwork should be located in the glovebox
- 4) Ensure the vehicle has a current safety check
  - a. Safety check paperwork should be located in the glovebox

**Transportation Agent Requirements**—all agents responsible for transporting medical marijuana must:

- 1) There will be at minimum two registered employees and/or transportation agents for every product shipment. Each transportation agent will play a separate and vital role.
  - o One transportation agent will be required to drive the transportation vehicle and to remain with the transportation vehicle at all times.
  - o The second transportation agent is to remain with the medical marijuana product be transported at all times and to ensure that the product is secure at all times during transport.
- 2) Wearing appropriate work attire
  - o Work attire for BPH transportation agents will be plain with no company logos, brands or identification.
  - o BPH transportation agents should not appear to indicate ownership or possession of marijuana.
    - Plain polo shirt
    - Plain khakis/jean pants
    - Plain dress/tennis shoes
  - Failure to arrive to a scheduled shift with proper attire will result in not being able to make transports, incident noted in personal file and possible disciplinary action.
- 3) Possess a current and valid State-issued marijuana industry worker identification;
- 4) Possess a current and valid State-issued driver's license;
- 5) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or marijuana-infused products pursuant to regulation, all transporting agents shall:

- 1) Carry a copy of the manifest/trip plan with him or her for the duration of the trip;
- 2) Wear their agent card and/or have Commission approved identification readily available;
- 3) Use a vehicle without any medical marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or marijuana-infused products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation as well as a back-up emergency cell phone; and
- 5) Ensure that the medical marijuana is not at all visible to the public.

**5) Delivery**

- 1) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the shipping manifest/trip plan
- 2) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

**6) Post-Delivery**



**Post-Delivery Protocol**—after transporting marijuana products or marijuana-infused products, pursuant to the regulations the employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.

**Documentation of Delivery**—both the transporting dispensing facility and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Division agents for review upon request.

**Deviations from Transportation Plan**—the transporting agent shall immediately report all diversion due to loss or theft of marijuana or marijuana-infused products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the state licensing authorities as required per state regulations. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



<b>Standard Operating Procedure:</b> Marijuana Product Transfer Manifest
<b>Purpose:</b> To explain the requirements for the marijuana products transfer manifest
<b>Scope:</b> To educate and train registered employees on the creation and use of the marijuana products transfer manifest
<b>Initial Training:</b> 1-2 hours

**Principles of the Electronic Manifest**

The transfer manifest will be required for each and every delivery of marijuana product from BPH’s production center. Registered employees will be required to complete the physical marijuana product transfer manifest form.

Prior to transporting or shipping a package containing marijuana and/or manufactured marijuana products, BPH will require registered employees to complete the marijuana product transfer manifest process. Registered employees will need to complete the manifest form and scan/email a copy of the manifest to the retail dispensary location recipient. Registered employees and/or transportation agents will also maintain two (2) physical copies of the manifest form to keep and have present during any transporting of marijuana products. Upon delivery of the marijuana products, the shipping registered employee will provide a physical copy of the manifest for the recipient to maintain.

**Requirements**

All transportation of products are required to use a manifest for chain of custody procedures and to ensure safe transport of marijuana products and that no theft or diversion is occurring during transport. BPH will utilize a manifest to record the chain of custody for the transportation of products containing marijuana. The manifest will include a chain of custody that records:

- The name and cell phone number of the registered employees in the vehicle;
- The transfer identification number;
- The weight and description of each individual package that is part of the shipment, and the total number of individual packages;
- The name of the registered employee that prepared the transfer;
- The name and address of the receiving licensee; and
- Any handling or storage instructions.

**Chain of Custody—Transport** with packages containing marijuana will need to be tracked and recorded throughout the shipping process within the inventory control system. The chain of custody for all shipments containing medical marijuana must be accurately documented within the manifest and inventory control system.

The inventory control system will contain, at a minimum, the following entries as a chain of custody, in the order listed:

- An entry by the registered employee who has prepared the delivery, including the date and time of preparation;
- An entry by a shipping licensee’s registered employee, of the date and time of the placement of the shipment into the marijuana product transport vehicle;
- An entry by licensee’s registered employee receiving the delivery including the date and time of the acceptance; and
- If any other person had custody or control of the delivery, that person’s identity, the circumstances, duration, and disposition.

A manifest **MUST** be created for **EACH** delivery of products containing medical marijuana.



BPH will require registered employees to complete a **Marijuana Product Transfer Manifest Form** prior to transporting or shipping any marijuana and/or manufactured marijuana products. Refer to the **Transfer Marijuana Products Transferring/Transportation SOP** for transportation requirements. **Marijuana Product Transfer Manifest Form can be seen below:**

		<b><u>Marijuana Product Transfer Manifest</u></b>		<b>Transfer Identification #:</b>		<i>Test results included for ALL products being shipped?</i> <b>YES</b> <input type="checkbox"/> <b>NO</b> <input type="checkbox"/>	
<i>*This form must be completed prior to the shipping of any marijuana or manufactured marijuana products. This Record for Transfer must be present along with the Transportation/Trip Manifest Form with ALL shipments of marijuana and/or manufactured marijuana products from the Licensed Premise.</i>							
Date Package/Shipment Sealed:		Time Package/Shipment Sealed:		License # of Originating Entity:			
Name of Registered Employee who prepared and sealed the package:							
Signature of Registered Employee who prepared and sealed the package:							
Name of Originating Entity: Blue Planet Healing LLC							
Address of Originating Entity:						Phone #:	
						Email:	
<i>*If you are delivering more than fifteen (15) products to one stop, use a second form to list the additional product(s).</i>							
<input type="checkbox"/> Check Here if multiple pages are used <i>List the total number of pages in the Manifest here</i> _____.							
<b>Receiving Retail Dispensary Location Information</b>				<b>Marijuana/Product(s) within the Shipment</b>		<b>Quantity/Weight</b>	<b>Attribute #/Product ID #</b>
Stop Number on Route:				1)			
Name of Receiving Party:		Blue Planet Healing LLC		2)			
License # of Retail Dispensary Location:				3)			
Address of Receiving Retail Dispensary Location:				4)			
				5)			
Phone # of Receiving Dispensary:				6)			
Date and Approximate Time of Departure:				7)			
Date and Approximate Time of Arrival:				8)			
Route to be Traveled:				9)			
				10)			
				11)			
				12)			
				13)			
				14)			
				15)			
Additional Description: <i>(add description/details about the marijuana products and/or manufactured marijuana product(s))</i>							
<b>PRODUCT REJECTION</b> <i>(if only a portion of the shipment is rejected, circle that portion above.)</i>							
Name of Person Receiving or Rejecting Product(s):						Date:	
<i>I confirm that the contents of this shipment match the weight records above, and I agree to the custody of those portions of this shipment NOT circled above. Those portions that ARE circled above were returned to the individual delivering this shipment.</i>							
Signature:				Signature of Individual Taking Receipt of Rejected Portion of this Shipment:			
Name of Person Transporting Product(s):				Signature of Person Transporting Product(s):			
Make, Model, License Plate #:						Date of Signature:	



**Standard Operating Procedure: Customer Complaints and Returns**

**Purpose:** To explain the steps involved for handling customer complaints and product returns.

**Scope:** Covers the steps involved to handle customer complaints and product returns appropriately.

**Documentation Log Sheets Required**

- 1) Customer Complaint Form
- 2) Returned Marijuana Products Log Sheet
- 3) Returned Marijuana Products Waste

**The Principles of Handling Customer Complaints and Product Returns**

It is important to have proper procedures in place for the handling of customer complaints and/or product returns. By having these initiatives in place you can ensure the most satisfied customer base possible. Below are best practice steps to take when confronted with a customer complaint and/or product return.

**State of Hawaii Requirements**

- In the event a complaint is associated with a serious adverse event, BPH will require registered employees to:
  - Promptly report the complaint to the Commission
  - Report the complaint to any licensed processor or licensed dispensaries that may have received a shipment containing medical marijuana from the batch determined to cause the complaint
- As required by State of Hawaii regulations, in the event a complaint associated with a serious adverse event, BPH will be required to promptly report the complaint to, (1) the Commission, (2) either the licensed grower from which the medical marijuana originated, or the licensed processor from which the medical marijuana concentrate originated, (3) the certifying physician caring for the qualifying patient.
  - As a licensed grower operation, BPH’s registered employees will be limited to report to the Commission in the event a complaint is associated with a serious adverse event.
    - Within 24-hours registered employees must report the complaint to the Commission

**Recalling of Medical Marijuana**—if a batch or lot of medical marijuana is determined through testing to fail to meet specification, BPH will do the following:

- Order a recall of all products derived from or included in the batch
- Notify all dispensaries and/or processors who may have obtained medical marijuana products from such a batch or lot of the recall
  - Using the inventory control system and/or physical documentation log sheets/records to identify all licensed processors and/or licensed dispensaries that may have received a distribution containing medical marijuana from the production batch or lot
  - After identifying the licensed processors and/or dispensaries, registered employees will be required to directly notify said companies.
- Offer and pay reimbursement for any returned medical marijuana
  - Offer to replace the medical marijuana product free of charge or offer full monetary reimbursement to the licensed processors and/or licensed dispensaries.

**Handling Customer Complaints**—when a customer wishes to make a formal complaint, follow the following procedures:

- Have customer wishing to form a complaint to complete the *Customer Complaint Form*



- File complaint within the customer complaint folder located within a limited-access area within the Licensed Premise
- Notify management of the formal complaint
- Notify the Department of the formal complaint

	<i>Customer Complaint Form</i>	
	Date:	Location:
	Customer Name:	
	Employee Documenting Complaint:	Supervisor on Duty:
	Description of Complaint:	
	Corrective Action to be Taken:	
	Customer Comments:	
	Customer Signature:	Date:
	Employee Signature:	Date:

In the event of a formal complaint regarding the quality or safety of medical marijuana is received, BPH will require registered employees to review and investigate the complaint within 24-hours to determine:

- If the complaint is substantive or reports a serious adverse event
- Determine the batch number of the marijuana—this can be accomplished using the records and documentation maintained throughout the cultivation process to determine if there were any deviations in production
  - If the complaint is substantive or reports a case of a serious adverse event, registered employees will determine the batch number of the marijuana
  - Registered employees will be required to investigate the record and circumstances of the production of the batch and lot to determine:
    - If there was a deviation from the standard operating procedure in the production of the medical marijuana by reviewing production logs, records and documentation
      - Test retention samples of the batch and lot to an independent testing laboratory.
        - Send retention samples from batch and lot in question to licensed testing laboratory for testing
          - If testing reveals that the batch or lot fails to meet specifications, follow steps for recall below in following SOP
          - Notify any and all patients, caregivers and dispensaries who may have obtained medical marijuana products from such a batch or lot of the recall
            - Use the inventory control system and physical records to determine who may have



- received a batch of medical marijuana from the recalled batch
- Upon identifying retail dispensary locations that have received marijuana from the batch in recall, registered employees will need to notify the licensed dispensary directly with two means:
  - Via phone call, AND
  - Via email

**Investigation of Complaint**—BPH will require registered employees to investigate all complaints regarding the quality or safety of medal marijuana. Registered employees will be required to review records and documentation from the cultivation operations to determine if there was any deviation from production.

- Review all cultivation records and documentation log sheets
  - Try to determine if there were any deviation in production
  - If the is a deviation in production, see **Standard Operating Procedures SOP**
  - Determine the batch number and/or lot number of the medical marijuana
    - Reviewing records and documentation for substantive changes in production
- Meet with complainant to understand the serious adverse event (*if applicable*)
  - Meeting with the complainant registered employees may be able to identify the medical marijuana batch associated with the complaint
- Order a recall of the medical marijuana batch if necessary; follow **Product Recall SOP**

**Handling Customer Returns** – When a customer wishes to return a product, perform the following procedure:

- Acquire the product needing to be returned and begin the process of completing the Returned Marijuana Products Log Sheet
- Ask for the reason as to why the product is being returned and record this information.
- Log the product as being returned into the electronic inventory tracking system
- Offer and pay reimbursement for the medical marijuana products tracking system.
- Ensure that the Returned Marijuana Products Log Sheet is completed and filed.

*Example of a Returned Marijuana Products Log Sheet:*

<b><u>Returned Marijuana Products Log Sheet</u></b>					
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Patient/Caregiver Returning Cannabis Product:</u>	<u>Marijuana Product Returned (Name/Attribute#):</u>	<u>Quantity/Weight:</u>	<u>Reason for Product Return</u>

*Example of a Returned Marijuana Waste Log Sheet:*

<b><u>Returned Marijuana Waste Log Sheet</u></b>						
<u>Date:</u>	<u>Registered Employee:</u>	<u>Qualified Patient/Caregiver:</u>	<u>Marijuana Product to Dispose:</u>	<u>Waste Weight:</u>	<u>Mixed With:</u>	<u>Total Weight to Dispose:</u>



Product Recall

<b>Standard Operating Procedure:</b> Product Recall
<b>Purpose:</b> To ensure that all required steps and procedures are take when there is a need to recall a marijuana product.
<b>Scope:</b> Procedures covering voluntary and involuntary product recalls.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required Within the Cultivation Facility**

- 1) Product Recall Log

**Principles of Product Recall**

Manufacturers, importers, distributors and retailers of consumer goods are liable for the products they provide to consumers and face the potential of product recalls for potentially dangerous or hazardous products. The same is true for the marijuana businesses as manufacturers and retailers of consumer medical marijuana products, for the facility may need to conduct a product recall in the future. For most consumer products the recall process is handled and regulated by the Consumer Product Safety Commission (CPSC), and for all intents and purposes the marijuana business recall plan will follow the guidelines of the CPSC.

The Consumer Product Safety Commission (CPSC) has compiled resources to assist companies that manufacture, import, distribute, retail, or otherwise sell consumer products. CPSC has developed a Recall Handbook that can be utilized in case a product recall needs to be ordered. The Recall Handbook details how to recognize potentially hazardous consumer products as soon as possible. The book explains how to develop and implement a “corrective action plan” (called a CAP) to address the hazards; it explains CPSC’s Fast Track Program. The Recall Handbook also discusses how to communicate recall information to consumers and how to monitor product recalls. The Consumer Product Safety Commission’s Recall Handbook will be a valuable tool utilized by the company if the need for a product recall ever arises.

The Recall Handbook should be referenced to determine exact protocol for recall and the requirements from the Consumer Product Safety Commission. The Recall Handbook can be obtained online from <http://www.cpsc.gov/PageFiles/106141/8002.pdf>.

**When to Recall Medical Marijuana Products**

As a manufacturer, distributor, and/or retailer of consumer products, the cultivation facility has a legal obligation to immediately report the following types of information:

- 1) A defective product that could create a substantial risk of injury to consumers;
- 2) A product that creates an unreasonable risk of serious injury or death;
- 3) Marijuana or manufactured marijuana is determined to contain a contaminate of some kind
- 4) Marijuana or manufactured marijuana batch did not successfully pass required testing but was released for distribution

Failure to fully and immediately report this information may lead to substantial civil or criminal penalties. Consumer Product Safety Commission’s staff advice is “when in doubt, report.” BPH will ensure communication with the required state and local authorities within 24 hours of becoming aware of the need for a product recall. BPH will then proceed to the recalling protocol and how to recall the product.

**How to Recall Medical Marijuana Products**

The facility will develop a recall plan following guidance from the Recall Handbook provided by the CPSC. Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory

management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by state regulations will ensure a streamlined recall process if ever necessary.

### **Corrective Action Plan (CAP)**

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and steps needed to be taken by the facility once a product recall is required.

#### **Step One: Industry Notification**

If a marijuana or manufactured marijuana product is believed to need a recall, BPH will contact all retail dispensary locations to notify them of the situation and the need for product recall. BPH will also contact required state and local authorities within 24 hours of obtaining reportable information. As the cultivator and/or manufacturer of the product needing to be recalled, BPH will need to contact the end users of the recalled product; contacting qualified patients will prove to be difficult, but will be possible through the utilization of the inventory control and POS systems. At this stage of the recall, retail dispensary locations will need to ensure that they have a proper recall process in place to contact qualified patients that were dispensed the product being recalled.

#### **Step Two: Public Notification**

The cultivation facility or dispensing establishment will post notifications about the product recall on its website as well as make partnering cultivation centers and dispensing organizations aware of the product recall. The actual recalling processes will be handled by both the cultivation center and the dispensing organizations.

As the dispensing organization issuing a recall notice, it will be important to reach the end users or the recalled product. The facility will post notification about the recall on Facility websites and social media as well as post written notices of the recall on location for patients and customers to view. The recall notice will include all pertinent information regarding the product being recalled, contact information and other information relating to the recall. Information will include but not be limited to:

- 1) Product name and unique attribute number
- 2) Product batch number
- 3) Dispensing date range of recalled product
- 4) Retail dispensary locations

Once the recall notification has been issued to all applicable dispensing organizations and medical marijuana patients, the facility will wait to receive recalled products from dispensing organizations and/or licensed medical marijuana patients and caregivers. Once recalled products have been received, the facility will properly dispose of all recalled products. The disposal of these products should conform to the state regulations for waste disposal.

#### **Step Three: Procurement**

BPH issuing a product recall to qualified patients and primary caregivers will need to be ready to obtain and secure recalled products from qualified patients. Patients should be able to bring in the products being recalled to the retail dispensary location. It will be at BPH's discretion whether to issue a refund, replace the recalled product at no cost, or to take other measures.

- Upon receiving recalled marijuana and/or manufactured marijuana products, registered employees will document the return of the recalled marijuana product
- After documentation, registered employees will securely store the recalled marijuana product in segregated storage until disposal
  - Recalled medical marijuana must be securely stored until properly destroyed and disposed of.



**Step Four: Documentation and Record Retention**

BPH will maintain all documentation all records regarding any and all product recalls issued. Registered employees will be required to fill out the required *Product Recall Log Sheet*.

<u><b>Product Recall Documentation Log Sheet</b></u>				
<u>Date:</u>	<u>Product Name</u>	<u>Product Attribute # or Unique ID #</u>	<u>Quantity to be Recalled</u>	<u>Supervisor</u>
List Potential Patient/Caregivers to Notify:				
Regulatory Agencies Notified: <input type="checkbox"/> MMCC <input type="checkbox"/> FDA <input type="checkbox"/> CSPA <input type="checkbox"/> Other				
<u>Date:</u>	<u>Quantity Collected:</u>	<u>Collected From (Patient/Caregiver):</u>	<u>Accepting Employee:</u>	<u>Notes/Details</u>

**Step Five: Disposal**

The facility will ensure that any and all recalled marijuana products are disposed of according to all state and local regulations. The facility will follow marijuana waste disposal and destruction procedures outlined within these SOP’s for proper disposal of recalled medical marijuana.

- Recalled material must not be destroyed or disposed of until authorized by the Commission.
  - Recalled medical marijuana will need to be stored and segregated until the disposal of recalled material is authorized by the Commission.
    - Stored recalled material in the quarantined secure storage area of the Licensed Premise.
- Once receipt of notification from the Commission that the disposal of recalled medical marijuana is authorized, registered employees will dispose of the medical marijuana according to the *Marijuana Waste Disposal SOP*.
  - Registered employees must dispose of medical marijuana within 24-hours of Commission authorization.



<b>Standard Operating Procedure:</b> Marijuana Waste Destruction and Disposal
<b>Purpose:</b> To explain required and proper disposal processes for marijuana waste.
<b>Scope:</b> Covers marijuana waste grinding, mixing and disposal measures within the retail dispensing facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Marijuana Waste Disposal Log

**Equipment/Tools Required**

- 1) Wood chipper/plant grinder
- 2) Mixing material (material to mix marijuana waste with at 50/50 ratio)
- 3) Trash bags
- 4) Dumpster/trash compactor

**Requirements of Marijuana Waste Disposal**

All marijuana waste, byproducts, undesired materials, green waste and returned/recalled marijuana will be destroyed by rendering the waste unrecognizable, unusable and unrecoverable.

BPH will require registered employees to weigh, document, record and destroy all marijuana waste according to the written standard operating procedures. All marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated will be destroyed and disposed of according to the written SOP.

**Secure, Segregated Storage**—all medical marijuana waste will be stored in secure, segregated storage on the Licensed Premise until receipt of authorization from the Commission of destroy and dispose of the medical marijuana waste.

- The secure, segregated storage will promote good growing and handling practices.

**Marijuana Waste Disposal**—all medical marijuana waste, byproducts and undesired products will be destroyed and disposed of according to all applicable state and local regulations. Facility management will ensure proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state regulations. Record all required information on the *Marijuana Waste Log Sheet*.

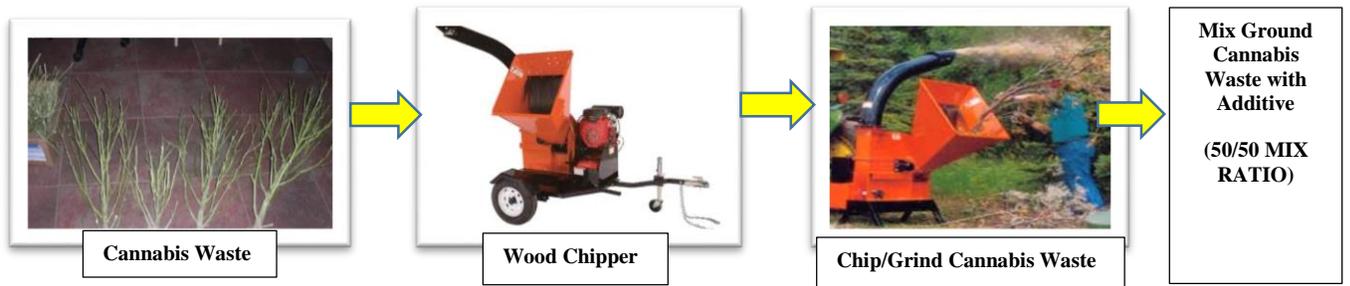
**Disposal**—Disposal of any marijuana product waste must be rendered unrecognizable, unusable and unrecoverable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.



Cannabis Stalks (waste)

**Grinding Marijuana Waste (Stalks, Stems, Leaves and Other Material)**



**\*\*BPH shall not dispose of marijuana product waste in an unsecured waste receptacle not in possession and control of the licensed premise. It is recommended to have a lock on the physical dumpster as well as the area where the dumpster is maintained.**



*Example of Marijuana Waste Documentation Log Sheet (see below):*





<b>Standard Operating Procedure:</b> Facility Cleaning and Sanitation
<b>Purpose:</b> To explain required and proper cleaning and sanitation practices.
<b>Scope:</b> Covers cleaning and sanitation measures within the cultivation facility.
<b>Initial Training:</b> 4-6 hours

**What is the Purpose of Cleaning and Sanitation?**

Proper cleaning and sanitation practices are essential within the cultivation facility. A clean and sanitary cultivation facility will reduce the risk of pests, insects and diseases. The marijuana plants can only be as clean as the room in which they are cultivated. The goal is to produce the safest medicinal marijuana within a clean and sanitary facility.

**Documentation Log Sheets Required**

- 1) Cleaning and Sanitation Log Sheet

**Equipment/Tools Required**

- 1) Personal Protective Equipment (PPE)
- 2) Broom and Dust Pan
- 3) Mop and Mop Bucket
- 4) Bleach
- 5) Cleaning Towels
- 6) Paper Towels

**Principles of Cleaning and Sanitation**

To prevent the accumulation of marijuana oils, resins, plant material, and any remaining pests, strict cleaning procedures must be followed. Cleaning and sterilizing surfaces will aid in pest management, as well as lowering overall microbial levels in processing areas, and on product. Cultivation areas will undergo thorough cleaning in between the harvest stages, and plants reentering the room. Once all plants are harvested, all non-permanent growing equipment will be removed, including pots, plant carts, scissors, etc. Registered employees will thoroughly vacuum all surfaces to remove dust, loose debris, and any plant material. The entire room will then be systematically misted with a chlorine dioxide solution. This chlorine dioxide solution will begin to break down and sterilize any organic material so it may be easily wiped off in the next step. This spray will also enter small spaces not easily reached by manual cleaning. Fans will remain running during this spraying operation to ensure mist is moved around the room thoroughly. Employees will then wipe all surfaces down with the same chlorine dioxide solution. These two steps combined will assure all surfaces are clean and sterile.

During daily operation tools, which come in contact with marijuana, will be soaked in isopropyl alcohol. Transport carts, worktables, and other cultivation furniture will undergo weekly cleaning and sterilizing. After growing medium is disposed, plant containers will be washed and sterilized using a powered washing machine. Pots will be sterilized using a hydrogen peroxide solution, and dried before use.

Due to the nature of marijuana products, cleaning surfaces in processing areas is crucial. Build up caused by marijuana can be very difficult to remove when left for long periods of time. For general removal of resins, a disposable cloth is coated with 91% isopropyl alcohol, and used to wipe all surfaces free of material. For heavily soiled areas use a metal scraper to remove resins. Marijuana trimming machines require daily cleaning to maintain performance, and sterility. Machines will be disassembled, and separated depending on cleaning method. Metal parts are cleaned using isopropyl alcohol; all other parts will be cleaned and sterilized using a steam cleaner.

Drying trays will be sterilized in between each use; wiping trays with isopropyl alcohol will do this. Drying trays will be thoroughly cleaned monthly by first soaking them in hot water to loosen and material, then wiping trays down with isopropyl alcohol. Curing containers will be cleaned and sterilized between uses by wiping down all surfaces with isopropyl alcohol. Drying racks will also be wiped with isopropyl alcohol in between uses.

All areas of the facility, which will contain any marijuana product, or equipment, will have Puradigm air & surface sterilizing technology installed. This system uses advanced oxidation, and multi-cluster ionization technology to instantly kill bacteria, mold, mildew, and other microbes. General maintenance is required on these systems including changing bulbs, changing filters, and general cleaning. This maintenance is done according to the manufacturers recommendations.

After each drying period is complete, drying rooms will be vacuumed to remove dust and plant debris. All surfaces in the room will be wiped with hydrogen peroxide or bleach solutions. The processing, drying, curing, and packaging rooms will be cleaned thoroughly after each harvest. All floors are first vacuumed to be free of dust and plant debris. All surfaces are wiped clean and sterilized using either hydrogen peroxide or bleach solution. This step will assure no microbial cross contamination between harvests.

Apart from clean entry protocols practiced by agents, incoming soil and equipment must also be sterilized. Incoming pallets of soil will be kept in a quarantine room containing Puradigm sterilizing technology. Once the allotted time of air sterilization occurs, the pallets will be moved into a clean room air shower. In the air shower, ions will be dispersed to remove static electricity from plastic bags. Compressed air is blasted at the contents of the air shower, and the air is removed, and filtered.

Major cleaning and sanitation should be done within the cultivation facility when specified by the ***Cleaning and Sanitation Schedule***. Vegetative/flowering rooms should be thoroughly cleaned after the zone/room is completely emptied of all plants. This will be done when moving vegetative plants from the vegetative zone/room into the flowering zone/room or once a flowering room's plants are completely harvested and the room is emptied.

#### **General Daily Cleaning at the Facility:**

- **Cultivation Room(s)**
  - All cultivation rooms should be swept daily
    - Mother room
    - Propagation/clone room
    - Vegetative room(s)
    - Flowering room(s)
  - All trash and plant waste material should be collected and removed from cultivation rooms
  - Foot bath should be checked/changed daily (*if applicable*)
- **General Area(s)**
  - All hallways and accesses will be swept and mopped daily
  - All trash and debris should be collected and removed from the facility general areas on a daily basis
  - The bathrooms should be kept clean and maintained by each employee on a daily basis
  - Parking lot area should be maintained on a regular basis; free of trash and debris
- **Entry (*man trap*)**
  - The "man trap" area should be thoroughly cleaned and sanitized on a daily basis
    - Sweep floor
    - Sanitize floor, walls, door handles
  - Sanitizing footbath solution will be changed every other day

#### **Specific Cleaning at the Facility:**

- **Harvested Cultivation Room(s):**
  - Beginning at the top of the room, dust, and wipe down all surfaces with a 5% bleach solution
    - Be sure to wipe all surfaces thoroughly
  - Sweep and vacuum (*wet/dry shop vac*) all floors
  - Mop all floors with a 5% bleach solution and allow to dry



- Check to assure all surfaces have been sterilized
- Once a zone/room has been properly cleaned and sanitized, employees are required to properly document the activities on the *Cleaning and Sanitation Documentation Log*.

*Example of Cleaning and Sanitation Documentation log sheet:*

<b><u>Cleaning and Sanitation Documentation</u></b>					
Date:	Zone/Room Cleaned:	Cleaning Agent(s) Used:	Reason for Cleaning:	Notes/Comments:	Cleaned By (initial) :





Equipment Operation

<b>Standard Operating Procedure:</b> Equipment Operation
<b>Purpose:</b> To identify the various equipment to be utilized within the facility
<b>Scope:</b> To identify the equipment to be utilized, and where employees can obtain copies of the manufacturer
<b>Initial Training:</b> 4-8 hours

### The Principles of Equipment Operation

For all 3<sup>rd</sup> party equipment being utilized within the facility it is recommended to refer to the manufacturer instructions and user manuals for proper operation, set-up, maintenance, cleaning or any other equipment information. Manufacturer instructions and user manuals should have been provided as a hard copy with all original equipment. If the original user manual has been lost or misplaced, refer to the manufacturer company website or contact them directly for a replacement manual.

Some manufacturing companies offer user manuals and instructions as an electronic version which can be obtained online from the company website.

Below are some of the specific equipment utilized by ACC along with the company website where user manuals and/or manufacturer instructions and suggests can be obtained.

#### 1) **AutoPots**

- a. Website: <http://autopot-usa.com/products/1pot-xl/product/56-1pot-xl-module-only>
- b. User Guide: [file:///C:/Users/Sam/Downloads/003\\_2015\\_1POT\\_MODULE\\_XL\\_SETUP\\_A5\\_BTT%20v2%20\(1\).pdf](file:///C:/Users/Sam/Downloads/003_2015_1POT_MODULE_XL_SETUP_A5_BTT%20v2%20(1).pdf)

#### 2) **Heliospectra LED Lighting**

- a. Spec Sheet: [https://cdn.shopify.com/s/files/1/0621/8261/files/Product\\_Leaflet\\_-\\_LX601.pdf?8354](https://cdn.shopify.com/s/files/1/0621/8261/files/Product_Leaflet_-_LX601.pdf?8354)
- b. User Guide: [http://www.heliospectra.com/sites/default/files/lx60\\_user\\_guide.pdf](http://www.heliospectra.com/sites/default/files/lx60_user_guide.pdf)

#### 3) **Lightstick T5 Fluorescent Lighting**

- a. Website: <http://www.brewtek.ca/en/fluorescent-lighting/t5-fixtures/lightstick-t5-4-4-tube-9440>
- b. User Guide: [http://sunlightsupply.s3.amazonaws.com/documents/product/960300\\_Instructions.pdf](http://sunlightsupply.s3.amazonaws.com/documents/product/960300_Instructions.pdf)

#### 4) **TRIMINATOR**

- a. Website: <http://thetriminator.com/wet-marijuana-trimmer-machine/>
- b. User Guide: <https://drive.google.com/a/americanmarijuanaconsulting.com/file/d/0B236JzITJeCVaVo1SG5IN1Vna05YU1ZMY3AyR283cGdfUW5J/view>

#### 5) **Roto-Scrub Pot washer**

- a. User Guide: [http://www.dillonfloral.com/pdfs/Roto\\_Scrub\\_documentation\\_032108.pdf](http://www.dillonfloral.com/pdfs/Roto_Scrub_documentation_032108.pdf)

#### 6) **Patriot Electric Wood Chipper**

- a. Website: <http://www.patriot-products-inc.com/P/31/WoodChipperLeafShredder15hpElectricInternational>
- b. User Guide: <http://www.patriot-products-inc.com/Content/files/eleccsvmanual.pdf>

#### 7) **RO system**

- a. Website: <http://purewatersolutions.com/>

#### 8) **Environmental Controller**

- a. Website: <http://www.agrowtek.com/>



- b. User Guide: [http://agrowtek.com/doc/GrowControl\\_GC-Pro.pdf](http://agrowtek.com/doc/GrowControl_GC-Pro.pdf)
- 9) **Emergency eye wash**
  - a. Website: <http://www.globalindustrial.com/p/safety/first-aid/eyewash-stations/portable-eye-wash-station-16-gallon-capacity>
- 10) **Air Locks/Shower**
  - a. Website: <http://www.terrauniversal.com/cleanroom-passthroughs/clean-room-air-showers.php>
  - b. User Guide: [http://www.terrauniversal.com/uploads/tech\\_resources/air\\_shower\\_installation\\_manual\\_20141217\\_with\\_appended\\_docs\\_121714115355.pdf](http://www.terrauniversal.com/uploads/tech_resources/air_shower_installation_manual_20141217_with_appended_docs_121714115355.pdf)
- 11) **26 Quart High Performance Blender**
  - a. Website: <http://www.webstaurantstore.com/26-quart-high-performance-vertical-tilting-blender-110v-220v/915LAR25.html>
  - b. User Guide: [http://www.webstaurantstore.com/documents/pdf/omcan\\_blendr\\_operating\\_manual.pdf](http://www.webstaurantstore.com/documents/pdf/omcan_blendr_operating_manual.pdf)
- 12) **Digital Scale**
  - a. Website: [http://www.coleparmer.com/Product/A\\_D\\_FX\\_2000iN\\_NTEP\\_Tploading\\_Balance\\_2200\\_g\\_x\\_0.1g/EW-11115-82](http://www.coleparmer.com/Product/A_D_FX_2000iN_NTEP_Tploading_Balance_2200_g_x_0.1g/EW-11115-82)
- 13) **Hanging Digital Scale**
  - a. Website: [http://www.americanweigh.com/product\\_info.php?cPath=46&products\\_id=1230](http://www.americanweigh.com/product_info.php?cPath=46&products_id=1230)



Equipment Maintenance, Cleaning and Sanitation

**Standard Operating Procedure: Equipment Maintenance, Cleaning and Sanitation**

**Purpose:** To explain facility equipment maintenance, cleaning and sanitation

**Scope:** To educate and train licensed premise employees on requirements and procedures pertaining to facility equipment maintenance and the proper cleaning and sanitation of facility equipment.

**Initial Training:** 2-4 hours

**Principles of Equipment Maintenance, Cleaning and Sanitation**

Equipment utilized within the cultivation operations at the licensed premise will need to be routinely maintenance, cleaned and sanitized. There are multiple reasons for this routine maintenance, cleaning and sanitation including operator safety. Regular maintenance should be done in order to keep the equipment operating and functioning properly, this reduce the risk of an operator getting injured while operating the equipment. The maintenance procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Equipment will need to be cleaned and sanitized after equipment comes into contact with medical marijuana it will need to be properly cleaned and sanitized. The cleaning and sanitation procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Licensed premise employees performing the maintenance and/or cleaning and sanitation will be required to document the maintenance and/or cleaning and sanitation within the *Equipment Maintenance, Cleaning and Sanitation Log Sheet*.

*Example of BPH's Equipment Maintenance, Cleaning and Sanitation Log Sheet:*

<b><u>Equipment Maintenance, Cleaning and Sanitation</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Equipment Name/Model #:</u>	<u>Date of Last Maintenance</u>	<u>Date of Last Cleaning &amp; Sanitation</u>	<u>Notes/Comments</u>





Facility Exit Protocol

<b>Standard Operating Procedure:</b> Facility Exit Protocol
<b>Purpose:</b> To explain how employees should exit the production center.
<b>Scope:</b> Covers the steps involved for properly exiting the production center.
<b>Initial Training:</b> 1-2 hours

When an employee has finished their work shift, they will exit the “clean” area of the cultivation facility in the same way they enter, however the process for exiting will be done in reverse.

**How to Exit the Production Center:**

1. Exit the clean area through the Air-Lock Chamber
2. Enter the locker room
3. Change out of provided work wear attire/uniform
  - a. Scrubs
  - b. Hair nets
  - c. Hats
  - d. Garden shoes
4. Place used work wear in the proper laundry bin
5. Change back into street clothes
6. Exit the locker room
7. Exit the facility through the man trap.
  - a. Arm the security alarm system to *AWAY (if applicable)*

Emergency Protocol

<b>Standard Operating Procedure:</b> Emergency Protocol
<b>Purpose:</b> To describe all steps and protocols to be followed by employees should an emergency occur within the facility.



**Scope:** Procedures covering emergency situations occurring within the facility.

**Initial Training:** 2-4 hours

### **Documentation Log Sheets Required**

- 1) Emergency Situation Documentation Sheet

### **Equipment/Tools Required**

- 1) Panic Alarm/Button
- 2) Fire Extinguisher
- 3) Chemical Spill Kit
- 4) Emergency eye wash station(s)
- 5) First Aid Kit
- 6) Emergency defibrillator

### **The Principles of Emergency Protocols**

A facility emergency management plan is designed to educate and train facility employees on the actions and procedures to follow in the event of an emergency. In the case of an emergency, facility employees will need to respond quickly and think strategically in order to successfully manage the emergency situation. Having a good understanding of the facility emergency management plan will enable employees to better adapt to and handle emergencies.

The most important thing to remember during an emergency situation is to try to stay calm, if the emergency situation is out of your control and you need assistance, contact emergency services immediately if possible.



**Burglary:** Burglary is legally defined as the criminal offense of breaking and entering a building illegally for the purpose of committing a crime. Burglaries generally will occur at the Licensed Premise after operating hours and while there are no registered employees present. Typically burglaries occur during the night and are not discovered until the next day during normal operating hours.

- If upon entering the Licensed Premise and a registered employees notice something is afoul and upon investigation a burglary was determined to have occurred in the previous night, then registered employees will be required to document the incident and notify all required authorities.
  - Registered employees will be required to report the incident of burglary to:
    - The Commission
    - Local medical marijuana authority (*if applicable*)
    - Local police

**Robbery or Theft:** Robbery is legally defined as the taking of money or goods in the possession of another, from his or her person or immediate presences, y force or intimidation. The number one rule registered employees will need to follow when/if dealing with a robbery is to comply with all robber demands

- If you are being robbed at gunpoint or if you feel as if your life is in danger, comply with all requests from perpetrator/suspect. Give them whatever they ask for.
- Try to signal for help using the personal security panic buttons provided, by activating one of multiple, strategically placed panic alarm buttons, or through the panic button/police services button located on the alarm panel.
- Contact law enforcement as soon as possible
- Notify any required State or local authorities immediately (within 24 hours)
  - Local police services
  - The Commission
- Comply with all applicable laws and regulations
- Document the situation in the *Emergency Situation Documentation* log sheet



**Alarm Panel**



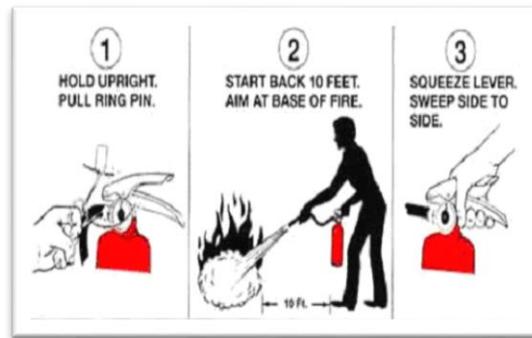
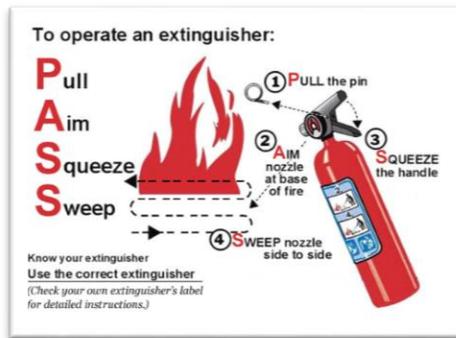
**Panic Alarms/Buttons**



**Fire Emergency:**

- If a small isolated fire is present, try to exhaust the fire with one of the fire extinguishers on site
- In case of a fire emergency, first leave the facility; once clear of the facility dial 911 and/or local fire authority for Fire Emergency Services or push the symbol on the alarm panel for fire emergency upon exiting the facility
- Document the situation in the *Emergency Situation Documentation* log sheet

**Fire Emergency Cont.**



**Chemical Emergency:**

- Dangerous Substance/Chemical Exposure:
  - If an employee accidentally has their eyes exposed to toxic, poisonous or dangerous substances or chemicals; said employee will need to locate the installed emergency eye wash station(s) to properly flush and clean their eyes. Notify emergency medical services for further assistance
- Chemical Spill:



- Try to use a chemical spill kit for smaller incidents of chemical spill
- If a chemical spill is large or you do not know how to handle the situation; get the facility manager to handle the situation and/or contact proper emergency services
  - Posted near or included with the chemical spill kit should be an emergency contact information sheet displaying which emergency services should be contacted.
    - For the BPH and the State of Hawaii this will include but not be limited to:
      - Environmental Protection Agency (EPA)
        - For emergencies and other sudden threats to public health, such as:
          - oil and/or chemical spills,
          - radiation emergencies, and
          - biological discharges,
            - call the National Response Center at 1-800-424-8802.
          - For **pesticide poisoning**, call 911 if the person is unconscious, has trouble breathing, or has convulsions. Otherwise, call **Poison Control at 1-800-222-1222**.
- Document the situation in the *Emergency Situation Documentation* log sheet



**Medical Emergency:**

- If it is a minor medical situation such as a small cut, scrape or minor burn; retrieve the first aid kit on site and treat wound with items found in the first aid kit
- If the situation appears to be a severe medical situation such as someone suffering from a heart attack, retrieve the emergency defibrillator and follow the instructions provided; notify 911 or local medical emergency services for further assistance
- If the medical situation is an emergency; contact medical emergency services immediately. This can be done through activating the medical response button found on the alarm panel, or by calling 911 for medical emergency services
- If a serious injury occurs while an employee is working, such as a slip and fall resulting in possible broken bones or a cut requiring stitches, BPH facility management will need to complete a worker compensation insurance claim form prior to the employee seeking medical assistance. This procedure does not take long, but the form will need to be completed in order for the injured employee to have a workers compensation medical claim.
- Document the situation in the *Emergency Situation Documentation* log sheet



**Other Emergencies:**

- Contact 911 if it is a current emergency. Contact your local police and/or State regulatory authorities for break-ins or burglaries that may have occurred when the facility operations were closed
- Contact any required State or local authority in cases of theft, break-ins or burglaries
- Document the situation in the *Emergency Situation Documentation* log sheet



**Example of Emergency Situation Documentation Log Sheet:**

<u><b>Emergency Situation Documentation</b></u>		
Date:	Reporting Employee:	Manger on Duty:
Type of Emergency: <input type="checkbox"/> Robbery of Theft <input type="checkbox"/> Fire Emergency <input type="checkbox"/> Chemical Spill <input type="checkbox"/> Medical Emergency <input checked="" type="checkbox"/> Other Emergency		
Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO	Which Authorities:	
Description of the Incident:		





Loss of Personnel

**Standard Operating Procedure: Loss of Personnel**

**Purpose:** To describe all steps and protocols to be followed prior to or after the loss of personnel.

**Scope:** Procedures covering loss of personnel situations occurring within the facility.

The following will cover procedures to follow when terminating a key employee as well as when a key employee decides to leave the organization on their own accord.

**Job Termination**—if the need arises to terminate the position of a key personnel there will be some basic steps and procedures to follow within operations.

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e. employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel
4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e. mutual separation and key personnel is always welcome back at BPH facilities under visitor status, employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was previously filled by key personnel. Key personnel positions will need to be filled as soon as possible by ownership and/or management without sacrificing quality of applicant pool. Some basic steps should be followed to find and place a suitable replacement for the vacant position.

1. Review resumes and applications from qualified applicants
2. Call said qualified applicants to conduct an informal, initial phone interview
  - a. If you get a good response from applicant, schedule an in-person interview
3. Conduct in-person interviews with qualified applicants
4. Review interviewed applicants
  - a. Select applicant who is most qualified for the vacant position
5. Contact said applicant and offer the vacant position
6. If applicant accepts the job offer, proceed with normal hiring procedure and required paperwork



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# STANDARD OPERATING PROCEDURES

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*State Of Hawai'i Production Center—Manufacturing Operations*





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**-----STATE REGULATORY COMPLIANCE DISCLOSURE-----**

*Medical marijuana facilities operate in a highly regulated industry, as such adherence to all applicable state and local laws pertaining to the cultivation, production, manufacturing, possessing and dispensing of marijuana and/or marijuana-infused products within the facility is of utmost importance. State and local laws and regulations will vary among states; it is recommended to read and have good understanding of the state and local laws and regulations in which you operate. Having a good understanding of the state and local laws is the first step in being educated on how to operate within regulations, the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within a regulated market.*

**-----CONFIDENTIALITY DISCLOSURE-----**

“Confidential Information and Intellectual Properties” means and includes any tangible or intangible information or material that is confidential or proprietary to Consultant that Client may obtain knowledge of through, or as a result of, its relationship with Consultant. Such information shall be deemed Consultant’s Confidential Information and Intellectual Properties whether or not owned or developed by Consultant. Confidential Information and Intellectual Properties shall also include, but is not limited to, any inventions, processes, designs, formulae, trade secrets, Standard Operating Procedures, know-how, confidential information, trademarks, copyrights, service marks, domain names, computer software, data and documentation, and all similar intellectual property.

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Client understands that all such Existing Consultant IP, including all Standard Operating Procedures shall remain the sole property of Consultant, and Client agrees that neither it, nor any of its officers, directors, employees, consultants, affiliates or anyone acting in concert with Client will: (i) acquire any ownership interest in any Existing Consultant IP; and (ii) will not, convey, sell, publicize, use, trade, distribute any Existing Consultant IP to any other person or business, or take or modify Existing Consultant IP in order to convey, sell or distribute to any other individual or business not a party to this Agreement, that results in competition with the consulting services offered by Consultant, or interferes with any existing or prospective business advantage Consultant may have. No other license to any Existing Consultant IP is granted or implied by this Agreement.

**DEFINITION**

Manufacturing Infused Product (“MIP”)—refers to the production center where manufacturing activities and operations occur. Also can refer to manufactured marijuana products.



Employee Qualifications

<b>Standard Operating Procedure:</b> Employee Qualifications
<b>Purpose:</b> To determine the qualifications possessed by registered employees
<b>Scope:</b> To evaluate prospective and current registered employee qualifications
<b>Initial Training:</b> TBD

BPH’s employment qualifications and requirements are detailed within the Employee Handbook which is a separate, additional document that can be viewed upon request.

**JOB DESCRIPTIONS/QUALIFICATIONS:**

A detailed Job Description will be developed for each employment position within the production facility. The following is a list of the initial anticipated employment positions:

- General Manager
- Extraction Manager
- Extraction Techs
- Production Manager
- Production Techs
- Quality Control
- Sanitation Associates
- Logistics Tech

**Duties, Authority, Responsibilities and Qualifications of Personnel:**

It is Company policy to employ individuals who are qualified to properly perform their assigned job responsibilities. These employee qualifications in compliance with applicable State regulations shall be documented in the job description and may consist of age restrictions, formal education, work experience, criminal history background checks, in-house training or combination thereof. Each job description summary will include a list of duties, authority, responsibilities and qualifications of personnel which will be used to determine employee qualifications for hiring and training purposes.

The Job descriptions will also include a list of the standard operating procedures that position is required to know.

**FACILITY EMPLOYMENT POLICIES:**

The following are general employment qualifications and training policies for the facility:

- 1) Documentation of each employee's formal education (degrees completed, courses taken, etc.) shall be kept on file.
- 2) Where appropriate, a summary of previous work experience (i.e. a resume) shall be adequate documentation to demonstrate an employee's qualifications to perform or supervise facility operations.
- 3) Supervision of Personnel: Given the sensitive nature of the industry it is vital that employees are adequately supervised at all times and in compliance with security protocols (see security plan guide). The Job Descriptions for each position includes identification of the reporting supervisor. The extraction and production manager will be onsite and is responsible for the overall supervision of all employees.
- 4) Adherence to Confidentiality Requirements: Each Employee and/or agent of the Company will be trained in and required to adhere to the Company’s confidentiality requirements. Each employee will be required to sign a Non-disclosure Agreement, as well as a Confidentiality Statement representing their covenant with the Company.



5) Periodic Performance Evaluations and Disciplinary Actions: Performance evaluations will occur bi-annually. The performance evaluations will be written and maintained in the employee's personnel file. This information will be used to determine compensation and pay increases as well as disciplinary actions and grounds for dismissal.

6) A written record documenting the completed individual training procedures shall be signed by the participants and trainer during each training session.

7) All company employees will attend in-house training conducted by qualified individuals in HACCP, current Good Manufacturing Procedures (cGMPs), and general sanitary practices and in the specific Standard Operating Procedures (SOPs) which pertain to their assigned work responsibilities. Such training shall be performed on an ongoing basis to assure the employee is familiar with these procedures and practices. Additionally each employee will supplement their training with review of relevant video educational materials for example:

**HACCP Video:**

Part 1 - [https://www.youtube.com/watch?v=7nbnjd\\_TnU8o](https://www.youtube.com/watch?v=7nbnjd_TnU8o)

Part 2 - [https://www.youtube.com/watch?v=gRJ7q\\_2Vkrc](https://www.youtube.com/watch?v=gRJ7q_2Vkrc)

**Principles of GMP**

<https://www.youtube.com/watch?v=JHkGgFUuZwE>

8) The General Manager/Quality Assurance Manager shall exercise oversight of the organizations practices and procedures and who have documented training and experience in quality assurance and quality procedures.

9) All registered employees will be twenty-one (21) years of age or older.

10) All staff members who could potentially come in contact with or handle medical marijuana or medical marijuana products will not include anyone who has been convicted of any felony of sale or possession of drugs, narcotics or controlled substances in accordance with the requirements of section thirty-three hundred sixty-four of the public health law.

11) All staff members who could potentially come in contact with or handle medical marijuana or medical marijuana products will not include anyone who has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding.

12) All staff members who could potentially come in contact with or handle medical marijuana or medical marijuana products shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by the Department.

13) Personnel engaged in the manufacture, processing, packing or holding of medical marijuana products shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand and arm coverings, shall be worn as necessary to protect products from contamination.

14) Any person shown at any time to have an apparent illness or open lesions that may adversely affect the safety or quality of a product shall be excluded from direct contact with components, product containers, closures, in-process materials and finished products. All personnel shall be instructed to inform their supervisor of any health conditions that may have an adverse effect on a product. All personnel shall practice good sanitation and health habits.

15) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, holding or shipment of each product. Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as a limited-access area. Records shall be maintained identifying those areas individuals are authorized to enter.

16) Consultants advising on the manufacture, processing, packing, holding or shipment of medical marijuana products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained with the name, address, and qualifications of any consultants and the type of service they provide.



## **FACILITY TRAINING PLAN:**

The training program for all manufacturing employees will include but is not limited to the following areas of focus:

1. Training on Commission Statutes and Rules and Other State and Local Laws and Regulations
2. Training on Company Standard Operating Procedures.
3. Training on Detection and Prevention of Diversion of Cannabis
4. Training on Security and the Company's Security System
5. Training on Hazards and Safety and Emergency Procedures such as a Medical Emergency, Fire, Chemical Spill, Security and a Threatening Event.
6. Training on Inventory Control and Record Keeping
7. Annual training to update and reinforce knowledge in above areas

All employees will attend in-house training conducted by qualified individuals in Current Good Manufacturing Practices (cGMP), general sanitary practices, and in the specific Standard Operating Procedures (SOPs) that pertain to their assigned work responsibilities. Such training will be performed on an ongoing basis to ensure the employee is familiar with these procedures and practices. A written record documenting the completed individual training procedures will be signed by the participants and trainer during each training session. Each SOP will include a section for signature of the employee to indicate they have completed training in the performance of the procedure.

The Department of Human Resources, in coordination with unit directors, is responsible for the development and execution of employee training. The Human Resources department will work in coordination with Quality Control and the Compliance Department to develop the curriculum for the Company's training system. Human resources and department heads are responsible to the Compliance Department who has the ultimate oversight responsibility for training requirements, and for auditing department training records.

The company shall develop a detailed training manual for the education of processor agents employed at the facility. In addition to the Company's training manual, additional training materials will be made available such as video presentations, industry guides, and GMP publications and other literature. These will be maintained within the facility in a library of information at all times available to the staff.

The company shall additionally make its training materials and attendance records available at all times, onsite, at our Production Facility for inspection by the Commission or its authorized representative.

The TRAINING MANUAL may include the following areas of focus:

1. A new-hire orientation training section - All new employees will go through an orientation training before starting their employment. The training manual will include an orientation section containing a review of all company policies, such as drug-free workplace rules and confidentiality requirements. This phase of training will also include an orientation to the SOP system and how to use it on the job.
2. Laws and Regulations: This section of the training manual will include critical laws and regulations the Company and employees are subject to. Certain of these laws and regulations will also be incorporated into the company's SOPs.
3. SOP training curriculum -The training manual will include a comprehensive copy of the Company's SOPs. The primary training curriculum for processor agents for the performance of their duties will be the SOPs themselves. The SOPs will have an administrative section which will include a signature line for employees and managers to indicate proficiency. This documentation will go into the employee's files to be available for audit and for inspection by the commission.
4. Detection and prevention of diversion - This section of the training manual will be created with the assistance of our professional security consultant. They will also develop the security plan for the company and will perform training sessions for the employees.
5. Processor Facility Security - This section of the training manual will be created with the assistance of our professional security consultant. They will also develop the security plan for the company and will perform training sessions for the employees.
6. Safety and emergencies - This section of the manual will be created with the assistance of our security consultants, processor consultants and local fire and safety agencies. All employees will be trained on emergency situations and periodic drills will be performed to ensure preparedness.



7. Inventory Control - The training manual will include a section that provides an overview of inventory control. The inventory control system is a third party software system which will have a comprehensive user manual. This user manual will be retained onsite and will be available for inspection at all times by the commission.

Consultants advising or training on the manufacture, processing, packing, holding or shipment of medical marijuana products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained with the name, address, and qualifications of any consultants and the type of service they provide.

#### **DOCUMENTATION**

Attendance at formal training classes will be mandatory and documented. Additionally, specific training on SOPs, including applicable laws and regulations, will be signed off by both the employee and a supervisor. This documentation will be retained in the employee's personnel file so that it can be audited by the compliance division. Human resource files and training documentation will be maintained in hard copy and an electronic environment for ease of interaction, retention, and inspection by the commission. Employment contracts will specify attendance at training classes, and in the event the employee does not complete the required training in the specified time, this would be grounds restricting their hours until the training is completed and ultimately dismissal.



<b>Standard Operating Procedure:</b> Standard Operating Procedures
<b>Purpose:</b> To explain the standard operating procedures needed to be adhered to within the Licensed Premise
<b>Scope:</b> To cover the education and training required pertaining to the standard operating procedures utilized within the Licensed Premise.
<b>Initial Training:</b> TBD

**Definitions**

**Standard Operating Procedure (SOP)**—a set of step-by-step instructions to achieve a predictable, standardized, desired result often within the context of a longer overall process. At its simplest, an SOP is a repeated application of unchanged processes and procedures and its documentation. These SOP’s are to be followed as directed and not deviated for the cultivation of marijuana within any Blue Planet Healing LLC (BPH) registered production centers.

**Material Change**—a material change is defined as a major deviation from the standard procedure, or changing the procedure or methodology drastically enough to notice a change. The material change is important enough to notice or to have an effect on the standard operating procedure.

**Principles of Standard Operating Procedures**

The cultivation of marijuana can be difficult for the rudimentary gardener. American Marijuana Company’s (ACC) Standard Operating Procedures (SOP’s) insure consistent production of high quality medical marijuana. BPH will utilize said SOP’s for all marijuana cultivation methodologies and operations. Understanding and abiding by the following SOP’s is mandatory for all registered employees working within BPH’s registered dispensary facilities.

The standard operating procedures must be practiced and utilized to cultivate each plant and to produce each batch of marijuana. The strict adherence to the written SOP’s will aid in BPH’s quality control program and measures. The written SOP’s have been developed within a regulated marijuana industry with the purpose of creating systems and procedures that result in a consistent and reproducible marijuana product. The cultivation process is broken down into each week of the plant’s lifecycle. Apply the following SOP instructions to the lifecycle of each plant in the facility. Do not deviate from exact instruction within these standard operating procedures.

- Failure to practice and utilize BPH’s written standard operating procedures is grounds for disciplinary action and possible job termination.

Written standard operating procedures will be utilized for all cultivation activities and operations, for the cultivation of all marijuana plants to ensure consistency of the batch with the variety and for accuracy of the day-to-day production. The written standard operating procedures will ensure consistency of batch and accuracy of day-to-day production if utilized properly and not deviated from.

- Registered employees will be required to record and maintain documentation log sheets and forms to record the cultivation process
  - Required documentation and record keeping is highlighted throughout the SOP’s and indicates which documentation log sheets and records are to be taken and maintained.
    - Registered employees will need to pay careful attention to each standard operating procedure to ensure proper documentation and record keeping
      - The documentation should demonstrate consistency of batch with the medical marijuana variety being cultivated
      - The documentation should also demonstrate the accuracy of the day-to-day production within the Licensed Premise.
- Any major deviation from the standard operating procedure defined as a material change that could impact the quality of batch must be documented, recorded and maintained on the Licensed Premise
  - Registered employees are required to document any major deviation in production of a batch from the standard operating procedure



**Deviation/Material Change to Standard Operating Procedures**

Upon recognizing the need for or making a material change to a standard operating procedure, registered employees will be required to document the material change within the *Material Change to SOP's* log sheet and update the current SOP to reflect the material change.

<b><u>Deviation/Material Change to SOP's</u></b>		
<b>Date:</b>	<b>Registered Employee:</b>	<b>Deviation in Production:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Reason for the deviation</b> ( <i>identify and describe in detail the deviation from the SOP</i> ) :		
<b>SOP requiring material change:</b>		
<b>Material Change made to the SOP</b> ( <i>please describe in detail</i> ) :		
<b>SOP Updated?</b> <input type="checkbox"/> YES	<b>Date Updated:</b>	<b>Update By:</b>
<b>Manager/Supervisor Awareness and Approval:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Manager/Supervisor Signature:</b>	
<b>Sample of production batch with deviation sent to independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Sample of production batch with deviation determined to meet specifications for the variety by BPH and the independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>Medical Cannabis Batch Released for Distribution?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Additional Notes/Comments:</b>	
<i>After documentation of a material change to a standard operating procedure, registered employees will be required to maintain the record of material change within a limit-access and secured area of the Licensed Premise.</i>		

**Deviations in Production—Independent Laboratory Testing**

Per State of Hawai'i regulations, BPH will not release any batch of marijuana or manufactured marijuana products if there was any deviation in production from the batch from the standard operating procedure. All medical marijuana will need to be securely held and stored until:

- The sample from the batch of marijuana and/or manufactured marijuana product with any deviation in production is sent to an independent testing laboratory for testing
  - The marijuana will not be released for distribution until after an independent testing laboratory and BPH determines, as a result of testing, that the batch meets the specifications for the variety and the determination is recorded.
- Follow *Samples for Laboratory Testing* and the *Transferring/Transporting and Shipping Medical Marijuana* standard operating procedures for procedures and requirements pertaining to laboratory testing and transport.
  - Ensure to follow Sampled for Laboratory Testing
    - Fill out and record all required documentation log sheets
      - Fill out *Material Change Samples for Laboratory Testing* log sheet (*can be seen below*)



**Material Change Samples for Laboratory Testing**



<b>Date:</b>	<b>Employee:</b>	<b>Attribute ID #/Product Batch #/Strain:</b>	<b>Sample Quantity:</b>	<b>Sample Attribute ID # (NEW) :</b>	<b>Receiving Laboratory:</b>



State Regulatory Compliance

<b>Standard Operating Procedure:</b> State Regulatory Compliance Training
<b>Purpose:</b> To explain the regulatory compliance needed to be adhered to in the State of Hawai'i.
<b>Scope:</b> To cover the regulations enacted within Hawaii pertaining to legally operating a marijuana business.
<b>Initial Training:</b> training done on individual time

**Required Documents**

- 1) State Regulations
- 2) Local/City Regulations (*if applicable*)

**The Principles of State Regulatory Compliance Training**

BPH will require all registered employees to read and become familiar with the State and Local/City regulations that have been enacted pertaining to operating a legal, licensed marijuana business.

BPH will keep a physical, up-to-date copy of any and all laws and regulation in which you must operate under at every licensed facility. Every registered employee will receive a hard copy of the laws and regulation which they can read and become familiar with.

Key State Regulations Employees Should be Familiar With:

- Who can have access to the facility
  - Visitor process
- Packaging and labeling compliances and requirements
- Allowed purchase amounts (quantities and distribution timeframe)
- Hours of allowed operation
- Inventory tracking and required record keeping
- Security procedures and protocols
- Laboratory testing requirements
- Transportation of marijuana products
- Etc.

**State of Hawaii**

- <http://health.hawaii.gov/medicalmarijuana/>



Record Keeping and Documentation

<b>Standard Operating Procedure:</b> Record Keeping and Documentation
<b>Purpose:</b> To ensure that all required marijuana cultivation records and data are properly recorded and documented. Including zone/room environments, transplant logs, IPM applications, inventory, etc.
<b>Scope:</b> Procedures covering record keeping and documentation for activities within the cultivation Licensed Premise.
<b>Initial Training:</b> 4-8 hours

### **What is the Purpose of Record Keeping and Documentation?**

Marijuana cultivation facilities operate in a highly regulated industry, as such proper record keeping and documentation are essential within the cultivation facility. Having records of crop inputs such as growing media records and pesticide applications will aid during the cultivation process to ensure proper feedings occur and that plants are not treated with chemicals more than absolutely necessary.

### **Equipment/Tools Required**

- 1) Pen or pencil
- 2) Clipboard
- 3) Log Sheets

### **Principles of Record Keeping and Documentation**

Adherence to all applicable state and local laws pertaining to the cultivation of marijuana within the production center facility is of utmost importance. State and local laws and regulations will vary among states; having a good understanding of the state and local laws is the first step in being educated on the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within Hawai'i's regulated market.

Required records and documentation are noted throughout the written Standard Operating Procedures; BPH's registered employees will be required to make such records and documentation as part of their job responsibilities. Registered employees will be required to make two sets of all records and documentation; one set of records and documentation will be made within the BioTrackTHC™ inventory control system, and a second set of records and documentation will be made using physical log sheets and templates. The physical records and documentation will be maintained on at the production center within a limited access area. Failure to create and maintain records and documentation will be grounds for disciplinary action and/or job termination.

Record Keeping and documentation are noted within other SOP's where documentation is required. The SOP's will also reference which documentation records and log sheets are required to be filled out and maintained.

### **Manufacturing Operational Records:**

- Manufactured Marijuana Products—Inventory
- POS Inventory
- Inventory Reconciliation
- Daily Marijuana Products Transfer/Shipping Log
- Marijuana Waste Log
- Finished Marijuana Log
- Cleaning and Sanitation Log
- Product Recall Log
- Returned Marijuana Log
- Employee List
- Visitor Documentation Log
- Etc.

## **Secondary Records**

BPH will maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution. BPH will require registered employees to maintain secondary records on the Licensed Premise. The physical records and documentation log sheets will serve as secondary, back-up records and documentation that will be maintained independent of the inventory control system.

Per Hawaii regulations, records required to be maintained separate of the inventory control system:

- **Records of Each Distribution**
  - Records of distribution must include:
    - The name and address of the recipient retail dispensary location
    - The quantity delivered
    - The name, strength, batch number of the product

### **Requirements of Secondary Records:**

- Records must be maintained independent of the inventory control system
  - Physical records will be maintained within a file cabinet, separate from the inventory control system
- Records must be searchable
  - Records will be organized and filed alphabetically according to recipient name
- Records must be secure
  - Records will be maintained within the Licensed Premise, located within a limited-access area inside a manager office equipped with an independent security alarm system. The records will be held within a lockable filing cabinet inside the secure office.
- Records must be tamper-evident
  - The file cabinet where secondary records are to be maintained will have a secure, tamper-evident locking mechanism on it.

## **Records and Documents Storage Retention**

Unless otherwise specified, BPH will retain and maintain all records and duplicate sets of records for a minimum of six (6) years.

### **Duplicate Records and Off-Site Storage**

BPH will maintain duplicate sets of all records required by regulation. These duplicate copies of BPH records will be maintained at a secure, off-site location. This location will only be disclosed to personnel with proper security clearance. The off-site record storage will be secured with a security alarm and surveillance system to ensure access is limited to authorized personnel only. BPH will maintain duplicate copies of all records at a secure storage facility within Hawaii.

## **Reports**

BPH can generate a list of the products and their specifications that have been offered for distribution. These reports can to be provided to the Department upon request.

- Reports can be created through the BioTrackTHC™ inventory control system
  - Within the inventory control system, BPH will be able to generate a list of all the products along with their specifications that were offered for distribution
  - This list can be generated for all products offered within specific date ranges



General Security/Diversion Prevention Training

<b>Standard Operating Procedure:</b> General Security/Diversion Prevention Training
<b>Purpose:</b> To explain the general security and diversion prevention training needed to be adhered to.
<b>Scope:</b> To understand security and diversion prevention training requirements.
<b>Initial Training:</b> 4-8 hours

**Diversion and Trafficking Prevention Training**

Diversion and trafficking prevention will primarily be done using the various security alarm and surveillance equipment installed and utilized at BPH’s production facility. The various security alarm and surveillance equipment utilized is explained in more detail within the Security Plan which is a separate, additional document that can be viewed upon request. All BPH registered employees will be trained on all security equipment, measures and policies prior to commencing work within the production center.

BPH will utilize BioTrackTHC’s inventory control system and industry best practices and policies to reduce the risk of diversion and theft of marijuana products. All marijuana plants will be tagged, recorded and tracked through the inventory control system from seed-to-sale.

The use of professional security systems from Securitas that will be installed at all of organization facilities will also help to reduce the risk to diversion, loss, theft or unauthorized access.

If any marijuana or manufactured marijuana product loss or discrepancy noticed by a registered employee, management shall be made aware of the loss immediately. Inventory discrepancies should be easily noticeable with the use of the inventory control system. The diversion or product loss must be documented on the **Product Loss** log sheet which can be seen below.

<b><u>Product Loss Log Sheet</u></b>				
<b><u>Date:</u></b>	<b><u>Product Name/Category</u></b>	<b><u>Product Attribute # or Unique ID #</u></b>	<b><u>Total Quantity</u></b> <b><u>Loss:</u></b>	<b><u>Product Loss</u></b> <b><u>Valuation:</u></b>
				\$
<b><u>Reporting</u></b> <b><u>Employee:</u></b>	<b><u>Manager/Supervisor:</u></b>	<b><u>Product Loss Due To:</u></b>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<b><u>Internal</u></b> <b><u>Investigation:</u></b>	<b><u>Required Authorities</u></b> <b><u>Notified:</u></b>	<b><u>Authorities Notified (list all) :</u></b>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<b><u>Note/Comments:</u></b>				



### **Video Surveillance System.**

Securitas will design video surveillance systems at BPH's production center that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

### **Alarm System.**

Each production center operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

### **System Failure.**

In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

### **Other Security Measures.**

All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH- approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

### **Production Center Specific Security Measures.**

In addition to all the above mentioned and all other security measures required by HRS Chapter 329D and HAR Chapter 11-850, BPH will utilize a perimeter security fence around each PC that surrounds the entire premise sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any marijuana in any form as required by HAR §1185052 (1). In addition, BPH will secure all marijuana and manufactured marijuana products in a locked room, vault or container which is securely fixed to a wall or the floor to ensure product safety and to prevent theft.

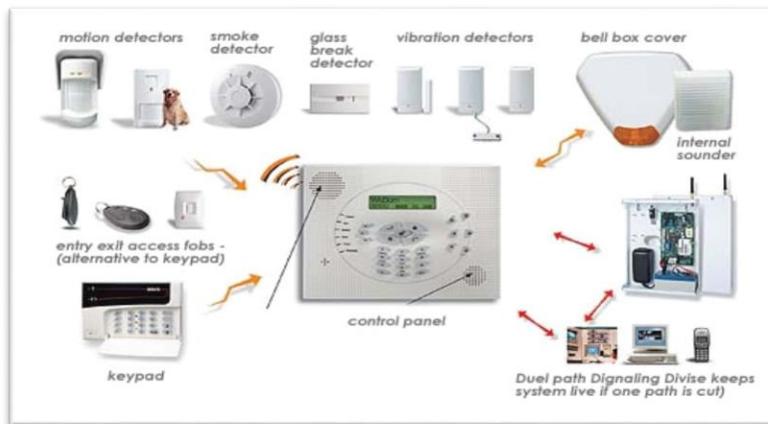
### **Transportation Security.**

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees. 3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH's tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be



packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

**Alarm Surveillance**—a primary alarm system will be installed at all BPH registered dispensary facilities by Securitas, a licensed alarm companies. An advanced security alarm system on all perimeter entry points, perimeter windows, and secured interior rooms. Motion detection equipment and camera equipment will be used to ensure the entire facility(s) is continuously safe from intrusion and product diversion.



**Video Surveillance**—an advanced video surveillance and recording system at all BPH facilities. All cameras will record in digital format and be maintained to meet the requirements outlined by State and local regulations. Video cameras will be maintained in each room and be used to identify any activity occurring within the room and be capable of recording and viewing in low light conditions. An onsite DVR and an additional offsite DVR will be utilized to store all footage; all video surveillance recording will be stored for a minimum of one year.



**Security Lighting**—security lighting around the entire perimeter of the production center to allow surveillance in low light conditions and deter potential intrusion.



**Motion Detector Alarms**—the professional security alarm system will utilize motion detectors that will detect intrusion and will automatically notify the proper authorities.



**Duress Alarms**—the security and alarm systems will utilize a duress alarm button on the alarm panels that can be pushed by employees in the case of an emergency. Different duress alarm buttons can be pushed to automatically notify the proper authority; police, fire or emergency services.



**On-Site Electronic Monitoring**—facility security rooms will have a large screen call-up monitor (at least 19”) and a video printer capable of immediately producing a clear still photo from all video cameras.



**Commercial Grade Door Locks**—commercial-grade, non- residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas. Key-card access door locks may also be utilized to further limit access at facilities.



**Safes and Product Storage**—Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana products and cash.



<b>Standard Operating Procedure:</b> Perpetual Inventory Control System
<b>Purpose:</b> To explain the principles and concepts of the perpetual inventory control system
<b>Scope:</b> To educate and train registered employees and licensed premise employees on the perpetual inventory control system
<b>Initial Training:</b> TBD

**Principles of the Perpetual Inventory Control System**

BPH will utilize a perpetual inventory system from a regulated marijuana industry-specific inventory system provider, BioTrackTHC™. This inventory control system has been developed specifically for the regulated marijuana industry and has been customized to include all marijuana business operational needs. The systems have been designed to be user friendly, the ability to be mobile, and with inventory control capabilities to track every medical marijuana plant and product from seed to sale.

The inventory control system will be designed to have the ability to promptly identify a discrepancy in stocks of marijuana plants and products. BPH administrators of the system will be notified of a substantial reduction in an inventory stock level and be prompted to investigate the inventory levels to insure no theft, diversion or discrepancies occurred. Administrators and users can run inventory reports from the inventory control system to check inventory stock levels that have been recorded in the inventory control system against a physical inventory audit to further determine inventory discrepancies.

**Inventory Control /POS System**—the tracking of all medical marijuana products from seed to sale will be done through inventory management through the use of template log sheets, computer systems, Secure Information Systems (SIS) and selected Point-of-Sale systems (POS). All medical marijuana plants and products are to be tagged, recorded and tracked through the inventory control system. Failure to do so can result in disciplinary action and/or job termination.



*\*Inventory control system and/or Point-of-Sale (POS) system training will be provided by an expert or consultant from the inventory control system supplier, BioTrackTHC™. This 3<sup>rd</sup> party training will be required for all BPH registered employees prior to working within the production center.*

Registered employees will be required to utilize the inventory control system to identify, record, monitor and track all medical marijuana plants and products from the time the medical marijuana is propagated from seed or cutting to the time it is delivered to a licensed dispensary, licensed processor or a qualifying patient or caregiver. The standard operating procedures detail multiple situations when plant tagging, monitoring and recording activities are required by registered employees within the production center.



Marijuana plants will be given a unique attribute number, assigned to a production batch which and recorded in the inventory control system. The plant will then be given a new and unique plant tag with the plants identification and specifications and be recorded in the inventory control system, the tag will remain with the plant throughout the plants lifecycle enabling the plant to be identified and tracked.

The inventory control system intended to be utilized within BPH's production center will in the event of a serious adverse event have the ability to track any marijuana plant or product back to the originating source, including the ability of tracking marijuana from a qualifying patient back to the source of the marijuana. The marijuana believed to have caused a serious adverse event should have a product label with product information and specifications such as the product name, unique attribute number, batch number and originating entity. With this information, the marijuana product will be able to be traced back to the originating source of the medical marijuana.



OSHA Compliance

<b>Standard Operating Procedure:</b> OSHA Compliance and Training
<b>Purpose:</b> To explain the principles and concepts of OSHA regulations.
<b>Scope:</b> To understand OSHA requirements to create a safe work environment.
<b>Initial Training:</b> 4-6 hours

**OSHA Training**

Registered employees have the right to a safe workplace, and BPH intends to provide a safe work environment for all registered employees at all BPH facilities. The Occupational Safety and Health Act of 1970 (OSH Act) was passed into law as a preventative measure for workers from being killed or seriously harmed while at work. The law requires employers to provide employees with working conditions that are free from known dangers.

The OSH Act created the Occupational Safety and Health Administration (OSHA). This regulatory agency sets and enforces protective workplace safety and health standards. OSHA is also charged with providing information, training and assistance to workers and employers to educate and train individuals on workplace safety. Employees may file a complaint if they feel necessary which will result in OSHA to inspect the workplace if they feel OSHA standards are not being met or that there may be serious hazards or danger. More information on the Occupational Safety and Health Administration can be found online at the website: <https://www.osha.gov/>.

**OSHA’s Mission**—With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

**OSHA Training**—The OSHA Outreach Training Program for General Industry provides training for workers and employers on the recognition, avoidance, abatement, and prevention of safety and health hazards and dangers in workplaces in general industry. This program also provides information regarding workers' rights, employer responsibilities, and how to file a complaint. Employees can attend a 10-hour or 30-hour class delivered by OSHA-authorized trainers. The 10-hour class is intended for entry level workers, while the 30-hour class is more appropriate for supervisors or workers with some safety responsibility. OSHA training helps to ensure that workers are more knowledgeable about workplace hazards, dangers and their rights.

Under the OSH Law, employers have a responsibility to provide a safe workplace free from known hazards or dangers. The OSHA website provides a short summary of employer responsibilities with which BPH will ensure compliance.

- Provide a workplace free from serious recognized hazards and comply with standards, rules and regulations issued under the OSH Act.
- Examine workplace conditions to make sure they conform to applicable OSHA standards.
- Make sure employees have and use safe tools and equipment and properly maintain this equipment.
- Use color codes, posters, labels or signs to warn employees of potential hazards.
- Establish or update operating procedures and communicate them so that employees follow safety and health requirements.
- Employers must provide safety training in a language and vocabulary workers can understand.
- Employers with hazardous chemicals in the workplace must develop and implement a written hazard communication program and train employees on the hazards they are exposed to and proper precautions (and a copy of safety data sheets must be readily available). See the OSHA page on Hazard Communication.
- Provide medical examinations and training when required by OSHA standards.
- Post, at a prominent location within the workplace, the OSHA poster (or the state-plan equivalent) informing employees of their rights and responsibilities.
- Report to the nearest OSHA office all work-related fatalities within 8 hours, and all work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours. Call our toll-free number: 1-800-321-OSHA (6742); TTY 1-877-889-5627. [Employers under federal OSHA's jurisdiction were required to



begin reporting by Jan. 1, 2015. Establishments in a state with a state-run OSHA program should contact their state plan for the implementation date].

- Keep records of work-related injuries and illnesses. (Note: Employers with 10 or fewer employees and employers in certain low-hazard industries are exempt from this requirement.)
- Provide employees, former employees and their representative's access to the Log of Work-Related Injuries and Illnesses (OSHA Form 300). On February 1, and for three months, covered employers must post the summary of the OSHA log of injuries and illnesses (OSHA Form 300A).
- Provide access to employee medical records and exposure records to employees or their authorized representatives.
- Provide to the OSHA compliance officer the names of authorized employee representatives who may be asked to accompany the compliance officer during an inspection.
- Not discriminate against employees who exercise their rights under the Act. See our "Whistleblower Protection" webpage.
- Post OSHA citations at or near the work area involved. Each citation must remain posted until the violation has been corrected, or for three working days, whichever is longer. Post abatement verification documents or tags.
- Correct cited violations by the deadline set in the OSHA citation and submit required abatement verification documentation.
- OSHA encourages all employers to adopt an Injury and Illness Prevention Program. Injury and Illness Prevention Programs, known by a variety of names, are universal interventions that can substantially reduce the number and severity of workplace injuries and alleviate the associated financial burdens on U.S. workplaces. Many states have requirements or voluntary guidelines for workplace Injury and Illness Prevention Programs. Also, numerous employers in the United States already manage safety using Injury and Illness Prevention Programs, and we believe that all employers can and should do the same. Most successful Injury and Illness Prevention Programs are based on a common set of key elements. These include: management leadership, worker participation, hazard identification, hazard prevention and control, education and training, and program evaluation and improvement. OSHA's Injury and Illness Prevention Programs topics page contains more information including examples of programs and systems that have reduced workplace injuries and illnesses.

### **Plan for OSHA Compliance**

Below details BPH's plan for compliance with OSHA will begin by ensuring that all organizational facilities are free from known hazards and/or dangers. Although OSHA is a federal organization and we are not currently held to OSHA standards, BPH feels it is best practices to be aware of OSHA guidelines and adhere to said guideline within our operations.

All registered employees will be provided basic training covering workplace safety pertaining to identifying and preventing potential hazards and or dangers such as trip hazards. This basic training will begin with training all new employees on policies and procedures. Proper and adequate training can help to reduce workplace accidents through educating and training employees on operations, policies and procedures. Employees will be given a tour of the facility property and areas in which the employee will have access to (limited or restricted). Other training to be included in BPH's plan for OSHA compliance will include:

- Training on SOP's
- Regulatory compliance training (laws and regulations pertaining to medical marijuana cultivation, processing or dispensing)
- Basic training on workplace safety
- Recognition of potential workplace hazards or dangers



<b>Standard Operating Procedure:</b> Employee Dress Code and Personal Hygiene
<b>Purpose:</b> To explain the employee dress code required.
<b>Scope:</b> Covers the dress code requirements for employees.
<b>Initial Training:</b> 30 minutes

### **Principles of Employee Dress Code**

The cultivation facility is considered a “clean” room type setting and as such employees of the cultivation facility will be required to change out of street clothes and into provided work wear to be worn during all scheduled work shifts. The work wear will consist of medical-type scrubs and garden shoes.

Employees are expected to arrive at facilities and enter the locker rooms immediately after entering the facility to shower and change into provided work wear. This will reduce the cultivation P areas from exposure to outside contaminants such as pests and diseases.

**Registered employees**—BPH registered employees working will be required to wear approved attire while working within the production center.

- Registered employees will be provided work attire to be worn while working within the Licensed Premise.
  - Work uniform such as scrubs
  - Closed-toe garden shoes such as Crocks
  - Hat (*optional*)

**Transportation Agents**— BPH registered employees working will be required to wear approved attire while on duty. Transportation agent work attire will differ from that of registered employees due to State regulations mandating transportation agents must not have any identifying logos or markings that could indicate ownership or possession of marijuana.

- Transportation agents will be required to wear un-identifying work attire
  - Plain jeans or khakis pants
  - Plain polo or button-up shirt
  - Closed-toe shoe

### **Personal Hygiene Policy**

This policy has been set forth in order to ensure that all employees are practicing good personal hygiene to ensure that are products are produced in safest and most sanitary means possible. The personal hygiene policy includes but is not limited to the following:

- A. Maintaining adequate personal hygiene
  - a. Arrive to work clean in appearance/clean clothes.
  - b. Showering every day is essential
  - c. Deodorant and a clean personal smell is required
- B. Men must be neatly groomed/shaven
  - a. Mustaches or beards allowed if maintained
  - b. We reserve the right to ask you to wear a beard cover if we deem it necessary
- C. Long hair must be constrained in a neat manner to avoid hair coming into contact with food items
  - a. A hat or hairnet is preferred
  - b. Jewelry of any kind is not permitted

- i. This includes earrings, rings, bracelets, watches, etc.
- D. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and
  - E. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

### **General Sanitary Requirements**

BPH will take all reasonable measures and precautions to ensure that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for medical marijuana products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.

BPH will have hand-washing facilities that are convenient and furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

That all registered employees working in direct contact with processing, preparation, weighing or repackaging of medical marijuana products shall conform to hygienic practices while on duty, including but not limited to:

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the processing, preparation, weighing or repackaging of medical marijuana products and at any other time when the hands may have become soiled or contaminated; and
- Refraining from having direct contact with preparation of medical marijuana products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical marijuana products.

Registered employees are required to ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical marijuana products are exposed. Registered employees are required to ensure that floors, walls, and ceilings are adequately cleaned and kept clean and kept in good repair.

That the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

Registered employees must ensure that all contact surfaces, including utensils and equipment used for the preparation of medical marijuana products shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used with medical marijuana and used in accordance with labeled instructions;

BPH requires all toxic cleaning compounds, sanitizing agents, solvents used in the production of medical marijuana and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of medical marijuana products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. That medical marijuana products that can support the rapid growth of undesirable microorganisms will be held in a manner that prevents the growth of these microorganisms; and the storage and transport of finished medical marijuana products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.



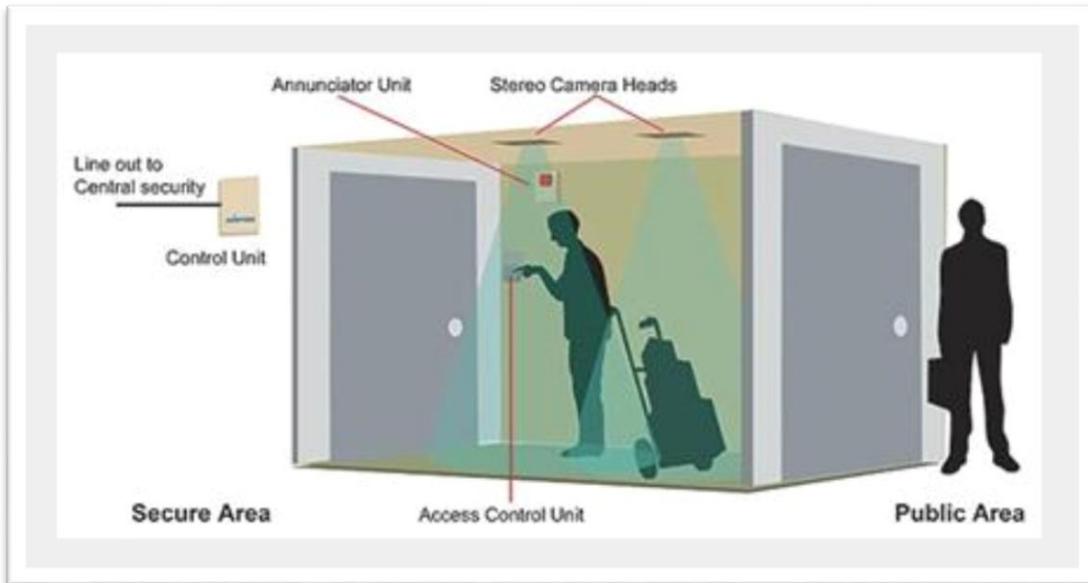
<b>Standard Operating Procedure:</b> Facility Entry Protocol and Good Handling Practices
<b>Purpose:</b> To explain how employees should enter the production center and procedures to follow to gain access to Limited Access Area(s).
<b>Scope:</b> Covers the steps involved for properly entering the production center as well as good handling practices
<b>Initial Training:</b> 2-4 hours

**Principles of Facility Entry Protocol**

The primary objective of having a specific facility entry protocol is to try to reduce the exposure and risk to outside contaminants from entering the facility. Containments can be anything from pests such as insects and diseases such as powdery mildew. It will be of utmost importance for employees to be mindful of where they have been immediately before arriving at the cultivation facility as this can determine the likelihood and types of contaminants possible.

Upon arriving at the cultivation facility, registered employees will enter the facility using their issued key/keycard or the like, enter the facility’s ‘entry vestibule’. This area is designed as a security measure against unwanted intruders. There will be a magnetic door that can only be opened by personnel with the proper security clearance. This door will be opened through the use of an access control unit.

***Example of a “Entry Vestibule”:***



Upon exiting the “Entry Vestibule” employees will head directly for the locker rooms where they will change out of all street clothes, take showers and change into provided work attire/uniform prior to entering the “clean” area of the cultivation facility.

**Locker Room Steps for Employees to Follow:**

1. Enter locker room
2. Remove **ALL** street clothes and place them in your locker
  - a. *ALL* clothes
    - i. Hats



- ii. Socks
    - iii. Shoes
  3. Take a shower
    - a. This is done as another preventative measure to ensure the production center is not exposed to any outside contaminants
  4. Change into provide work attire/uniform
    - a. Scrubs
    - b. Hair nets
    - c. Hat (optional)
    - d. Garden shoes

Upon successfully showering and changing into the provided work wear, employees will be ready to begin their work shift within the “clean” area of the production center.

Upon exiting the locker room, employees will go through an “air-lock” chamber to remove any remaining potential contaminants prior to entering the clean area. Upon exiting the Air-Lock chamber, the employee will be in the “clean” area of the production center.

***Example of an Air-Lock Chamber:***



**Good Handling Practices**

The indoor environment offers little help to registered employees in terms of biosecurity, so preventative maintenance and clean protocols are essential in operations. Plants are typically cultivated and arranged in close proximity and as such plants in close proximity to each other spread diseases, molds, mildews, and insects with ease in comparison to the natural growing conditions found outside. Due to this, very strict clean entry protocols, as well as quarantine, and biosecurity procedures are necessary.

The facility will be divided into a “clean zone” and a “dirty zone”.

- The clean zone represents any area where marijuana products will be whether in plant form, flower form, concentrate, or infused product.
  - All “clean zones” in the facility will require registered employees to follow the clean entry protocol to enter.
- The dirty zone represents any area where no marijuana product will ever be (excluding marijuana waiting destruction and disposal), including soil receiving, and administration offices.



Limited Access Areas

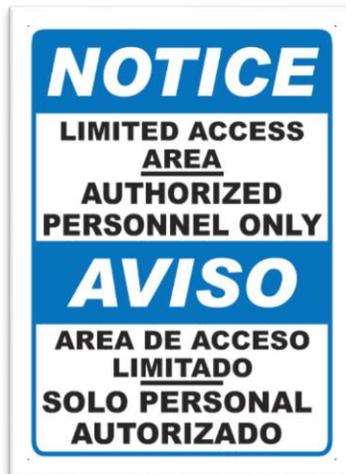
<b>Standard Operating Procedure:</b> Limited Access Areas
<b>Purpose:</b> To explain Limited Access Areas, who is allowed in these areas, and procedures to follow within the Limited Access Area.
<b>Scope:</b> Covers the steps involved in escorting visitors in limited access areas.
<b>Initial Training:</b> 1 hour

### The Principles of Limited Access Areas

A Limited Access Area is a building, room, or other contiguous area upon the Licensed Premises where medical marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee. Limited Access Areas are areas within the licensee's facility where only certain people will have the required permission to access.

Limited Access Areas may have people in them without the proper permission as long as the Visitor SOPs and state regulatory required protocols are followed. Registered employees will follow the *Visitor SOP*; with allowed visitors being escorted by a registered employee at all times while in the facility and Limited Access Areas.

Limited access areas should be limited to State licensed, facility employees only. If a visitor needs to access the limited access areas, registered employees will be required to follow the written *Visitor SOP*.





Visitors

<b>Standard Operating Procedure: Visitors</b>
<b>Purpose:</b> To explain the processes involved to accept/allow visitors into the retail dispensary.
<b>Scope:</b> Covers the required steps to follow to allow visitors into the facility.
<b>Initial Training:</b> 1 hour

**Requirements**

- 1) Visitor Log Sheet
- 2) Visitor pass

Pursuant to 329D-15 and 329D-16, unauthorized access to retail dispensing locations and/or a production center is a Class C felony. Due to the strict penalties for infractions, BPH will take steps to identify all potential subcontractors, maintenance workers, and any other individual identified as needing to visit one of BPH retail dispensing locations or our production center. Such steps will allow said individuals to submit proactively to fingerprint cards and background checks and be aware of the information submitted to the Department. In order to obtain Department approval, BPH also intends to identify secondary, back-up individuals who can be utilized as resources if the primary resource is unavailable; these secondary subcontractors and resources will also be required to submit fingerprint cards and authorize consent for background investigations to ensure the individual does not have any felony convictions or other offenses listed in §11-850-17.

**The Principles of Visitor Protocol**

BPH’s visitor protocol will follow industry best practices and current regulations. There will be situations that arise that will require someone to enter the registered dispensary facility premises who is not a State-licensed industry worker or not a State-registered patient or caregiver but they will need access to the facility. Common visitors typically will be support-type businesses such as HVAC, electric and plumbing, general contractors, etc.

All visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

Approved visitors will be required to provide a BPH registered employee with a current, valid government-issued identification. The registered employee will confirm the individual is on the BPH’s Department-approved list, make a photocopy of the visitor’s ID and maintain the photocopy with the visitor log book; visitors will be required to sign in and out with a registered employee and provide a written reason for the visit (e.g. maintenance work, HVAC, repairs, etc.). Upon completing these requirements, the registered employee will issue a ‘visitor badge’ for the visitor to wear and display while at any BPH registered dispensary facility. BPH will also require a registered employee to remain with the visitor for the duration of the visit to ensure the visitor does not interact with or handle any marijuana plant, material, product, or manufactured marijuana product.

- **Government-Issued ID**—all visitors must have a current and valid government-issued ID (passport, Driver’s License, military ID)
  - Ensure that the government-issued ID is current (check expiration date on ID)
- **Verification**—Verify the validity of the government-issued ID and that the visitor is on the current Department-approved list
- **Photocopy**— Make photocopy of visitor’s government-issued ID
  - Make a photocopy of visitor’s ID; Photocopy is to remain with *Visitor Log Sheet*

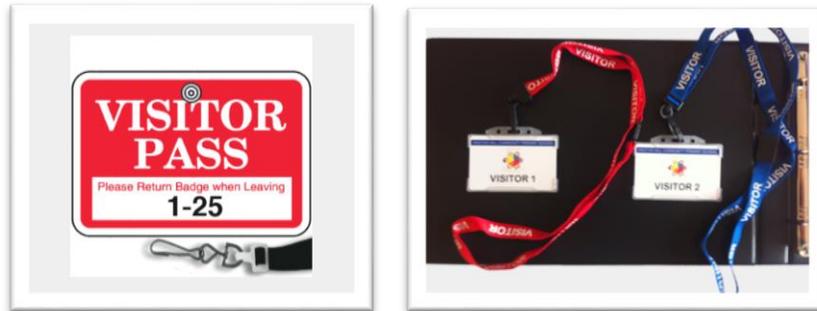


- **Access**—Allow or deny access to the facility
  - Allow entry to dispensary if the visitor has a valid government-issued ID.
  - Deny entry to the facility if the visitor does not have a valid government-issued ID.
- **Record/Documentation**—Have visitor fill out the *Visitor Log Sheet*
  - *Visitor Log Sheet* will document visitors name, company, date, time-in, time-out, signature, reason for the visit
  - Maintain photocopy of visitor ID with the *Visitor Log Sheet*
  - This record of visit must be retained and maintain on the licensed premise for a minimum of two (2) years.

**Visitor Access Process:**

- 1) Check visitors ID and credentials at the check-in station
  - a. Make photocopy of Visitor’s ID
- 2) Verify with management that visitors are expected and on the current Department-approved list
- 3) Fill out *Visitor Log Sheet*
- 4) Have said visitor sign-in and date the *Visitor Log Sheet*
- 5) Give visitor a ‘*Visitor Pass*’
- 6) When visitor is finished at the licensed premises:
  - a. Have visitor sign-out on *Visitor Log Sheet*
  - b. Collect the ‘*Visitor Pass*’ from said visitor

*Example of a Visitor Pass can be seen below:*



*Example of Visitor Sign-In Documentation Log Sheet:*

<u>Visitor Sign-In Documentation Log Sheet</u>							
<u>Date</u>	<u>Time In</u>	<u>Time Out</u>	<u>Visitor Name</u>	<u>Visitor's Company</u>	<u>Visitor Signature</u>	<u>Reason for Visit</u>	<u>Registered Employee Escort</u>



Receipt of Material

<b>Standard Operating Procedure: Receipt of Materials</b>
<b>Purpose:</b> Explain procedure and requirements for receiving raw materials
<b>Scope:</b> To educate and train licensed premise employees on the procedures and requirements involved with receipt of materials.
<b>Initial Training:</b> 1-2 hours

**Principles of Receipt of Material**

The process of receipt of material or receiving raw materials is not as simple as just taking the raw materials into the licensed premise. There are regulations, guidelines and procedures to follow when receiving raw materials or other inventory into the cultivation facility licensed premise.

Upon receiving any raw materials, inventory or other items used in operations said items will be placed in a quarantine storage area within the receiving area of the licensed premise. Employees will need to quarantine any materials received to be used to produce marijuana. These items will include but not be limited to:

- Medical marijuana seeds
- Medical marijuana cutting/clones
- Medical marijuana plants
- Soil
- Fertilizers
- Pesticides, insecticides and fungicides
- Growing containers

**Receipt of Materials**—upon receiving materials into the licensed premise, registered employees and/or licensed premise employees will need to document the receipt of materials on the *Receipt of Materials* log sheet.

*Example of Receipt of Materials Log Sheet can be seen below:*

<b>Receipt of Materials</b>							
<u>Date of Receipt:</u>	<u>Receiving Employee #1:</u>	<u>Receiving Employee #2:</u>	<u>Product/Strain/Attribute ID #:</u>	<u>Quantity Received:</u>	<u>Received From:</u>	<u>Materials Placed in Quarantine:</u>	<u>Materials Pass Visual Inspection:</u>
						YES NO	YES NO
<i>Describe why Materials did not pass visual inspection:</i>				<i>Corrective action to be taken:</i>			
<u>Materials Pass Visual Inspection after Corrective Action:</u>	<i>Describe why Materials did not pass visual inspection after corrective action:</i>			<i>Next corrective action to be taken:</i>			
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>If materials passed visual inspection, and are determined to be acceptable for use as intended, said materials may be released from the quarantine areas and used as intended.</i>							
<u>Date of Release of Materials:</u>	<u>Employee(s)/Supervisor Releasing Materials:</u>		<u>Product/Strain/Attribute ID # of Released Material(s):</u>		<u>Quantity Released:</u>		
<u>Record of Receipt of Materials Made in Perpetual Inventory Control System (POS)?</u>	<u>Required POS Records: date of receipt, quantity of material, types/variety of material date of release</u>		<u>Employee Making POS Record Entry:</u>	<u>Employee Witnessing POS Record Entry:</u>			
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>Notes/Comments:</i>							



**Quarantine Storage Area**—the quarantine storage area will be within the licensed premise and clearly identified on the facility floor plan diagram. The quarantine area will be classified as a “dirty” zone within the cultivation facility. Materials will be held within the quarantine area where they will be segregated from the rest of the cultivation licensed premise and/or “clean” areas of the facility.

**Inspection**—after received inventory items/materials are placed in quarantine, the items will need to be inspected to ensure there are no defects or contamination. All received items/materials will remain in the quarantined area until said material pass inspection and is determined to be acceptable for use as intended.

- Registered employees will be required to inspect all materials for visible defects and contamination
- Inspecting materials for contamination is essential for the facilities clean protocols and IPM measures
  - If a contamination is identified proper cleaning and/or segregation procedures will be implemented.
    - Cleaning and sanitizing the contamination: if the contamination is deemed reasonable to clean and sanitize you will need to clean and sanitize all surface areas of the material if possible. This should be done using a cleaning/sterilizing agent such as bleach.
    - If cleaning and sanitizing is not an option, the materials will be segregated within the quarantine area until they are properly destroyed and disposed of.
    - If contaminated with pests, insects or disease; immediately segregate the material while trying to identify the contamination.
      - Refer to the *IPM SOP* for proper identification and treatment of material (plants)
  - Once the materials are properly cleaned and sanitized and believed to be free from contamination they will need to be inspected a second time.
    - Materials will need to pass this second inspection prior to being released for their intended use.

**Release**—upon the received materials passing inspection and being determined to be acceptable for use as intended, the materials will be released from the quarantine receiving/storage area. At this time the materials can be used within the licensed premise for their intended use.

- Release materials if they pass initial inspection
- Release materials once they are cleaned and sanitized and pass secondary inspection

**Documentation and Record**—upon the materials being released from quarantine and determined to be acceptable for use as intended BPH registered employees and/or licensed premise employees will be required to log the materials into the inventory control system.

- Document and record new materials released from quarantine in the inventory control system (POS system)
- Ensure record is accurate with physical inventory on hand
- Ensure the *Receipt of Material* log sheet is filled out properly and completed



Quality Control

<b>Standard Operating Procedure: Quality Control</b>
<b>Purpose:</b> To describe the quality control
<b>Scope:</b> To train registered employees on quality control measures to be utilized within the cultivation operations
<b>Initial Training:</b> TBD

Quality control measures will primarily be in the form of adherence to the written standard operating procedures to ensure quality and consistency of products produced within the facility. BPH will utilize the established and proven SOP's for all cultivation operations. BPH will use standard operating procedures (SOP's) to promote good growing and handling practices including:

- All aspects of the:
  - Irrigation, propagation, cultivation, fertilization;
  - Harvesting, drying, curing;
  - Rework or reprocessing;
  - Packaging, labeling, and handling of medical marijuana products, byproduct; and
  - Waste products, and the control thereof, to promote good growing and handling practices.

BPH will require that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical marijuana has received the training, education, or experience necessary to perform assigned functions; and will also require that all registered employees practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

BPH will require grower agents to follow the protocol for Receipt of Material including:

- BPH shall quarantine received material that will be used to produce marijuana and/or manufactured marijuana products
- BPH shall inspect materials for defects and contamination.
- Material may not be released from quarantine by a BPH until the material:
  - Passes inspection; and
  - Is determined to be acceptable for use as intended.

**UNM QUALITY ASSURANCE PLAN**

Possible contamination will be tracked through the use of a Hazard Analysis Critical Control Point (HACCP) Plan. Critical control points will be identified, monitored and preventative procedures recorded throughout the production of marijuana products. The shelf stability of all products will be confirmed. Process controls for water activity, pH levels, and proper packaging will be utilized.

**Corrective Action**

Corrective actions are detailed within the CCP Hazard Analysis Chart. If contamination is discovered after a Production Lot has shipped then the Product Recall Plan will be used.

**Shelf Stability Testing**

Shelf stability testing will be conducted on site. Shelf stability is the time that a product will retain throughout its period of storage and use, the same properties and characteristics that is possessed at the time of its packaging. Forms will be tested and approved before production for patients begins.

Shelf stability testing will cover the four areas of concern:

1. **Chemical:** The product retains its chemical integrity and potency, within specified limits.
2. **Physical:** The original physical properties, including appearance, palatability, odor, and wholesomeness are retained.



3. **Microbiological:** Resistance to microbial growth and product safety is retained according to specified requirements overall bacterial growth is maintained within acceptable levels.
4. **Toxicological:** No significant increase in toxicity occurs.

### **Control by Water Activity, pH, Chemicals, and Packaging**

Water activity and pH will be directly controlled in all products produced within the Production Area. A combination of controls, rather than relying on only one will be utilized. Inhibitors to growth of microbiological contaminants will be added to the marijuana product in the form of food safe additives or substances such as citric acid, if needed. In addition, adjustments to the atmosphere of the packaged product using special packaging techniques will be implemented during packaging, if needed. This is because a one-control system carried to the extreme, can be harsh, making food unacceptable to consumers. The use of multiple controls is called the 'Hurdle Concept'. Microbiological controls using pH, water activity, inhibitors, and atmosphere will be described in this section.

### **pH CONTROL**

Every microorganism has a minimum, optimum, and maximum pH for growth. Yeasts and molds can grow at low pH, but 4.6 is generally considered the level that will prevent the growth and toxin production for pathogens. Some pathogens, in particular *E. coli* 0157:H7, can survive acidic conditions for extended periods of time, even if their growth is inhibited. pH is considered primarily a means of growth inhibition and not a method for destruction of existing pathogens. However, at low pH values many microorganisms will be destroyed if held at that pH for significant time. A pH 4.6 is used as a divider between high-acid and low-acid foods. Some products that are naturally low-acid are processed in a way that makes them a high-acid products. This is called acidification.

### **Measuring pH**

The pH meter will be a two electrode. One is the reference electrode and one is the measuring electrode. When not in use, the electrodes are stored submerged in distilled water or other solutions as recommended by the manufacturer. The instrument must be checked each day of use with two different buffer solutions -- one on either side of the expected equilibrium pH. After calibration, the electrodes should be rinsed off with distilled water and then they can be used for testing. The operation and calibration of the pH meter must follow the meter manufacturer's instructions.

### **Thermometer Calibration**

1. Fill a 2-quart measure with ice.
2. Add water to within 1 inch of top of container.
3. Stir mixture well.
4. Let sit for one minute.
5. Place thermometer in container so that the sensing area of stem or probe is completely submerged over the dimple.
6. Keep the thermometer from touching sides or bottom of container.
7. Let thermometer stay in ice water for 30 seconds or until the dial stops moving.
8. Place the calibration tool on the hex adjusting nut and rotate until the dial reads 32 °F, while in ice water.
9. Some digital stemmed thermometers (thermistors) and thermocouples have a reset button that should be pushed.
10. Repeat process with each thermometer.

### **pH METER CALIBRATION PROCEDURE AND ANALYSIS:**

1. The pH meter is calibrated at least once on the day of use as outlined in section
2. The standard buffers used are pH 4.0, pH 7.0, and pH 10.0. A small amount is dispensed into a smaller container for calibration. Per manufacturers recommendations the standard pH buffers should be used for calibration only one time and disposed after calibration has been finalized.
3. If the final pH of the reagent or medium falls between a pH of 7.0 and 10.0, use the pH 7.0 and 10.0 calibration buffer solutions for the two point calibration.
4. If the final pH of the reagent or medium falls between a pH of 4.0 and 7.0, use the pH 4.0 and 7.0 calibration buffer solutions for the two point calibration.

### **WATER ACTIVITY CONTROL**

Like pH, every microorganism has a minimum, optimum, and maximum water activity for growth. Yeasts and molds can grow at a low water activity, however 0.85 is considered the safe cutoff level for pathogen growth. A water activity

of 0.85 is based on the minimum water activity needed for *S. aureus* toxin production. Products above a water activity of 0.85 will utilize acidification as the barrier to control the growth of pathogens. Products with water activities between 0.60 and 0.85 are classified as intermediate moisture foods. These do not require refrigeration to control pathogens, but have a limited shelf-life because of spoilage, primarily by yeast and mold. For the most part, products with a water activity below 0.60 have an extended shelf-life, even without refrigeration.

### **PACKAGING**

Reduced oxygen packaging is used to prevent the growth of microorganisms in order to extend the shelf-life of the product and keep the integrity of the product intact. Packaging is different from the other methods of control. Although packaging is sometimes used to control microbiological growth, it is limited to the control of spoilage microorganisms. Packaging serves two functions:

1. it prevents contamination of the food or
2. it extends the effectiveness of food preservation methods

### **QUALITY ASSURANCE: Marijuana Product CCP Hazard Analysis Chart**

Issued:

Reviewed:

Next Review:

CCP	Hazard & Source/ Cause	Critical Limit	Monitoring Procedure	Corrective Actions	Record Keeping	Verification
CCP1 – Marijuana Product is moved to Climate Controlled Secure Storage. Marijuana Product is moved	<b>Microbiological Hazards</b> -Microbiological growth due to breakdown of refrigeration unit.	Temperature of Ingredients must be stored at consistent temperature.	<b>Who:</b> Production Manager <b>What:</b> monitor temperature of Climate Controlled Secure Storage <b>How Often:</b> Twice daily using calibrated thermometer.	Properly discard of Marijuana Product if temperature variance is greater than 20 degrees Fahrenheit	Refrigeration Log Calibration Log	Production Manager reviews and signs off on Refrigeration and Calibration Logs
CCP2 - Proper sanitation of all packaging	<b>Physical Hazards</b> -Physical contamination from operator -Foreign body/broken glass/dust contamination from source of origin and/or storage environment <b>Chemical Hazards</b> -Chemical contamination from high ppm of sanitizer.	Any foreign objects present.  50 -200 ppm sanitizer concentration	<b>Who:</b> Production Manager or Sanitation Manager <b>What:</b> Properly inspects bottles and caps for physical hazards. Follows sanitation SOP and use testing strips for ppm accuracy <b>How Often:</b> As Needed	Discard any broken bottles and foreign objects.  Use ppm test strips to for proper sanitizer mixture.	Sanitation Log	Sanitation Manager logs ppm test strip readings in Sanitation Log. Daily sign off by Production Manager.
CCP3 - Use Filling Equipment to fill all packaging.	<b>Physical Hazards</b> -Physical contamination from operator -Foreign body/dust contamination from production environment.  <b>Microbiological Hazard</b>	Any foreign objects present.  Temperature must be consistent and ph of products in filler must be <4.6ph	<b>Who:</b> Production Manager <b>What:</b> Follow SOP and Hygiene Guidelines. Take ph and monitor temperature. <b>How Often:</b> Every Production Batch	re- test for proper pH level after adding citric acid or food safe equivalent. Minimum pH level required is 4.6 or <.	-Staff hygiene policy/program in place with all site staff trained and records of training maintained and retained on personnel files. -Controlled by proper sanitation of production environment.	Production Manager logs all ph and temperature readings into Production Log. Calibration of Thermometers and ph tester entered into Calibration Log.



	-Microbiological growth due to improper pH levels before filling. -Microbiological growth due to improper temperature monitoring.				-Proper pH levels are monitored with a properly calibrated pH meter, calibrated with proper pH 4 and pH 7 buffers. -Staff pH policy/training in place with all site staff trained and records of training retained in personnel records. -The critical limit is established at 4.0 or below by the appropriate manufacturer's recommendation. -Staff awareness/training programs in place with records of training retained and filed.	
CCP4 – Marijuana Product is moved to Climate Controlled Secure Storage. Marijuana Product is moved	<b>Microbiological Hazards</b> -Microbiological growth due to breakdown of refrigeration unit.	Temperature of Ingredients must be stored at consistent temperature.	<b>Who:</b> Production Manager <b>What:</b> monitor temperature of Climate Controlled Secure Storage <b>How Often:</b> Twice daily using calibrated thermometer.	Properly discard of Marijuana Product if temperature variance is greater than 20 degrees Fahrenheit	Refrigeration Log Calibration Log	Production Manager reviews and signs off on Refrigeration and Calibration Logs

VALIDATION:

Name:

Name:

Position:

Position:

Date:

Date:



<b>Standard Operating Procedure:</b> Weights and Measurements and Scale Calibration
<b>Purpose:</b> To explain how to use certified scales for weights and measurements
<b>Scope:</b> To train registered employees on proper use of NTEP certified scales to be used for weights and measures as well as scale calibration/certification
<b>Initial Training:</b> 1 hour

**Types of Scales to be used**

BPH will utilize NTEP-certified scales for the weighing of all medical marijuana, medical marijuana products, medical marijuana waste and all green waste.

**NTEP Certification**— The National Conference on Weights and Measures issues an NTEP Certificate of Conformance following successful completion of an evaluation of a device. It indicates that the device(s) described in the Certificate is/are capable of meeting applicable requirements of the *NIST Handbook 44*.\* <http://www.ncwm.net/ntep/faqs#WhatIsNTEPcertificate>

**Scale Use**

All medical marijuana harvested at BPH’s licensed premise will be weighed and packaged using NTEP-certified scales certified for legal trade and that have been calibrated and certified ISO/IEC 17025 accredited by a Hawaii calibration service supplier.

**Scale Calibration and Frequency**

BPH will ensure that all scales and balances are calibrated by an accredited calibration service supplier. The frequency of having BPH scales calibrated will be on a six (6) month basis. This routine calibration will be documented on the Scale Calibration Log sheet and maintain on the licensed premise.

*Example of the Scale Calibration Log Sheet:*

<b><u>Scale Calibration</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Scale Serial #/ID #:</u>	<u>Calibration Service Supplier:</u>	<u>Scale Calibrated</u>	<u>Notes/Comment:</u>
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
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				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	





## Equivalent Weights for Manufactured Marijuana Products

### **Assessment of the pre-mixed total weight (in ounces or grams) of usable marijuana contained within in an extract, oil, or infused product.**

The pre-mixed total weight of usable marijuana contained in an extract, oil or infused product is determined by the amount of marijuana plant material used to make the marijuana extract or oil. To determine the amount of usable marijuana in an infused product the additional step of determining the amount of extract or oil used to make an infused product is necessary.

Equivalency of marijuana flower or trim to extract, oil or infused product can vary due to several variables;

1. The tetrahydrocannabinol (THC) content of the marijuana flower or trim.
2. The THC content of the extract or oil produced from marijuana flower or trim.
3. The amount of THC infused into the infused product.

The average tetrahydrocannabinol (THCa) percentage of medical marijuana flower ranges from 15 - 19%. THCa is the form of THC found within the marijuana plant material. THCa is the non-psychoactive bio-synthetic precursor to THC. THCa must be decarboxylated to become bioavailable to the human body and is done so in the production of some extracts an oil and with all infused product production. During decarboxylation the THCa loses carbon and oxygen molecules, and about 12.3 percent of its weight. This must be taken into account when determining the usable weight of marijuana found in extract, oil, or infused products.

Extraction efficiency for CO2 Sub/Supercritical Extract and Oil average from an average between 60% - 80%. This range provides an estimated average total of 70% of the total THC milligrams available within the plant will be extracted. The oil or extract is then lab tested to determine the exact amount of active cannabinoids in the product. These lab results are then used to determine how much in weight or volume of the extract or oil is to be used in the infused product formulation. Infused products are measured in activated milligrams of THC. No more than 10 milligrams THC per dose. No more than 100 total THC milligrams per package.

Projected extracted milligrams of THC per gram of plant material based on average extraction efficiencies of yield and THC percentage:

1. Beginning plant material THC % is 15%.
2. Extraction efficiency is 70%.
3. Infused Product is to contain 10 milligrams of active THC

Example: of 1 gram of medical marijuana = 1000mg Total Weight

- A. The medical marijuana is 15% THC the total available THC milligrams within that one gram is 150 milligrams. (1000mg X 15% = 150mg)
- B. The CO2 Extraction efficiency is equal to 70% total amount of THC milligrams extracted 105 mg THC per gram of plant material.
- C. 105 mg of THC will produce 10.5 units of 10 mg THC infused products.
- D. 1/10 gram would be the pre mixed total weight of usable marijuana contained within the infused product.



Manufacturing Operations

<b>Standard Operating Procedure:</b> Manufacturing Operations
<b>Purpose:</b> To explain post-harvest activities, procedures and protocols. Including: manufacturing, processing, weighing, packaging and labeling.
<b>Scope:</b> Covers the manufacturing activities within the cultivation facility.
<b>Initial Training:</b> TBD

-----**UNM EXTRACTION AND PRODUCTION GENERAL OPERATIONS**-----

**Overview**

The extraction and production area of the production center will manage and produce the extraction of cannabinoids from the leaves and flowers of the female marijuana plant and the production of these extractions into medical marijuana products. The extraction and production area shall meet or exceed requirements set forth by the State of Hawaii. All extraction, packaging and labeling of medical marijuana products will comply with all state and local laws. All local and state fire, safety and building codes will be followed and internal manufacturing systems will be approved before operation.

The medical marijuana product extraction and production area will be physically separated from the other areas within the manufacturing facility and shall be considered a Limited Access Area. Only employees designated to work within the area will be permitted access. The extraction and production area will have designated areas for: Production, Packaging and Labeling, Climate Controlled Storage (walk-in coolers, reach-in coolers and freezers), Secured Storage and Toxic and/or Flammable Materials Storage. The area for the extraction and production of medical marijuana products will have mechanical ventilation of sufficient capacity as necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke and fumes.

The extraction and production area will have independent exhaust vents respectively in addition to the facility HVAC system. Equipment and surfaces used throughout the areas of extraction, manufacturing, processing and packaging of medical marijuana products will be constructed of NSF certified stainless steel. All equipment and utensils used will be lab grade or of commercial kitchen standards and meet or exceed State of Hawaii requirements. The extraction and production areas will be open and free as to provide ample space for preparation and sanitation.

**Extraction**

Marijuana concentrate is extracted from raw, cured marijuana by the use of:

- CO2 Sub/Super-Critical Extraction provides pure, solvent-free extracts by utilizing carbon dioxide. CO2 is a green alternative to solvent-based extraction techniques. The properties of a supercritical fluid can be altered by varying the pressure and temperature, allowing selective extraction. The low viscosity of supercritical carbon dioxide allows it to penetrate into the material more easily while its diffusivity allows for faster extractions. CO<sub>2</sub> is an environmentally friendly solvent that leaves no residue. Known as the “Entourage Effect” these “Whole Plant Extractions” are known to be more effective medicinally by four unique qualities:
  - Ability to affect multiple targets within the body
  - Ability to improve the absorption of active ingredients
  - Ability to overcome bacterial defense mechanisms
  - Ability to minimize adverse side effects.

CO2 extractions will be performed in a professional-grade, closed- loop extraction system, rated to minimum 900 pounds per square inch.

All solvents will be stored in secure and approved flammable materials storage containers. All MSDS sheets will be displayed along with emergency procedures to provide proper response to an accident involving a solvent.

Employees will be trained by the industry's best practices and company extraction Standard Operating Procedures (SOPs). Marijuana flower and trim is cured in the Cultivation Area of the Manufacturing Facility. After the curing process, cured flower and trim will be delivered securely to the Extraction Area of the Manufacturing Facility and prepared for the extraction process. Marijuana from the cultivation area will be delivered securely to the extraction area when properly cured and ready to be extracted. The chain of custody of the marijuana plant material from cultivation to extraction will be documented within the Seed-to-Sale Inventory Tracking Software. The extraction staff will properly and securely store the marijuana leaves and flowers until the cannabinoids are processed and extracted. Marijuana extract shall be assigned a lot number immediately upon creation. Extraction employees will be trained in the best practices of all emergency procedures.

The extraction area ventilation system will be spark-resistant and separate from the main manufacturing HVAC system. All employees working in the Extraction and Production Area will be trained in Standard Operating Procedures, Good Manufacturing Practices and Emergency Procedures.

## **CHEMICAL HANDLING**

### **Material Safety Sheets:**

Safety data sheets (SDS), material safety data sheets (MSDS), and product safety data sheets (PSDS) are an important component of product stewardship and occupational safety and health. They are intended to provide workers and emergency personnel with procedures for handling or working with that substance in a safe manner, and include information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment, and spill-handling procedures.

Our standard operating procedures will include reference to relevant safety data sheets applicable to that specific process documented in the SOP. In addition, the Company will maintain a comprehensive database of all safety data sheets in hard copy and electronic scanned copies on site. The Company will ensure the SDSs are readily accessible to employees for all hazardous chemicals in their workplace. We will also designate a person responsible for obtaining and maintaining the SDSs and contacting the manufacturer to obtain one.

Employees will be trained with regard to the use of safety data sheets as part of the orientation process as well as the specific training provided by their supervisor in the performance of their duties. OSHA has published a "brief" describing the "Hazard Communication Standard: Safety Data Sheets". Section 7 of this brief covers the Handling and Storage of chemicals and outlines the type of information that will be included in the SDS for a chemical. This brief will be provided to all employees in the training process to provide guidance to help workers who handle hazardous chemicals to become familiar with the format and to understand the contents of the SDSs. It will also be included in relevant SOPs as a clickable link.

### **OSHA Protocols for handling and storage of chemicals:**

The safety of our employees and the public is our foremost business consideration. The prevention of accidents and injuries takes precedence over expedience. In the conduct of our business, every attempt will be made to prevent accidents from occurring. The Company's safety SOPs address both OSHA regulations and good laboratory practice. Key laboratory personnel will be required to participate in OSHA Certification in Health and Safety educational classes. All employees will be fully trained in the safe and efficient use of chemicals, tools, and machinery.

There are several key safety precautions necessary for extraction operations:

The room must be well ventilated and separate from all other processes. The area will have a CO2 monitor as a safety precaution designed to sound when the level of CO2 in the room nears an unsafe level. Equipment safety features must be maintained so that in the event of a leak, pressure will no longer be maintained by the system and the pump will shut off.

Standards will be established, documented and followed for chemical receiving, tracking, storage, and disposal. The General Manager and department supervisors will implement and maintain the PPE program. The program will be compliant with OSHA and EPA standards and address:

1. Hazards present;
2. Selection, maintenance, and use of PPE;
3. Training; and
4. Monitoring.

Personnel will be required to wear protective clothing, chemical resistant gloves and goggles when handling hazardous chemicals.

For each of the chemicals we are using in our production process we will determine the appropriate OSHA protocols. OSHA has defined specific protocols for handling and storage of chemicals in their CFR regulations. These are included in OSHA CFR 29, Standard number 1910, subpart H. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

All employees will be appropriately trained on spill response. Every employee is responsible for participating in spill response activities. A fully stocked spill kit will be maintained in the processing and laboratory facilities.

Our batch processing for extraction generally uses CO<sub>2</sub>, though other chemicals may be used for processing and sanitation. Hence we will adopt, CFR 29 H 1910.101 which concerns the general requirement for Compressed Gases. This will apply to our use of CO<sub>2</sub> in extraction during the chemical processing stage of production. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

Another example is CFR 29 H 1910.106 which concerns the requirements for Flammable liquids. This OSHA protocol will also be applicable to certain of our processes for production, such as those processes which use ethanol, and for sanitation where flammable liquids or aerosols are used. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

#### **MANUFACTURING PROCESS VALIDATION**

GMP defines Validation as: “Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting predetermined specifications and quality attributes.”

These production runs will be of limited units, produced under routine conditions and the number of production runs and observations made will be sufficient to allow for the normal extent of variation and trends to be established and provide sufficient data for evaluation. This will include at a minimum, 10 batches of any new concentrate, product or process. A state of control will be maintained with the use of procedures for monitoring and control systems for process performance and product quality. The facility will utilize an ISO9001 ‘Process Approach’ Quality-Management System to analyze hazards and place managerial controls on each process.

Before any batch or lot is commercially-distributed, we will have gained a high-degree of assurance that processes will consistently produce products meeting attributes of identity, strength, quality, purity, and potency. Additionally, FDA211.180 (e) states the quality standards of each product will be evaluated “annually” to determine the need for changes in product specifications, manufacturing or control procedures.

The FDA describes process-validation in three stages:

- (1) Process Design: The commercial-manufacturing process is defined during this stage.
- (2) Process Qualification: The process design is evaluated to determine if the process is capable of reproducible, commercial manufacturing.
- (3) Continued Process Verification: Ongoing assurance is gained during routine production that processes remains in a state of control.

The following are examples of circumstances requiring validation:

1. Major site changes
2. Major changes to equipment
3. Major Changes in Composition and Components:
  - a. addition of a new product
  - b. addition of a new dietary ingredient to a formulation;
  - c. changes to excipient concentration that are likely to have detectable impact on formulation quality and performance.
4. Major Process Changes: Changes to the type of process used in the manufacturing of the product, such as change from wet granulation to direct compression of dry product.
5. Major Changes to Specification: usually as a result of a formulation change;
6. When an adverse event is experienced where a process has failed to provide the desired result, such as contamination, and the process must be re-evaluated.

### **VALIDATION MASTER PLAN:**

The Company will create an SOP to document our master plan and standard protocols for validation, summarized as follows:

1. Establish predetermined specifications that define a successful validation result.
2. Determine appropriate resources and assign responsibilities for the project.
3. Define equipment and instruments to be used.
4. Define ingredients and chemicals to be used.
5. Establish review team.
6. Establish time-line and number of production runs included in the test.
7. Determine number of units or volume of production in each run.
8. Define test protocols (number of units in each lot to be “sampled”, sampling methods, testing protocols and laboratories).
9. Documents used:
  - a. Validation plan
  - b. Validation report
  - c. Discrepancy forms
  - d. SOPs
  - e. System-change request forms
  - f. Test results
10. Perform validation on a minimum of 10 lots produced according to a single manufacturing order during the same cycle of manufacture.
11. Acceptance. All documentation obtained and filed in the established Validation Filing System.

### **VARIATION**

During Production of validation Lots employees will identify sources of variation affecting process performance and product quality for improvement to reduce or control variation. Scrutiny of intra-batch and inter-batch variation is part of a comprehensive process-verification program under 21CFR§211.180(e). Control Procedures shall be established to monitor the output and validate performance of manufacturing processes that may be responsible for variability in the characteristics of in-process material and the drug product.

Sources of Variation include:

Employees -Employees will be trained to analyze parameters and attributes identified in the control strategy to verify continued operation within a state of control. Employees will provide feedback on product quality from both internal and external sources (e.g., complaints, product rejections, non-conformances, recalls, deviations, audits and regulatory inspections). Employees will be provided proper tools to perform their duties and receive ongoing education and training. Supervisors will perform Direct Observation of SOPs during Process-Validation runs.

Raw Materials - Strict SOPs of sourcing raw ingredients will be followed. Specifications of quality for suppliers have been developed to limit the variability of raw materials and packaging. We have the advantage of purchasing raw material from suppliers with existing strategic partnerships with our consultants. All suppliers have proven cGMP and tested product. Product received into the facility will be inspected upon arrival, recorded, refused or received, and stored in accordance with FDA cGMP Sec.211.80, 211.82 and 211.86. These controls are a foundation of the validation process by limiting the variable of compromised or inconsistent packaging and raw-materials entering the facility. We will source our marijuana from our own vertically-integrated cultivation facility located contiguous to our processing operation. In addition to a lab-testing facility we will utilize in-house testing at critical control points (including: raw marijuana, marijuana concentrate, marijuana infused final product) throughout the production facility to control intrinsic variables.

Equipment - Equipment used in production will be used for its intended use and will be of “appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.” (FDA cGMP Sec211.63) All equipment will be regularly maintained and documented. (FDA cGMP Sec211.67) Employees will be properly trained and certified on equipment.

Measurement Systems -Acceptance criteria for sampling and testing conducted by the quality control unit shall be adequate to assure the batches meet each appropriate specification and appropriate quality control criteria as a condition for their approval and release.

SOP– SOPs are discussed in detail in other sections of the application and will document every movement and method in the process.

Environment -Managerial control measures will be implemented in all phases of the operation. Controls of critical control-points will be supported with proper documentation in accordance to FDA cGMP Sec.211.100. Data collection of the production process is ongoing with direct-observation documentation of all critical control-points throughout receiving, extraction, production, storage, sample collection, and lab testing. Documentation provides a record that appropriate corrective actions were taken when critical limits were not met due to internal or external variables.

The validation process will allow us to:

1. Understand the sources of variation
2. Detect the presence and degree of variation
3. Understand the impact of variation on the process and ultimately on product attributes
4. Control variation in a manner commensurate with the risk it represents to the process
5. Judge whether we have gained sufficient understanding to provide a high degree of assurance in our manufacturing process to justify commercial distribution.

#### **DOCUMENTATION**

All Validation Protocols, final Validation Reports and associated testing results required by this procedure shall be retained for at least five years after distribution of the product manufactured, processed or packaged utilizing that that process or equipment.

### **-----Blue Planet Healing Manufactured Marijuana Product Descriptions-----**

#### **1. Medical Marijuana Sublingual Tincture**

Medical Marijuana Sublingual Tinctures are administered sublingually by the use of a measured dropper. Sublingual tinctures shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The droppers have measurement demarcations as to provide safe and easy dosing levels. Sublingual Tinctures offer patients the ability to ‘micro-dose’ cannabinoids in measurements of 2-3 mg of active cannabinoids. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana Sublingual Tinctures will be labeled and packaged in ASTM certified child resistant re-sealable dropper caps that will maintain the child resistant effectiveness for multiple openings.

#### **2. Medical Marijuana Infused Sublingual Tablet**

Medical Marijuana Infused Sublingual Tablets are designed to dissolve slowly in a patient’s mouth making an effective sublingual administered product. Each individual Sublingual Tablet shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. The product will be lab tested for accurate active cannabinoid profile. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana infused sublingual tablets will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **3. CO2 Medical Marijuana Concentrate**

A concentrated extract of cannabinoids, including but not limited to THC, CBD, and CBN created using a Closed-Loop Sub/Supercritical CO2 Extraction. CO2 is a non-polar solvent, which is efficient at extracting the Cannabinoids, Terpenes, and Flavonoids from Medical Marijuana plant matter. This concentrated form of Medical Marijuana can have up to a 90% concentration of cannabinoids. The product will be lab tested for accurate active cannabinoid profile.



Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **4. Medical Marijuana Infused Lotion**

Medical Marijuana Infused Lotion products are an oil based lotion to be applied directly to the skin, not meant for oral consumption. Infused Lotions shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Marijuana infused lotions will be packaged in squeeze tubes with an ASTM certified child resistant re-sealable cap that will maintain the child resistant effectiveness for multiple opening.

#### **5. Medical Marijuana Infused Salve**

The Medical Marijuana Infused Salve is an ointment, not meant for oral consumption, to promote the healing of the skin and muscles. The Salve provides gentle relief for abrasions, sores, dry, cracked or chapped skin. Infused Salves shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The unique formulation of active cannabinoids and all natural soothing and plant based pain relief provides convenient and fast acting relief for patients. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **6. Medical Marijuana Infused Serum**

The Medical Marijuana Infused Serum, not meant for oral consumption, is a water based formulation of active cannabinoids, antioxidants, all natural ingredients to provide patient relief. It is a fast absorbing active ingredients that penetrate the skin faster than lotions or gels. Serums are super-efficient delivery methods as small amounts are absorbed into the skin quickly and deeply. Infused Serums shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **7. Medical Marijuana Infused Gel**

The Medical Marijuana Infused Gel, not meant for oral consumption, is a Aloe based gentle moisturizer, with a proprietary formulation of herbs, essential oils and active cannabinoids. The Gel provides fast and long lasting muscle relief for patients. Infused Gels shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **8. Medical Marijuana Infused Capsule**

Medical Marijuana Infused Capsules are a blend of active cannabinoids and all natural ingredients within a gelatin capsule. The gelatin capsule dissolves in the stomach of the patient releasing the cannabinoids and ingredients. Each individual Capsule shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. Medical Marijuana Capsules will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **-UNM MANUFACTURING PRODUCTION STANDARD OPERATING PROCEDURES-**

#### **PRODUCTION OF SALVE**

#### **PRODUCT DESCRIPTION**

1oz Medical Marijuana Infused Salve

#### **POLICY**

To prepare and package Topical salve in child resistant packaging. All production will be documented.

#### **RESPONSIBILITY**

Production Manager or their designee.

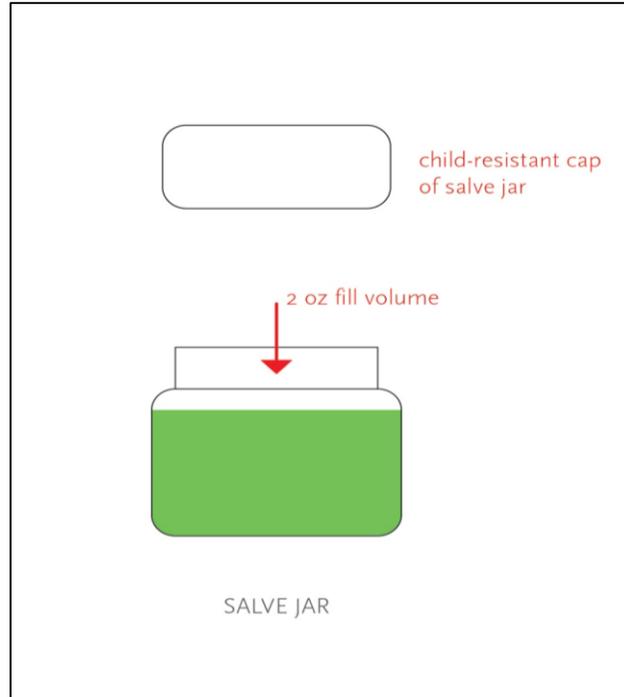
#### **RECORDS**



Production Log  
Inventory Tracking Software

**PROCEDURE**

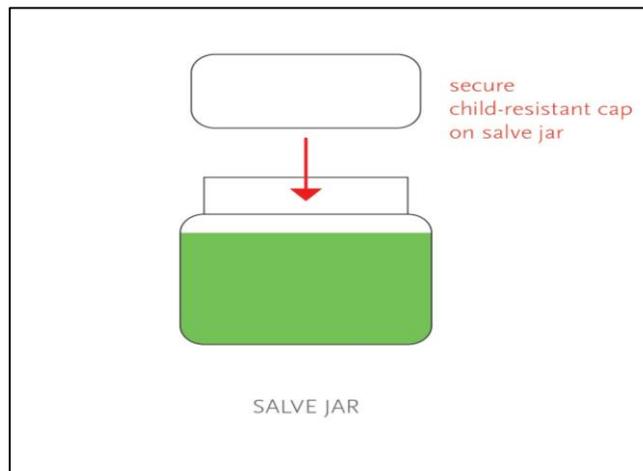
1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers, caps or droppers. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers, caps or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\#)\text{mg/THC} = (\#) \text{ total mg needed}$
  - o **divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.
  - o  $(\#) \text{ total mg needed}/(\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Fill Topical salves to the 1 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



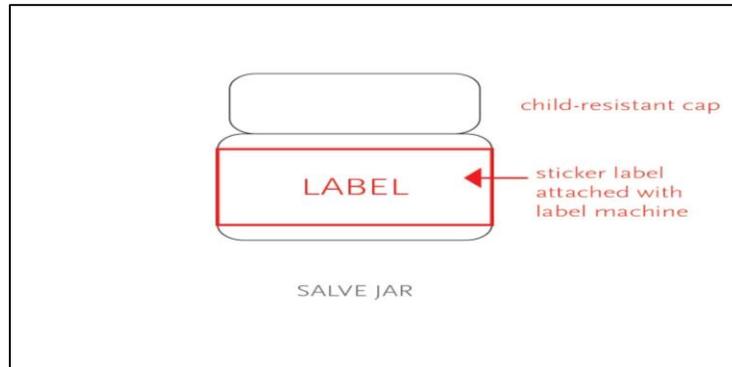
13. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.

14.

Apply the child resistant cap to the jar. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

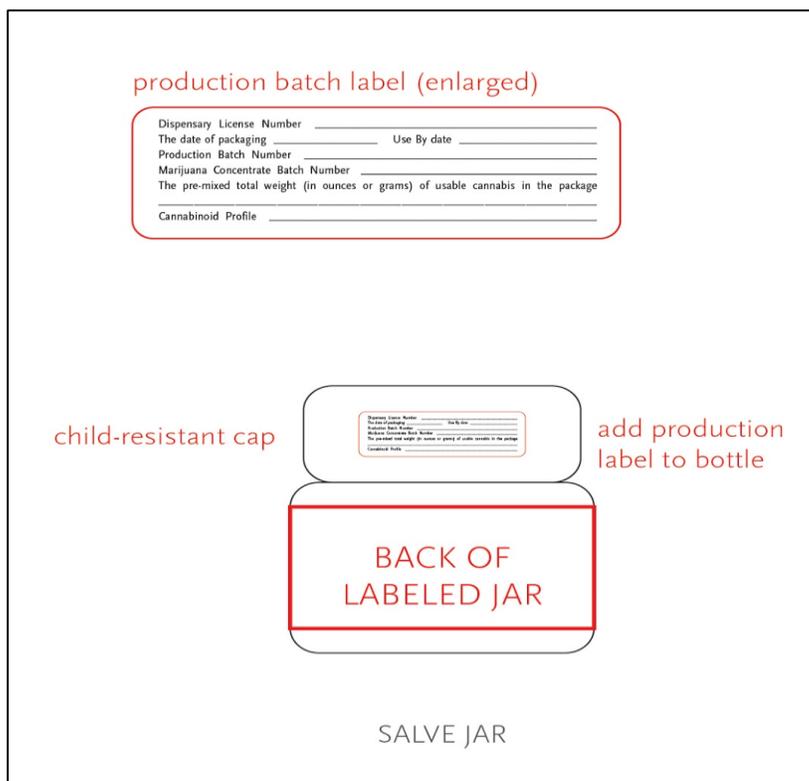


15. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Salve package properly so that front of label is centered on front of the package.



16. Apply the Production Batch Sticker which will contain the following information:

- Dispensary License Number
- The date of packaging and “use by” date
- Production Batch Number
- Marijuana Concentrate Batch Number
- The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
- A list of cannabinoid content by weight.



17. Final Quality Control Inspection of product includes:

- proper label applied correctly
- proper production batch label applied correctly
- dropper cap is applied correctly
- package is clean and dry



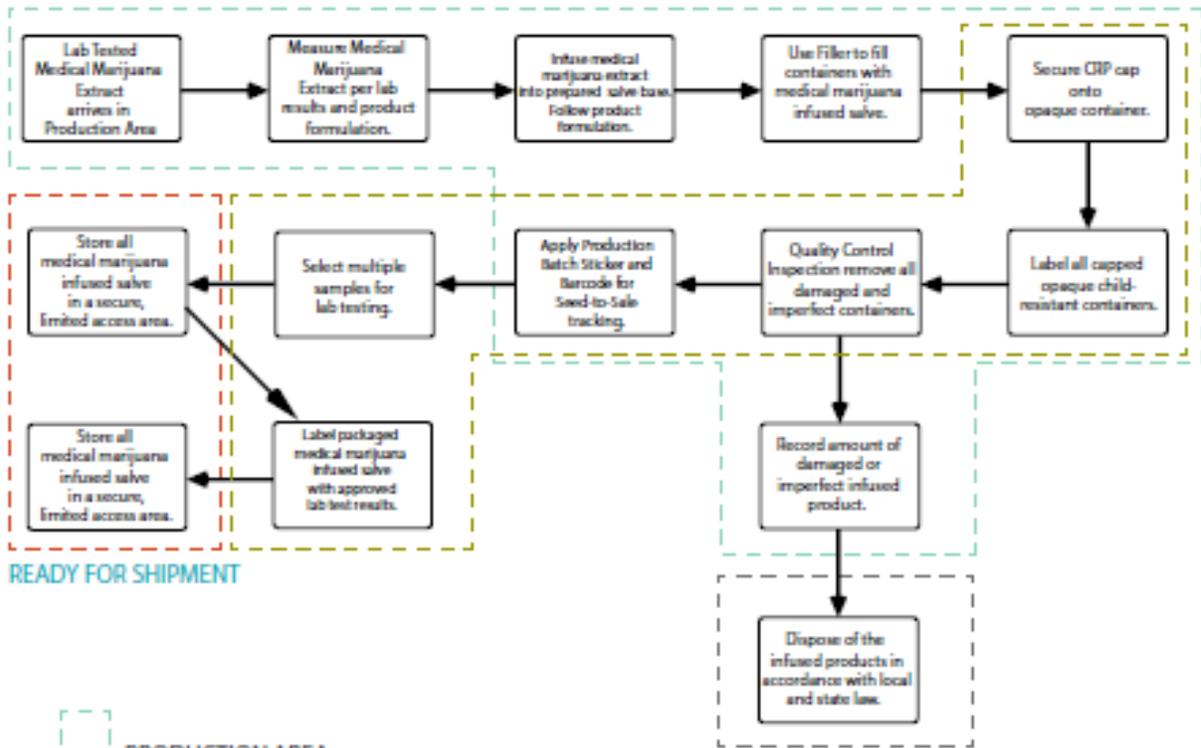
18. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
19. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
20. Complete the Production Form and enter information into Inventory Tracking Software.
21. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
22. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
23. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Salve can be seen below:*



## MEDICAL MARIJUANA INFUSED SALVE PROCESS FLOW DIAGRAM

BEGIN PROCESS →



READY FOR SHIPMENT

- PRODUCTION AREA
- PACKAGING AREA
- STORAGE AREA
- DISPOSAL

## PRODUCTION OF INFUSED TOPICAL SERUM

### PRODUCT DESCRIPTION

1oz Medical Marijuana Infused Topical Serum

### POLICY

To prepare and package Topical Serum in child resistant packaging. All production will be documented.

### RESPONSIBILITY

Production Manager or their designee.

### RECORDS

Production Log

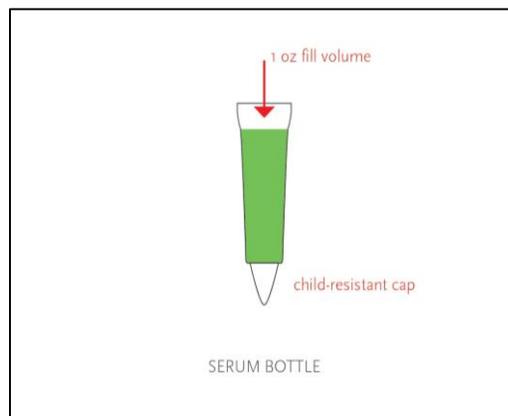
Inventory Tracking Software

### PROCEDURE

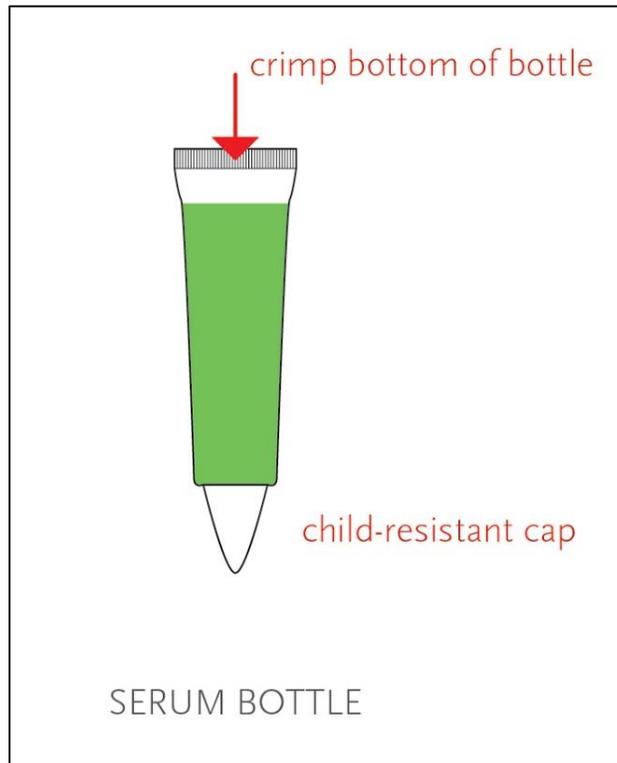
1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' Fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$



- **divide the total mg needed by the mg of THC per gram of the concentrate.**
  - **(#) total mg needed/(#) mg THC per gram = grams of concentrate to use in production**
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
  11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
  12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
  13. Fill Topical Serums to the 1 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



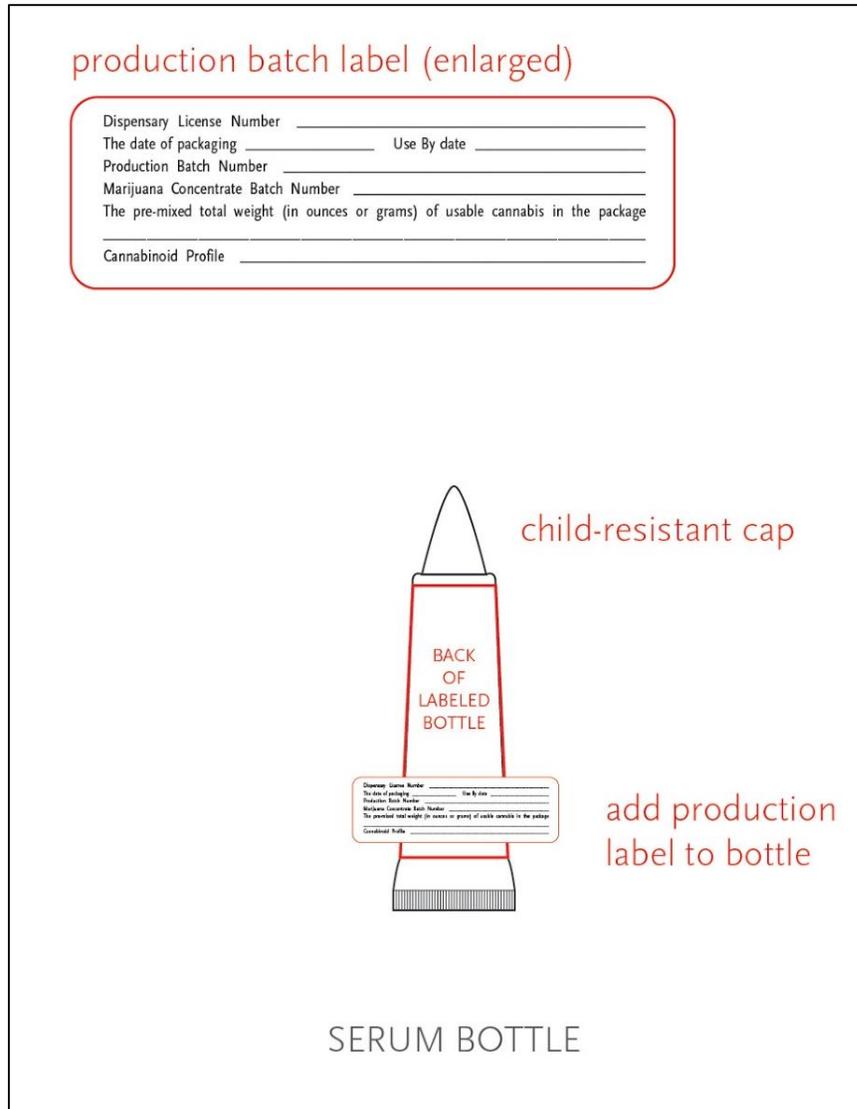
14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Serum package properly so that front of label is centered on front of the package.



17. Apply the Production Batch Sticker which will contain the following information:
1. Dispensary License Number
  2. The date of packaging and "use by" date
  3. Production Batch Number
  4. Marijuana Concentrate Batch Number
  5. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  6. A list of cannabinoid content by weight.



18. Final Quality Control Inspection of product includes:
  1. proper label applied correctly
  2. proper production batch label applied correctly
  3. dropper cap is applied correctly
  4. package is clean and dry
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
21. Complete the Production Form and enter information into Inventory Tracking Software.
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the

consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
24. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
25. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Serum can be seen below:*

## **PRODUCTION OF TOPICAL GEL**

### **PRODUCT DESCRIPTION:**

3oz Medical Marijuana Infused Gel

### **POLICY:**

To prepare and package Topical Gel in child resistant packaging. All production will be documented.

### **RESPONSIBILITY**

Production Manager or their designee.

### **RECORDS**

Production Log

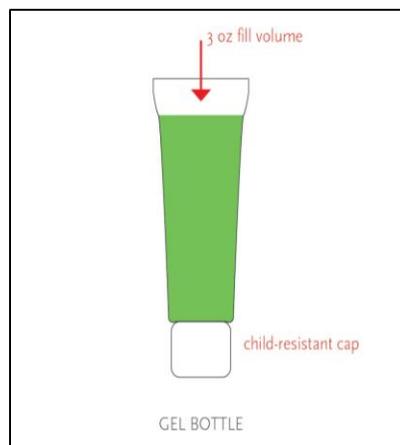
Inventory Tracking Software

### **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.



5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\# \text{ mg/THC}) = (\#) \text{ total mg needed}$
  - o **divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.
  - o  $(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
13. Fill Topical Gels from the open tube side with the child resistant cap facing down. Fill to the 3oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.





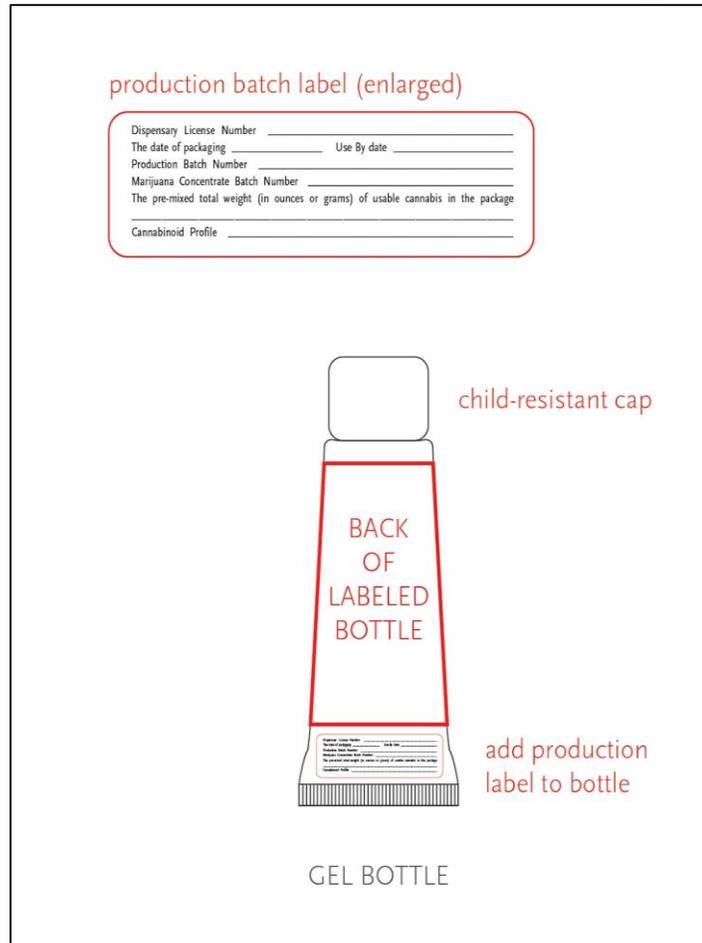
14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube closed. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Gel package properly so that front of label is centered on front of the package.



17. Apply the Production Batch Sticker which will contain the following information:
  1. Dispensary License Number
  2. The date of packaging and "use by" date
  3. Production Batch Number
  4. Marijuana Concentrate Batch Number
  5. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  6. A list of cannabinoid content by weight.



18. Final Quality Control Inspection of product includes:
  1. proper label applied correctly
  2. proper production batch label applied correctly
  3. dropper cap is applied correctly
  4. package is clean and dry
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, Reason for disposal, and Quantity of the marijuana product to be disposed of.
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
21. Complete the Production Form and enter information into Inventory Tracking Software.
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

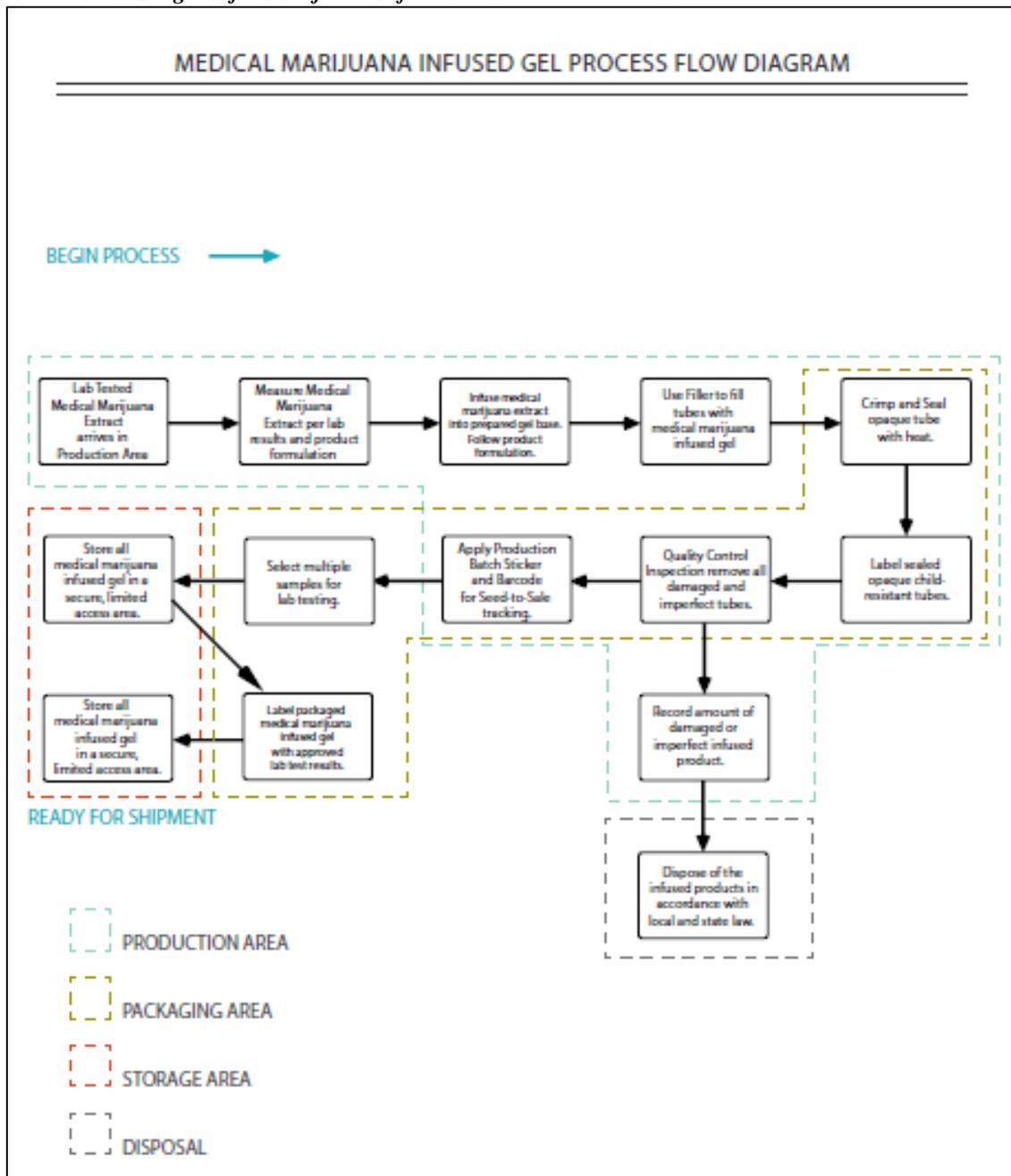


23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.

Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.

24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Gel can be seen below:*



## PRODUCTION OF SUBLINGUAL MARIJUANA TINCTURES

### PRODUCT DESCRIPTION

2oz Sublingual Medical Marijuana Tincture. 2ml Dropper for Metered Dosing.

### POLICY

To prepare and package sublingual marijuana tinctures in child resistant packaging. All production will be documented.

### RESPONSIBILITY

Production Manager or their designee.

### RECORDS

Production Log  
Inventory Tracking Software

### PROCEDURE

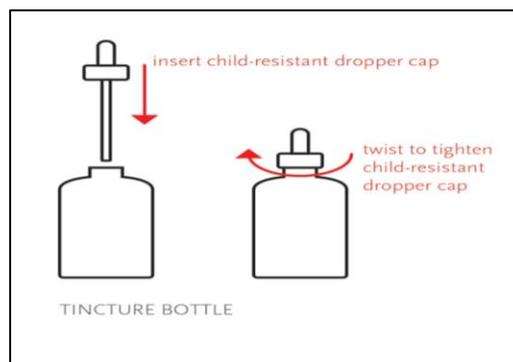
1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all containers and droppers. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers, caps or droppers. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - a. **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - b.  $(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$



- c. **divide the total mg needed by the mg of THC per gram** of the concentrate.
  - d.  $(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
  11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
  12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
  13. Fill Tinctures to the 2 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.

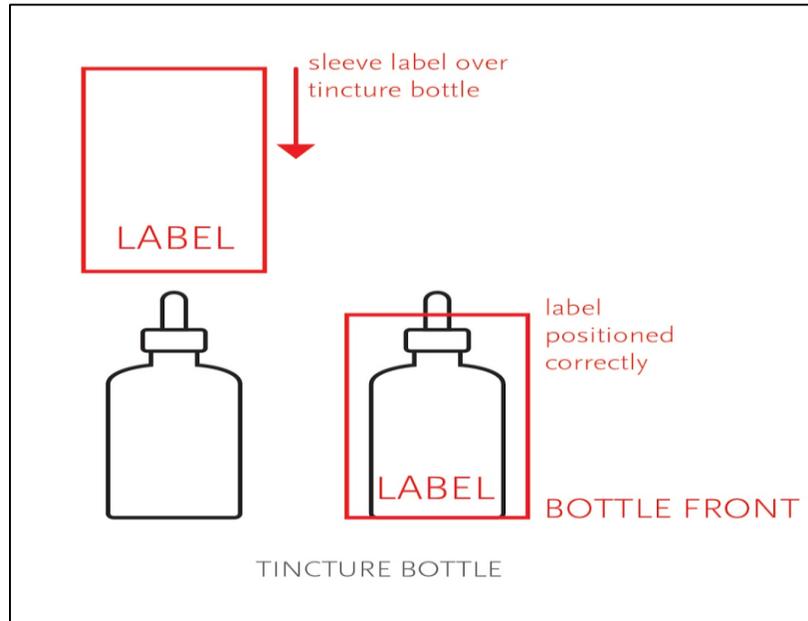


14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Secure and seal child resistant dropper cap. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.





16. Turn power on to the Heat Shrink Tunnel. Set speed control to '3' and Heat control to 180F. For tincture labeling close top 4 heat tunnel vents, leaving only the bottle 2 vents open. Allow 15 minutes for Heat Tunnel to reach temperature. If applicable turn on exhaust fan to remove hot air from production area.
1. Label with tamper evident, opaque shrink-wrap label. Perform and document Direct Observation Quality Control that labels contain all required information. "Sleeve" the bottled product. -- Place shrink wrap label onto every filled and capped tincture bottle by sliding the label over the container and positioning the label properly so that front of label is centered on front of bottle.



2. Run Sleeved product through the heat tunnel. Carefully place each unit onto the conveyor belt so that the Tincture bottle stays upright. Bottle placement should be so that the front of the bottle faces the left side of the Heat Tunnel. As tincture bottles exit the Heat Tunnel each unit should be Quality Control inspected for tearing, wrinkling, stretching, or improper label placement. Adjust Heat Tunnel controls if necessary. Next, Label products with Production Batch Label.

Apply the Production Batch Sticker which will contain the following information:

- a. Dispensary License Number
- b. The date of packaging and "use by" date
- c. Production Batch Number
- d. Marijuana Concentrate Batch Number
- e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
- f. A list of cannabinoid content by weight.



Final Quality Control Inspection of product includes:

- proper label applied correctly
- proper production batch label applied correctly
- dropper cap is applied correctly
- package is clean and dry

Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.

Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.

Complete the Production Form and enter information into Inventory Tracking Software.

Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab

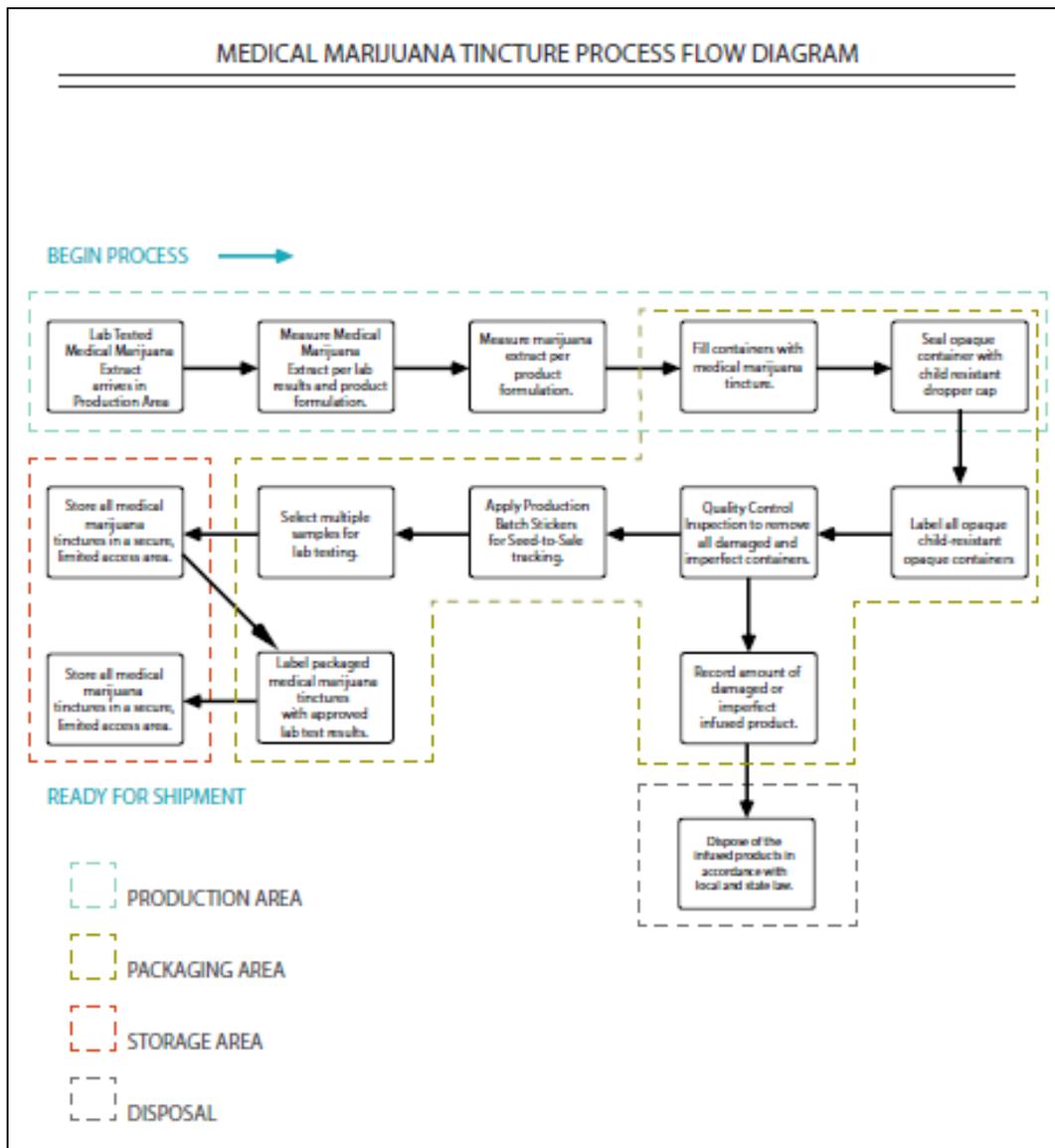
facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

Move all final marijuana products to a secure storage area within the Production Area to await lab test results.

Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.

Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Tincture can be seen below:*



**PRODUCTION OF MARIJUANA SUBLINGUAL TABLET**

**PRODUCT DESCRIPTION**

## Medical Marijuana Sublingual Tablet

### **POLICY**

To prepare and package marijuana concentrate into accurately dosed sublingual Tablets.

### **RESPONSIBILITY**

Production Manager or their designee.

### **RECORDS**

Production Log

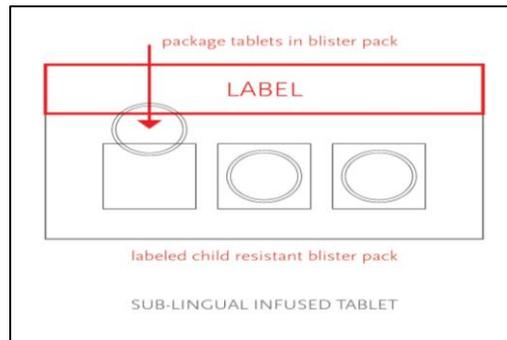
Seed-to-Sale Inventory Tracking System

### **PROCEDURE**

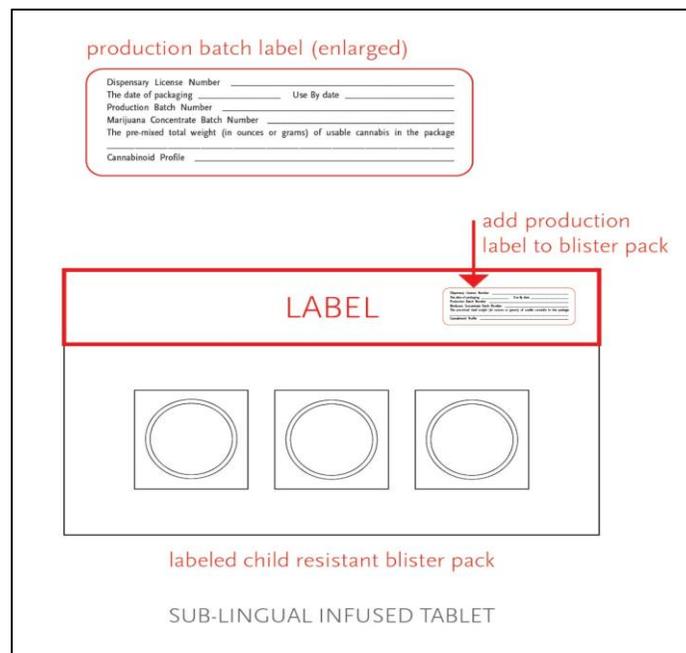
1. Before daily processing begins, sanitize work surface with 50 - 200 ppm sanitizer solution.
2. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level.
3. Wipe all work surfaces with bleach solution, allow to air dry
4. Ensure that all utensils are cleaned and sanitized.
5. Have a container with sanitizer on the table at all times.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form by assigning a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name. The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form Inventory Tracking Software Inventory Tracking software will be used to track all medical marijuana products.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a State certified testing lab ensure consistent and metered medical marijuana products.
9. Use a NTEP approved scale to measure an accurate amount of marijuana extract per medical marijuana product formulation.
10. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Use the assembled and sanitized equipment to form the tablets. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of medical marijuana product. Quality Control Direct Observation of the tablets to provide a safe and consistent medical marijuana product.



13. Operate the packaging equipment to package tablets in child resistant packaging. The packaging provides a consistent and recognizable child resistant packaging to provide safety for the patient.



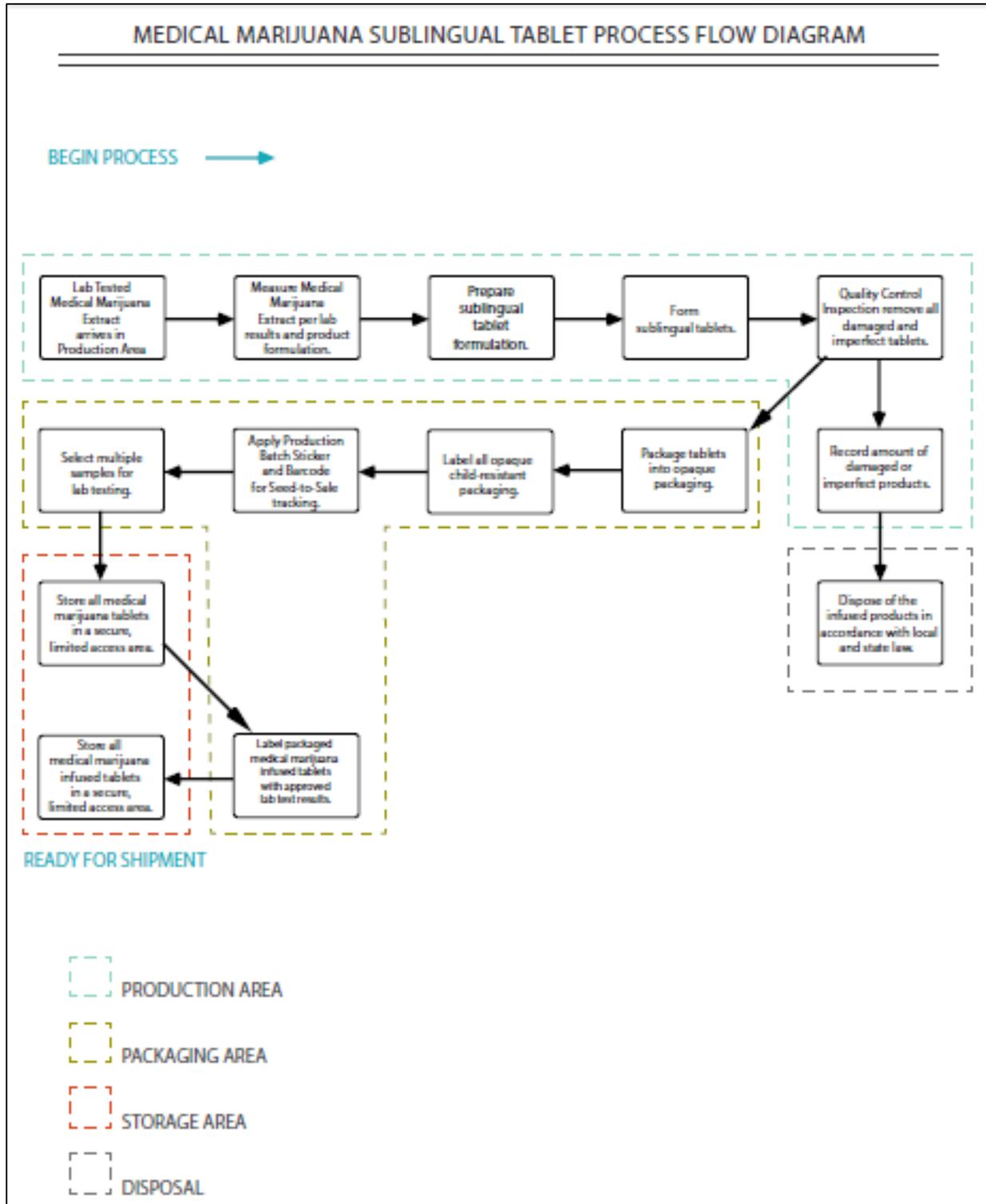
14. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information.



15. Final Quality Control Inspection of product.
16. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
17. Once documented render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
18. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch.
19. Enter Batch Number, quantity produced, date of production, and marijuana extract Batch information into Inventory Tracking Software.

20. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
21. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
22. Upon receiving approved test results for the marijuana product Production Batch, apply Production Batch Sticker to the final product. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
23. Apply the Production Batch Sticker which will contain the following information:
  - a. Dispensary License Number
  - b. The date of packaging and “use by” date
  - c. Production Batch Number
  - d. Marijuana Concentrate Batch Number
  - e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - f. A list of cannabinoid content by weight.
24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

***The Process Flow Diagram for Marijuana Infused Sublingual Tablet can be seen below:***



### PRODUCTION OF INFUSED TOPICAL LOTION

#### PRODUCT DESCRIPTION

6oz Medical Marijuana Infused Lotion

#### POLICY

To prepare and package Infused Topical Lotion in child resistant packaging. All production will be documented.

## RESPONSIBILITY

Production Manager or their designee.

## RECORDS

Production Log

Inventory Tracking Software

## PROCEDURE

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.

**multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run

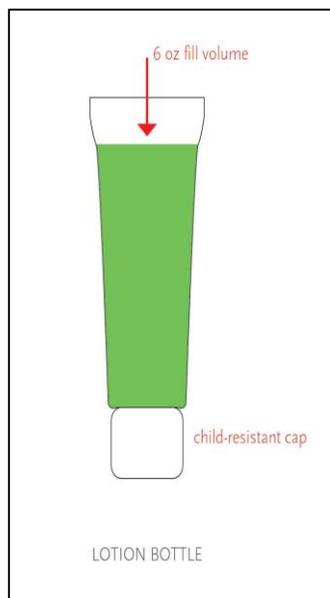
$(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$

**divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.



(#) total mg needed/(#) mg THC per gram =  
grams of concentrate to use in production

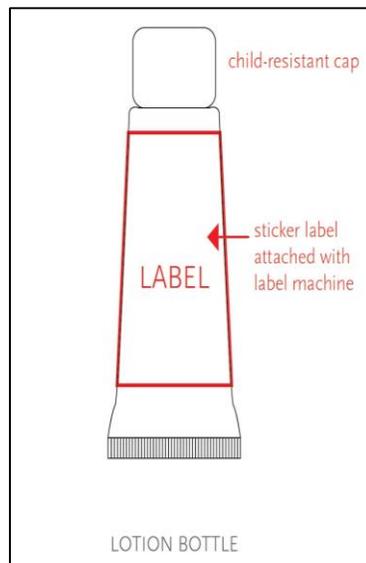
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
13. Fill Topical Lotions to the 6oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Lotion package properly so that front of label is centered on front of the package.



18. Apply the Production Batch Sticker which will contain the following information:
- Dispensary License Number
  - The date of packaging and “use by” date
  - Production Batch Number
  - Marijuana Concentrate Batch Number
  - The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - A list of cannabinoid content by weight.

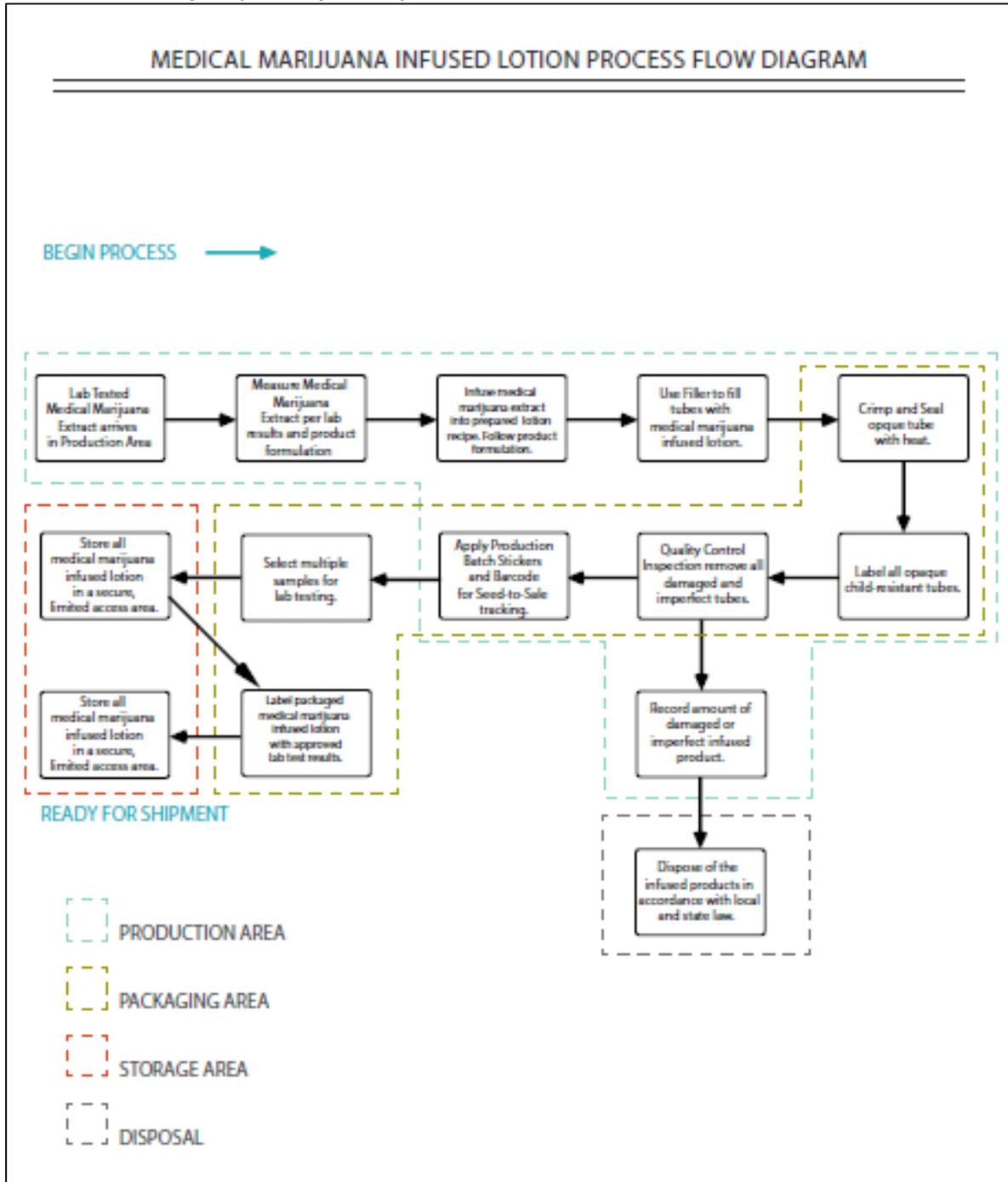


19. Final Quality Control Inspection of product includes:
  - a. proper label applied correctly
  - b. proper production batch label applied correctly
  - c. dropper cap is applied correctly
  - d. package is clean and dry
20. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
21. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
22. Complete the Production Form and enter information into Inventory Tracking Software.
23. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
24. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
25. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.



26. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

The Process Flow Diagram for Marijuana Infused Lotion can be seen below:



**PRODUCTION OF MARIJUANA CAPSULE**

**PRODUCT DESCRIPTION**

Medical Marijuana Infused Capsule

## **POLICY**

To prepare and package marijuana concentrate into consistent and metered capsules.

## **RESPONSIBILITY**

Production Manager or their designee.

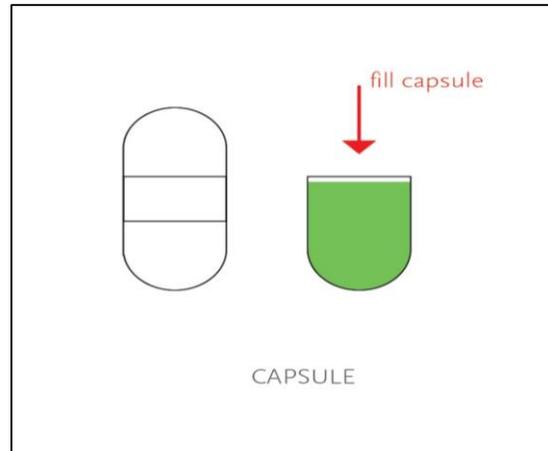
## **RECORDS**

Production Log

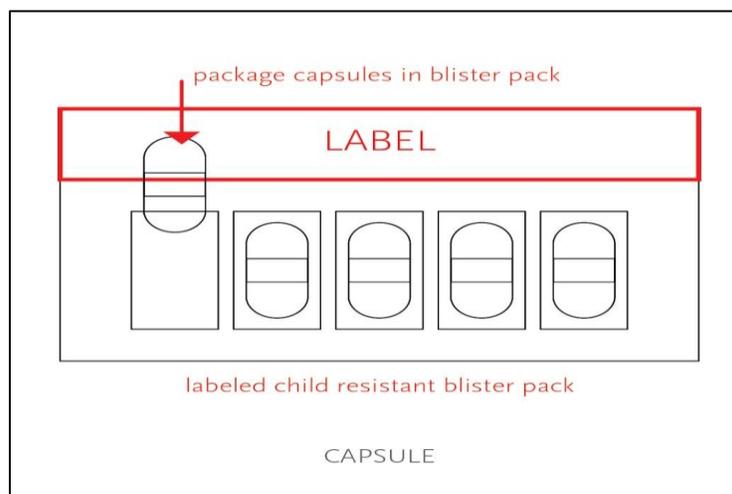
Seed-to-Sale Inventory Tracking System

## **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50 - 200 ppm sanitizer solution.
2. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level.
3. Wipe all work surfaces with bleach solution, allow to air dry.
4. Ensure that all utensils are cleaned and sanitized.
5. Have a container with sanitizer on the table at all times.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form by assigning a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name. The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form Inventory Tracking Software Inventory Tracking software will be used to track all medical marijuana products.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a State certified testing lab ensure consistent and metered medical marijuana products.
9. Use a NTEP approved scale to measure an accurate amount of marijuana extract per medical marijuana product formulation.
10. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Using the assembled and sanitized packaging equipment to fill and seal Capsules. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product. Quality Control Direct Observation of the filled and sealed containers will document proper quantity amounts and sealing of each container to provide a safe and consistent marijuana product.



13. Operate the packaging equipment to package and label capsules in child resistant packaging. The packaging provides a consistent and recognizable child resistant packaging to provide safety for the patient.



14. Final Quality Control Inspection of product.

15. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, Reason for disposal, and Quantity of the marijuana product to be disposed of.

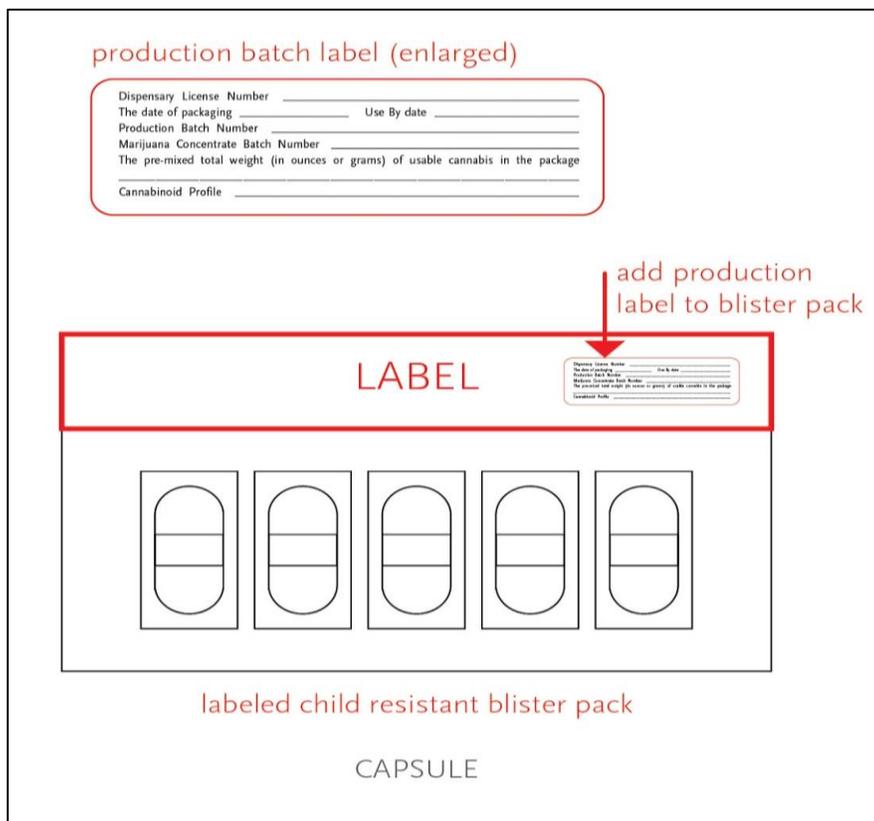
16. Once documented render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.

17. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch.

18. Enter Batch Number, quantity produced, date of production, and marijuana extract Batch information into Inventory Tracking Software.

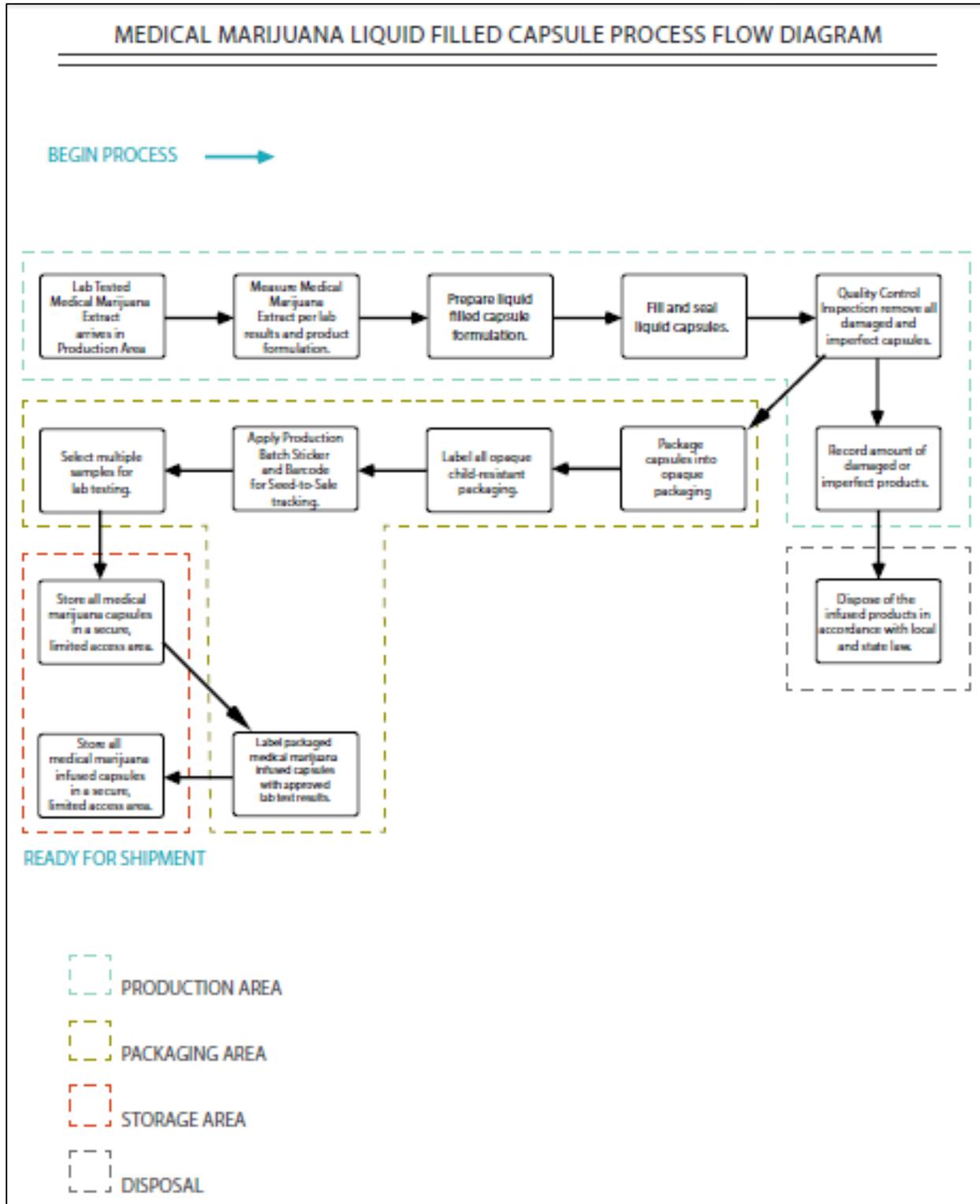


19. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
20. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
21. Upon receiving approved test results for the marijuana product Production Batch, apply Production Batch Sticker to the final product. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
22. Apply the Production Batch Sticker which will contain the following information:
  - a. Dispensary License Number
  - b. The date of packaging and “use by” date
  - c. Production Batch Number
  - d. Marijuana Concentrate Batch Number
  - e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - f. A list of cannabinoid content by weight.



23. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Liquid Filled Capsule can be seen below:*





-----**CLOSED LOOP SUB AND SUPERCRITICAL CO<sub>2</sub>**-----

**EXTRACTION**

**PRODUCT DESCRIPTION**

A concentrated extract of cannabinoids including but not limited to THC, THCA, THCV, CBD, CBDA, CBDV, CBN, CBG, and CBC derived from the leaves and flowers of the female marijuana plant.

**EXTRACTION METHOD**

CO<sub>2</sub> has a polarity that is compatible for the solubilization of lipophilic compounds such as lipids and essential oils. The low polarity index makes SFE CO<sub>2</sub> highly advantageous during medical marijuana extraction. Closed-Loop Sub/Supercritical CO<sub>2</sub> and Co-Solvent Introduction. CO<sub>2</sub> is a non-polar solvent. We utilize the latest Subcritical (17 MPa / 2500 PSI and below) and Supercritical (above 17 MPa/ 2500 PSI) Fluid Extraction (**SFE**) technologies and combine them with our own proprietary processes, formulas and equipment. SFE allows the processing of our medical grade marijuana at low temperatures limiting thermal degradation while preserving the most vital medicinal components of the plant.

**POLICY**

To follow all company standard operating procedures and sanitation protocols while manufacturing marijuana extract in compliance with Hawaii State and local law.

**RESPONSIBILITY**

Lab Manager or their designee.

**RECORDS**

Seed-to-Sale Inventory Tracking Software

**EQUIPMENT**

- 1) One extraction vessel 5000 mL in size.
- 2) Two separators each 1500 ML in size.
- 3) Temperature range maintained between 40 and 50 °C.
- 4) Pressures are created to subject the marijuana flowers to either a subcritical extraction process or a supercritical extraction process.

Pressure variance applied to each process:

- subcritical extraction process pressures: (17 MPa\* and below)
- supercritical extraction process pressures: (above 17 MPa to 69 MPa)

\* MPa: 1 megapascal (MPa) = 145.037738 pound-force/square inch (PSI)

**Our Sub/Supercritical Extraction Process is illustrated in 8 procedures:**

2. Penetration of matrix (marijuana plant matter).
3. SCF solubilizes the solutes inside the pores.
3. Intra-particle (or internal) diffusion of the solutes takes place until the external surface is fully saturated with solvent.
4. External (or film) diffusion of the solutes from solid-fluid interface to the SCF bulk.
5. Precipitation of target solutes in the trapping system by changing the pressure and/or temperature of the fluid.
6. Apply proprietary formulas that vary time intervals and solvent quantities to control and output the anticipated extraction grade and type.



7. Apply proprietary extract refinement processes to complete the end product output.
8. Based on the final extract output selected, Co-solvents are sometimes introduced at different phases of the extraction process.

**(8a) CO-SOLVENT Introduction:**

Co-solvents are introduced at different time phases of the extraction process based on the desired final product. Primary intervals are 25%, 50%, and 75% time interval to completion of the extraction process.

Additional Extraction Runs, Matrix Disposal and further Solvent Reclaim:

Due to our closed-loop extraction equipment, all solvents are reclaimed for re-use or disposed per State of Hawaii solvent removal procedures. Due to the primary extraction process achieving a greater than 90% efficiency very little extract potential resides within the marijuana plant matter. The remaining extract potential of the marijuana is subjected to a primary ethanol solvent rinse to capture all remaining marijuana extract. The exhausted post extract marijuana plant matter is then classified as “unusable” and packaged for safe removal and disposal from the lab.

A) Subcritical extraction process (17 MPa and below)

Time Interval to completion of process is related to the percentage (%) of co-solvent introduced of total solvent in system at a temperature range: 40- 50 °C.

- 25% / 10%
- 50% / 5%
- 75% / 2%

B) Supercritical extraction process (above 17 MPa to 69 MPa)

Time Interval to completion of process is related to the percentage (%) of co-solvent introduced of total solvent in system at a temperature range: 40- 50 °C

- 25% / 10%
- 50% / 5%
- 75% / 2%

**Extraction Process Yield:**

Yields utilizing our proprietary CO<sub>2</sub> and co-solvent methods are expected to be greater than **90+%**.

The remaining extract potential of the marijuana is subjected to a primary food-grade ethanol solvent rinse to capture all remaining marijuana extract from the plant matter.

The extraction equipment schematic is illustrated in **Diagram Two:**

First, the liquid carbon dioxide is pumped through a heat exchanger to reach the system at supercritical state. Next, the SC CO<sub>2</sub> is uniformly pumped into the extractor where the dry and ground plant material forms a fixed bed of solid matrix. The extraction can be performed in static (with no follow-through) or dynamic (with follow-through) mode or in a mixed approach. During extraction, the supercritical solvent passes through the plant matrix bed and dissolves the soluble compounds. The mixture solvent-plant solutes are separated in flash tanks (cyclonic and gravimetric separators) usually changing drastically the solvent power of CO<sub>2</sub> by depressurization or temperature change or both. Then, CO<sub>2</sub> is cooled at liquid state and compressed to return to the extractor.



American Cannabis Company  
growing the next frontier

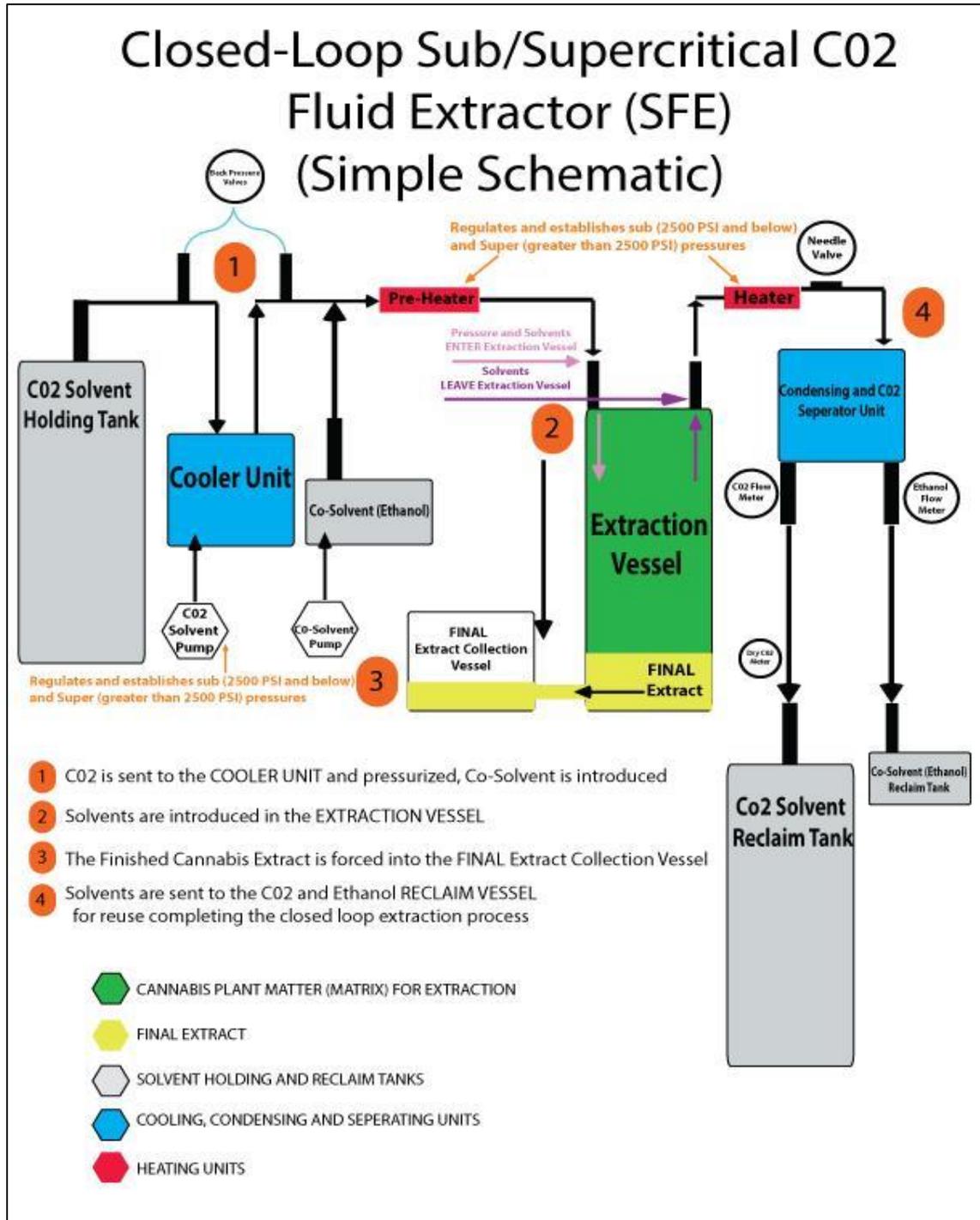
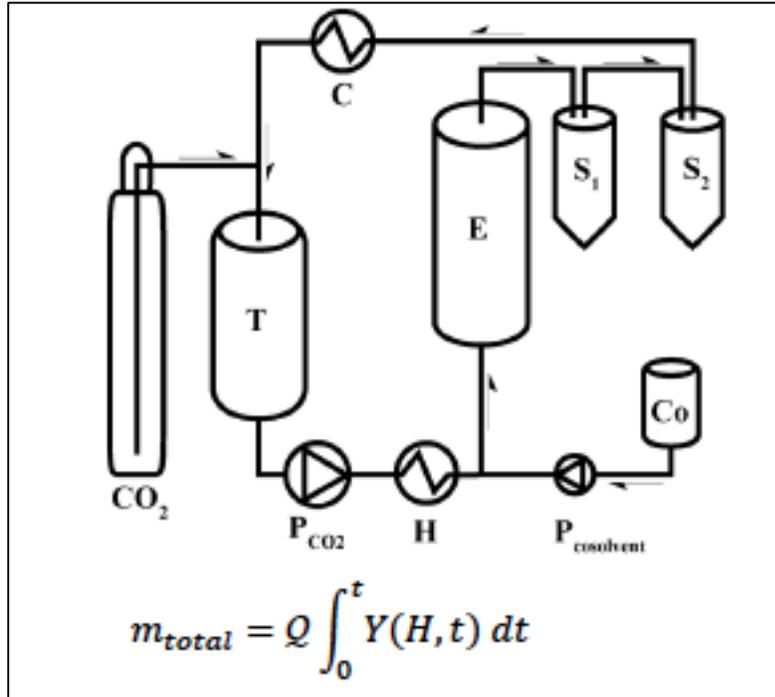


Diagram Three:

Raw Diagram of the supercritical fluid extraction process:



Legend Descriptor for Supercritical Extraction machine:

- (T): Storage Tank
- (PCO2): CO<sub>2</sub> Pump
- (H): Heat exchanger
- (Co): Solvent Pump
- (E): Extraction vessel
- (S1-S2): Separation cells
- (C): Condenser

The versatility of SC CO<sub>2</sub> as extraction technology utilizes the solvent's efficiency through the simple change of pressure and temperature. The range of variation of SC CO<sub>2</sub> density is relatively wide, from 0.2 g cm<sup>-3</sup> at 8 MPa and 40 °C to 1.0 g cm<sup>-3</sup> at 69 MPa and 50 °C. Furthermore, the increase of temperature leads to reduction of density of supercritical fluids but, on the other hand, the increase of temperature affects the volatility of target compounds. For volatile marijuana oil extraction through SC CO<sub>2</sub>, small changes in temperature cause significant changes in solubility with a non-linear relationship. The operative pressure is one of the primary parameters we utilize to influence the fluid density and therefore the solvent power of supercritical fluid and co-solvent. We also utilize the effects of temperature depends on the nature of plant material and has to be determined case by case.

For the analysis of solubility of target compounds and for the design of extraction process, four parameters are extremely helpful in the understanding of solute behavior in supercritical fluids. The miscibility or threshold pressure, that is the pressure at which the solute starts to be transferred into the supercritical fluid; the pressure of maximum solubility of solute; the fractionation pressure range, that is the pressure region between the miscibility and maximum solubility pressures and; the physical properties of the solute, particularly its melting point. The determination of the last two parameters allows us to define the best conditions for solubility and selectivity, because these compounds diffuse better above their melting points and an operative pressure between miscibility and maximum solubility increases the selectivity of extraction.

By closely monitoring, utilizing and adjusting the pressure and temperature during extraction, the global yield of the marijuana plant matter is determined and maintained. Global yield refers to a single target compound or to the global

mixture of compounds. This parameter is closely related to the solubility of the solute in the supercritical fluid. Moreover, the solubility of target compounds can be determined also from the slope of the linear portion of the extraction curve in the stage of constant-extraction rate period (CER).

Beyond the extraction parameters related to the engineering aspects such as pressure, temperature and flow rate, other factors related to the nature of plant material can influence the SFE. The particle size, shape, surface area, porosity, and moisture level of extractable solutes are variables that depend on the nature of the matrix or pretreatment of the plant material. As a rule, the smaller the particle size of the marijuana plant material, the more exposed surface for SC CO<sub>2</sub> penetration and solute heat transfer. However, the excessive grinding of the material might produce an extraction bed extremely thick and the SC CO<sub>2</sub> could find fast tracks inside the extractor (fluid channeling effect), thus reducing the contact with the plant material. This is closely monitored during our extraction phase to negate this occurring since it reduces the overall efficiency of the extraction process.

Moreover, the moisture content of the solid material influences not only the extraction quality and yield but also the fluid dynamics of the solvent. Water can act as co-solvent by interacting with the supercritical solvent and by changing the overall polarity of the fluid. However, extracted water can increase the formation of ice blockages. Therefore, drying the raw material is recommended in order to have a water content of around 4–14%.

Co-solvents act through two hypothetical mechanisms: solute-co-solvent interaction, and matrix swelling which facilitates the contact of the solutes with the solvent. The co-solvents do not have absolute mechanism of action; their effects are related to the type of co-solvent, plant material and target compounds. Studies about the effects of co-solvents at constant pressure and temperature evaluated the extraction efficiency of different modifiers at increasing percentages for volatile marijuana oil extractions. The addition of ethanol decreases the number of extracted terpenes with respect to pure SC CO<sub>2</sub> but increases the overall “whole plant” being extracted given the polarity of stated co-solvent.

We use co-solvents, especially at high percentages to change the critical parameters of the solvent mixture. Our co-solvent is food grade ethanol added in a percentage that varies from 1% to 15%

#### **4) ADVANCEMENT OF SFE EXTRACTION TECHNOLOGY:**

SFE is a technology that allows extraction of a wide range of diverse compounds. Our focus on utilizing, refining and expanding its use insures the best possible medical grade marijuana extracts available in the market.

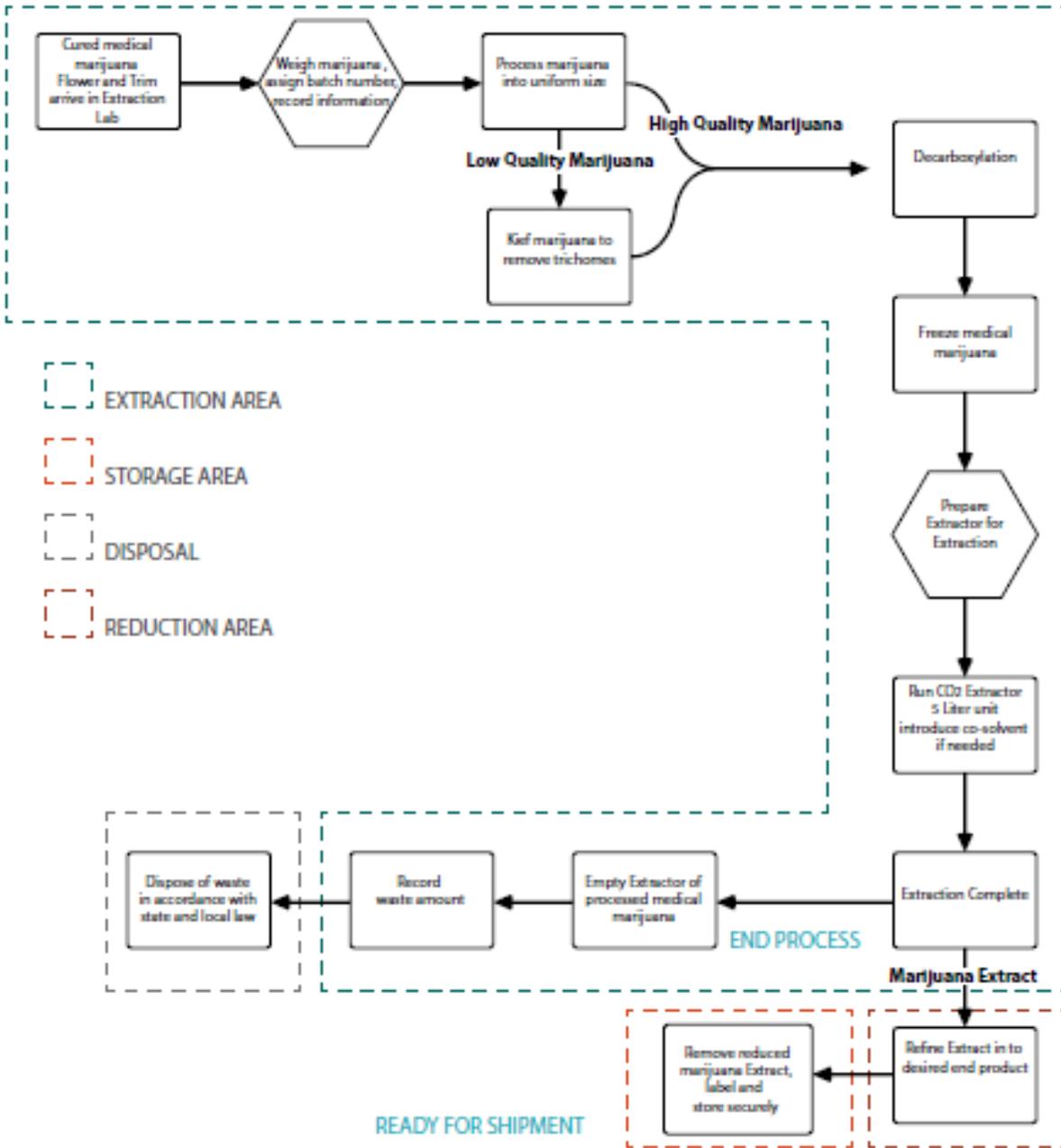
By focusing our efforts on natural solvents such as CO<sub>2</sub> and food grade ethanol we will continue to provide the most environmentally friendly, medically centered medicinal-grade marijuana extracts to patients. With our focus on “whole plant” extracts we continue to advance the accepted medical focus on the entourage effect, namely that the sum of the plant together offers far more medicinal benefits than a strict isolation and assimilation of any one component of the marijuana plant. Additionally, since SFE adds a new dimension to the pharmaceutical and nutraceutical medicine advancement, its potential technologically and economy provides new, sustainable, and safe marijuana extract based medicine to patients.

*The Process Flow Diagram for Marijuana CO<sub>2</sub> Oil can be seen below:*



### CO2 SUB/SUPERCritical EXTRACTION FOR PRODUCTS AND CONCENTRATES (SOLVENT AND CO-SOLVENT) PROCESS FLOW DIAGRAM

BEGIN PROCESS →





---

## -----PACKAGING OF CO<sub>2</sub> OIL-----

---

### **PRODUCT DESCRIPTION**

CO<sub>2</sub> Oil packaged in child resistant containers

### **POLICY**

To prepare and package CO<sub>2</sub> Oil packaged in child resistant containers. All production will be documented.

### **RESPONSIBILITY**

Production Manager or their designee.

### **RECORDS**

Production Log

Inventory Tracking Software

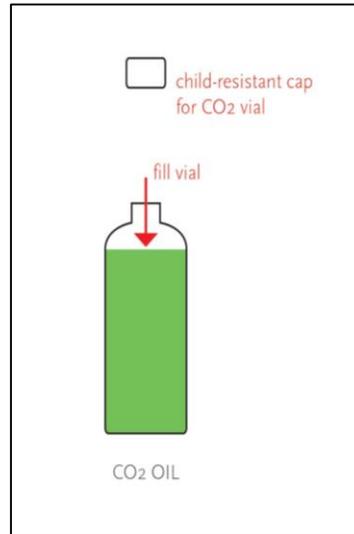
### **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all containers and droppers. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers and caps. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve CO<sub>2</sub> Oil from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Date and Product Name.
8. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
9. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
10. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the packaging of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to



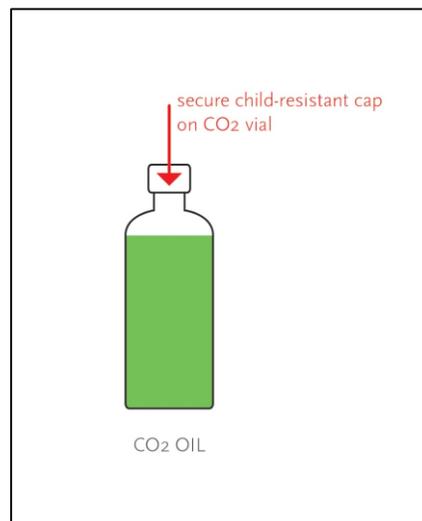
ensure safe and consistent medical marijuana products.

11. Fill CO<sub>2</sub> oil vial using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



12. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.

13. Secure and seal child resistant cap. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

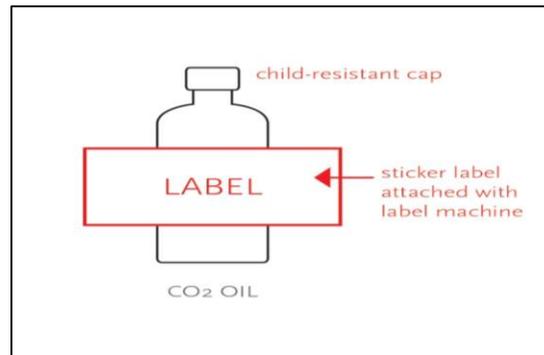


14. Turn power on to the Heat Shrink Tunnel. Set speed control to '3' and Heat control to 180F. For CO<sub>2</sub> oil vial labeling close top 4 heat tunnel vents, leaving only the bottle 2 vents open. Allow 15 minutes for Heat Tunnel to reach temperature. If applicable turn on exhaust fan to remove hot air from production area.

15. Label with tamper evident, opaque shrink-wrap label. Perform and document Direct Observation Quality Control that labels contain all required information. "Sleeve" the bottled product. -- Place shrink wrap label onto

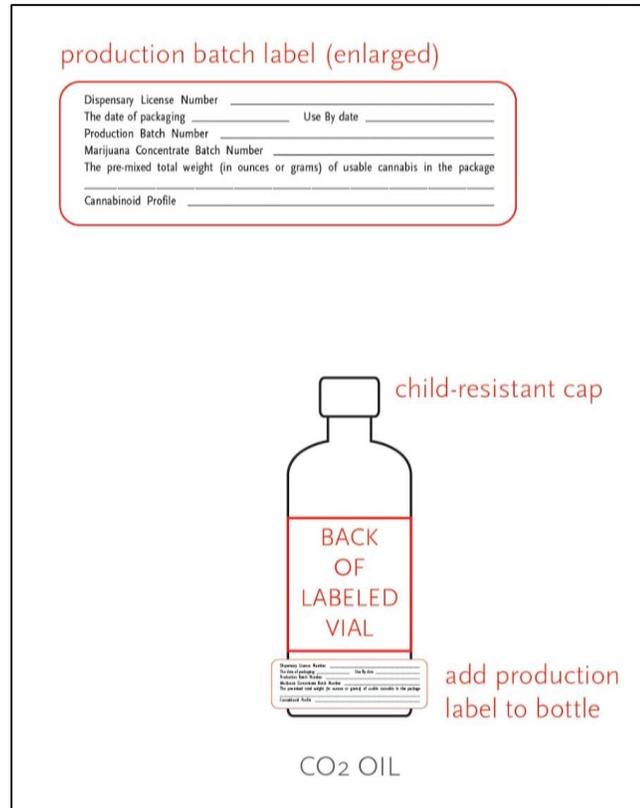


every filled and capped CO<sub>2</sub> oil vial by sliding the label over the container and positioning the label properly so that front of label is centered on front of bottle.



16. Run Sleeved product through the heat tunnel. Carefully place each unit onto the conveyor belt so that the CO<sub>2</sub> oil vial stays upright. Bottle placement should be so that the front of the bottle faces the left side of the Heat Tunnel. As CO<sub>2</sub> oil vial exit the Heat Tunnel each unit should be Quality Control inspected for tearing, wrinkling, stretching, or improper label placement. Adjust Heat Tunnel controls if necessary. Next. Label products with Production Batch Label.

17. Apply the Production Batch Sticker which will contain the following information:
- Dispensary License Number
  - The date of packaging and “use by” date
  - Production Batch Number
  - Marijuana Concentrate Batch Number
  - The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - A list of cannabinoid content by weight.



18. Final Quality Control Inspection of product includes:
  - a. proper label applied correctly
  - b. proper production batch label applied correctly
  - c. dropper cap is applied correctly
  - d. package is clean and dry
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for Disposal, and Quantity of the marijuana product to be disposed of.
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
21. Complete the Production Form and enter information into Inventory Tracking Software.
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
24. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and

consistent.

25. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

**-----PACKAGING AND LABELING MANUFACTURED MARIJUANA PRODUCTS-----**

**Weighing and Packaging Medical Marijuana**—is the process of accurately weighing the medical marijuana to be put into packages for distribution. Packaging regulations and requirements may vary, so it is essential to reference the state and local laws and regulations pertaining to packaging requirements for medical marijuana business. Use of NTEP certified scales for the weighing of all marijuana products is mandatory.

- All BPH packing will be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
- Packaging must be opaque so that the product cannot be seen from outside the packaging;
- The packaging must be constructed to protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.
- Packages must not contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; providing that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
- Marijuana will be carefully weighed and packaged at the production center. All products will be packaged, recorded into the inventory system, and labeled per Hawai'i regulations.



- Upon marijuana being weighed and packaged registered employees are required to document the marijuana weight associated to the product with a unique attribute number and batch number. This documentation must be done with two registered employees, one employee to make the record in the inventory control system and a second to witness the record.
- Ensure inventory control system is updated to show the packaged marijuana weights and specifications.

It is important for qualifying, registered patients' to understand the importance of packaging and labeling medical marijuana products. Proper packaging and labeling will achieve two primary objectives; 1) the medical marijuana product will be properly labeled to identify who the product is intended for, dosage rates and instruction and other important information pertaining to the patient or the medical marijuana derivative products, and 2) proper child-resistant packaging will help to ensure children cannot easily access the medical marijuana derivative product(s).

**Examples of Child-Resistant Packaging:**





Child Resistant Packaging to be used for pill-form edibles (*capsules*)



Child Resistant Packaging to be used for oils (*for sublingual administration*)



Metered Dosage Packaging to be used for oils (*vaporization administration*)



Tamper-Evident Packaging to be used for pill-form edibles (*capsules*)



Tamper-Evident Packaging to be used for oils (*for sublingual administration*)



Tamper-Evident Packaging to be used for oils (*for vaporization*)



**Labeling**—all packages of medical marijuana will require a label to be conspicuously placed on the package.

- Labels must be made of weather resistant and tamper-evident material
- As a redundancy, registered employees will be required to recheck each package for a label prior to shipping and package containing medical marijuana from the Licensed Premise.
- **Hawaii specific labeling requirements:**
  - Labels must use black lettering only on a white background with no pictures or graphics
  - Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
    - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
    - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
  - The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
  - The batch number and date of packaging;
  - A computer tracking inventory identification number barcode generated by tracking software;
  - Date of harvest or manufacture and a "use by date";
  - Instructions for use;
  - The phrases "For medical use only" and "Not for resale or transfer to another person";
  - The following warnings:
    - "This product may be unlawful outside of the State of Hawai'i and it is unlawful to possess or use under federal law";
    - "This product has intoxicating effects and may be habit forming";



- “Smoking is hazardous to your health”;
  - “There may be health risks associated with consumption of this product”;
  - “This product is not recommended for use by women who are pregnant or breast feeding”;
  - “Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug”;
  - “When eaten or swallowed, the effects of this drug may be delayed by two or more hours”
- A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
  - The name of the laboratory that performed the testing

**Examples of manufactured marijuana product labels:**

**SAMPLE PRODUCT LABEL: LOTION**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**LOTION**

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH**

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_  
NAME OF PRODUCTION CENTER

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: SALVE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**SALVE**

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH**

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_  
NAME OF PRODUCTION CENTER

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: SERUM**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**SERUM**

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH**

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_  
NAME OF PRODUCTION CENTER

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: GEL**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**GEL**

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH**

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_  
NAME OF PRODUCTION CENTER

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.



**SAMPLE PRODUCT LABEL: CAPSULE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**CAPSULE**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, time, or other details. Do not use if tamper-evident seal is broken, if the seal is missing, or if the seal is damaged. Do not use if the seal is damaged. Do not use if the seal is damaged. Do not use if the seal is damaged.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: TABLET**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**TABLET**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, time, or other details. Do not use if tamper-evident seal is broken, if the seal is missing, or if the seal is damaged. Do not use if the seal is damaged. Do not use if the seal is damaged.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: TINCTURE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**TINCTURE**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, time, or other details. Do not use if tamper-evident seal is broken, if the seal is missing, or if the seal is damaged. Do not use if the seal is damaged. Do not use if the seal is damaged.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: CO<sub>2</sub> OIL**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

**THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.** Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

**CO<sub>2</sub> OIL**

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Medicines can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**FOR MEDICAL USE ONLY**  
**SMOKING IS HAZARDOUS TO YOUR HEALTH.**

**THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREAST FEEDING.**

**INSTRUCTIONS FOR USE:**  
Type of device has method used including strength, amount, time, or other details. Do not use if tamper-evident seal is broken, if the seal is missing, or if the seal is damaged. Do not use if the seal is damaged. Do not use if the seal is damaged.

**ALLERGEN LABELING:**  
This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under Federal law.

**Net Wt:**

**NAME OF PRODUCTION CENTER**

**PRODUCTION BATCH STICKER**  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

- 1) **Secure, Segregated Storage**—Upon manufactured marijuana products being packaged, BPH registered employees will be required to hold the marijuana in secure, segregated storage until released for distribution
  - o The secure, segregated storage will be within the production center vault(s).



<b>Standard Operating Procedure:</b> Inventory Reconciliation Procedure
<b>Purpose:</b> To explain the purpose and processes involved with inventory reconciliation.
<b>Scope:</b> Covers the steps involved with inventory reconciliation.
<b>Initial Training:</b> 4-6 hours

### **The Principles of Inventory Reconciliation**

It is recommended to perform physical inventory on weekly or monthly basis. At minimum, a monthly inventory reconciliation is to be performed the production center. This is where every product within the facility will be physically counted, documented and then reconciled (*compared*) against the inventory recorded in the POS system or computer inventory system.

The physical inventory on-hand that is counted should be identical to the inventory that is recorded within the POS system. If there are deviations in these numbers then action must be taken to determine the shortage(s).

- 1) Count **ALL** on-hand inventory at the facility
  - Marijuana raw material
    - Marijuana trim leaf
    - Marijuana flower
  - Finished manufactured marijuana products
- 2) Document all counted on-hand inventories on the appropriate ***Marijuana Products Inventory*** log sheet.
- 3) Reconcile counted on-hand inventories against on-hand inventories in the POS system
  - Document discrepancies on the appropriate ***Marijuana Products Inventory*** and the ***POS Inventory Reconciliation*** and ***Product Loss Log Sheet*** between the counted on-hand inventory and POS inventory.
  - Investigate all discrepancies
- 4) Inventory Discrepancies—discrepancies between the inventory stock and the inventory within the inventory control system (*outside of normal weight loss due to moisture loss and handling*)
  - Investigate all discrepancies within one (1) business day
    - Perform inventory audit and reconciliation
    - Review transactions within the inventory control system
    - Review security surveillance footage
  - Report theft or diversion to the Department AND local Police within one business day
    - Contact the Department and local Police in multiple fashions as a redundancy
      1. Contact directly through phone conversation
      2. Contact electronically through email, fax or other electronic means
  - Within 30 days
    - the inventory discrepancy investigation must be conducted and completed
    - the standard operating procedures amended (*if needed*)
    - send an investigation report and audit to the Department

***Example of Manufactured Marijuana Products Inventory log sheet:***



### Manufactured Marijuana Products Inventory

<u>Date:</u>	<u>Raw Material Product Batch #/Plant ID #/Strain:</u>	<u>Raw Material Quantity:</u>	<u>Manufactured Marijuana Product Batch #:</u>	<u>Quantity</u>	<u>Employee 1:</u>	<u>Employee 2:</u>

Example of POS Inventory log sheet:

### Manufactured Products POS Inventory Reconciliation



<u>Date:</u>	<u>Product Name:</u>	<u>Product Batch #/Unique ID #:</u>	<u>Quantity On Hand:</u>	<u>Quantity in POS System:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Notes:</u>

Example of Product Loss log sheet:

### Product Loss Log Sheet



<u>Date:</u>	<u>Product Name/Category</u>	<u>Product Attribute # or Unique ID #</u>	<u>Total Quantity Loss:</u>	<u>Product Loss Valuation:</u>
				\$
<u>Reporting Employee:</u>	<u>Manager/Supervisor:</u>	<u>Product Loss Due To:</u>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<u>Internal Investigation:</u>	<u>Required Authorities Notified:</u>	<u>Authorities Notified (list all) :</u>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<u>Note/Comments:</u>				



Laboratory Testing

<b>Standard Operating Procedure:</b> Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana and manufactured marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Cultivation Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

**Equipment/Tools Required**

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

**POLICY**

To submit medical marijuana for lab testing.

**RESPONSIBILITY**

Production Manager, Extraction Manager or their designee.

**RECORDS**

BioTrackTHC™ Seed-to-Sale Inventory Tracking System and physical documentation log sheets

**PROCEDURES**

Any medical marijuana sample is tested at the lab for the required cannabinoid profile, contaminants, any pesticide/herbicide/fungicide used during production of the medical marijuana product, and any growth regulator used during production of the medical marijuana product. Test results will be transmitted directly from the Testing Lab to the Extraction Manager. The Extraction Manager will assign the test results to the extraction batch number and document results in inventory tracking software. The accurate cannabinoid profile information will be utilized in the production formulations and standard operating procedures for medical marijuana product production to ensure safe, secure, accurate and consistent cannabinoid dosing and labeling

**1. Post-Harvest:**

- a. The first phase of quality control consists of visually inspecting the leaves and flowers of harvested and cured marijuana. Upon approved inspection, samples of the leaves and flowers will be sent to a lab to test for potency and contaminants. A medical marijuana “leaves and flowers sample collection” SOP will be followed. Lab test results will be used:
  - i. to compare against post extraction results
  - ii. to ensure the cultivated and cured marijuana plants are of consistent quality and THC/CBD concentrations
  - iii. to create concentrates of consistent quality.
- b. Uniform and homogenous leaves and flowers samples will be placed within sealed, child-resistant containers. One sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the



sample to the testing lab. Remaining samples will be kept securely stored for future testing as required.

## 2. Post Processing:

- a. The second phase of quality control will test the extract produced from the leaves and flowers of the marijuana plant. A sample from each lot of extract will be tested to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. A uniform and homogenous sample will be placed within a sealed, child-resistant container. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab.

## 3. Finished Product:

- a. A number of samples, which accurately represent the production lot of the final medical marijuana product, will be selected for lab testing. Cannabinoid profile and contaminant testing will be performed to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. “Final medical marijuana product samples” will be submitted to the testing lab facility, sealed, packaged and labeled exactly as they will be delivered to a patient obtaining the product at a dispensing facility.
- c. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab. All final medical marijuana products will be kept secured in a limited access area until approved test results are received. No final medical marijuana product will be shipped to a dispensing facility until approved lab test results are received and the final marijuana product is labeled with test results.

## Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

## State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)



- Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.
  - If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the *Marijuana Waste SOP* upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

### **Preparation of Medical Marijuana Samples to be Tested**

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Manufactured marijuana products—ensure adequate quantity from batch for sampling (~2-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# MIP001 → Create new ‘Sample Package’: MIPT101
- Fill out all required documentation/log sheets
  - *Samples for Laboratory Testing*
  - *Marijuana Product Shipping Manifest*



### Marijuana Samples for Laboratory Testing

Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:

- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow *Shipping, Transferring/Transporting SOP*

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show marijuana product potency, cannabinoid profiles, terpene profiles, contaminants (if any present). The testing laboratory will provide BPH test results from each batch tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meets all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**— there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm$  90-100% of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating



It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.

- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<b><u>Marijuana Batch Samples for Laboratory Testing</u></b>						
<b>Date Sample Prepared:</b>	<b>Grower Agent #1:</b>	<b>Grower Agent #2:</b>	<b>Product Attribute ID #, Batch# and Strain/Variety</b>	<b>Sample Quantity/Weight:</b>	<b>Test Sample ID # (NEW) :</b>	<b>Receiving Laboratory:</b>
<b>Date Sample Shipped:</b>	<b>Sample Pass Testing</b>		<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>If sample failed testing, will batch be reprocessed or destroyed?</b>		<b>Licensed Processor to Send Batch to:</b>
	<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed		
<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>			<b>Notes/Details:</b>	
<b>Date of 6-month interval test:</b>	<b>Sample Pass Testing</b>	<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
<b>Notes/Comments:</b>						

**Release for Distribution**

All batches of marijuana products are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH’s registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.



- This process will be completed by two (2) registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

**Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.



Transferring/Transporting Marijuana Products Transferring/Transporting

## **Standard Operating Procedure: Transferring/Transporting Marijuana Products**

**Purpose:** To explain the steps required to be followed to transport marijuana and manufactured marijuana products to BPH retail dispensary locations.

**Scope:** Covers the training required and procedures for registered employees covering the transferring/transporting of marijuana and manufactured marijuana products.

**Initial Training:** 2-4 hours

### **The Principles of the Transferring/Transporting Procedure**

transport

#### **The Shipping Process:**

- 1) New Transfer/Transport Order
- 2) Fulfillment
- 3) Create Manifest/Trip Plan
- 4) Transportation
- 5) Delivery
- 6) Post-Delivery

#### **1) New Shipping Order**

- 1) Fill out *Marijuana Products Shipment (Outgoing)* log sheet
- 2) Create a new invoice for transport order
  - a. Date that order is placed
  - b. Products and quantities ordered
  - c. Prices of products
  - d. Estimated delivery date

#### **2) Fulfillment**

- 1) Collect products needed for transfer/transport order
- 2) Take ordered/collected products out of the inventory control system
- 3) Package the order of products into a container that is constructed on tamper-evident, opaque material
  - a. The use of tamper-evident cardboard boxes, hard plastic opaque cases that can be locked with tamper-evident seals or locks, or a similar shipping package that will meet Hawaii requirements
  - b. Seal said tamper-evident package with tamper-evident tape.
  - c. If shipping multiple packages to the same recipient, the packages will need to be shipped within one large opaque tamper-evident container.
- 4) **Repackaging**—if necessary, registered employees may have to repackage the shipment into a container that is constructed of tamper-evident opaque materials and sealed with tamper-evident tape
  - a. This will typically only happen if the original packaging is defective or gets destroyed.
  - b. Medical marijuana will need to be repackaged if not originally packaged in an opaque container.
  - c. Repackaging may be required if multiple packages are identified as being shipped to the same recipient
    - i. If this is the case, then the packages will need to be repackaged into one large opaque tamper-evident container and sealed with tamper-evident tape
      1. Ensure package is sealed with tamper-evident tape; seal all entry/access points
- 5) Complete the *Marijuana Products Daily Transfer/Transport* log sheet
  - a. Example of *Marijuana Products Daily Transfer/Transport* log sheet can be seen below:



### Manufactured Marijuana Products Daily Transfer

<u>Date:</u>	<u>Employee Preparing Transfer:</u>	<u>Manufactured Marijuana Product Name/Batch ID #/Strain:</u>	<u>Quantity Transported:</u>	<u>Receiving Retail Dispensary Location:</u>	<u>Receiving Employee:</u>

- 6) Create new record within the inventory control system for the products being shipped—registered employees will need to create a record of the products prior to shipping any marijuana products.
  - a. Information required on record:
    - i. Date and time of the sealing of the package for shipment
    - ii. Name a signature of the registered grower agent who prepared and sealed the package
    - iii. Name and address of BPH
    - iv. Shipment identification number
    - v. A description of the package being shipped including the weight of each item
    - vi. The name and address of the party receiving the shipment

### 3) Manifest/Trip Plan Creation—See *Marijuana Product Shipping Manifest SOP*

Prior to the transportation of any marijuana products or marijuana-infused products a facility agent will generate a manifest/trip plan including at a minimum:

- 1) The name of the agent(s) who will be transporting;
- 2) The automobile license plate, make and model;
- 3) The date, start time of the trip and estimated delivery time;
- 4) A description including the exact amount, type and batch of any marijuana products and marijuana-infused products being transported; and
- 5) The intended route of transportation.

Facility management shall maintain a copy of the manifest/trip plan document at the location of departure, record the manifest/trip plan with any needed authorities, and the transporting employees will maintain a copy of the manifest/trip plan during the transportation.

### 4) Transportation/Shipping

This section covers how to transport the wholesale order to the purchasing organization/facility. All applicable state and local laws/regulations pertaining to transportation of medical marijuana products will need to be strictly adhered to by all organization team members. All transportation/shipping to be done in-house by BPH registered employees and/or transportation agents. BPH does not intend to use a secure transportation company unless deemed absolutely necessary.

**Transportation Vehicle Requirements**—all agents responsible for transporting medical marijuana must:

- 1) Use of an unmarked, unidentifiable vehicle
  - a. Vehicle should not have any BPH markings, logos or identifiers on the vehicle
  - b. Vehicle should not raise awareness that it may be transporting medical marijuana and/or medical marijuana products of any kind



- 2) Ensure the vehicle has current, valid registration from the State
  - a. Registration paperwork should be located in vehicle glovebox
  - b. Vehicle license plate should have current, valid registration sticker
- 3) Ensure the vehicle has current valid proof of insurance
  - a. Proof of insurance paperwork should be located in the glovebox

**Transportation Agent Requirements**—all agents responsible for transporting medical marijuana must:

- 1) There will be at minimum two registered employees and/or transportation agents for every product shipment. Each transportation agent will play a separate and vital role.
  - o One transportation agent will be required to drive the transportation vehicle and to remain with the transportation vehicle at all times.
  - o The second transportation agent is to remain with the medical marijuana product be shipped at all times and to ensure that the product is secure at all times during transport.
- 2) Wearing appropriate work attire
  - o Work attire for BPH transportation agents will be plain with no company logos, brands or identification.
  - o BPH transportation agents should not appear to indicate ownership or possession of marijuana.
    - Plain polo shirt
    - Plain khakis/jean pants
    - Plain dress/tennis shoes
    - Failure to arrive to a scheduled shift with proper attire will result in not being able to make transports, incident noted in personal file and possible disciplinary action.
- 3) Possess a current and valid State-issued marijuana industry worker license;
- 4) Possess a current and valid State-issued driver's license;
- 5) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or marijuana-infused products pursuant to regulation, all transporting agents shall:

- 1) Carry a copy of the manifest/trip plan with him or her for the duration of the trip;
- 2) Wear their agent card and/or have Commission approved identification readily available;
- 3) Use a vehicle without any medical marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or marijuana-infused products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation as well as a back-up emergency cell phone; and
- 5) Ensure that the medical marijuana is not at all visible to the public.

## **5) Delivery**

- 1) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the shipping manifest/trip plan
- 2) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

## **6) Post-Delivery**

**Post-Delivery Protocol**—after transporting marijuana products or marijuana-infused products, pursuant to the regulations the employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.



**Documentation of Delivery**—both the transporting dispensing facility and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Division agents for review upon request.

**Deviations from Transportation Plan**—the transporting agent shall immediately report all diversion due to loss or theft of marijuana or marijuana-infused products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the state licensing authorities as required per state regulations. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



<b>Standard Operating Procedure:</b> Marijuana Product Transport Manifest
<b>Purpose:</b> To explain the requirements for the marijuana products shipping manifest
<b>Scope:</b> To educate and train registered employees on the creation and use of the marijuana products shipping manifest
<b>Initial Training:</b> 1-2 hours

**Principles of the Electronic Manifest**

The shipping manifest will be required for each and every transfer/transport of marijuana product from BPH’s production center. Registered employees will be required to complete the physical marijuana product shipping manifest form.

Prior to transporting a package containing marijuana and/or manufactured marijuana products, BPH will require registered employees to complete the marijuana product shipping manifest process. Registered employees will need to complete the manifest form and scan/email a copy of the manifest to the retail dispensary location recipient. Registered employees and/or transportation agents will also maintain two (2) physical copies of the manifest form to keep and have present during any transporting of marijuana products. Upon delivery of the marijuana products, the shipping registered employee will provide a physical copy of the manifest for the recipient to maintain.

**Requirements**

All shipment are required to use a manifest for chain of custody procedures and to ensure safe transport of marijuana products and that no theft or diversion is occurring during transport. BPH will utilize a manifest to record the chain of custody for the shipment of products containing marijuana. The manifest will include a chain of custody that records:

- The name and address of the shipping licensee;
- The shipping licensee’s shipment identification number;
- The weight and description of each individual package that is part of the shipment, and the total number of individual packages;
- The name of the registered employee that prepared the shipment;
- The name and address of the receiving licensee; and
- Any handling or storage instructions.

**Chain of Custody**—shipments with packages containing marijuana will need to be tracked and recorded throughout the transport process within the inventory control system. The chain of custody for all transports containing medical marijuana must be accurately documented within the manifest and inventory control system.

The inventory control system will contain, at a minimum, the following entries as a chain of custody, in the order listed:

- An entry by the registered employee who has prepared the shipment, including the date and time of preparation;
- An entry by a shipping licensee’s registered employee, of the date and time of the placement of the shipment into the marijuana product transport vehicle;
- An entry by licensee’s registered employee receiving the shipment including the date and time of the acceptance; and
- If any other person had custody or control of the shipment, that person’s identity, the circumstances, duration, and disposition.



A manifest **MUST** be created for **EACH** shipment of products containing medical marijuana.

BPH will require registered employees to complete a ***Marijuana Product Transport Manifest Form*** prior to transporting or shipping any marijuana and/or manufactured marijuana products. Refer to the ***Transport/Transfer Marijuana Products SOP*** for transportation requirements. ***Marijuana Product Transport Manifest Form can be seen below:***

		<b><u>Marijuana Product Transport Manifest</u></b>		<b>Transfer Identification #:</b>		<i>Test results included for ALL products being shipped?</i> YES NO	
*This form must be completed prior to the shipping of any marijuana or manufactured marijuana products. This Record for Transfer must be present along with the Transportation/Trip Manifest Form with ALL shipments of marijuana and/or manufactured marijuana products from the Licensed Premise.							
Date Package/Shipment Sealed:		Time Package/Shipment Sealed:		License # of Originating Entity:			
Name of Registered Employee who prepared and sealed the package:							
Signature of Registered Employee who prepared and sealed the package:							
Name of Originating Entity: Blue Planet Healing LLC							
Address of Originating Entity:						Phone #:	
						Email:	
*If you are delivering more than fifteen (15) products to one stop, use a second form to list the additional product(s).							
<input type="checkbox"/> Check Here if multiple pages are used <span style="float: right;">List the total number of pages in the Manifest here _____.</span>							
Receiving Retail Dispensary Location Information			Marijuana/Product(s) within the Shipment	Quantity/Weight	Attribute #/Product ID #		
Stop Number on Route:			1)				
Name of Receiving Party:	Blue Planet Healing LLC		2)				
License # of Retail Dispensary Location:			3)				
Address of Receiving Retail Dispensary Location:			4)				
			5)				
Phone # of Receiving Dispensary:			6)				
Date and Approximate Time of Departure:			7)				
Date and Approximate Time of Arrival:			8)				
Route to be Traveled:			9)				
			10)				
			11)				
			12)				
			13)				
			14)				
			15)				
Additional Description: <i>(add description/details about the marijuana products and/or manufactured marijuana product(s))</i>							
<b>PRODUCT REJECTION</b> <i>(if only a portion of the shipment is rejected, circle that portion above.)</i>							
Name of Person Receiving or Rejecting Product(s):						Date:	
<i>I confirm that the contents of this shipment match the weight records above, and I agree to the custody of those portions of this shipment NOT circled above. Those portions that ARE circled above were returned to the individual delivering this shipment.</i>							
Signature:				Signature of Individual Taking Receipt of Rejected Portion of this Shipment:			
Name of Person Transporting Product(s):				Signature of Person Transporting Product(s):			
Make, Model, License Plate #:						Date of Signature:	



Customer Complaints and Returns

**Standard Operating Procedure: Customer Complaints and Returns**

**Purpose:** To explain the steps involved for handling customer complaints and product returns.

**Scope:** Covers the steps involved to handle customer complaints and product returns appropriately.

**Documentation Log Sheets Required**

- 1) Customer Complaint Form
- 2) Returned Marijuana Products Log Sheet
- 3) Returned Marijuana Products Waste

**The Principles of Handling Customer Complaints and Product Returns**

It is important to have proper procedures in place for the handling of customer complaints and/or product returns. By having these initiatives in place you can ensure the most satisfied customer base possible. Below are best practice steps to take when confronted with a customer complaint and/or product return.

**State of Hawaii Requirements**

- In the event a complaint is associated with a serious adverse event, BPH will require registered employees to:
  - Promptly report the complaint to the Commission
  - Report the complaint to any licensed processor or licensed dispensaries that may have received a shipment containing medical marijuana from the batch determined to cause the complaint
- As required by State of Hawaii regulations, in the event a complaint associated with a serious adverse event, BPH will be required to promptly report the complaint to, (1) the Commission, (2) either the licensed grower from which the medical marijuana originated, or the licensed processor from which the medical marijuana concentrate originated, (3) the certifying physician caring for the qualifying patient.
  - As a licensed grower operation, BPH's registered employees will be limited to report to the Commission in the event a complaint is associated with a serious adverse event.
    - Within 24-hours registered employees must report the complaint to the Commission

**Recalling of Medical Marijuana**—if a batch or lot of medical marijuana is determined through testing to fail to meet specification, BPH will do the following:

- Order a recall of all products derived from or included in the batch
- Notify all dispensaries and/or processors who may have obtained medical marijuana products from such a batch or lot of the recall
  - Using the inventory control system and/or physical documentation log sheets/records to identify all licensed processors and/or licensed dispensaries that may have received a distribution containing medical marijuana from the production batch or lot
  - After identifying the licensed processors and/or dispensaries, registered employees will be required to directly notify said companies.
- Offer and pay reimbursement for any returned medical marijuana
  - Offer to replace the medical marijuana product free of charge or offer full monetary reimbursement to the licensed processors and/or licensed dispensaries.

**Handling Customer Complaints**—when a customer wishes to make a formal complaint, follow the following procedures:

- Have customer wishing to form a complaint to complete the *Customer Complaint Form*
- File complaint within the customer complaint folder located within a limited-access area within the Licensed Premise
- Notify management of the formal complaint
- Notify the Department of the formal complaint

	<i>Customer Complaint Form</i>	
	<b>Date:</b>	<b>Location:</b>
	<b>Customer Name:</b>	
	<b>Employee Documenting Complaint:</b>	<b>Supervisor on Duty:</b>
	<b>Description of Complaint:</b>	
	<b>Corrective Action to be Taken:</b>	
	<b>Customer Comments:</b>	
<b>Customer Signature:</b>		
<b>Date:</b>		
<b>Employee Signature:</b>		
<b>Date:</b>		

In the event of a formal complaint regarding the quality or safety of medical marijuana is received, BPH will require registered employees to review and investigate the complaint within 24-hours to determine:

- If the complaint is substantive or reports a serious adverse event
- Determine the batch number of the marijuana—this can be accomplished using the records and documentation maintained throughout the cultivation process to determine if there were any deviations in production
  - If the complaint is substantive or reports a case of a serious adverse event, registered employees will determine the batch number of the marijuana
  - Registered employees will be required to investigate the record and circumstances of the production of the batch and lot to determine:
    - If there was a deviation from the standard operating procedure in the production of the medical marijuana by reviewing production logs, records and documentation
      - Test retention samples of the batch and lot to an independent testing laboratory.
        - Send retention samples from batch and lot in question to licensed testing laboratory for testing
          - If testing reveals that the batch or lot fails to meet specifications, follow steps for recall below in following SOP
          - Notify any and all patients, caregivers and dispensaries who may have obtained medical



marijuana products from such a batch or lot of the recall

- Use the inventory control system and physical records to determine who may have received a batch of medical marijuana from the recalled batch
- Upon identifying retail dispensary locations that have received marijuana from the batch in recall, registered employees will need to notify the licensed dispensary directly with two means:
  - Via phone call, AND
  - Via email

**Investigation of Complaint**—BPH will require registered employees to investigate all complaints regarding the quality or safety of medical marijuana. Registered employees will be required to review records and documentation from the cultivation operations to determine if there was any deviation from production.

- Review all cultivation records and documentation log sheets
  - Try to determine if there were any deviation in production
  - If there is a deviation in production, see *Standard Operating Procedures SOP*
  - Determine the batch number and/or lot number of the medical marijuana
    - Reviewing records and documentation for substantive changes in production
- Meet with complainant to understand the serious adverse event (*if applicable*)
  - Meeting with the complainant registered employees may be able to identify the medical marijuana batch associated with the complaint
- Order a recall of the medical marijuana batch if necessary; follow *Product Recall SOP*

**Handling Customer Returns** – When a customer wishes to return a product, perform the following procedure:

- Acquire the product needing to be returned and begin the process of completing the Returned Marijuana Products Log Sheet
- Ask for the reason as to why the product is being returned and record this information.
- Log the product as being returned into the electronic inventory tracking system
- Offer and pay reimbursement for the medical marijuana products tracking system.
- Ensure that the Returned Marijuana Products Log Sheet is completed and filed.

*Example of a Returned Marijuana Products Log Sheet:*

<b><u>Returned Marijuana Products Log Sheet</u></b>					
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Patient/Caregiver Returning Cannabis Product:</u>	<u>Marijuana Product Returned (Name/Attribute#):</u>	<u>Quantity/Weight:</u>	<u>Reason for Product Return</u>



*Example of a Returned Marijuana Waste Log Sheet:*



### Returned Marijuana Waste Log Sheet

<u>Date:</u>	<u>Registered Employee:</u>	<u>Qualified Patient/Caregiver:</u>	<u>Marijuana Product to Dispose:</u>	<u>Waste Weight:</u>	<u>Mixed With:</u>	<u>Total Weight to Dispose:</u>

Product Recall

<b>Standard Operating Procedure:</b> Product Recall
<b>Purpose:</b> To ensure that all required steps and procedures are take when there is a need to recall a marijuana product.
<b>Scope:</b> Procedures covering voluntary and involuntary product recalls.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required Within the Cultivation Facility

- 1) Product Recall Log

#### Principles of Product Recall

Manufacturers, importers, distributors and retailers of consumer goods are liable for the products they provide to consumers and face the potential of product recalls for potentially dangerous or hazardous products. The same is true for the marijuana businesses as manufacturers and retailers of consumer medical marijuana products, for the facility may need to conduct a product recall in the future. For most consumer products the recall process is handled and regulated by the Consumer Product Safety Commission (CPSC), and for all intents and purposes the marijuana business recall plan will follow the guidelines of the CPSC.

The Consumer Product Safety Commission (CPSC) has compiled resources to assist companies that manufacture, import, distribute, retail, or otherwise sell consumer products. CPSC has developed a Recall Handbook that can be utilized in case a product recall needs to be ordered. The Recall Handbook details how to recognize potentially hazardous consumer products as soon as possible. The book explains how to develop and implement a “corrective action plan” (called a CAP) to address the hazards; it explains CPSC’s Fast Track Program. The Recall Handbook also discusses how to communicate recall information to consumers and how to monitor product recalls. The Consumer Product Safety Commission’s Recall Handbook will be a valuable tool utilized by the company if the need for a product recall ever arises.

The Recall Handbook should be referenced to determine exact protocol for recall and the requirements from the Consumer Product Safety Commission. The Recall Handbook can be obtained online from <http://www.cpsc.gov/PageFiles/106141/8002.pdf>.

#### **When to Recall Medical Marijuana Products**

As a manufacturer, distributor, and/or retailer of consumer products, the cultivation facility has a legal obligation to immediately report the following types of information:

- 1) A defective product that could create a substantial risk of injury to consumers;
- 2) A product that creates an unreasonable risk of serious injury or death;
- 3) Marijuana or manufactured marijuana is determined to contain a contaminate of some kind

- 4) Marijuana or manufactured marijuana batch did not successfully pass required testing but was released for distribution

Failure to fully and immediately report this information may lead to substantial civil or criminal penalties. Consumer Product Safety Commission's staff advice is "when in doubt, report." BPH will ensure communication with the required state and local authorities within 24 hours of becoming aware of the need for a product recall. BPH will then proceed to the recalling protocol and how to recall the product.

### **How to Recall Medical Marijuana Products**

The facility will develop a recall plan following guidance from the Recall Handbook provided by the CPSC. Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by state regulations will ensure a stream-lined recall process if ever necessary.

### **Corrective Action Plan (CAP)**

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and steps needed to be taken by the facility once a product recall is required.

### **Step One: Industry Notification**

If a marijuana or manufactured marijuana product is believed to need a recall, BPH will contact all retail dispensary locations to notify them of the situation and the need for product recall. BPH will also contact required state and local authorities within 24 hours of obtaining reportable information. As the cultivator and/or manufacturer of the product needing to be recalled, BPH will need to contact the end users of the recalled product; contacting qualified patients will prove to be difficult, but will be possible through the utilization of the inventory control and POS systems. At this stage of the recall, retail dispensary locations will need to ensure that they have a proper recall process in place to contact qualified patients that were dispensed the product being recalled.

### **Step Two: Public Notification**

The cultivation facility or dispensing establishment will post notifications about the product recall on its website as well as make partnering cultivation centers and dispensing organizations aware of the product recall. The actual recalling processes will be handled by both the cultivation center and the dispensing organizations.

As the dispensing organization issuing a recall notice, it will be important to reach the end users or the recalled product. The facility will post notification about the recall on Facility websites and social media as well as post written notices of the recall on location for patients and customers to view. The recall notice will include all pertinent information regarding the product being recalled, contact information and other information relating to the recall. Information will include but not be limited to:

- 1) Product name and unique attribute number
- 2) Product batch number
- 3) Dispensing date range of recalled product
- 4) Retail dispensary locations

Once the recall notification has been issued to all applicable dispensing organizations and medical marijuana patients, the facility will wait to receive recalled products from dispensing organizations and/or licensed medical marijuana patients and caregivers. Once recalled products have been received, the facility will properly dispose of all recalled products. The disposal of these products should conform to the state regulations for waste disposal.

### **Step Three: Procurement**



BPH issuing a product recall to qualified patients and primary caregivers will need to be ready to obtain and secure recalled products from qualified patients. Patients should be able to bring in the products being recalled to the retail dispensary location. It will be at BPH’s discretion whether to issue a refund, replace the recalled product at no cost, or to take other measures.

- Upon receiving recalled marijuana and/or manufactured marijuana products, registered employees will document the return of the recalled marijuana product
- After documentation, registered employees will securely store the recalled marijuana product in segregated storage until disposal
  - Recalled medical marijuana must be securely stored until properly destroyed and disposed of.

**Step Four: Documentation and Record Retention**

BPH will maintain all documentation all records regarding any and all product recalls issued. Registered employees will be required to fill out the required *Product Recall Log Sheet*.

<u><b>Product Recall Documentation Log Sheet</b></u>				
<u>Date:</u>	<u>Product Name</u>	<u>Product Attribute # or Unique ID #</u>	<u>Quantity to be Recalled</u>	<u>Supervisor</u>
List Potential Patient/Caregivers to Notify:				
Regulatory Agencies Notified: <input type="checkbox"/> MMCC <input type="checkbox"/> FDA <input type="checkbox"/> CSPA <input type="checkbox"/> Other				
<u>Date:</u>	<u>Quantity Collected:</u>	<u>Collected From (Patient/Caregiver):</u>	<u>Accepting Employee:</u>	<u>Notes/Details</u>

**Step Five: Disposal**

The facility will ensure that any and all recalled marijuana products are disposed of according to all state and local regulations. The facility will follow marijuana waste disposal and destruction procedures outlined within these SOP’s for proper disposal of recalled medical marijuana.

- Recalled material must not be destroyed or disposed of until authorized by the Commission.
  - Recalled medical marijuana will need to be stored and segregated until the disposal of recalled material is authorized by the Commission.
    - Stored recalled material in the quarantined secure storage area of the Licensed Premise.
- Once receipt of notification from the Commission that the disposal of recalled medical marijuana is authorized, registered employees will dispose of the medical marijuana according to the *Marijuana Waste Disposal SOP*.
  - Registered employees must dispose of medical marijuana within 24-hours of Commission authorization.



Marijuana Waste Destruction and Disposal

<b>Standard Operating Procedure:</b> Marijuana Waste Destruction and Disposal
<b>Purpose:</b> To explain required and proper disposal processes for marijuana waste.
<b>Scope:</b> Covers marijuana waste grinding, mixing and disposal measures within the retail dispensing facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Marijuana Waste Disposal Log

**Equipment/Tools Required**

- 1) Wood chipper/plant grinder
- 2) Mixing material (material to mix marijuana waste with at 50/50 ratio)
- 3) Trash bags
- 4) Dumpster/trash compactor

**Requirements of Marijuana Waste Disposal**

All marijuana waste, byproducts, undesired materials, green waste and returned/recalled marijuana will be destroyed by rendering the waste unrecognizable, unusable and unrecoverable.

BPH will require registered employees to weigh, document, record and destroy all marijuana waste according to the written standard operating procedures. All marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated will be destroyed and disposed of according to the written SOP.

**Secure, Segregated Storage**—all medical marijuana waste will be stored in secure, segregated storage on the Licensed Premise until receipt of authorization from the Commission of destroy and dispose of the medical marijuana waste.

- The secure, segregated storage will promote good growing and handling practices.

**Marijuana Waste Disposal**—all medical marijuana waste, byproducts and undesired products will be destroyed and disposed of according to all applicable state and local regulations. Facility management will ensure proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state regulations. Record all required information on the *Marijuana Waste Log Sheet*.

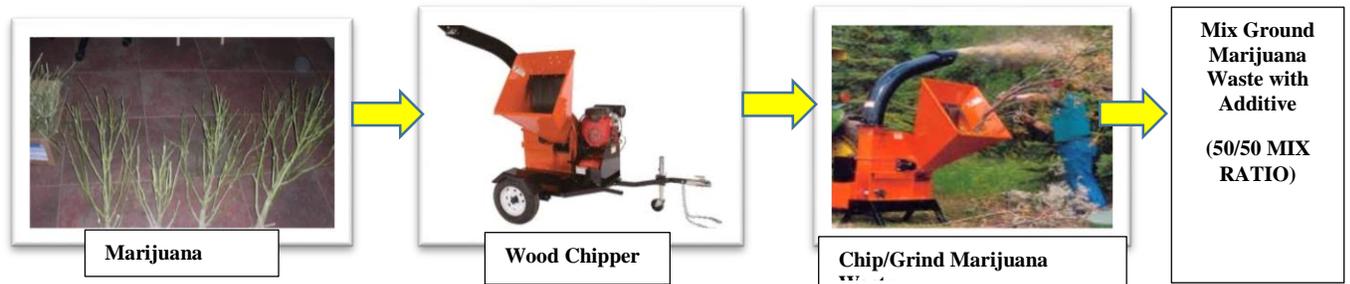
**Disposal**—Disposal of any marijuana product waste must be rendered unrecognizable, unusable and unrecoverable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:



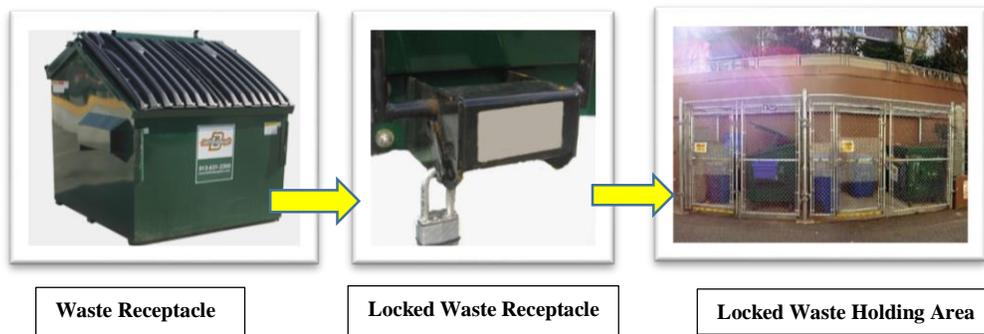
- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.



**Grinding Marijuana Waste (Stalks, Stems, Leaves and Other Material)**



**\*\*BPH shall not dispose of marijuana product waste in an unsecured waste receptacle not in possession and control of the licensed premise. It is recommended to have a lock on the physical dumpster as well as the area where the dumpster is maintained.**







Facility Cleaning and Sanitation

<b>Standard Operating Procedure:</b> Facility Cleaning and Sanitation
<b>Purpose:</b> To explain required and proper cleaning and sanitation practices.
<b>Scope:</b> Covers cleaning and sanitation measures within the cultivation facility.
<b>Initial Training:</b> 4-6 hours

### **What is the Purpose of Cleaning and Sanitation?**

Proper cleaning and sanitation practices are essential within the cultivation facility. A clean and sanitary cultivation facility will reduce the risk of pests, insects and diseases. The marijuana plants can only be as clean as the room in which they are cultivated. The goal is to produce the safest medicinal marijuana within a clean and sanitary facility.

### **Documentation Log Sheets Required**

- 1) Cleaning and Sanitation Log Sheet

### **Equipment/Tools Required**

- 1) Personal Protective Equipment (PPE)
- 2) Broom and Dust Pan
- 3) Mop and Mop Bucket
- 4) Bleach
- 5) Cleaning Towels
- 6) Paper Towels

### **Principles of Cleaning and Sanitation**

To prevent the accumulation of marijuana oils, resins, plant material, and any remaining pests, strict cleaning procedures must be followed. Cleaning and sterilizing surfaces will aid in pest management, as well as lowering overall microbial levels in processing areas, and on product. Cultivation areas will undergo thorough cleaning in between the harvest stages, and plants reentering the room. Once all plants are harvested, all non-permanent growing equipment will be removed, including pots, plant carts, scissors, etc. Registered employees will thoroughly vacuum all surfaces to remove dust, loose debris, and any plant material. The entire room will then be systematically misted with a chlorine dioxide solution. This chlorine dioxide solution will begin to break down and sterilize any organic material so it may be easily wiped off in the next step. This spray will also enter small spaces not easily reached by manual cleaning. Fans will remain running during this spraying operation to ensure mist is moved around the room thoroughly. Employees will then wipe all surfaces down with the same chlorine dioxide solution. These two steps combined will assure all surfaces are clean and sterile.

During daily operation tools, which come in contact with marijuana, will be soaked in isopropyl alcohol. Transport carts, worktables, and other cultivation furniture will undergo weekly cleaning and sterilizing. After growing medium



is disposed, plant containers will be washed and sterilized using a powered washing machine. Pots will be sterilized using a hydrogen peroxide solution, and dried before use.

Due to the nature of marijuana products, cleaning surfaces in processing areas is crucial. Build up caused by marijuana can be very difficult to remove when left for long periods of time. For general removal of resins, a disposable cloth is coated with 91% isopropyl alcohol, and used to wipe all surfaces free of material. For heavily soiled areas use a metal scraper to remove resins. Marijuana trimming machines require daily cleaning to maintain performance, and sterility. Machines will be disassembled, and separated depending on cleaning method. Metal parts are cleaned using isopropyl alcohol; all other parts will be cleaned and sterilized using a steam cleaner.

Drying trays will be sterilized in between each use; wiping trays with isopropyl alcohol will do this. Drying trays will be thoroughly cleaned monthly by first soaking them in hot water to loosen and material, then wiping trays down with isopropyl alcohol. Curing containers will be cleaned and sterilized between uses by wiping down all surfaces with isopropyl alcohol. Drying racks will also be wiped with isopropyl alcohol in between uses.

All areas of the facility, which will contain any marijuana product, or equipment, will have Puradigm air & surface sterilizing technology installed. This system uses advanced oxidation, and multi-cluster ionization technology to instantly kill bacteria, mold, mildew, and other microbes. General maintenance is required on these systems including changing bulbs, changing filters, and general cleaning. This maintenance is done according to the manufacturers recommendations.

After each drying period is complete, drying rooms will be vacuumed to remove dust and plant debris. All surfaces in the room will be wiped with hydrogen peroxide or bleach solutions. The processing, drying, curing, and packaging rooms will be cleaned thoroughly after each harvest. All floors are first vacuumed to be free of dust and plant debris. All surfaces are wiped clean and sterilized using either hydrogen peroxide or bleach solution. This step will assure no microbial cross contamination between harvests.

Apart from clean entry protocols practiced by agents, incoming soil and equipment must also be sterilized. Incoming pallets of soil will be kept in a quarantine room containing Puradigm sterilizing technology. Once the allotted time of air sterilization occurs, the pallets will be moved into a clean room air shower. In the air shower, ions will be dispersed to remove static electricity from plastic bags. Compressed air is blasted at the contents of the air shower, and the air is removed, and filtered.

Major cleaning and sanitation should be done within the cultivation facility when specified by the ***Cleaning and Sanitation Schedule***. Vegetative/flowering rooms should be thoroughly cleaned after the zone/room is completely emptied of all plants. This will be done when moving vegetative plants from the vegetative zone/room into the flowering zone/room or once a flowering room's plants are completely harvested and the room is emptied.

#### **General Daily Cleaning at the Facility:**

- **General Area(s)**
  - All hallways and accesses will be swept and mopped daily
  - All trash and debris should be collected and removed from the facility general areas on a daily basis
  - The bathrooms should be kept clean and maintained by each employee on a daily basis
  - Parking lot area should be maintained on a regular basis; free of trash and debris
- **Entry (*man trap*)**
  - The "man trap" area should be thoroughly cleaned and sanitized on a daily basis
    - Sweep floor
    - Sanitize floor, walls, door handles
  - Sanitizing footbath solution will be changed every other day

#### **Specific Cleaning at the Facility:**

- **Manufacturing Room(s):**
  - Beginning at the top of the room, dust, and wipe down all surfaces with a 5% bleach solution
    - Be sure to wipe all surfaces thoroughly
  - Sweep and vacuum (*wet/dry shop vac*) all floors



- Mop all floors with a 5% bleach solution and allow to dry
- Check to assure all surfaces have been sterilized
- Once a zone/room has been properly cleaned and sanitized, employees are required to properly document the activities on the *Cleaning and Sanitation Documentation Log*.

*Example of Cleaning and Sanitation Documentation log sheet:*

<u><b>Cleaning and Sanitation Documentation</b></u>					
<b>Date:</b>	<b>Zone/Room Cleaned:</b>	<b>Cleaning Agent(s) Used:</b>	<b>Reason for Cleaning:</b>	<b>Notes/Comments:</b>	<b>Cleaned By (initial) :</b>

**GENERAL PRINCIPLES OF SANITATION**

**PURPOSE/POLICY:**

The purpose of this policy is to define the general principles of sanitation throughout the marijuana product manufacturing area of the facility. All equipment will be maintained and sanitized in each operating unit at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality or purity of the medical marijuana product beyond its established specifications. Marijuana and marijuana products will be handled and held in a manner that prevents growth of pathogenic microorganism or formation of toxins. Major equipment will be assigned individual maintenance logs. Written programs will be established and followed for the maintenance of major equipment.

**ENVIRONMENTAL HEALTH (EHS) STATEMENT:**

“Any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have an infection, communicable disease (including but not limited to: diphtheria, measles, Salmonella enterica serotype Typhi infection, shigellosis), open or draining skin lesion, or any illness accompanied by diarrhea or vomiting, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, packaging components, in-process materials, marijuana, marijuana products, or contact surfaces, shall be excluded from working in any operations that may result in contamination until the health condition no longer exists. Employees are required to report any personal health condition that might compromise the cleanliness or quality of the medical marijuana the employee might handle.”

**SANITATION SYSTEMS:**

- ProKure-V
- Puradigm or AirOClean 420 air purification system

**RESPONSIBILITIES:**

- All Facility personnel must be aware of and have a proficient understanding of Company Sanitation policies and procedures:
- General Manager
- Extraction Manager
- Production Manager



- Extraction Tech
- Production Tech
- Sanitation Manager or his or her designee

## PROCEDURES:

1. The production facility will include an air purification system appropriate for the size of the room which will be checked daily to ensure it is functioning properly. This system will be employed to kill airborne molds and fungus. (Paradigm or AirOClean 420).
2. Before daily processing begins, evaluate that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for marijuana or marijuana product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.
3. All persons working in direct contact with preparation of marijuana or marijuana product shall conform to hygienic practices while on duty, including but not limited to:
  - a. Maintaining adequate personal cleanliness.
  - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Marijuana Product and at any other time hands/gloves may have become soiled or contaminated.
  - c. Wear company-issued, disinfected, outer-garments (scrubs) in a manner that protects against the contamination of components, packaging components, in-process materials, marijuana, marijuana-derived products, or any contact surface.
  - d. Remove all unsecured jewelry and other objects that might fall into components, marijuana products, equipment, or packaging, and removing hand jewelry that cannot be adequately cleaned during periods in which components, packaging components, in-process materials, or marijuana are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that effectively protects against contamination.
  - e. Maintain gloves of an impermeable material used in handling components, packaging components, in-process materials, and marijuana in an intact, clean, and sanitary condition.
  - f. Wear, where appropriate, hairnets, caps, beard covers, or other effective hair restraints.
  - g. Not eat food, chewing gum, drink beverages, or use tobacco products in areas where components, packaging components, in-process materials, marijuana products or any contact surfaces are exposed, or where contact surfaces are washed.
  - h. Take any other precautions necessary to protect against the contamination of components, packaging components, in-process materials, marijuana, marijuana-derived products, or contact surfaces with microorganisms, or other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
  - i. Take all precautions necessary to prevent unauthorized access to controlled access areas, and to maintain strict control of in-process materials marijuana and marijuana waste.
4. All persons working must ensure there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Marijuana or Marijuana Product.
5. All persons working must ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Marijuana or Marijuana Products are exposed.
6. All persons working must ensure that floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair.
7. All persons working must ensure that there is adequate safety-type lighting in all areas where Marijuana or Marijuana Products are processed or stored and where utensils or equipment are cleaned.



8. All persons working must ensure that the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming attractant, harborage, or breeding place for pests.
9. Bi-monthly room sanitation will be performed by fumigation (ie: fogging the room with ProKure-V).
10. Daily sanitation will also include spraying all production and extraction surfaces and equipment with ProKure-V).
11. All persons working must ensure that any buildings, fixtures, and other facilities are maintained in a sanitary condition.
12. All persons working must ensure that all contact surfaces, including utensils and equipment used for the preparation of Marijuana or Marijuana Product shall be cleaned and sanitized as frequently as necessary to protect against contamination.
  - a. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.
  - b. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Marijuana or Marijuana Product Manufacturing Facility and used in accordance with labeled instructions.
13. All persons working must ensure that toxic cleaning compounds, sanitizing agents, solvents used in the production of Marijuana Concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Marijuana, Marijuana Concentrate or Marijuana Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance.
14. All persons working must ensure that the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system.
15. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs.
16. Plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the facility and that shall properly convey sewage and liquid disposable waste from the Licensed Premises.
  - a. There shall be no cross-connections between the potable and wastewater lines.
17. All persons working must ensure that the Manufacturing Facility is providing its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair.
18. All persons working must ensure that all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Marijuana or Marijuana Product shall be conducted in accordance with adequate sanitation principles.
19. All persons working must ensure that Marijuana or Marijuana Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.
20. All persons working must ensure that storage and transport of finished Marijuana Product shall be under conditions that will protect against physical, chemical, and microbial contamination as well as against deterioration of any container.

#### **Corrective Action**

1. If, after visually inspecting all areas mentioned in the General Sanitary Requirements list, the supervisor finds areas that are not clean or in compliance, all procedures must be repeated until cleanliness is achieved.
2. Record corrective actions on Laboratory or Food Safety Checklist.



## **CLEANING AND SANITATION OF FILLER**

**RESPONSIBILITY:** Sanitation Supervisor or his or her designee

**FREQUENCY:** Sanitation to take place immediately before daily operations begin; 2. Filler to be rinsed with water only at each break (mid-morning, lunch, mid-afternoon); 3. Full cleaning and rinsing to take place after each work shift

**RECORDS:** *Production Kitchen Sanitation Checklist*

### **PROCEDURE:**

1. Before daily processing begins, sanitize filler and all filler parts with 65 p.p.m chlorine solution. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper p.p.m level. Pour bleach solution into filler. No rinse is necessary.
2. At mid-morning break, during lunch break, and during the mid-afternoon break, use yellow broom and black shovel to remove debris. Use black shovel to scoop debris into inedible waste container.
3. Use yellow mop bucket with mop to remove gross debris and sanitize floor, under filler and adjacent areas, with 200 ppm chlorine solution. Mix 3 gallons of water with 2 teaspoons full of unscented bleach in a 5 gallon bucket. Check the chlorine solution with tester strips to ensure proper ppm level. Pour bleach solution into mop bucket and use mop to remove gross debris and sanitize floor.
4. At the end of the shift, use yellow broom and black shovel to remove debris from floor. Use black shovel to scoop debris into inedible waste container.
5. Use yellow mop bucket with mop to remove gross debris and sanitize floor, under filler and adjacent areas, with 200 ppm chlorine solution. Mix 3 gallons of water with 2 teaspoons full of unscented bleach in a 5 gallon bucket. Check the chlorine solution with tester strips to ensure proper ppm level. Pour bleach solution into mop bucket and use mop to remove gross debris and sanitize floor.
6. Rinse filler and parts with water from a 5 gallon bucket full of hot water. Remove all filler parts and place into the wash compartment of the three compartment sink for proper cleaning, rinsing, and sanitizing. Mix 5 gallons of water with 2 tablespoons full of High Performance Double-Action Detergent. Pour detergent solution into the wash compartment of three compartment sink. Pour 5 gallons of hot water into the rinse compartment of the three compartment sink. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a 5 gallon bucket. Check the bleach solution with tester strip to ensure it is at the proper 65 ppm level for sanitizing. Pour bleach solution into the sanitize compartment of the three compartment sink.
7. Dip a green Scotch-Brite Heavy Duty pad into solution and scrub all filler parts. Place all filler parts into the rinse compartment of three compartment sink. Visually inspect all filler parts to ensure all soap has been removed. Place all filler parts into the sanitize compartment of three compartment sink. Let all filler parts sit in bleach solution for one minute. Remove all filler parts from solution and allow to air dry. No rinse is necessary. Visually inspect filler parts for cleanliness. Put away filler parts wearing freshly washed gloves.
8. Ask cleaning crew supervisor to inspect for cleanliness.

Complete *Production Kitchen Sanitation Checklist*



**Corrective Action:** If, after rinsing, visual inspection by cleaning crew supervisor finds areas that are not clean, cleaning procedures must be repeated until cleanliness is achieved. Record corrective actions on Production Kitchen Sanitation Checklist.

Equipment Maintenance, Cleaning and Sanitation

<b>Standard Operating Procedure:</b> Equipment Maintenance, Cleaning and Sanitation
<b>Purpose:</b> To explain facility equipment maintenance, cleaning and sanitation
<b>Scope:</b> To educate and train licensed premise employees on requirements and procedures pertaining to facility equipment maintenance and the proper cleaning and sanitation of facility equipment.
<b>Initial Training:</b> 2-4 hours

**Principles of Equipment Maintenance, Cleaning and Sanitation**

Equipment utilized within the cultivation operations at the licensed premise will need to be routinely maintenance, cleaned and sanitized. There are multiple reason for this routine maintenance, cleaning and sanitation including operator safety. Regular maintenance should be done in order to keep the equipment operating and functioning properly, this reduce the risk of an operator getting injured while operating the equipment. The maintenance procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Equipment will need to be cleaned and sanitized after equipment comes into contact with medical marijuana it will need to be properly cleaned and sanitized. The cleaning and sanitation procedure for each piece of equipment will vary and manufacture recommendations should be followed.

Licensed premise employees performing the maintenance and/or cleaning and sanitation will be required to document the maintenance and/or cleaning and sanitation within the *Equipment Maintenance, Cleaning and Sanitation Log Sheet*.

*Example of BPH's Equipment Maintenance, Cleaning and Sanitation Log Sheet:*

<b><u>Equipment Maintenance, Cleaning and Sanitation</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Equipment Name/Model #:</u>	<u>Date of Last Maintenance</u>	<u>Date of Last Cleaning &amp; Sanitation</u>	<u>Notes/Comments</u>



Facility Exit Protocol

<b>Standard Operating Procedure:</b> Facility Exit Protocol
<b>Purpose:</b> To explain how employees should exit the cultivation/MIP facility.
<b>Scope:</b> Covers the steps involved for properly exiting the cultivation and/or MIP facility.
<b>Initial Training:</b> 1-2 hours

When an employee has finished their work shift, they will exit the “clean” area of the cultivation facility in the same way they enter, however the process for exiting will be done in reverse.

**How to Exit the Production Center:**

1. Exit the clean area through the Air-Lock Chamber
2. Enter the locker room
3. Change out of provided work wear attire/uniform
  - a. Scrubs
  - b. Hair nets
  - c. Hats
  - d. Garden shoes
4. Place used work wear in the proper laundry bin
5. Change back into street clothes
6. Exit the locker room
7. Exit the facility through the man trap.
  - a. Arm the security alarm system to *AWAY (if applicable)*



Emergency Protocol

<b>Standard Operating Procedure:</b> Emergency Protocol
<b>Purpose:</b> To describe all steps and protocols to be followed by employees should an emergency occur within the facility.
<b>Scope:</b> Procedures covering emergency situations occurring within the facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Emergency Situation Documentation Sheet

**Equipment/Tools Required**

- 1) Panic Alarm/Button
- 2) Fire Extinguisher
- 3) Chemical Spill Kit
- 4) Emergency eye wash station(s)
- 5) First Aid Kit
- 6) Emergency defibrillator

**The Principles of Emergency Protocols**

A facility emergency management plan is designed to educate and train facility employees on the actions and procedures to follow in the event of an emergency. In the case of an emergency, facility employees will need to respond quickly and think strategically in order to successfully manage the emergency situation. Having a good understanding of the facility emergency management plan will enable employees to better adapt to and handle emergencies.

The most important thing to remember during an emergency situation is to try to stay calm, if the emergency situation is out of your control and you need assistance, contact emergency services immediately if possible.





**Burglary:** Burglary is legally defined as the criminal offense of breaking and entering a building illegally for the purpose of committing a crime. Burglaries generally will occur at the Licensed Premise after operating hours and while there are no registered employees present. Typically burglaries occur during the night and are not discovered until the next day during normal operating hours.

- If upon entering the Licensed Premise and a registered employees notice something is afoul and upon investigation a burglary was determined to have occurred in the previous night, then registered employees will be required to document the incident and notify all required authorities.
  - Registered employees will be required to report the incident of burglary to:
    - The Commission
    - Local medical marijuana authority (*if applicable*)
    - Local police

**Robbery or Theft:** Robbery is legally defined as the taking of money or goods in the possession of another, from his or her person or immediate presences, y force or intimidation. The number one rule registered employees will need to follow when/if dealing with a robbery is to comply with all robber demands

- If you are being robbed at gunpoint or if you feel as if your life is in danger, comply with all requests from perpetrator/suspect. Give them whatever they ask for.
- Try to signal for help using the personal security panic buttons provided, by activating one of multiple, strategically placed panic alarm buttons, or through the panic button/police services button located on the alarm panel.
- Contact law enforcement as soon as possible
- Notify any required State or local authorities immediately (within 24 hours)
  - Local police services
  - The Commission
- Comply with all applicable laws and regulations
- Document the situation in the *Emergency Situation Documentation* log sheet



Alarm Panel

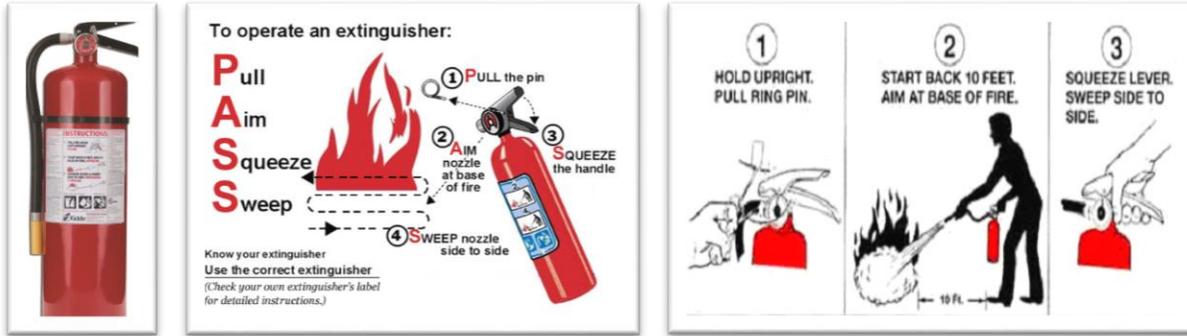
Panic Alarms/Buttons



**Fire Emergency:**

- If a small isolated fire is present, try to exhaust the fire with one of the fire extinguishers on site
- In case of a fire emergency, first leave the facility; once clear of the facility dial 911 and/or local fire authority for Fire Emergency Services or push the symbol on the alarm panel for fire emergency upon exiting the facility
- Document the situation in the *Emergency Situation Documentation* log sheet

*Fire Emergency Cont.*



**Chemical Emergency:**

- Dangerous Substance/Chemical Exposure:
  - If an employee accidentally has their eyes exposed to toxic, poisonous or dangerous substances or chemicals; said employee will need to locate the installed emergency eye wash station(s) to properly flush and clean their eyes. Notify emergency medical services for further assistance
  
- Chemical Spill:
  - Try to use a chemical spill kit for smaller incidents of chemical spill
  - If a chemical spill is large or you do not know how to handle the situation; get the facility manager to handle the situation and/or contact proper emergency services
    - Posted near or included with the chemical spill kit should be an emergency contact information sheet displaying which emergency services should be contacted.
      - For the BPH and the State of Hawaii this will include but not be limited to:
        - Environmental Protection Agency (EPA)
          - For emergencies and other sudden threats to public health, such as:
            - oil and/or chemical spills,
            - radiation emergencies, and
            - biological discharges,
              - call the National Response Center at 1-800-424-8802.
            - For **pesticide poisoning**, call 911 if the person is unconscious, has trouble breathing, or has convulsions. Otherwise, call **Poison Control at 1-800-222-1222.**
  
- Document the situation in the *Emergency Situation Documentation* log sheet



**Medical Emergency:**



- If it is a minor medical situation such as a small cut, scrape or minor burn; retrieve the first aid kit on site and treat wound with items found in the first aid kit
- If the situation appears to be a severe medical situation such as someone suffering from a heart attack, retrieve the emergency defibrillator and follow the instructions provided; notify 911 or local medical emergency services for further assistance
- If the medical situation is an emergency; contact medical emergency services immediately. This can be done through activating the medical response button found on the alarm panel, or by calling 911 for medical emergency services
- If a serious injury occurs while an employee is working, such as a slip and fall resulting in possible broken bones or a cut requiring stitches, SFN facility management will need to complete a worker compensation insurance claim form prior to the employee seeking medical assistance. This procedure does not take long, but the form will need to be completed in order for the injured employee to have a workers compensation medical claim.
- Document the situation in the *Emergency Situation Documentation* log sheet



**Other Emergencies:**

- Contact 911 if it is a current emergency. Contact your local police and/or State regulatory authorities for break-ins or burglaries that may have occurred when the facility operations were closed
- Contact any required State or local authority in cases of theft, break-ins or burglaries
- Document the situation in the *Emergency Situation Documentation* log sheet



*Example of Emergency Situation Documentation Log Sheet:*



<b><u>Emergency Situation Documentation</u></b>		
Date:	Reporting Employee:	Manger on Duty:
Type of Emergency: <input type="checkbox"/> Robbery of Theft <input type="checkbox"/> Fire Emergency <input type="checkbox"/> Chemical Spill <input type="checkbox"/> Medical Emergency <input type="checkbox"/> Other Emergency		
Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO		Which Authorities:
Description of the Incident:		

Loss of Personnel

<b>Standard Operating Procedure: Loss of Personnel</b>
<b>Purpose:</b> To describe all steps and protocols to be followed prior to or after the loss of personnel.
<b>Scope:</b> Procedures covering loss of personnel situations occurring within the facility.

The following will cover procedures to follow when terminating a key employee as well as when a key employee decides to leave the organization on their own accord.

**Job Termination**—if the need arises to terminate the position of a key personnel there will be some basic steps and procedures to follow within operations.

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e. employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel



4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e. mutual separation and key personnel is always welcome back at SFN facilities under visitor status, employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was previously filled by key personnel. Key personnel positions will need to be filled as soon as possible by ownership and/or management without sacrificing quality of applicant pool. Some basic steps should be followed to find and place a suitable replacement for the vacant position.

1. Review resumes and applications from qualified applicants
2. Call qualified applicants to conduct an informal, initial phone interview
  - a. If you get a good response from applicant, schedule an in-person interview
3. Conduct in-person interviews with qualified applicants
4. Review interviewed applicants
  - a. Select applicant who is most qualified for the vacant position
5. Contact said applicant and offer the vacant position
6. If applicant accepts the job offer, proceed with normal hiring procedure and required paperwork



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# STANDARD OPERATING PROCEDURES

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*State Of Hawaii Retail Dispensary Locations*





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**-----STATE REGULATORY COMPLIANCE DISCLOSURE-----**

*Medical marijuana facilities operate in a highly regulated industry, as such adherence to all applicable state and local laws pertaining to the dispensing of marijuana and/or manufactured marijuana products within the facility is of utmost importance. State and local laws and regulations will vary among states; it is recommended to read and have good understanding of the state and local laws and regulations in which you operate. Having a good understanding of the state and local laws is the first step in being educated on how to operate within regulations, the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within a regulated market.*

**-----CONFIDENTIALITY DISCLOSURE-----**

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<b>Standard Operating Procedure:</b> Standard Operating Procedures
<b>Purpose:</b> To explain the standard operating procedures needed to be adhered to within the Licensed Premise
<b>Scope:</b> To cover the education and training required pertaining to the standard operating procedures utilized within the Licensed Premise.
<b>Initial Training:</b> TBD

**Definitions**

**Standard Operating Procedure (SOP)**—a set of step-by-step instructions to achieve a predictable, standardized, desired result often within the context of a longer overall process. At its simplest, an SOP is a repeated application of unchanged processes and procedures and its documentation. These SOPs are to be followed as directed and not deviated for the retail dispensing of marijuana within any Blue Planet Healing LLC (BPH) registered retail dispensary locations.

**Material Change**—a material change is defined as a major deviation from the standard procedure, or changing the procedure or methodology drastically enough to notice a change. The material change is important enough to notice or to have an effect on the standard operating procedure.

**Principles of Standard Operating Procedures**

American Cannabis Company’s (ACC) Standard Operating Procedures (SOPs) ensure consistent dispensing of high quality medical marijuana products. BPH will utilize said SOPs for all dispensing methodologies and operations. Understanding and abiding by the following SOPs is mandatory for all registered employees working within BPH’s registered dispensary facilities.

The standard operating procedures must be practiced and utilized to dispense each batch of marijuana and/or manufactured marijuana products. The strict adherence to the written SOPs will aid in BPH’s quality control, inventory control and state regulatory compliance. The written SOPs have been developed within a regulated marijuana industry with the purpose of creating systems and procedures that result in compliant operations. Apply the following SOP instructions to the daily retail dispensing activities within the facility. Do not deviate from exact instruction within these standard operating procedures.

- Failure to practice and utilize BPH’s written standard operating procedures is grounds for disciplinary action and possible job termination.
- Registered employees will be required to record and maintain documentation log sheets and forms to record the dispensing process
  - Required documentation and record keeping is highlighted throughout the SOPs and indicates which documentation log sheets and records are to be taken and maintained.
    - Registered employees will need to pay careful attention to each standard operating procedure to ensure proper documentation and record keeping
      - The documentation should demonstrate consistency of operations
      - The documentation should also demonstrate the accuracy of the day-to-day dispensing.
- Any major deviation from the standard operating procedure defined as a material change that could impact the quality of batch must be documented, recorded and maintained at the retail dispensing location.
  - Registered employees are required to document any major deviation in production of a batch from the standard operating procedure

**Deviation/Material Change to Standard Operating Procedures**

Upon recognizing the need for or making a material change to a standard operating procedure, registered employees will be required to document the material change within the *Material Change to SOPs* log sheet and update the current SOP to reflect the material change.



<b><u>Deviation/Material Change to SOP's</u></b>		
<b>Date:</b>	<b>Registered Employee:</b>	<b>Deviation in Production:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Reason for the deviation</b> ( <i>identify and describe in detail the deviation from the SOP</i> ) :		
<b>SOP requiring material change:</b>		
<b>Material Change made to the SOP</b> ( <i>please describe in detail</i> ) :		
<b>SOP Updated?</b> <input type="checkbox"/> YES	<b>Date Updated:</b>	<b>Update By:</b>
<b>Manager/Supervisor Awareness and Approval:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Manager/Supervisor Signature:</b>	
<b>Sample of production batch with deviation sent to independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Sample of production batch with deviation determined to meet specifications for the variety by BPH and the independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>Medical Cannabis Batch Released for Distribution?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Additional Notes/Comments:</b>	
<i>After documentation of a material change to a standard operating procedure, registered employees will be required to maintain the record of material change within a limit-access and secured area of the Licensed Premise.</i>		



<b>Standard Operating Procedure:</b> State Regulatory Compliance Training
<b>Purpose:</b> To explain the regulatory compliance needed to be adhered to in the State of Hawai'i.
<b>Scope:</b> To cover the regulations enacted within Hawaii pertaining to legally operating a marijuana business.
<b>Initial Training:</b> training done on individual time

**Required Documents**

- 1) State Laws
- 2) Local/City Regulations (*if applicable*)

**The Principles of State Regulatory Compliance Training**

BPH will require all registered employees to read and become familiar with the State and Local/City regulations that have been enacted pertaining to operating a legal, licensed marijuana business.

BPH will keep a physical, up-to-date copy of any and all laws and regulation in which you must operate under at every licensed facility. Every registered employee will receive a hard copy of the laws and regulation which they can read and become familiar with.

Key State Laws Employees Should be Familiar With:

- Who can have access to the facility
  - Visitor process
- Packaging and labeling compliances and requirements
- Allowed purchase amounts (quantities and distribution timeframe)
- Hours of allowed operation
- Inventory tracking and required record keeping
- Security procedures and protocols
- Laboratory testing requirements
- Transportation of marijuana products
- Etc.

**State of Hawaii**

- <http://health.hawaii.gov/medicalmarijuana/>

*BPH and registered employees of BPH will not distribute any medical marijuana to any person if BPH or registered employee knows, or may have reason to know, that the distribution does not comply with any provision of the Hawaii regulations.*

*BPH will ensure that BPH or a registered employee thereof will not distribute any medical marijuana to any person if BPH or registered employee knows, or may have reason to know, that the medical marijuana does not comply with any regulations of Hawaii.*



**Standard Operating Procedure: Record Keeping and Documentation**

**Purpose:** To ensure that all required marijuana dispensing records and data are properly recorded and documented.

**Scope:** Procedures covering record keeping and documentation for activities within retail dispensary locations.

**Initial Training:** 4-8 hours

**What is the Purpose of Record Keeping and Documentation?**

The marijuana retail dispensary locations operate in a highly regulated industry, as such proper record keeping and documentation are essential within the retail dispensary locations.

**Equipment/Tools Required**

- 1) Pen or pencil
- 2) Clipboard
- 3) Log Sheets

**Principles of Record Keeping and Documentation**

Adherence to all applicable state and local laws pertaining to the dispensing of marijuana within the retail dispensary locations is of utmost importance. Having a good understanding of the state and local laws is the first step in being educated on the records and documents needed to be maintained to be in full compliance and to continue operating a marijuana business within a regulated market.

Required records and documentation are noted throughout the written Standard Operating Procedures; BPH's registered employees will be required to make such records and documentation as part of their job responsibilities. Employees will be required to make two sets of all records and documentation; one set of records and documentation will be made within the BioTrackTHC™ inventory control system, and a second set of records and documentation will be made using physical log sheets and templates. The physical records and documentation will be maintained on at the retail dispensary location within a limited access area. Failure to create and maintain records and documentation will be grounds for disciplinary action and/or job termination.

Record Keeping and documentation are noted within other SOPs where documentation is required. The SOPs will also reference which documentation records and log sheets are required to be filled out and maintained.

**Dispensary Licensed Premise Records:**

- 1) Cash Drawer Balances
- 2) Receiving Marijuana Products (Incoming Shipments)
- 3) Closing Log Sheet
- 4) Marijuana Waste Log
- 5) Cleaning and Sanitation Log
- 6) Product Recall Log
- 7) Employee List
- 8) Emergency Situation Documentation
- 9) Primary Patient List
- 10) Visitor Sign-In
- 11) Etc.

**Secondary Records**

BPH will maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution. BPH will require employees to maintain secondary records on the Licensed Premise. The physical records and documentation log sheets will serve as secondary, back-up records and documentation that will be maintained independent of the inventory control system.

Per Hawaii regulations, records required to be maintained separate of the inventory control system:

- **Records of Each Distribution**
  - Records of distribution must include:
    - The name and address of the qualified patient
    - The quantity dispensed
    - The name, strength, batch number, and lot number of the product
    - Date and time of distribution

#### **Requirements of Secondary Records:**

- Records must be maintained independent of the inventory control system
  - Physical records will be maintained within a file cabinet, separate from the inventory control system
- Records must be searchable
  - Records will be organized and filed alphabetically according to recipient name
- Records must be secure
  - Records will be maintained within the Licensed Premise, located within a limited-access area inside a manager office equipped with an independent security alarm system. The records will be held within a lockable filing cabinet inside the secure office.
- Records must be tamper-evident
  - The file cabinet where secondary records are to be maintained will have a secure, tamper-evident locking mechanism on it.

#### **Certifying Physician Records Request**

BPH will require registered employees to provide in a reasonable time and manner to a certifying physician a copy of the record of each distribution by BPH to a qualifying patient of the certifying physician of the quantity delivered, name, strength, batch number and lot number of medical marijuana.

- Reasonable time to be defined as within 48 hours of receipt of request

#### **Records and Documents Storage Retention**

Unless otherwise specified, BPH will retain and maintain all records and duplicate sets of records for a minimum of six (6) years.

#### **Duplicate Records and Off-Site Storage**

As per State of Hawaii regulations, BPH will maintain duplicate sets of all records required by regulation. These duplicate copies of BPH records will be maintained at a secure, off-site location. This location will only be disclosed to personnel with proper security clearance. The off-site record storage will be secured with a security alarm and surveillance system to ensure access is limited to authorized personnel only.

#### **Quarterly Report**

BPH will submit a quarterly report to the department on January 15, April 15, July 15, and October 15. In the event that those dates fall on a weekend or holiday, the report can be submitted the following business day.

- This report must include but not limited to:
  - Records of entry and exit for all individuals who entered a dispensary facility
  - Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale
  - Amounts by category of marijuana and manufactured marijuana products sold
  - A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed

- A summary of financial statement
- Laboratory results of all tests conducted
- Description of any breach or halt in its security system and tracking system
- Any other information requested by the Department of Health

The inventory report can be created through the inventory control system

- Within the inventory control system, BPH will be able to generate a list of all the products along with their specifications that were offered for distribution
- This list can be generated for all products offered with specific date ranges



<b>Standard Operating Procedure:</b> General Security/Diversion Prevention Training
<b>Purpose:</b> To explain the general security and diversion prevention training needed to be adhered to.
<b>Scope:</b> To understand security and diversion prevention training requirements.
<b>Initial Training:</b> 4-8 hours

**Diversion and Trafficking Prevention Training**

Diversion and trafficking prevention will primarily be done using the various security alarm and surveillance equipment installed and utilized at BPH’s retail dispensing locations. The various security alarm and surveillance equipment utilized is explained in more detail within the Security Plan which is a separate, additional document that can be viewed upon request. All BPH registered employees will be trained on all security equipment, measures and policies prior to commencing work within the retail dispensing location.

BPH will utilize BioTrackTHC’s inventory control system and industry best practices and policies to reduce the risk of diversion and theft of marijuana products. All marijuana plants will be tagged, recorded and tracked through the inventory control system from seed-to-sale.

The use of professional security systems from Securitas that will be installed at all of organization facilities will also help to reduce the risk to diversion, loss, theft or unauthorized access.

If any marijuana or manufactured marijuana product loss or discrepancy noticed by a registered employee, management shall be made aware of the loss immediately. Inventory discrepancies should be easily noticeable with the use of the inventory control system. The diversion or product loss must be documented on the **Product Loss** log sheet which can be seen below.

<b><u>Product Loss Log Sheet</u></b>				
<b><u>Date:</u></b>	<b><u>Product Name/Category</u></b>	<b><u>Product Attribute # or Unique ID #</u></b>	<b><u>Total Quantity</u></b> <b><u>Loss:</u></b>	<b><u>Product Loss</u></b> <b><u>Valuation:</u></b>
				\$
<b><u>Reporting</u></b> <b><u>Employee:</u></b>	<b><u>Manager/Supervisor:</u></b>	<b><u>Product Loss Due To:</u></b>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<b><u>Internal</u></b> <b><u>Investigation:</u></b>	<b><u>Required Authorities</u></b> <b><u>Notified:</u></b>	<b><u>Authorities Notified (list all) :</u></b>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<b><u>Note/Comments:</u></b>				

### **Video Surveillance System.**

Securitas will design video surveillance systems at BPH's retail dispensary facilities that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

### **Alarm System.**

Each retail dispensary location operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH.

### **System Failure.**

In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

### **Other Security Measures.**

All entrances, exits, windows and other points of entry will be equipped with commercial-grade locks and/or other functioning mechanical or electrical security devices to prevent and detect unauthorized access to all BPH Dispensary Facilities. All BPH Dispensary Facilities will be designed and constructed with secured entry points to allow for the screening of individuals to determine if they are authorized to enter the facility. At this secured entry point, individuals will be screened by BPH to ensure they are either on BPH's current DOH-approved list of persons authorized to enter that facility for an authorized purpose pursuant to HRS §329D-15 and/or 329D-16 or are otherwise permitted access pursuant to HAR §11-850-51(3)(B). BPH will utilize an entry protocol, sign in system which will record the names of all persons listed in HAR §11-850-51(a) (3) entering a Dispensary Facility and the date and time of entry to and exit therefrom.

### **Retail Dispensary Location (RDL) Specific Security.**

BPH will implement and follow specific security procedures and policies for all RDL operations including: written SOPs for admitting registered patients and primary caregivers with valid government-issued photo identification cards issued pursuant to HRS Chapter 329 into the secure rooms for sales. BPH will design and construct each RDL with separate, secure room(s) for sales wherein marijuana and manufactured marijuana products are secured and locked in display cases for viewing.

As required by HAR §11-850-53(3), BPH will follow written policies and procedures to ensure that a maximum occupancy limit ratio is maintained in all secured sales rooms of two customers to everyone RDL employee. BPH will store all marijuana products within a locked room, vault or in a locked container securely affixed to a wall or floor. All RDLs shall have exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities.

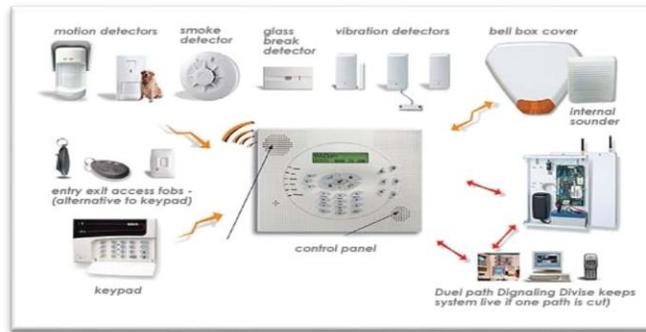
### **Transportation Security.**

BPH's transportation of marijuana and manufactured marijuana products between its facilities, and to a laboratory for testing shall require that: 1) only employees designated by BPH, who are trained and knowledgeable with the transportation protocols required by Hawai'i law, shall transport marijuana and manufactured marijuana products. 2) Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.



3) Each time marijuana and manufactured marijuana products are transported, BPH shall prepare a manifest on a form prescribed by DOH that lists the elements required by DOH’s tracking system. 4) BPH shall only transport marijuana or manufactured marijuana products that are listed on the manifest. 5) BPH shall transport marijuana or manufactured marijuana products in secured containers and BPH shall include a copy of the manifest in the interior and on the exterior of the container. 6) For transport between or among Dispensary Facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a Dispensary Facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras. 7) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety. 8) Upon receipt of marijuana and manufactured marijuana products BPH or the laboratory shall immediately report to DOH any discrepancies between what is received and what is on the manifest. 9) The designated BPH employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest. 10) BPH shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion. 11) BPH shall not transport marijuana or manufactured marijuana products: a) off site to qualifying patients or to primary caregivers; b) to another county or another island within the same county; or c) to, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

**Alarm Surveillance**—a primary alarm system will be installed at all BPH registered dispensary facilities by Securitas, a licensed alarm companies. An advanced security alarm system on all perimeter entry points, perimeter windows, and secured interior rooms. Motion detection equipment and camera equipment will be used to ensure the entire facility(s) is continuously safe from intrusion and product diversion.



**Video Surveillance**—an advanced video surveillance and recording system at all BPH facilities. All cameras will record in digital format and be maintained to meet the requirements outlined by State and local regulations. Video cameras will be maintained in each room and be used to identify any activity occurring within the room and be capable of recording and viewing in low light conditions. An onsite DVR and an additional offsite DVR will be utilized to store all footage; all video surveillance recording will be stored for a minimum of one year.



**Security Lighting**—security lighting around the entire perimeter of the production center to allow surveillance in low light conditions and deter potential intrusion.



**Motion Detector Alarms**—the professional security alarm system will utilize motion detectors that will detect intrusion and will automatically notify the proper authorities.



**Panic-Button Alarm**—employees will be required to wear a panic-button alarm that is discrete and can notify authorities in the case of an emergency.



**Hold-Up Alarm**—the security and alarm system will have a hold-up alarm that will be a silent alarm signal that is generated by manual activation of a device which will signal a robbery in progress and automatically notify the local police authorities.



**Duress Alarms**—the security and alarm systems will utilize a duress alarm button on the alarm panels that can be pushed by employees in the case of an emergency. Different duress alarm buttons can be pushed to automatically notify the proper authority; police, fire or emergency services.



**On-Site Electronic Monitoring**—facility security rooms will have a large screen call-up monitor (at least 19") and a video printer capable of immediately producing a clear still photo from all video cameras.



**Commercial Grade Door Locks**—commercial-grade, non-residential door locks at all points of ingress and egress to the facilities exterior and all limited access areas. Key-card access door locks may also be utilized to further limit access at facilities.



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**Safes and Product Storage**—Commercial grade safes will be installed and utilized in a limited access area for the storage of marijuana products and cash.





<b>Standard Operating Procedure:</b> Perpetual Inventory Control System
<b>Purpose:</b> To explain the principles and concepts of the perpetual inventory control system
<b>Scope:</b> To educate and train registered employees and licensed premise employees on the perpetual inventory control system
<b>Initial Training:</b> TBD

**Principles of the Perpetual Inventory Control System**

BPH will utilize a perpetual inventory system from a regulated marijuana industry-specific inventory system provider, BioTrackTHC™. This inventory control system has been developed specifically for the regulated marijuana industry and has been customized to include all marijuana business operational needs. The systems have been designed to be user friendly, the ability to be mobile, and with inventory control capabilities to track every medical marijuana plant and product from seed to sale. The inventory control system will be designed to have the ability to promptly identify a discrepancy in stocks of marijuana and manufactured marijuana products. BPH administrators of the system will be notified of a substantial reduction in an inventory stock level and be prompted to investigate the inventory levels to insure no theft, diversion or discrepancies occurred. Administrators and users can run inventory reports from the inventory control system to check inventory stock levels that have been recorded in the inventory control system against a physical inventory audit to further determine inventory discrepancies.

**Inventory Control /POS System**—the tracking of all marijuana products from seed to sale will be done through inventory management through the use of template log sheets, computer systems, Secure Information Systems (SIS) and selected Point-of-Sale systems (POS). All medical marijuana plants and products are to be tagged, recorded and tracked through the inventory control system. Failure to do so can result in disciplinary action and/or job termination.



*\*Inventory control system and/or Point-of-Sale (POS) system training will be provided by an expert or consultant from the inventory control system supplier, BioTrackTHC™. This 3<sup>rd</sup> party training will be required for all BPH registered employees prior to working within the production center.*

Registered employees will be required to utilize the inventory control system to identify, record, monitor and track all marijuana and products from the time the marijuana product is delivered to a licensed retail dispensary location. The standard operating procedures detail multiple situations when product monitoring and recording activities are required by registered employees within the retail dispensary location. Marijuana products will be given a unique attribute number, assigned to a production batch which and recorded in the inventory control system. The product will then be given a new and unique tag with the products identification and specifications and be recorded in the inventory control system, the tag will remain with the product throughout the products lifecycle enabling the plant to be identified and tracked. The inventory control system intended to be utilized within BPH’s retail dispensary locations will aid in the event of a serious adverse event by having the ability to track any marijuana plant or product back to the originating source, including the ability of tracking marijuana from a qualifying patient back to the source of the marijuana. The marijuana believed to have caused a serious adverse event should have a product label with product information and specifications such as the product name, unique attribute number, batch number and originating entity. With this information, the marijuana product will be able to be traced back to the originating source of the medical marijuana.



<b>Standard Operating Procedure:</b> OSHA Compliance and Training
<b>Purpose:</b> To explain the principles and concepts of OSHA regulations.
<b>Scope:</b> To understand OSHA requirements to create a safe work environment.
<b>Initial Training:</b> 4-6 hours

**OSHA Training**

Registered employees have the right to a safe workplace, and BPH intends to provide a safe work environment for all registered employees at all BPH facilities. The Occupational Safety and Health Act of 1970 (OSH Act) was passed into law as a preventative measure for workers from being killed or seriously harmed while at work. The law requires employers to provide employees with working conditions that are free from known dangers.

The OSH Act created the Occupational Safety and Health Administration (OSHA). This regulatory agency sets and enforces protective workplace safety and health standards. OSHA is also charged with providing information, training and assistance to workers and employers to educate and train individuals on workplace safety. Employees may file a complaint if they feel necessary which will result in OSHA to inspect the workplace if they feel OSHA standards are not being met or that there may be serious hazards or danger. More information on the Occupational Safety and Health Administration can be found online at the website: <https://www.osha.gov/>.

**OSHA’s Mission**—With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

**OSHA Training**—The OSHA Outreach Training Program for General Industry provides training for workers and employers on the recognition, avoidance, abatement, and prevention of safety and health hazards and dangers in workplaces in general industry. This program also provides information regarding workers' rights, employer responsibilities, and how to file a complaint. Employees can attend a 10-hour or 30-hour class delivered by OSHA-authorized trainers. The 10-hour class is intended for entry level workers, while the 30-hour class is more appropriate for supervisors or workers with some safety responsibility. OSHA training helps to ensure that workers are more knowledgeable about workplace hazards, dangers and their rights.

Under the OSH Law, employers have a responsibility to provide a safe workplace free from known hazards or dangers. The OSHA website provides a short summary of employer responsibilities with which BPH will ensure compliance.

- Provide a workplace free from serious recognized hazards and comply with standards, rules and regulations issued under the OSH Act.
- Examine workplace conditions to make sure they conform to applicable OSHA standards.
- Make sure employees have and use safe tools and equipment and properly maintain this equipment.
- Use color codes, posters, labels or signs to warn employees of potential hazards.
- Establish or update operating procedures and communicate them so that employees follow safety and health requirements.
- Employers must provide safety training in a language and vocabulary workers can understand.
- Employers with hazardous chemicals in the workplace must develop and implement a written hazard communication program and train employees on the hazards they are exposed to and proper precautions (and a copy of safety data sheets must be readily available). See the OSHA page on Hazard Communication.
- Provide medical examinations and training when required by OSHA standards.
- Post, at a prominent location within the workplace, the OSHA poster (or the state-plan equivalent) informing employees of their rights and responsibilities.
- Report to the nearest OSHA office all work-related fatalities within 8 hours, and all work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours. Call our toll-free number: 1-800-321-OSHA (6742); TTY 1-877-889-5627. [Employers under federal OSHA's jurisdiction were required to



begin reporting by Jan. 1, 2015. Establishments in a state with a state-run OSHA program should contact their state plan for the implementation date].

- Keep records of work-related injuries and illnesses. (Note: Employers with 10 or fewer employees and employers in certain low-hazard industries are exempt from this requirement.)
- Provide employees, former employees and their representative's access to the Log of Work-Related Injuries and Illnesses (OSHA Form 300). On February 1, and for three months, covered employers must post the summary of the OSHA log of injuries and illnesses (OSHA Form 300A).
- Provide access to employee medical records and exposure records to employees or their authorized representatives.
- Provide to the OSHA compliance officer the names of authorized employee representatives who may be asked to accompany the compliance officer during an inspection.
- Not discriminate against employees who exercise their rights under the Act. See our "Whistleblower Protection" webpage.
- Post OSHA citations at or near the work area involved. Each citation must remain posted until the violation has been corrected, or for three working days, whichever is longer. Post abatement verification documents or tags.
- Correct cited violations by the deadline set in the OSHA citation and submit required abatement verification documentation.
- OSHA encourages all employers to adopt an Injury and Illness Prevention Program. Injury and Illness Prevention Programs, known by a variety of names, are universal interventions that can substantially reduce the number and severity of workplace injuries and alleviate the associated financial burdens on U.S. workplaces. Many states have requirements or voluntary guidelines for workplace Injury and Illness Prevention Programs. Also, numerous employers in the United States already manage safety using Injury and Illness Prevention Programs, and we believe that all employers can and should do the same. Most successful Injury and Illness Prevention Programs are based on a common set of key elements. These include: management leadership, worker participation, hazard identification, hazard prevention and control, education and training, and program evaluation and improvement. OSHA's Injury and Illness Prevention Programs topics page contains more information including examples of programs and systems that have reduced workplace injuries and illnesses.

### **Plan for OSHA Compliance**

Below details BPH's plan for compliance with OSHA will begin by ensuring that all organizational facilities are free from known hazards and/or dangers. Although OSHA is a federal organization and we are not currently held to OSHA standards, BPH feels it is best practices to be aware of OSHA guidelines and adhere to said guideline within our operations.

All registered employees will be provided basic training covering workplace safety pertaining to identifying and preventing potential hazards and or dangers such as trip hazards. This basic training will begin with training all new employees on policies and procedures. Proper and adequate training can help to reduce workplace accidents through educating and training employees on operations, policies and procedures. Employees will be given a tour of the facility property and areas in which the employee will have access to (limited or restricted). Other training to be included in BPH's plan for OSHA compliance will include:

- Training on SOPs
- Regulatory compliance training (laws and regulations pertaining to medical marijuana cultivation, processing or dispensing)
- Basic training on workplace safety
- Recognition of potential workplace hazards or dangers



**Standard Operating Procedure: Employee Dress Code and Personal Hygiene**

**Purpose:**

To explain the employee dress code required.

**Scope:**

Covers the dress code requirements for employees.

**Principles of Employee Dress Code**

The dress code to be implemented at retail dispensary locations will be casual or business casual and may include a company logoed polo shirt, and nice jeans, khakis pants or nice shorts or a shirt; all clothing must be free of holes and tears.

Employees are expected to arrive at facilities in clean working attire ready to begin the scheduled work shift.

**Personal Hygiene Policy**

This policy has been set forth in order to ensure that all employees are practicing good personal hygiene to ensure that are products are produced in safest and most sanitary means possible. The personal hygiene policy includes but is not limited to the following:

- A. Maintaining adequate personal hygiene
  - a. Arrive to work clean in appearance/clean clothes.
  - b. Showering every day is essential
  - c. Deodorant and a clean personal smell is required
- B. Men must be neatly groomed/shaven
  - a. Mustaches or beards allowed if maintained
  - b. We reserve the right to ask you to wear a beard cover if we deem it necessary
- C. Long hair must be constrained in a neat manner to avoid hair coming into contact with marijuana and/or manufactured marijuana products
  - a. A hat or hairnet is preferred
  - b. Jewelry of any kind is not permitted
    - i. This includes earrings, rings, bracelets, watches, etc.
- D. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and
- E. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

**General Sanitary Requirements**

BPH will take all reasonable measures and precautions to ensure that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for medical marijuana products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.



BPH will have hand-washing facilities that are convenient and furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

That all registered employees working in direct contact with processing, preparation, weighing or repackaging of medical marijuana products shall conform to hygienic practices while on duty, including but not limited to:

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the processing, preparation, weighing or repackaging of medical marijuana products and at any other time when the hands may have become soiled or contaminated; and
- Refraining from having direct contact with preparation of medical marijuana products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical marijuana products.

Registered employees are required to ensure that litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical marijuana products are exposed. Registered employees are required to ensure that floors, walls, and ceilings are adequately cleaned and kept clean and kept in good repair.

That the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

Registered employees must ensure that all contact surfaces, including utensils and equipment used for the preparation of medical marijuana products shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used with medical marijuana and used in accordance with labeled instructions;

BPH requires all toxic cleaning compounds, sanitizing agents, solvents used in the production of medical marijuana and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of medical marijuana products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. That medical marijuana products that can support the rapid growth of undesirable microorganisms will be held in a manner that prevents the growth of these microorganisms; and the storage and transport of finished medical marijuana products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.



Limited Access Areas

<b>Standard Operating Procedure:</b> Limited Access Areas
<b>Purpose:</b> To explain Limited Access Areas, who is allowed in these areas, and procedures to follow within the Limited Access Area.
<b>Scope:</b> Covers the steps involved in escorting visitors in limited access areas.
<b>Initial Training:</b> 1 hour

**The Principles of Limited Access Areas**

A Limited Access Area is a building, room, or other contiguous area upon the Licensed Premises where marijuana is stored, weighed, packaged, sold, or processed for sale, under control of the retail dispensary location. Limited Access Areas are areas within the licensee’s facilities where only certain people will have the required permission to access.

Limited Access Areas may have people in them without the proper permission as long as the State required protocols are followed. Typically this involves following the *Visitor SOP*; being escorted by a licensed employee at all times while in the facility and Limited Access Areas.

Limited access areas should be limited to State licensed, facility employees only. If a visitor needs to access the limited access areas, registered employees will be required to follow the written *Visitor SOP*.





## **Standard Operating Procedure: Patient Confidentiality**

### **Purpose:**

To explain the steps involved for handling patient confidentiality.

### **Scope:**

Covers the steps involved to protect patient confidentiality.

## **The Principles of Protecting Patient Confidentiality**

This section will cover the best practices in patient privacy and confidentiality. When operating a business within the marijuana industry it is important to ensure that your patient's records and information are secured and kept private. A breach in such privacy can result in HIPAA violations, legal ramifications and a potential cease and desist order. Below you will find some helpful tips in keeping patient information private.

### **Patient Record Privacy & Confidentiality Tips**

- 1) Keep all patient records in a secure lockbox or lockable cabinet. Having these records all in one place can help to ensure that no patient records are being kept in exposed areas where it is possible for an information breach.



- 2) When patient records are gathered for the first time, be sure to place the information in a secured and lockable location.
- 3) Upon acceptance of new patient records, provide a verbal disclosure statement to the patient. This verbal statement should make the patient aware that their records are being kept per state law and that they will be maintained in such a way that their information will remain confidential and kept from public view or oversight.
- 4) Have only employees who can be trusted and held responsible to work with and maintain patient records.
- 5) Train ALL registered employees to never disclose the specific names of patients with non-employees. It is important that the names of patients not be shared with the public in any way, as this would result in a HIPAA violation.
- 6) Store patient records in a secure place that is away from any cash or inventory vault. By keeping this location separate and secured you will minimize the chance that records could potentially go missing, get stolen, etc.



- 7) NEVER leave patient records out on a receptionist's desk or patient intake desk while the station is unattended.
- 8) Get HIPAA trained! It would be beneficial to have all employees' complete basic HIPAA training. This training will provide employees with HIPAA compliance training and ensure patients with more peace of mind knowing that the employees understand HIPAA privacy rules and procedures. See <http://www.hipaatraining.com/>
- 9) Host a monthly or bi-monthly meeting with all employees to go over privacy and confidentiality measures. This will provide further accountability on all staff levels to make sure privacy/legal compliance is met.
- 10) Designate record maintaining/record processing employees and limit patient records access. By doing this you will limit the potential for complications within your internal operations.



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HIPAA Compliance Training

**Standard Operating Procedure: HIPAA Compliance Training**

**Purpose:**

To explain the steps involved with becoming HIPAA-compliant trained.

**Scope:**

Covers the steps involved to obtain certified HIPAA training.

The primary goal of the federal HIPAA law is to make it easier for people to keep health insurance, protect the confidentiality and security of healthcare information and help the healthcare industry control administrative costs. **HIPAA** provides for the protection of individually identifiable health information that is transmitted or maintained in any form or medium. The privacy rules affect the day-to-day business operations of all organizations that provide medical care and maintain personal health information, this includes medical marijuana businesses and establishments.

Patient confidentiality will be of utmost importance during operations and maintaining patient records as confidential and properly stored and secured on the premise will be done according to required laws and regulations.



All patient records or files that are maintained as a “hard” or physical document will be properly stored in a locking file cabinet within a limited or restricted access area of the premise. If patient records or files are maintained electronically, said records or files will be maintained on a secure, HIPAA-compliant computer which will also be stored securely within a limited or restricted access area of the premise. The computer will be secure from physical theft but also electronic theft of records through the use of virus protection and secured servers on other security measures. Access to confidential patient records and files will be limited to BPH employees with proper clearance levels.

**General HIPAA Policies:**

- All employees that will have direct contact with confidential patient information will complete basic HIPAA training. This training will help employees understand HIPAA privacy rules and procedures. Visit the website: <http://www.hipaatraining.com/>



- Upon acceptance of new patient records, provide a verbal disclosure statement to the patient. This verbal statement should make the patient aware that their records are being kept per State law and that they will be maintained in such a way that their information will remain confidential and kept from public view or oversight.
- Access to confidential patient records will be limited to employees with the proper clearance level. These records will be accessible only by ownership, management and patient advocates. Limiting employee access



to confidential patient records will help reduce the risk to exposure. Additional employees may be granted the proper clearance level to access confidential patient records as needed in the future.

- Keep all patient records in a secure locking file cabinet or lockable filing system within a limited or restricted access area of the premise. Having all confidential patient files centrally located in can help ensure that no confidential patient records are being kept in exposed areas where it is possible for an information breach.



- When patient records are initially gathered, be sure to create a new patient folder and place the patient records within said folder. All folders should be marked confidential and place in a secured and lockable file cabinet within a limited or restricted access area of the facility (e.g. the general manager's office).



- ALL employees will receive training to never disclose the specific names of patients with non-employees or parties outside the organization. It is important that the names of patients not be shared with the public in any way, as this would result in a HIPAA violation.
- NEVER leave patient records unattended or unsecure within the file cabinet.
- Organization will host a monthly or bi-monthly meeting with all employees to go over privacy and confidentiality policies, procedures and measures. This will provide further accountability on all staff levels to make sure privacy/legal compliance is met.



<b>Standard Operating Procedure:</b> Patient Education
<b>Purpose:</b> To explain what is expected from employees regarding patient education.
<b>Scope:</b> Covers what educational materials should be offered at retail dispensary, house menus, effects, dosage, etc.
<b>Initial Training:</b> TBD

**Educational Documents**

- 1) State and/or local laws/regulations
- 2) Dispensary menu—brochure of all product offering, descriptions, test results, etc.
- 3) Patient education materials
- 4) Other educational materials as BPH sees fit
  - a. Medicate responsibly materials
  - b. Drug abuse prevention materials
  - c. Signs of impaired driving materials
  - d. Etc.

**The Principles of Patient Education**

Medical marijuana is a new treatment option for qualifying patient’s and as such, said patients will need to be educated on marijuana as a medicine. Medical marijuana patients will work closely with their physicians to determine the optimal medical marijuana treatment plan including routes of administration, dosage and usage recommendations and quantities of medical marijuana products to be dispensed. Patients will also have a close relationship with the dispensary staff who will be dispensing the medical marijuana products and as a result patients will most likely discuss their conditions with dispensary staff.

Individual patients will have different reactions to the medical marijuana products available, so patients will need to be educated about the potential effects of each medical marijuana product. A knowledgeable dispensary staff will be able to reference patient ailments with the medical marijuana products available and ultimately be able to recommend a medical marijuana product suitable for the patient. Medical marijuana patients will need to take the recommendations from dispensary staff to their physician to discuss routes of administration, dosage rates and quantities to be dispensed. The medical marijuana patient’s physician will determine what they feel is the best treatment option for said patient.

Patient education at a minimum will cover the following:

1. Medical marijuana’s effect on the human body
2. Physical effects based on route of administration of marijuana derivative product
3. Amount of time to feel impairment
4. Visible signs of impairment
5. Recognizing the signs of impairment
6. Packaging and labeling
- 7.

Patient education is detailed below; BPH will also create and provide detailed educational materials to be distributed to qualifying patients at the retail dispensary locations.

**1. Medical Marijuana’s Effect on the Human Body**

Medical marijuana will have different effects on every individual person and the effects may vary depending on quantity consumed, dosage rate, whether or not the marijuana was vaporized or ingested and other factors may contribute to the effects on the human body. The information below will describe some common effects associated with consuming medical marijuana products.



## 2. Physical Effects Based on Route of Administration of Marijuana Derivative Product

Medical marijuana is a new treatment option for patients in the State of Florida and patients seeking medical marijuana as a treatment option will need to be aware of the physical effects marijuana can have. Marijuana has an active ingredient called THC, which is what makes people feel 'high'. THC and other compounds in marijuana can also affect the way your body works. Marijuana affects almost every organ in the body, the nervous system and immune system. Vaporizing marijuana can increase the heart rate by as much as two times and can increase bleeding, lower blood pressure, and affect blood sugar. When vaporizing marijuana, the body absorbs THC immediately into the blood stream via capillary action in the lungs, if you consume or ingest a baked good or another marijuana-infused item, it may take much longer for the body to absorb THC because it has to break down in your stomach before it enters the bloodstream.

Other physical effects of marijuana consumption include:

- Dizziness
- Shallow breathing
- Red eyes and dilated pupils
- Dry mouth
- Increased appetite
- Slowed reaction time

Smoking marijuana can have less-pleasant effects on one's mind and mood such as:

- A distorted sense of time
- Random thinking
- Paranoia
- Anxiety
- Depression
- Short-term forgetfulness

## 3. Amount of Time to Feel Impairment

The amount of time it takes to feel impairment will differ and vary for everyone. Generally speaking, effects are typically immediate after consuming marijuana through vaporizing but the time to feel the effects after consuming marijuana through eating or ingesting could take up to 2 or 3 hours.

## 4. Visible Signs of Impairment

The most immediate signs of marijuana impairment are:

- Red eyes and dilated pupils
- Increased heart rate
- Increased appetite
- Memory impairment
- Difficulty paying attention or solving problems
- Dizziness
- Shallow breathing
- Dry mouth

## 5. Recognizing Signs of Impairment

The following information is being provided to assist persons in recognizing the signs and/or symptoms of marijuana impairment and for purposes of determining if an individual may be under the influence. This information is intended for informational purposes only and is not intended for use as training material, or to assist individuals in becoming drug recognition experts and should not be used in lieu of recommendations or advice from qualified professionals.

Generally speaking, if you notice an individual having trouble with balance, trouble walking or using motor functions, the individual may be impaired from consuming marijuana or marijuana-infused products. Redness of the eyes, dilated pupils and dryness of the mouth can also be indicators of impairment. If you suspect a patient is impaired or under the influence of marijuana or any other substance, do not let them drive or operate a motor vehicle of any kind. Offer to call a taxi or to arrange another means of transportation for the patient.



### 6. Packaging and Labeling

It is important for qualifying, registered patients’ to understand the importance of packaging and labeling medical marijuana products. Proper packaging and labeling will achieve two primary objectives; 1) the medical marijuana product will be properly be labeled to identify who the product is intended for, dosage rates and instruction and other important information pertaining to the patient or the medical marijuana derivative products, and 2) proper child-resistant packaging will help to ensure children cannot easily access the medical marijuana derivative product(s).

Child Resistant Packaging to be used for pill-form edibles (*capsules*)



Child Resistant Packaging to be used for oils (*for sublingual administration*)



Metered Dosage Packaging to be used for oils (*vaporization administration*)



Tamper-Evident Packaging to be used for pill-form edibles (*capsules*)



Tamper-Evident Packaging to be used for oils (*for sublingual administration*)



Tamper-Evident Packaging to be used for oils (*for vaporization*)



**Exit Packaging**—this exit packaging will be used to place the pre-package medical marijuana product(s) in at the medical dispensary prior to patients and/or a patients’ legal representative exiting the dispensary. This exit packaging will create a double redundancy to ensure children cannot unintentionally access the medical marijuana derivative product(s). Exit packaging will be opaque concealing the contents inside and will allow patients and/or caregiver discretion upon exiting the dispensary. Exit packaging is also utilized to minimize the risk to product diversion or the medical marijuana product(s) falling into the wrong hands.

The Satchel™ is a pouch-like case designed as a high-quality, child-resistant exit package solution for the regulated marijuana industry. The Satchel™ meets child-safety requirements of the Consumer Products Safety Commission (CPSC), making it compliant in all states. The Satchel™ is also tested and approved by the American Society for Testing and Supplies (ASTM). The Satchel™ features a child-resistant closure completely concealing the contents inside.

***THE SACHEL™***



American Cannabis Company  
growing the next frontier



**Other Education**

Employees of the retail dispensing locations will need to be very knowledgeable not only on the relevant State and Local laws and regulations, but they will also need to be very knowledgeable on all of the dispensaries product offerings, recommended dosage rates, potential side effects, and other pertinent information.

Individual patients will have different reactions to the medical marijuana strains available, so patients will need to be educated about the potential effects of each marijuana strain. A knowledgeable retail staff will be able to reference patient ailments with the marijuana strains available and ultimately be able to recommend a marijuana strain suitable for the patient. Registered employees are encouraged to educate themselves on marijuana as a medical treatment option.



### Opening Procedure

<b>Standard Operating Procedure:</b> Opening Procedure
<b>Purpose:</b> To explain the steps involved with the opening procedure.
<b>Scope:</b> Covers the steps involved to open the store for daily business activities.
<b>Initial Training:</b> 1 hour

### Documentation Log Sheets Required

- 1) Cash Drawer Balances

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels
- 4) Child-Resistant Exit Packaging

### The Principles of Opening Procedure

The opening responsibilities will primarily be comprised of getting the retail sales floor ready for daily activities. This will consist of the following:

- Entering the store, disable security alarm, clock in for a work shift
- Inventory management:
  - Stocking display cases with various medical marijuana products and manufactured marijuana products
  - Ensuring the retail sales floor has sufficient amounts of product for sale during shift (back-stock supply)
- Balancing and assigning cash drawer to each POS terminal

### **Opening Procedure:**

- 1) Enter the store
- 2) Disable security alarm
- 3) Clock-in for work shift
- 4) Prepare sale floor for daily activities:
  - a. Ensure sales floor is clean:
    - i. Sales counters are clean (Dust and Windex surfaces)
    - ii. Floors are free of debris (sweep, mop, vacuum, etc.)
  - b. Count and balance cash drawers for POS system(s)
    - i. Record beginning cash drawer balance on **Cash Drawer Balances** log sheet.
  - c. Retrieve marijuana products and marijuana-infused products from safe/vault.
  - d. Set up display cases with marijuana products and marijuana-infused products.
- 5) Ensure retail dispensary is adequately stocked with product to support the daily sales activity
  - a. You may need to place an order to receive more product from the cultivation facility and/or 3<sup>rd</sup> party organizations.
- 6) Turn on 'OPEN' sign and begin daily sales operations.





Example of Cash Drawer Balance log sheet (see below):

<u>Cash Drawer Balances</u>							
Date:	Employee:	Drawer 1		Drawer 2		Drawer 3	
		Open	Close	Open	Close	Open	Close





<b>Standard Operating Procedure:</b> Patient and Caregiver Intake
<b>Purpose:</b> To explain the processes involved to process patients and/or caregivers into the retail dispensary.
<b>Scope:</b> Covers the required steps to allow patients and/or caregivers into the facility.
<b>Initial Training:</b> 2 hours

### **The Principles of Patient and Caregiver Intake**

Patients and caregivers wishing to patron any retail dispensing facility will need to have a valid state Medical Marijuana Program Registration Card. After entry into retail dispensing facility, team members will verify the validity of each patient's Medical Marijuana Program Registration Card through the state electronic verification system in the reception room. After the verification process has been completed, the patient and/or caregiver will be allowed entry into the secured sales rooms.

The retail facility manager will create and maintain a database within the POS system for inventory and tracking purposes. This will enable team members to adhere to all laws regarding the quantities of medical marijuana products patients and/or caregivers are allowed to have in a given time period.

#### **Electronic Verification**

Facility employees will verify each and every patient's and/or caregiver's Medical Marijuana Program Registration Card prior to entry into any secured sales rooms. The electronic verification process will need to be completed for every single patient and/or caregiver *EVERY* time they wish to patron the facility.

- 1) **Medical Marijuana Program Registration Card**—Accept patient and/or caregivers state-issued medical marijuana license
  - a. Ensure the state-issued medical marijuana license is current (check expiration date on Card)
- 2) **State-Issued ID**—Patients and/or caregivers must also have a current and valid State-issue ID (passport, Driver's License, etc.)
  - a. Ensure that the state-issued ID is current (check expiration date on ID)
- 3) **Verification**—Verify the validity of the state-issued Medical Marijuana Program Registration Card
  - a. Verify validity of the Medical Marijuana Program Registration Card license through the state electronic verification system
- 4) **Access**—Allow or deny access to patient and/or caregiver
  - a. Allow entry to retail dispensary if the patient and/or caregiver has a valid state-issued Medical Marijuana Program Registration Card.
  - b. Deny entry to retail dispensary if the patient and/or caregiver does not have a valid state-issued Medical Marijuana Program Registration Card.
    - i. If you feel the patient and/or caregiver is trying to use a fake or fraudulent Medical Marijuana Program Registration Card; confiscate said Medical Marijuana Program Registration Card and contact required state authorities.



Visitors

<b>Standard Operating Procedure: Visitors</b>
<b>Purpose:</b> To explain the processes involved to accept/allow visitors into the retail dispensary.
<b>Scope:</b> Covers the required steps to follow to allow visitors into the facility.
<b>Initial Training:</b> 1 hour

**Requirements**

- 1) Visitor Log Sheet
- 2) Visitor pass

Pursuant to 329D-15 and 329D-16, unauthorized access to retail dispensing locations and/or a production center is a Class C felony. Due to the strict penalties for infractions, BPH will take steps to identify all potential subcontractors, maintenance workers, and any other individual identified as needing to visit one of BPH retail dispensing locations or our production center. Such steps will allow said individuals to submit proactively to fingerprint cards and background checks and be aware of the information submitted to the Department. In order to obtain Department approval, BPH also intends to identify secondary, back-up individuals who can be utilized as resources if the primary resource is unavailable; these secondary subcontractors and resources will also be required to submit fingerprint cards and authorize consent for background investigations to ensure the individual does not have any felony convictions or other offenses listed in §11-850-17.

**The Principles of Visitor Protocol**

BPH’s visitor protocol will follow industry best practices and current regulations. There will be situations that arise that will require someone to enter the registered dispensary facility premises who is not a State-licensed industry worker or not a State-registered patient or caregiver but they will need access to the facility. Common visitors typically will be support-type businesses such as HVAC, electric and plumbing, general contractors, etc.

All visitors at any BPH registered dispensary facility must be on the Department-approved list prior to entering the facility. Visitors must be free of any felony convictions and sign a waiver from BPH acknowledging this fact. Visitors will be required to adhere to a visitor procedure and check in and out with a BPH registered employee. A registered employee will escort visitors and maintain visual contact at all times. BPH will not permit the consumption of marijuana or manufactured marijuana products at any registered dispensary facility.

Approved visitors will be required to provide a BPH registered employee with a current, valid government-issued identification. The registered employee will confirm the individual is on the BPH’s Department-approved list, make a photocopy of the visitor’s ID and maintain the photocopy with the visitor log book; visitors will be required to sign in and out with a registered employee and provide a written reason for the visit (e.g. maintenance work, HVAC, repairs, etc.). Upon completing these requirements, the registered employee will issue a ‘visitor badge’ for the visitor to wear and display while at any BPH registered dispensary facility. BPH will also require a registered employee to remain with the visitor for the duration of the visit to ensure the visitor does not interact with or handle any marijuana plant, material, product, or manufactured marijuana product.

- **Government-Issued ID**—all visitors must have a current and valid government-issued ID (passport, Driver’s License, military ID)
  - Ensure that the government-issued ID is current (check expiration date on ID)
- **Verification**—Verify the validity of the government-issued ID and that the visitor is on the current Department-approved list
- **Photocopy**— Make photocopy of visitor’s government-issued ID
  - Make a photocopy of visitor’s ID; Photocopy is to remain with *Visitor Log Sheet*

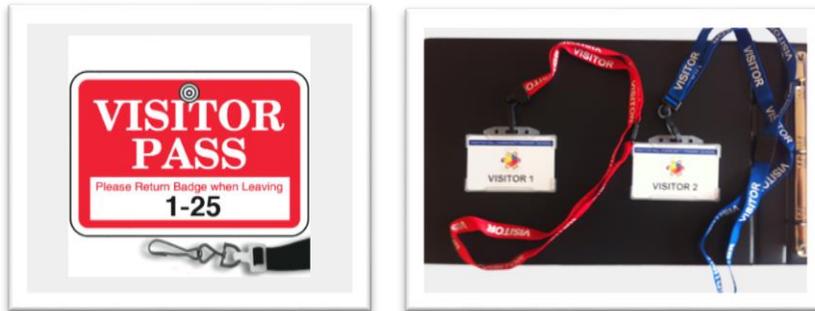


- **Access**—Allow or deny access to the facility
  - Allow entry to dispensary if the visitor has a valid government-issued ID.
  - Deny entry to the facility if the visitor does not have a valid government-issued ID.
  
- **Record/Documentation**—Have visitor fill out the *Visitor Log Sheet*
  - *Visitor Log Sheet* will document visitors name, company, date, time-in, time-out, signature, reason for the visit
  - Maintain photocopy of visitor ID with the *Visitor Log Sheet*
  - This record of visit must be retained and maintain on the licensed premise for a minimum of two (2) years.

**Visitor Access Process:**

- 1) Check visitors ID and credentials at the check-in station
  - a. Make photocopy of Visitor’s ID
- 2) Verify with management that visitors are expected and on the current Department-approved list
- 3) Fill out *Visitor Log Sheet*
- 4) Have said visitor sign-in and date the *Visitor Log Sheet*
- 5) Give visitor a ‘*Visitor Pass*’
- 6) When visitor is finished at the licensed premises:
  - a. Have visitor sign-out on *Visitor Log Sheet*
  - b. Collect the ‘*Visitor Pass*’ from said visitor

*Example of a Visitor Pass can be seen below:*



*Example of Visitor Sign-In Documentation Log Sheet:*

<u><b>Visitor Sign-In Documentation Log Sheet</b></u>							
<u>Date</u>	<u>Time In</u>	<u>Time Out</u>	<u>Visitor Name</u>	<u>Visitor's Company</u>	<u>Visitor Signature</u>	<u>Reason for Visit</u>	<u>Registered Employee Escort</u>





Receipt of Material

<b>Standard Operating Procedure: Receipt of Materials</b>
<b>Purpose:</b> Explain procedure and requirements for receiving raw materials
<b>Scope:</b> To educate and train licensed premise employees on the procedures and requirements involved with receipt of materials.
<b>Initial Training:</b> 1-2 hours

**Principles of Receipt of Material**

The process of receipt of material or receiving raw materials is not as simple as just taking the marijuana product materials into the retail dispensary location. There are regulations, guidelines and procedures to follow when receiving marijuana product materials or other inventory into the retail dispensary locations.

Upon receiving any raw materials, inventory or other items used in operations said items will be placed in a quarantine storage area within the receiving area of the licensed premise. These items will include but not be limited to:

- Marijuana flower product
- Manufactured marijuana products

**Receipt of Materials**—upon receiving materials into the licensed premise, registered employees and/or licensed premise employees will need to document the receipt of materials on the *Receipt of Materials* log sheet.

*Example of Receipt of Materials Log Sheet can be seen below:*

<b>Receipt of Materials</b>							
<u>Date of Receipt:</u>	<u>Receiving Employee #1:</u>	<u>Receiving Employee #2:</u>	<u>Product/Strain/Attribute ID #:</u>	<u>Quantity Received:</u>	<u>Received From:</u>	<u>Materials Placed in Quarantine:</u>	<u>Materials Pass Visual Inspection:</u>
						YES NO	YES NO
<i>Describe why Materials did not pass visual inspection:</i>				<i>Corrective action to be taken:</i>			
<u>Materials Pass Visual Inspection after Corrective Action:</u>		<i>Describe why Materials did not pass visual inspection after corrective action:</i>		<i>Next corrective action to be taken:</i>			
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>If materials passed visual inspection, and are determined to be acceptable for use as intended, said materials may be released from the quarantine areas and used as intended.</i>							
<u>Date of Release of Materials:</u>	<u>Employee(s)/Supervisor Releasing Materials:</u>		<u>Product/Strain/Attribute ID # of Released Material(s):</u>		<u>Quantity Released:</u>		
<u>Record of Receipt of Materials Made in Perpetual Inventory Control System (POS)?</u>		<u>Required POS Records:</u> <i>date of receipt, quantity of material, types/variety of material date of release</i>		<u>Employee Making POS Record Entry:</u>		<u>Employee Witnessing POS Record Entry:</u>	
<input type="checkbox"/> YES <input type="checkbox"/> NO							
<i>Notes/Comments:</i>							

**Inspection**—after received inventory items/materials are placed in quarantine, the items will need to be inspected to ensure there are no defects or contamination. All received items/materials will remain in a secure area until said material pass inspection and is determined to be acceptable for use as intended.

- Registered employees will be required to inspect all materials for visible defects and contamination



**Release**—upon the received materials passing inspection and being determined to be acceptable for use as intended, the materials will be released from the quarantine receiving/storage area. At this time the materials can be used within the licensed premise for their intended use.

- Release materials if they pass initial inspection

**Documentation and Record**—upon the materials being released from quarantine and determined to be acceptable for use as intended BPH registered employees and/or licensed premise employees will be required to log the materials into the inventory control system.

- Document and record new materials released from quarantine in the inventory control system (POS system)
- Ensure record is accurate with physical inventory on hand
- Ensure the *Receipt of Material* log sheet is filled out properly and completed



<b>Standard Operating Procedure:</b> Weights and Measurements and Scale Calibration
<b>Purpose:</b> To explain how to use certified scales for weights and measurements
<b>Scope:</b> To train registered employees on proper use of NTEP certified scales to be used for weights and measures as well as scale calibration/certification
<b>Initial Training:</b> 1 hour

BPH will pre-package all marijuana and manufactured marijuana products at the production center. Due to this fact, BPH should not have the use for a commercial scale at the retail dispensary locations, however BPH will keep certified scales on the premise in case a need should arise.

**Types of Scales to be used**

BPH will utilize NTEP-certified scales for the weighing of all medical marijuana, medical marijuana products, medical marijuana waste and all green waste.

**NTEP Certification**— The National Conference on Weights and Measures issues an NTEP Certificate of Conformance following successful completion of an evaluation of a device. It indicates that the device(s) described in the Certificate is/are capable of meeting applicable requirements of the *NIST Handbook 44*.\* <http://www.ncwm.net/ntep/faqs#WhatIsNTEPCertificate>

**Scale Use**

All medical marijuana harvested at BPH’s licensed premise will be weighed and packaged using NTEP-certified scales certified for legal trade and that have been calibrated and certified ISO/IEC 17025 accredited by a Hawaii calibration service supplier.

**Scale Calibration and Frequency**

BPH will ensure that all scales and balances are calibrated by an accredited calibration service supplier. The frequency of having BPH scales calibrated will be on a six (6) month basis. This routine calibration will be documented on the Scale Calibration Log sheet and maintain on the licensed premise.

*Example of the Scale Calibration Log Sheet:*

<b><u>Scale Calibration</u></b>					
<u>Date:</u>	<u>Employee:</u>	<u>Scale Serial #/ID #:</u>	<u>Calibration Service Supplier:</u>	<u>Scale Calibrated</u>	<u>Notes/Comment:</u>
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	
				YES NO	



**Standard Operating Procedure: Dispensing/Sales Procedure**

**Purpose:** To explain the processes involved in the sales procedure at the retail dispensing facility.

**Scope:** Covers the steps to follow when making a sale.

BPH will ensure that all retail dispensary sales are conducted at the retail dispensary location within a secure sales room. BPH will also have policies and procedures in place to ensure there are more more than 2 qualifying patient to every 1 registered dispensary employee within the secure sales rooms.

**The Principles of the Sales Procedure**

The sales procedure needs to be completely accurate for every sales transaction. If sales records are not accurate, then the inventory will reflect discrepancies that could result in regulatory compliance issues. Retail team members will complete extensive training on the POS system and the sales process before commencing operations.

Prior to making a sale, registered employees will have checked a government-issued ID from the qualified patient/caregiver. (*refer to qualified patient/caregiver intake SOP*)

**Making a Sale**—Prior to initializing a sale, a retail team member should make sure the current medical marijuana patient information is in the POS system and/or electronic database; if it is the patient’s first visit to the retail facility, the team member will need to create a new record for that patient. After verifying the medical marijuana patient’s information, the retail team member should check the POS system to determine how much/many medical marijuana products the patient is allowed to purchase. Quantity limits will be set forth in individual qualified patient records within the inventory control system.

Blue Planet Healing will ensure compliance with §11-850-42 by utilizing BioTrackTHC™, an inventory tracking system that will ensure registered employees dispense the correct amount of marijuana or manufactured marijuana products to registered patients. The state regulatory measure §11-850-42 dictates sales limits for qualifying patients. BPH will educate and train all registered employees to ensure sales limits are strictly adhered to. BPH will not dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that exceeds four (4) ounces of marijuana or its dry weight equivalent during a period of fifteen (15) consecutive days, and will not exceed eight (8) ounces of marijuana or its dry weight equivalent during a period of thirty (30) consecutive days.

**Department Data Network**

Before any distribution or dispensing of medical marijuana, BPH will require a registered employee to query the Department data network. Registered employees will be required to query the Department data network to:

- Verify that the qualifying patient or caregiver is currently registered.
- Verify that a verifying physician issued a valid written certification to the qualifying patient.
- Verify that the amount of medical marijuana already dispensed pursuant to the written certification.
  - To ensure qualified patients do not receive any combination of marijuana or marijuana manufactured products that exceed 4 ounces of marijuana during a period of fifteen (15) consecutive days.
    - Every sale of marijuana is measured on a scale and added up towards the tally
    - Manufactured marijuana products will all have the amount of marijuana used to produce the product labeled on its packaging and listed on the BioTrackTHC inventory system to be added up towards the tally
- Confirmations of Department of Health data network queries will be recorded by the registered employee into the Applicant’s inventory control system, and maintained as part of the qualified patient or caregiver electronic file.



- This entry is automatically time-date stamped and require the agent's electronic signature to attest to the verification of the Department of Health data network query. This protocol is required prior to every distribution, dispensing and/or transaction involving medical marijuana products.

**Packaging and Labeling Compliance**—all medical marijuana products will be packaged according to all applicable state and local laws. Employees will place all medical marijuana products into opaque, child-resistant, tamper-evident, and re-sealable containers prior to dispensing to any patient or caregiver.

**Sales Tax**—all sales transactions will be subject to applicable sales tax rates. The proper sales tax rates will be programmed into each POS system to ensure sales tax is being collected.

**Cash Handling**—all cash handling at the POS area should be done in view of a surveillance camera. This will help ensure honesty and reduce theft by employees. Also see Cash Handling SOP.

*Record of Dispensed Marijuana Product(s) (see below):*

Record of Distributed Medical Cannabis Products			
	Retail Dispensary Location License #:		Dispensary Phone #:
	Location Address:		
Qualified Patient Name:		Patient Address (street, city, state, ZIP):	
DOB:	Patient Registry ID #:		
Patient Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender			
Fill Out Caregiver Information IF Applicable			
Designated Caregiver Name:			
DOB:		Caregiver Registry ID #:	
Dispensing Information			
Date Marijuana Product was Dispensed:	Quantity of Medical Marijuana Product(s):	Marijuana Product Attribute #:	Number of Days Supply that was Dispensed:
Product Batch #:		Date Distributed:	
Payment Method: <input type="checkbox"/> Cash <input type="checkbox"/> Credit <input type="checkbox"/> Other		Payment Amount: \$	



<b>Standard Operating Procedure:</b> Inventory Reconciliation Procedure
<b>Purpose:</b> To explain the purpose and processes involved with inventory reconciliation.
<b>Scope:</b> Covers the steps involved with inventory reconciliation.
<b>Initial Training:</b> 4-6 hours

### **The Principles of Inventory Reconciliation**

It is recommended to perform physical inventory on weekly or monthly basis. At minimum, a monthly inventory reconciliation is to be performed at each facility. This is where every product within the facility will be physically counted, documented and then reconciled (*compared*) with the inventory recorded in the POS system or computer inventory system.

The physical inventory on-hand that is counted should be identical to the inventory that is recorded within the POS system. If there are deviations in these numbers then action must be taken to determine the shortage(s).

- 1) Count **ALL** on-hand inventory at the retail dispensary location
  - Marijuana flower product
  - Manufactured marijuana products
- 2) Document all counted on-hand inventories on the appropriate ***Marijuana Products Inventory*** (*daily, weekly, or monthly*) log sheet.
- 3) Reconcile counted on-hand inventories against on-hand inventories in the POS system
  - Document discrepancies on the appropriate ***Marijuana Products Inventory*** (*daily, weekly, or monthly*) **log** sheet between the counted on-hand inventory and POS inventory.
  - Investigate all discrepancies
- 4) Inventory Discrepancies—discrepancies between the inventory stock and the inventory within the inventory control system (*outside of normal weight loss due to moisture loss and handling*)
  - Investigate all discrepancies within one (1) business day
    - Perform inventory audit and reconciliation
    - Review transactions within the inventory control system
    - Review security surveillance footage
  - Report theft or diversion to the Department of Health AND Honolulu Police Department within one business day
    - Contact the Department of Health and Honolulu Police Department in multiple fashions as a redundancy
      1. Contact directly through phone conversation
      2. Contact electronically through email, fax or other electronic means
  - Within 30 days
    - the inventory discrepancy investigation must be conducted and completed
    - the standard operating procedures amended (*if needed*)
    - send an investigation report and audit to the Department of Health



Example of Receiving Marijuana Products (Incoming Shipment) log sheet:

<b>Receiving Marijuana Products (Incoming Shipments)</b>						
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Product Name/Attribute ID #/ Strain:</u>	<u>Quantity Received:</u>	<u>Quantity Fulfilled:</u>	<u>Fulfilled By:</u>	<u>Wholesaled To:</u>

Example of Marijuana Products Inventory log sheet:

<b>On-Hand Marijuana Product Inventory Log Sheet</b>								
<u>Date:</u>	<u>Product Name:</u>	<u>Batch#/Unique ID #:</u>	<u>Quantity On Hand:</u>	<u>Quantity in POS System:</u>	<u>Discrepancy Amount:</u>	<u>Employee #1:</u>	<u>Employee #2:</u>	<u>Notes:</u>

Example of Product Loss log sheet:

<b>Product Loss Log Sheet</b>				
<u>Date:</u>	<u>Product Name/Category</u>	<u>Product Attribute # or Unique ID #</u>	<u>Total Quantity Loss:</u>	<u>Product Loss Valuation:</u>
				\$
<u>Reporting Employee:</u>	<u>Manager/Supervisor:</u>	<u>Product Loss Due To:</u>		
		<input type="checkbox"/> Employee Theft/Diversion <input type="checkbox"/> Burglary/Robbery <input type="checkbox"/> Error/Destruction <input type="checkbox"/> Other		
<u>Internal Investigation:</u>	<u>Required Authorities Notified:</u>	<u>Authorities Notified (list all):</u>		
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO			
<u>Note/Comments:</u>				



**Standard Operating Procedure: Cleaning of Equipment/Displays**

**Purpose:** To explain the purpose and processes involved with cleaning the retail dispensary locations.

**Scope:** Covers the steps involved with required daily cleaning.

**Principles of Cleaning**

BPH prides itself on the cleanliness and presentation of the dispensary sales floor area and the entire retail dispensary location as a whole. Registered employees will be required to maintain the cleanliness and appearance of the entire Licensed Premise with a specific attention to detail regarding the service areas.

The maintenance of the cleanliness of any and all building or equipment used to store or display medical marijuana will be required as an essential job function of registered employees. Employees will be required to clean certain areas, equipment and other property on a routine basis.

Registered employees will be required to maintain the cleanliness of the following:

- Medical marijuana display cases
- Medical marijuana display jars/containers
- Service area sales counters
- Service area sales equipment—POS system

BPH will require that medical marijuana is always handled by employees with stainless steel forceps, which shall be decontaminated in 70 percent isopropyl alcohol soak overnight, or while donning non-latex, non-powdered gloves.

Routine hand washing is required for employees and agents shall be required to wear company issued work attire while working in the dispensary Licensed Premise. (*refer to employee dress code SOP*)

Medical marijuana shall be handled for processing and repackaging only in the operations area, and the area shall be cleaned between handling different batches. Registered employees will document, record and maintain cleaning logs.

No individual other than a registered employees are permitted to handle medical marijuana or medical marijuana-infused products at any time.

**Required Cleaning**

BPH will require registered employees to routinely clean the service area of the Licensed Premise periodically throughout each day of operations. The cleanliness of the Licensed Premise should mirror the cleanliness one would find in a pharmacy; qualified patients and caregivers will expect a clean facility where medical marijuana is dispensed. This will include the cleanliness of the areas of the building where medical marijuana products are dispensed, equipment used to store, display or dispense medical marijuana products and the registered employee dispensing the medical marijuana. (*refer to employee dress code SOP and personal hygiene policy*)

- Registered employees will be required to maintain the cleanliness of the service area.
  - The service area of the Licensed Premise is where the medical marijuana products are dispensed to qualified patients and caregivers and this area should be held to the highest standard for cleanliness at the premise.
- Medical marijuana displayed in a jar or container:
  - The jar or container used to store and/or display medical marijuana will need to be cleaned and maintained daily.
  - Registered employees will be required to wipe down the jar or container after every use with a cloth to remove oils and/or resins if present.
  - The jar/container will be required to be thoroughly cleaned on a weekly basis.



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- Registered employees will be required to clean the jar/container with 70 percent isopropyl alcohol to remove any plant oil, resins or contaminants.
- This weekly cleaning is to be documented within the cleaning and sanitation of jars log sheet.
- Stainless steel forceps must be kept clean and sanitary
  - Registered employees are required to handle stainless steel forceps while wearing non-latex, non-powdered nitrile gloves
  - If gloves are not used during forceps use, registered employees must store the forceps in 70% isopropyl alcohol overnight



Cash Handling

<b>Standard Operating Procedure: Cash Handling</b>
<b>Purpose:</b> To explain the steps involved with daily cash handling.
<b>Scope:</b> Covers the steps involved to handle cash and assemble weekly deposits.
<b>Initial Training:</b> TBD

**The Principles of Cash Handling**

This section will cover how to properly handle cash at the dispensary level. Specifically, this section will be split into subsections that will easily guide the employee/manager through all requirements necessary to mitigate risk as it pertains to the constant physical handling of cash.

Many of these procedures are performed in “**dual control**” meaning that two members of the staff are to simultaneously observe the action being taken as well as sign off on the completion or verification of said action. *Note:* In dual control, at least one of the two employees must be, at minimum, a manager.

The Licensee or Owner of the establishment should assign a “**drawer limit**” to all POS cash drawers. This limit indicates the maximum amount of cash allowed in the drawer at any given time. As soon as a drawer limit is reached or surpassed, it is the responsibility of the employee running the POS cash drawer to notify his/her manager of the occurrence. The employee and manager will then go into “dual control” where the cash overage will be transferred from the POS drawer to the vault. For more details, see the below subsection entitled “Drawer Limit Transfers.”

**Cash Handling – Opening Procedure**

- 1) In dual control, open the vault.
- 2) Once vault is opened, each employ in dual control signs the *Cash Vault Opening/Closing Log* signifying that the vault is now open.
- 3) In dual control, the manager will take out the proper amount of cash necessary to place into the appropriate POS cash drawer(s).
- 4) Both the manager and the employee count the cash that will be extracted from vault and place correct amount of cash into the appropriate POS cash drawer(s).
- 5) Once cash has been counted and placed into the POS drawer(s), dual control employees will complete the *Cash Transfer Log*, detailing the amount of cash leaving the vault and each bill denomination placed into each individual POS drawer. The amount of cash being transferred to the POS drawer will be considered that drawer’s beginning balance for the day.
- 6) Update the *Vault Balance Sheet* to reflect the new balance of the vault (no physical cash count of the entire vault is necessary at this point)
- 7) In dual control, close the vault.
- 8) Once the vault is closed, dual control employees sign the *Cash Vault Opening/Closing Log*.
- 9) Remaining in dual control, employees will take POS cash drawers to the appropriate POS station.
- 10) Engage in sales operations!

**Cash Handling – Mid-Day Procedure**

- 1) Throughout the day, it is the duty of the manager to perform at least one Random Drawer Audit (RDA) on each employee as they are signed on to a cash drawer. The manager will complete a *Random Drawer Audit (RDA) Form* ensuring that the cash balance reflects what the tracking system shows. These audits are to be unannounced so that employees may be held accountable for a balanced drawer at all times.



Manager's Note: While RDAs are to be performed routinely, do not perform audits at the same time daily. It is important to perform these audits as randomly as possible to help mitigate risk.

- 2) Once the RDA has been complete, both the manager and the employee being randomly audited will initial/sign the *RDA Form*, signifying that the cash is in balance.

**Cash Handling – Closing Procedure**

- 1) Once inventory has been reconciled at the end of the business day, the cash in each POS cash drawer will be counted in dual control with at least one manager present.
- 2) The dual control employees will complete an *End-of-Day Drawer Balance Sheet*, detailing all cash located in the drawer, including the denomination of each bill.
- 3) Remaining in dual control, the manager and employee will transfer all of the cash from the drawer to the vault, using the *Cash Transfer Log* to track the transfer.
- 4) Once vault is opened, each employ in dual control signs the *Cash Vault Opening/Closing Log* signifying that the vault is now open.
- 5) When all cash has been transferred to the vault, the dual control members will make complete straps of cash (See *Cash Strapping Procedures* below).
- 6) Once cash has been strapped appropriately, the dual control members will update the *Vault Balance Sheet* to reflect the amount of cash secured.
- 7) Once all cash is fully secured in the vault, the dual control members will complete the *Cash Vault Opening/Closing Log* ensuring that the vault has been closed.

**Vault Balancing**

- 1) A physical hard count of the cash in the vault should ideally be completed at the end of each business day. It is up to the Owner/Licensee how frequently a hard count of the vault cash should be performed.
- 2) In dual control, employees will open the vault.
- 3) Once vault is opened, each employ in dual control signs the *Cash Vault Opening/Closing Log* signifying that the vault is now open.
- 4) The dual control members will unstrap cash, perform a physical count of the cash, and then re-strap the cash (you can use the original strap to re-strap currency)
- 5) Once all cash has been counted and re-strapped, record balance and denominations on the *Vault Balance Sheet* and note on the sheet that a physical count was performed.
- 6) Once all cash is fully secured in the vault, the dual control members will complete the *Cash Vault Opening/Closing Log* ensuring that the vault has been closed.

**Cash Strapping Procedures**

- 1) Cash should be strapped using the bank standard format:

\$1's    X 100 = \$100  
 \$5's    X 100 = \$500  
 \$10's   X 100 = \$1,000  
 \$20's   X 100 = \$2,000  
 \$50's   X 100 = \$5,000  
 \$100's X 100 = \$10,000



2) Coin should be rolled using the bank standard format:

Pennies	X 50	= \$0.50
Nickels	X 40	= \$2.00
Dimes	X 50	= \$5.00
Quarters	X 40	= \$10.00
Half-Dollar	X 20	= \$10.00
Dollar	X 25	= \$25.00



**Drawer Limit Transfers**

- 1) It is strongly recommended that POS cash drawers be designated with a Drawer Limit. This limit represents the maximum amount of cash allowed inside the drawer at all times. The purpose of establishing a Drawer Limit is to ensure that cash is controlled. If in the event that robbery/theft occurs, the loss can be minimized if the Drawer Limit threshold is not surpassed. When RDAs are performed on employees, managers should be checking to make sure that the drawer limit has not been reached.
- 2) If an employee’s drawer limit is reached, a manager should be notified immediately
- 3) Once manager is notified of the drawer limit being reached, the employ and manager will be put into dual control
- 4) The dual control members will collect the cash necessary to bring the drawer limit down, and record the information on the *Cash Transfer Log*.
- 5) The vault is then opened, and each employ in dual control signs the *Cash Vault Opening/Closing Log* signifying that the vault is now open
- 6) The dual control members place the cash into the vault and strap the currency if need be.
- 7) The dual control members adjust the *Vault Balance Sheet* to reflect the cash added to the vault.
- 8) Once all cash is fully secured in the vault, the dual control members will complete the *Cash Vault Opening/Closing Log* ensuring that the vault has been closed.

*Example of Cash Vault Opening/Closing Log Sheet:*



<b>Cash Vault Opening/Closing Log</b>							
Date	Time	Open Amount	Close Amount	Employee 1 Name	Employee 1 Signature	Employee 2 Name	Employee 2 Signature
12/5/2015	4:00	12500	27500	John Smith		Jack John	

*Example of Vault Balance Sheet can be seen below:*

<b>Vault Balance Sheet</b>				
Date Updated	Time	Updated Vault Balance	Physically Counted? (Y/N)	Denominations - If Physically Counted
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>
		\$		Pennies: 1's: Nickels: 2's: Dimes: 5's: Quarters: 10's: Halves: 20's: Dollar: 50's: 100's: <b>Total: \$</b>

**Weekly Deposits/Outgoing Cash**

- 1) Once cash is ready to leave the establishment, dual control members of the company will open the vault.
- 2) The vault is then opened, and each employee in dual control signs the *Cash Vault Opening/Closing Log* signifying that the vault is now open.
- 3) The dual control members will then extract the straps of currency/rolls of coin needed to be transferred out of the establishment.
- 4) The currency to be transferred out of the facility will then be unstrapped/unrolled and physically counted in dual control.



- 5) Once currency is counted, it should be re-strapped and re-rolled, ready to transfer.
- 6) The **Vault Balance Sheet** should then be updated to reflect the amount of money leaving the vault.
- 7) The strapped cash and rolled coin ready for transport is then placed inside of a tamper-evident bag. See example below:



- 8) Once the money is placed inside the tamper-evident bag, record the amount placed as well as the bag number.
- 9) The dual control members will then complete the **Cash Transfer Log** indicating how much currency is leaving the location and where the tamper-evident bag is being delivered.

Cash Transfer Slip		Cash Transfer Slip	
Date:		Date:	
	<b>Amount</b>		<b>Amount</b>
	Pennies		Pennies
	Nickels		Nickels
	Dimes		Dimes
	Quarters		Quarters
	Half Dollars		Half Dollars
	Dollar Coins		Dollar Coins
	1's		1's
	2's		2's
	5's		5's
	10's		10's
	20's		20's
	50's		50's
	100's		100's
	<b>Total: \$</b>		<b>Total: \$</b>
From:	Initials #1:	From:	Initials #1:
To:	#2:	To:	#2:
Cash Transfer Slip		Cash Transfer Slip	
Date:		Date:	
	<b>Amount</b>		<b>Amount</b>
	Pennies		Pennies
	Nickels		Nickels
	Dimes		Dimes
	Quarters		Quarters
	Half Dollars		Half Dollars
	Dollar Coins		Dollar Coins
	1's		1's
	2's		2's
	5's		5's
	10's		10's
	20's		20's
	50's		50's
	100's		100's
	<b>Total: \$</b>		<b>Total: \$</b>
From:	Initials #1:	From:	Initials #1:
To:	#2:	To:	#2:

### **Cash Transportation**

- 1) The Licensee/Owner of the establishment will determine whether or not an armed guard courier service is necessary to transport cash.
- 2) If no armed guard courier service is utilized, all cash that is transported should be done in dual control. One of the members of dual control must be a high-level manager or Owner of the establishment. The cash will be guarded at all times in dual control until the tamper-evident bags have arrived safely at the destination.
- 3) Once the cash has been safely delivered, the dual control members must receive some kind of document proving receipt of currency transferred
- 4) The dual control members will then take the documented receipt and deliver it back to the licensed establishment. The receipts of cash transfers should then be filed in the establishment's business records.



**Standard Operating Procedure: Customer Complaints and Returns**

**Purpose:** To explain the steps involved for handling customer complaints and product returns.

**Scope:** Covers the steps involved to handle customer complaints and product returns appropriately.

**Documentation Log Sheets Required**

- 1) Customer Complaint Form
- 2) Returned Marijuana Products Log Sheet
- 3) Returned Marijuana Products Waste

**The Principles of Handling Customer Complaints and Product Returns**

It is important to have proper procedures in place for the handling of customer complaints and/or product returns. By having these initiatives in place you can ensure the most satisfied customer base possible. Below are best practice steps to take when confronted with a customer complaint and/or product return.

**Handling Customer Complaints** – When confronted by a customer with a complaint, perform the following:

- 1) Listen to the customer’s complaint fully and completely so that you can better understand the scope of the problem or issue needing to be addressed (Hint: Be open and reflect understanding of the customer’s problem. Repeat back to the customer your understanding of the complaint and recognize that the customer is not attacking you personally so there is no reason to get defensive).
- 2) Be empathetic, and display genuine care for the customer (Hint: Try to imagine being in the customer’s shoes. By doing so you will not only understand the problem more clearly, you will also display a calmer tone and more open demeanor towards the customer).
- 3) Ask clarifying questions to further understand the issue at hand.
- 4) Apologize for the inconvenience that was caused, however, do not resort to placing blame on anyone or the company.
- 5) Provide at least one solution for the customer. The more solutions you provide the customer, the more they will feel that you genuinely want to help (regardless of whether or not any solution provided is acceptable to the customer).
- 6) Provide the chosen solution, or if the solution is not in your capacity, connect with the appropriate co-worker or upper management employee that will provide the solution.

**State of Hawaii Requirements**

- In the event a complaint is associated with a serious adverse event, BPH will require registered employees to:
  - Promptly report the complaint to the BPH management
  - Report the complaint to the other BPH licensed retail dispensary location that may have received a shipment containing marijuana from the batch determined to cause the complaint
- In the event a complaint associated with a serious adverse event, BPH will be required to promptly report the complaint to, (1) the Department, (2) either the licensed grower from which the medical marijuana originated, or the licensed processor from which the marijuana and/or manufactured marijuana product originated.
  - BPH’s registered employees will report to the Department in the event a complaint is associated with a serious adverse event.
    - Within 24-hours registered employees must report the complaint to the Department



**Recalling of Medical Marijuana**—if a batch of marijuana is determined through testing to fail to meet specification, BPH will do the following:

- Order a recall of all products derived from or included in the batch
- Notify all retail dispensary locations and/or qualified patients and/or primary caregivers who may have obtained marijuana products from such a batch of the recall
  - Using the inventory control system and/or physical documentation log sheets/records to identify all dispensary locations and/or qualified patients that may have received a distribution containing marijuana from the production batch
  - After identifying the dispensaries and/or patients, registered employees will be required to directly notify said parties.
- Offer and pay reimbursement for any returned marijuana product
  - Offer to replace the marijuana product free of charge or offer full monetary reimbursement.

**Handling Customer Complaints**—when a customer wishes to make a formal complaint, follow the following procedures:

- Have customer wishing to form a complaint to complete the *Customer Complaint Form*
- File complaint within the customer complaint folder located within a limited-access area within the Licensed Premise
- Notify management of the formal complaint
- Notify the Department of the formal complaint

	<i>Customer Complaint Form</i>	
	Date:	Location:
	Customer Name:	
	Employee Documenting Complaint:	Supervisor on Duty:
	Description of Complaint:	
	Corrective Action to be Taken:	
	Customer Comments:	
	Customer Signature:	Date:
	Employee Signature:	Date:

In the event of a formal complaint regarding the quality or safety of medical marijuana is received, BPH will require registered employees to review and investigate the complaint within 24-hours to determine:

- If the complaint is substantive or reports a serious adverse event
- Determine the batch number of the marijuana—this can be accomplished using the records and documentation maintained throughout the cultivation process to determine if there were any deviations in production



- If the complaint is substantive or reports a case of a serious adverse event, registered employees will determine the batch number of the marijuana
- Registered employees will be required to investigate the record and circumstances of the production of the batch and lot to determine:
  - If there was a deviation from the standard operating procedure in the production of the medical marijuana by reviewing production logs, records and documentation
    - Test retention samples of the batch and lot to an independent testing laboratory.
      - Send retention samples from batch and lot in question to licensed testing laboratory for testing
        - If testing reveals that the batch or lot fails to meet specifications, follow steps for recall below in following SOP
        - Notify any and all patients, caregivers and dispensaries who may have obtained medical marijuana products from such a batch or lot of the recall
          - Use the inventory control system and physical records to determine who may have received a batch of medical marijuana from the recalled batch
          - Upon identifying retail dispensary locations that have received marijuana from the batch in recall, registered employees will need to notify the licensed dispensary directly with two means:
            - Via phone call, AND
            - Via email

**Investigation of Complaint**—BPH will require registered employees to investigate all complaints regarding the quality or safety of medical marijuana. Registered employees will be required to review records and documentation from the cultivation operations to determine if there was any deviation from production.

- Review all cultivation records and documentation log sheets
  - Try to determine if there were any deviation in production
  - If there is a deviation in production, see **Standard Operating Procedures SOP**
  - Determine the batch number and/or lot number of the medical marijuana
    - Reviewing records and documentation for substantive changes in production
- Meet with complainant to understand the serious adverse event (*if applicable*)
  - Meeting with the complainant registered employees may be able to identify the medical marijuana batch associated with the complaint
- Order a recall of the medical marijuana batch if necessary; follow **Product Recall SOP**

**Handling Customer Returns** – When a customer wishes to return a product, perform the following procedure:

- Acquire the product needing to be returned and begin the process of completing the Returned Marijuana Products Log Sheet
- Ask for the reason as to why the product is being returned and record this information.
- Log the product as being returned into the electronic inventory tracking system
- Offer and pay reimbursement for the medical marijuana products tracking system.
- Ensure that the Returned Marijuana Products Log Sheet is completed and filed.

**Example of a Returned Marijuana Products Log Sheet:**



<b><u>Returned Marijuana Products Log Sheet</u></b>					
<u>Date:</u>	<u>Receiving Employee:</u>	<u>Patient/Caregiver Returning Cannabis Product:</u>	<u>Marijuana Product Returned (Name/Attribute#):</u>	<u>Quantity/Weight:</u>	<u>Reason for Product Return</u>

*Example of a Returned Marijuana Waste Log Sheet:*

<b><u>Returned Marijuana Waste Log Sheet</u></b>						
<u>Date:</u>	<u>Registered Employee:</u>	<u>Qualified Patient/Caregiver:</u>	<u>Marijuana Product to Dispose:</u>	<u>Waste Weight:</u>	<u>Mixed With:</u>	<u>Total Weight to Dispose:</u>

Product Recall

<b>Standard Operating Procedure:</b> Product Recall
<b>Purpose:</b> To ensure that all required steps and procedures are take when there is a need to recall a marijuana product.
<b>Scope:</b> Procedures covering voluntary and involuntary product recalls.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required Within the Cultivation Facility**

- 1) Product Recall Log

**Principles of Product Recall**

Manufacturers, importers, distributors and retailers of consumer goods are liable for the products they provide to consumers and face the potential of product recalls for potentially dangerous or hazardous products. The same is true for the marijuana businesses as manufacturers and retailers of consumer medical marijuana products, for the facility may need to conduct a product recall in the future. For most consumer products the recall process is handled and regulated by the Consumer Product Safety Commission (CPSC), and for all intents and purposes the marijuana business recall plan will follow the guidelines of the CPSC.

The Consumer Product Safety Commission (CPSC) has compiled resources to assist companies that manufacture, import, distribute, retail, or otherwise sell consumer products. CPSC has developed a Recall Handbook that can be utilized in case a product recall needs to be ordered. The Recall Handbook details how to recognize potentially hazardous consumer products as soon as possible. The book explains how to develop and implement a “corrective action plan” (called a CAP) to address the hazards; it explains CPSC’s Fast Track Program. The Recall Handbook also discusses how to communicate recall information to consumers and how to monitor product recalls. The Consumer Product Safety Commission’s Recall Handbook will be a valuable tool utilized by the company if the need for a product recall ever arises.

The Recall Handbook should be referenced to determine exact protocol for recall and the requirements from the Consumer Product Safety Commission. The Recall Handbook can be obtained online from <http://www.cpsc.gov/PageFiles/106141/8002.pdf>.

### **When to Recall Medical Marijuana Products**

As a manufacturer, distributor, and/or retailer of consumer products, the cultivation facility has a legal obligation to immediately report the following types of information:

- 1) A defective product that could create a substantial risk of injury to consumers;
- 2) A product that creates an unreasonable risk of serious injury or death;
- 3) Marijuana or manufactured marijuana is determined to contain a contaminate of some kind
- 4) Marijuana or manufactured marijuana batch did not successfully pass required testing but was released for distribution

Failure to fully and immediately report this information may lead to substantial civil or criminal penalties. Consumer Product Safety Commission's staff advice is "when in doubt, report." BPH will ensure communication with the required state and local authorities within 24 hours of becoming aware of the need for a product recall. BPH will then proceed to the recalling protocol and how to recall the product.

### **How to Recall Medical Marijuana Products**

The facility will develop a recall plan following guidance from the Recall Handbook provided by the CPSC. Once the need for a product recall has been determined, the facility will proceed with the product recall Corrective Action Plan (CAP). If the need for a product recall arises, cultivation centers and dispensing organizations will have inventory management systems in place to determine and pinpoint which products to recall, how many of those products are in the supply chain, and will be able to determine exactly where those products are within the supply chain. The inventory management systems and procedures required by state law will ensure a stream-lined recall process if ever necessary.

#### **Corrective Action Plan (CAP)**

A corrective action plan is a schedule of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. The goal of a corrective action plan should be to retrieve as many hazardous products from the distribution chain and from consumers as possible in the most efficient, cost-effective manner. The CAP will outline the procedures and steps needed to be taken by the facility once a product recall is required.

#### **Step One: Industry Notification**

If a marijuana or manufactured marijuana product is believed to need a recall, BPH will contact all retail dispensary locations to notify them of the situation and the need for product recall. BPH will also contact required state and local authorities within 24 hours of obtaining reportable information. As the cultivator and/or manufacturer of the product needing to be recalled, BPH will need to contact the end users of the recalled product; contacting qualified patients will prove to be difficult, but will be possible through the utilization of the inventory control and POS systems. At this stage of the recall, retail dispensary locations will need to ensure that they have a proper recall process in place to contact qualified patients that were dispensed the product being recalled.

#### **Step Two: Public Notification**

The cultivation facility or dispensing establishment will post notifications about the product recall on its website as well as make partnering cultivation centers and dispensing organizations aware of the product recall. The actual recalling processes will be handled by both the cultivation center and the dispensing organizations.

As the dispensing organization issuing a recall notice, it will be important to reach the end users or the recalled product. The facility will post notification about the recall on Facility websites and social media as well as post written notices of the recall on location for patients and customers to view. The recall notice will include all pertinent information regarding the product being recalled, contact information and other information relating to the recall. Information will include but not be limited to:



- 1) Product name and unique attribute number
- 2) Product batch number
- 3) Dispensing date range of recalled product
- 4) Retail dispensary locations

Once the recall notification has been issued to all applicable dispensing organizations and medical marijuana patients, the facility will wait to receive recalled products from dispensing organizations and/or licensed medical marijuana patients and caregivers. Once recalled products have been received, the facility will properly dispose of all recalled products. The disposal of these products should conform to the state law for waste disposal.

**Step Three: Procurement**

BPH issuing a product recall to qualified patients and primary caregivers will need to be ready to obtain and secure recalled products from qualified patients. Patients should be able to bring in the products being recalled to the retail dispensary location. It will be at BPH’s discretion whether to issue a refund, replace the recalled product at no cost, or to take other measures.

- Upon receiving recalled marijuana and/or manufactured marijuana products, registered employees will document the return of the recalled marijuana product
- After documentation, registered employees will securely store the recalled marijuana product in segregated storage until disposal
  - Recalled medical marijuana must be securely stored until properly destroyed and disposed of.

**Step Four: Documentation and Record Retention**

BPH will maintain all documentation all records regarding any and all product recalls issued. Registered employees will be required to fill out the required *Product Recall Log Sheet*.

<u><b>Product Recall Documentation Log Sheet</b></u>				
<u>Date:</u>	<u>Product Name</u>	<u>Product Attribute # or Unique ID #</u>	<u>Quantity to be Recalled</u>	<u>Supervisor</u>
List Potential Patient/Caregivers to Notify:				
Regulatory Agencies Notified: <input type="checkbox"/> MMCC <input type="checkbox"/> FDA <input type="checkbox"/> CSPA <input type="checkbox"/> Other				
<u>Date:</u>	<u>Quantity Collected:</u>	<u>Collected From (Patient/Caregiver):</u>	<u>Accepting Employee:</u>	<u>Notes/Details</u>

### Step Five: Disposal

The facility will ensure that any and all recalled marijuana products are disposed of according to all state and local regulations. The facility will follow marijuana waste disposal and destruction procedures outlined within these SOPs for proper disposal of recalled medical marijuana.

- Recalled material must not be destroyed or disposed of until authorized by the Department of Health.
  - Recalled medical marijuana will need to be stored and segregated until the disposal of recalled material is authorized by the Commission.
    - Stored recalled material in the quarantined secure storage area of the Licensed Premise.
- Once receipt of notification from the Department of Health that the disposal of recalled medical marijuana is authorized, registered employees will dispose of the medical marijuana according to the *Marijuana Waste Disposal SOP*.
  - Registered employees must dispose of medical marijuana within 24-hours of Department of Health authorization.



<b>Standard Operating Procedure:</b> Marijuana Waste Destruction and Disposal
<b>Purpose:</b> To explain required and proper disposal processes for marijuana waste.
<b>Scope:</b> Covers marijuana waste grinding, mixing and disposal measures within the retail dispensing facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Marijuana Waste Disposal Log

**Equipment/Tools Required**

- 1) Wood chipper/plant grinder
- 2) Mixing material (material to mix marijuana waste with at 50/50 ratio)
- 3) Trash bags
- 4) Dumpster/trash compactor

**Requirements of Marijuana Waste Disposal**

All marijuana waste, byproducts, undesired materials, green waste and returned/recalled marijuana will be destroyed by rendering the waste unrecognizable, unusable and unrecoverable.

BPH will require registered employees to weigh, document, record and destroy all marijuana waste according to the written standard operating procedures. All marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated will be destroyed and disposed of according to the written SOP.

**Secure, Segregated Storage**—all medical marijuana waste will be stored in secure, segregated storage on the Licensed Premise until receipt of authorization from the Department of Health of destroy and dispose of the medical marijuana waste.

- The secure, segregated storage will promote good growing and handling practices.

**Marijuana Waste Disposal**—all medical marijuana waste, byproducts and undesired products will be destroyed and disposed of according to all applicable state and local regulations. Facility management will ensure proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state law. Record all required information on the *Marijuana Waste Log Sheet*.

**Disposal**—Disposal of any marijuana product waste must be rendered unrecognizable, unusable and unrecoverable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.



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Cannabis Stalks (waste)



**Grinding Marijuana Waste (Stalks, Stems, Leaves and Other Material)**



Cannabis Waste



Wood Chipper



Chip/Grind Cannabis Waste



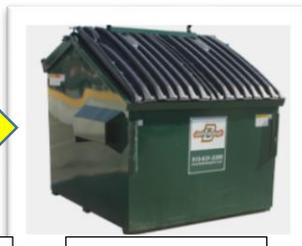
Mix Ground Cannabis Waste with Additive  
(50/50 MIX RATIO)



50/50 Mix Ratio

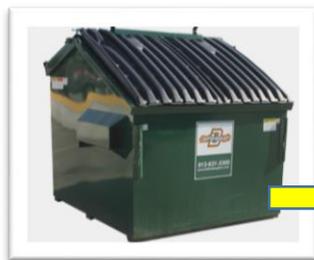


Bagged Waste Ready for Disposal



Waste Receptacle

**\*\*BPH shall not dispose of marijuana product waste in an unsecured waste receptacle not in possession and control of the licensed premise. It is recommended to have a lock on the physical dumpster as well as the area where the dumpster is maintained.**



Waste Receptacle



Locked Waste Receptacle



Locked Waste Holding Area

*Example of Marijuana Waste Documentation Log Sheet (see below):*





Equipment Operation

<b>Standard Operating Procedure:</b> Equipment Operation
<b>Purpose:</b> To identify the various equipment to be utilized within the facility
<b>Scope:</b> To identify the equipment to be utilized, and where employees can obtain copies of the manufacturer
<b>Initial Training:</b> 4-8 hours

**The Principles of Equipment Operation**

For all 3<sup>rd</sup> party equipment being utilized within the facility it is recommended to refer to the manufacturer instructions and user manuals for proper operation, set-up, maintenance, cleaning or any other equipment information. Manufacturer instructions and user manuals should have been provided as a hard copy with all original equipment. If the original user manual has been lost or misplaced, refer to the manufacturer company website or contact them directly for a replacement manual.

Some manufacturing companies offer user manuals and instructions as an electronic version which can be obtained online from the company website. Below are some of the specific equipment utilized by ACC along with the company website where user manuals and/or manufacturer instructions and suggests can be obtained.

**1) Patriot Electric Wood Chipper**

- a. Website: <http://www.patriot-products-inc.com/P/31/WoodChipperLeafShredder15hpElectricInternational>
- b. User Guide: <http://www.patriot-products-inc.com/Content/files/electsvmanual.pdf>

**2) 26 Quart High Performance Blender**

- a. Website: <http://www.webstaurantstore.com/26-quart-high-performance-vertical-tilting-blender-110v-220v/915LAR25.html>
- b. User Guide: [http://www.webstaurantstore.com/documents/pdf/omcan\\_blendr\\_operating\\_manual.pdf](http://www.webstaurantstore.com/documents/pdf/omcan_blendr_operating_manual.pdf)

**3) Digital Scale**

- a. Website: [http://www.coleparmer.com/Product/A\\_D\\_FX\\_2000iN\\_NTEP\\_Tploading\\_Balance\\_2200\\_g\\_x\\_0\\_1g/EW-11115-82](http://www.coleparmer.com/Product/A_D_FX_2000iN_NTEP_Tploading_Balance_2200_g_x_0_1g/EW-11115-82)



<b>Standard Operating Procedure:</b> Closing Procedure
<b>Purpose:</b> To explain the steps and process involved in closing the sales floor/store on a daily basis.
<b>Scope:</b> Covers closing responsibilities and procedures.
<b>Initial Training:</b> TBD

**The Principles of the Closing Procedure**

The closing responsibilities will primarily be comprised of closing the retail sales floor and securing product for safe storage throughout the night. Closing responsibilities will consist of the following:

- 1) Close the POS system(s) for the day
  - a. Run daily sales report
  - b. Remove cash drawer to count/balance
- 2) Cash balancing and reconciliation
  - a. Count the cash drawer; record numbers on **Closing Log Sheet** (cash, credit, check, payout, etc.)
  - b. Once all CASH is counted, hold back enough cash to ‘rebuild’ the cash drawer till (this should be ~\$200.00/drawer)
    - i. Record the ‘new till’ amount on the **Cash Drawer Balance** (close)
  - c. Complete **Closing Log Sheet**
- 3) Pull all medical marijuana products and marijuana-infused products located in display cases to be stored in a safe/vault, located in a secure access area, for nightly storage.
- 4) Close retail sales floor and secure facility for nightly closure
  - a. Ensure all entrances/exits are locked and secured
  - b. Arm the security alarm panel
  - c. Exit facility; ensure that the door you are exiting closes completely and is locked/secure for the evening.

**Nightly Product Storage**—Management will ensure that all marijuana and manufactured marijuana products are securely stored each night on the retail dispensary locations. All marijuana products shall be safely stored in a limited access area within a secured storage vault or safe. Management will be responsible for ensuring that the storage area meets or exceeds state requirements for the storage environment.

*Example of Close-Out Sheet (see below):*



Date:	Employee:	Register:
Cash	\$ _____	
	+	
Credit Cards	\$ _____	
	+	
Checks	\$ _____	
	+	
Payouts	\$ _____	
	=	
Total On Hand	\$ _____	
	-	
Less Starting Cash Balance	\$ _____	
	=	
Daily Total	\$ _____	
	X	
Tax Rate	\$ _____	
	=	
Daily Sales	\$ _____	
	-	
Daily Total	\$ _____	
	=	
Daily Tax	\$ _____	

*Example of Cash Drawer Balances Log Sheet:*

<u>Cash Drawer Balances</u>							
Date:	Employee:	Drawer 1		Drawer 2		Drawer 3	
		Open	Close	Open	Close	Open	Close





Emergency Protocol

<b>Standard Operating Procedure:</b> Emergency Protocol
<b>Purpose:</b> To describe all steps and protocols to be followed by employees should an emergency occur within the facility.
<b>Scope:</b> Procedures covering emergency situations occurring within the facility.
<b>Initial Training:</b> 2-4 hours

**Documentation Log Sheets Required**

- 1) Emergency Situation Documentation Sheet

**Equipment/Tools Required**

- 1) Panic Alarm/Button
- 2) Fire Extinguisher
- 3) Chemical Spill Kit
- 4) Emergency eye wash station(s)
- 5) First Aid Kit
- 6) Emergency defibrillator

**The Principles of Emergency Protocols**

A facility emergency management plan is designed to educate and train facility employees on the actions and procedures to follow in the event of an emergency. In the case of an emergency, facility employees will need to respond quickly and think strategically in order to successfully manage the emergency situation. Having a good understanding of the facility emergency management plan will enable employees to better adapt to and handle emergencies.

The most important thing to remember during an emergency situation is to try to stay calm, if the emergency situation is out of your control and you need assistance, contact emergency services immediately if possible.



**Burglary:** Burglary is legally defined as the criminal offense of breaking and entering a building illegally for the purpose of committing a crime. Burglaries generally will occur at the Licensed Premise after operating hours and while there are no registered employees present. Typically burglaries occur during the night and are not discovered until the next day during normal operating hours.

- If upon entering the Licensed Premise and a registered employees notice something is afoul and upon investigation a burglary was determined to have occurred in the previous night, then registered employees will be required to document the incident and notify all required authorities.
  - Registered employees will be required to report the incident of burglary to:



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- The Department of Health
- Local medical marijuana authority (*if applicable*)
- Honolulu Police Department

**Robbery or Theft:** Robbery is legally defined as the taking of money or goods in the possession of another, from his or her person or immediate presences, y force or intimidation. The number one rule registered employees will need to follow when/if dealing with a robbery is to comply with all robber demands

- If you are being robbed at gunpoint or if you feel as if your life is in danger, comply with all requests from perpetrator/suspect. Give them whatever they ask for.
- Try to signal for help using the personal security panic buttons provided, by activating one of multiple, strategically placed panic alarm buttons, or through the panic button/police services button located on the alarm panel.
- Contact law enforcement as soon as possible
- Notify any required State or local authorities immediately (within 24 hours)
  - Honolulu Police Department
  - The Department of Health
- Comply with all applicable laws and regulations
- Document the situation in the *Emergency Situation Documentation* log sheet



Alarm Panel

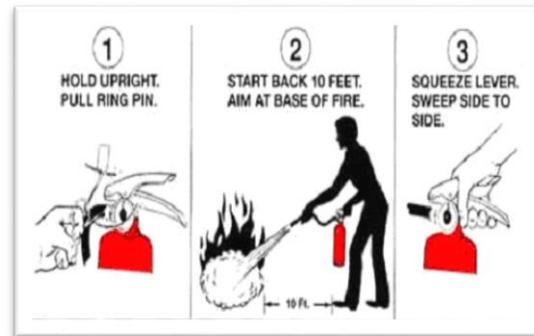
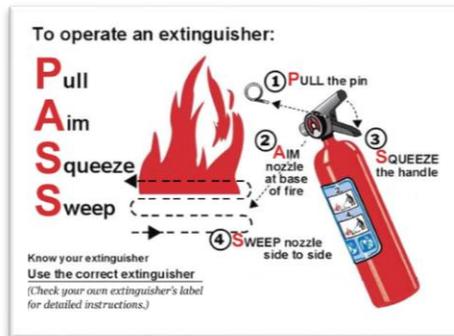
Panic Alarms/Buttons



**Fire Emergency:**

- If a small isolated fire is present, try to exhaust the fire with one of the fire extinguishers on site
- In case of a fire emergency, first leave the facility; once clear of the facility dial 911 and/or local fire authority for Fire Emergency Services or push the symbol on the alarm panel for fire emergency upon exiting the facility
- Document the situation in the *Emergency Situation Documentation* log sheet

**Fire Emergency Cont.**



**Chemical Emergency:**

- Dangerous Substance/Chemical Exposure:
  - If an employee accidentally has their eyes exposed to toxic, poisonous or dangerous substances or chemicals; said employee will need to locate the installed emergency eye



wash station(s) to properly flush and clean their eyes. Notify emergency medical services for further assistance

- Chemical Spill:
  - Try to use a chemical spill kit for smaller incidents of chemical spill
  - If a chemical spill is large or you do not know how to handle the situation; get the facility manager to handle the situation and/or contact proper emergency services
    - Posted near or included with the chemical spill kit should be an emergency contact information sheet displaying which emergency services should be contacted.
      - For the BPH and the State of Hawaii this will include but not be limited to:
        - Environmental Protection Agency (EPA)
          - For emergencies and other sudden threats to public health, such as:
            - oil and/or chemical spills,
            - radiation emergencies, and
            - biological discharges,
              - call the National Response Center at 1-800-424-8802.
            - For **pesticide poisoning**, call 911 if the person is unconscious, has trouble breathing, or has convulsions. Otherwise, call **Poison Control at 1-800-222-1222**.
- Document the situation in the *Emergency Situation Documentation* log sheet



**Medical Emergency:**

- If it is a minor medical situation such as a small cut, scrape or minor burn; retrieve the first aid kit on site and treat wound with items found in the first aid kit
- If the situation appears to be a severe medical situation such as someone suffering from a heart attack, retrieve the emergency defibrillator and follow the instructions provided; notify 911 or local medical emergency services for further assistance
- If the medical situation is an emergency; contact medical emergency services immediately. This can be done through activating the medical response button found on the alarm panel, or by calling 911 for medical emergency services
- If a serious injury occurs while an employee is working, such as a slip and fall resulting in possible broken bones or a cut requiring stitches, BPH facility management will need to complete a worker compensation insurance claim form prior to the employee seeking medical assistance. This procedure does not take long, but the form will need to be completed in order for the injured employee to have a workers compensation medical claim.
- Document the situation in the *Emergency Situation Documentation* log sheet



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**Other Emergencies:**

- Contact 911 if it is a current emergency. Contact your local police and/or State regulatory authorities for break-ins or burglaries that may have occurred when the facility operations were closed
- Contact any required State or local authority in cases of theft, break-ins or burglaries
- Document the situation in the *Emergency Situation Documentation* log sheet



**Example of Emergency Situation Documentation Log Sheet:**

<u><b>Emergency Situation Documentation</b></u>		
Date:	Reporting Employee:	Manger on Duty:
Type of Emergency: <input type="checkbox"/> Robbery of Theft <input type="checkbox"/> Fire Emergency <input type="checkbox"/> Chemical Spill <input type="checkbox"/> Medical Emergency <input checked="" type="checkbox"/> Other Emergency		
Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO	Which Authorities:	
Description of the Incident:		





**Standard Operating Procedure: Loss of Personnel**

**Purpose:** To describe all steps and protocols to be followed prior to or after the loss of personnel.

**Scope:** Procedures covering loss of personnel situations occurring within the facility.

The following will cover procedures to follow when terminating a key employee as well as when a key employee decides to leave the organization on their own accord.

**Job Termination**—if the need arises to terminate the position of a key personnel there will be some basic steps and procedures to follow within operations.

1. Notify key personnel of job termination
2. Obtain all facility keys, ID badges or other company property
3. Disable/change all terminated key personnel facility security access codes or passwords
4. Notify required authorities of the job termination of the key personnel
5. Notify all remaining staff of the job termination of the key personnel and inform them of the conditions of termination (i.e., employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
6. Contact security vendor and monitoring company to notify them of the job termination of key personnel.
  - a. Remove terminated key personnel from any notification, contact or call lists.

**Job Separation**—at times key personnel may decide to part ways on their own accord. In such circumstances there will be some basic steps and procedures to follow in for job separations.

1. Obtain all facility keys, ID badges or other company property
2. Disable/change all key personnel facility security access codes or passwords
3. Notify required authorities of the job separation of the key personnel
4. Notify all remaining staff of the job separation of the key personnel and inform them of the conditions of separation (i.e., mutual separation and key personnel is always welcome back at SFN facilities under visitor status, employee is no longer allowed on the premise and to notify police or other authorities if said employee returns, etc.)
5. Contact security vendor and monitoring company to notify them of the job separation of key personnel.
  - a. Remove key personnel from any notification, contact or call lists.

**Replacement of Key Personnel Position**—find and interview a suitable replacement for the position that was previously filled by key personnel. Key personnel positions will need to be filled as soon as possible by ownership and/or management without sacrificing quality of applicant pool. Some basic steps should be followed to find and place a suitable replacement for the vacant position.

1. Review resumes and applications from qualified applicants
2. Call said qualified applicants to conduct an informal, initial phone interview
  - a. If you get a good response from applicant, schedule an in-person interview
3. Conduct in-person interviews with qualified applicants
4. Review interviewed applicants
  - a. Select applicant who is most qualified for the vacant position
5. Contact said applicant and offer the vacant position
6. If applicant accepts the job offer, proceed with normal hiring procedure and required paperwork

## Attachment 7.4



Operations Documentation Log Sheet Note Book





## Cultivation Log Sheets





Vegetative Room(s)		
Temp.:	Humidity:	Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO
Plant Vegetative Lifecycle Week:		
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO	Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Overall Plant Health:		
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO	What type of disease/pest infestation?	
Notes/Details:		
Number of Plants:	POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO	Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO
Action Items ( <i>if any</i> ):		
Additional Notes/Details:		
Flowering Room(s)		
Temp.:	Humidity:	Plant Medium Moisture Level ( <i>plants need to be watered?</i> ): <input type="checkbox"/> YES <input type="checkbox"/> NO
CO2 Level:	Plant Flowering Lifecycle Week:	
Lights functioning properly? <input type="checkbox"/> YES <input type="checkbox"/> NO	Growing equipment functioning properly ( <i>Autopots, etc.</i> )? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Overall Plant Health:		
Any signs of disease/pest infestation? <input type="checkbox"/> YES <input type="checkbox"/> NO	What type of disease/pest infestation?	
Notes/Details:		
Number of Plants:	POS System Accurate? <input type="checkbox"/> YES <input type="checkbox"/> NO	Adjustment(s) Made? <input type="checkbox"/> YES <input type="checkbox"/> NO
Action Items ( <i>if any</i> ):		
Additional Notes/Details:		

## Daily Zone/Room Environment Documentation



### Daily Zone/Room Environment Documentation

<b>Monday</b>	<b>Date:</b>		<b>Time:</b>		<b>Employee:</b>			
<u>Clone Room</u>	<u>Vegetative Room(s)</u>		<u>Flowering Room(s)</u>		<u>Dry Room</u>		<u>Cure Room</u>	
Temp:	Temp:		Temp:		Temp:		Temp:	
Humidity:	Humidity:		Humidity:		Humidity:		Humidity:	
Notes/Details:								
<b>Tuesday</b>	<b>Date:</b>		<b>Time:</b>		<b>Employee:</b>			
<u>Clone Room</u>	<u>Vegetative Room(s)</u>		<u>Flowering Room(s)</u>		<u>Dry Room</u>		<u>Cure Room</u>	
Temp:	Temp:		Temp:		Temp:		Temp:	
Humidity:	Humidity:		Humidity:		Humidity:		Humidity:	
Notes/Details:								
<b>Wednesday</b>	<b>Date:</b>		<b>Time:</b>		<b>Employee:</b>			
<u>Clone Room</u>	<u>Vegetative Room(s)</u>		<u>Flowering Room(s)</u>		<u>Dry Room</u>		<u>Cure Room</u>	
Temp:	Temp:		Temp:		Temp:		Temp:	
Humidity:	Humidity:		Humidity:		Humidity:		Humidity:	
Notes/Details:								
<b>Thursday</b>	<b>Date:</b>		<b>Time:</b>		<b>Employee:</b>			
<u>Clone Room</u>	<u>Vegetative Room(s)</u>		<u>Flowering Room(s)</u>		<u>Dry Room</u>		<u>Cure Room</u>	
Temp:	Temp:		Temp:		Temp:		Temp:	
Humidity:	Humidity:		Humidity:		Humidity:		Humidity:	
Notes/Details:								
<b>Friday</b>	<b>Date:</b>		<b>Time:</b>		<b>Employee:</b>			
<u>Clone Room</u>	<u>Vegetative Room(s)</u>		<u>Flowering Room(s)</u>		<u>Dry Room</u>		<u>Cure Room</u>	
Temp:	Temp:		Temp:		Temp:		Temp:	
Humidity:	Humidity:		Humidity:		Humidity:		Humidity:	
Notes/Details:								
<b>Saturday</b>	<b>Date:</b>		<b>Time:</b>		<b>Employee:</b>			
<u>Clone Room</u>	<u>Vegetative Room(s)</u>		<u>Flowering Room(s)</u>		<u>Dry Room</u>		<u>Cure Room</u>	
Temp:	Temp:		Temp:		Temp:		Temp:	
Humidity:	Humidity:		Humidity:		Humidity:		Humidity:	
Notes/Details:								
<b>Sunday</b>	<b>Date:</b>		<b>Time:</b>		<b>Employee:</b>			
<u>Clone Room</u>	<u>Vegetative Room(s)</u>		<u>Flowering Room(s)</u>		<u>Dry Room</u>		<u>Cure Room</u>	
Temp:	Temp:		Temp:		Temp:		Temp:	
Humidity:	Humidity:		Humidity:		Humidity:		Humidity:	
Notes/Details:								









## Pest and Disease Identification Documentation



Date of 1st Sign of Infestation:	Type of Issue: <input type="checkbox"/> Pest/Insect Infestation <input type="checkbox"/> Mold/Fungal Infestation <input type="checkbox"/> Bacterial Infestation <input type="checkbox"/> Other
Name of Pest or Disease ( <i>if known</i> ):	Zone/Room of Infestation:
Corrective Action to be Taken:	
Notes:	
Date of 1st Sign of Infestation:	Type of Issue: <input type="checkbox"/> Pest/Insect Infestation <input type="checkbox"/> Mold/Fungal Infestation <input type="checkbox"/> Bacterial Infestation <input type="checkbox"/> Other
Name of Pest or Disease ( <i>if known</i> ):	Zone/Room of Infestation:
Corrective Action to be Taken:	
Notes:	
Date of 1st Sign of Infestation:	Type of Issue: <input type="checkbox"/> Pest/Insect Infestation <input type="checkbox"/> Mold/Fungal Infestation <input type="checkbox"/> Bacterial Infestation <input type="checkbox"/> Other
Name of Pest or Disease ( <i>if known</i> ):	Zone/Room of Infestation:
Corrective Action to be Taken:	
Notes:	
Date of 1st Sign of Infestation:	Type of Issue: <input type="checkbox"/> Pest/Insect Infestation <input type="checkbox"/> Mold/Fungal Infestation <input type="checkbox"/> Bacterial Infestation <input type="checkbox"/> Other
Name of Pest or Disease ( <i>if known</i> ):	Zone/Room of Infestation:
Corrective Action to be Taken:	
Notes:	
Date of 1st Sign of Infestation:	Type of Issue: <input type="checkbox"/> Pest/Insect Infestation <input type="checkbox"/> Mold/Fungal Infestation <input type="checkbox"/> Bacterial Infestation <input type="checkbox"/> Other
Name of Pest or Disease ( <i>if known</i> ):	Zone/Room of Infestation:
Corrective Action to be Taken:	
Notes:	





## Nutrients, Supplements and/or Growth Additives



<u>Date:</u>	<u>Employee:</u>	<u>Grow Room:</u>	<u>Plant Attribute # and Batch #</u>	<u>Lifecycle Stage:</u>	<u>Week:</u>
				<input type="checkbox"/> Vegetative <input type="checkbox"/> Flowering	
<b>Nutritional Deficiency Identified?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>What is the nutritional deficiency</b> ( <i>reason for application</i> ) ?		<b>Nutrient, Supplement and/or Growth Additive Applied:</b>	<b>Amount Applied:</b>	<b>Applied By:</b>

Note/Comments:

<u>Date:</u>	<u>Employee:</u>	<u>Grow Room:</u>	<u>Plant Attribute # and Batch #</u>	<u>Lifecycle Stage:</u>	<u>Week:</u>
				<input type="checkbox"/> Vegetative <input type="checkbox"/> Flowering	
<b>Nutritional Deficiency Identified?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>What is the nutritional deficiency</b> ( <i>reason for application</i> ) ?		<b>Nutrient, Supplement and/or Growth Additive Applied:</b>	<b>Amount Applied:</b>	<b>Applied By:</b>

Note/Comments:

<u>Date:</u>	<u>Employee:</u>	<u>Grow Room:</u>	<u>Plant Attribute # and Batch #</u>	<u>Lifecycle Stage:</u>	<u>Week:</u>
				<input type="checkbox"/> Vegetative <input type="checkbox"/> Flowering	
<b>Nutritional Deficiency Identified?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>What is the nutritional deficiency</b> ( <i>reason for application</i> ) ?		<b>Nutrient, Supplement and/or Growth Additive Applied:</b>	<b>Amount Applied:</b>	<b>Applied By:</b>

Note/Comments:













# Marijuana Batch Log



<u>Date:</u>	<u>Attribute # and Batch#:</u>	<u>Plant Strain:</u>	<u>Package ID#:</u>	<u>Package Weight:</u>	<u>Package Quantity:</u>	<u>Packaged By</u> <i>(initial) :</i>	<u>Witnessed By</u> <i>(initial) :</i>	<u>Storage Area:</u>
Date Sample Shipped:	Sample Pass Testing: <input type="checkbox"/> YES <input type="checkbox"/> NO Date:	Certificate of Analysis Provided w/ Supporting Data? <input type="checkbox"/> YES <input type="checkbox"/> NO	Batch Cleared for Release for Distribution? <input type="checkbox"/> YES <input type="checkbox"/> NO	Inventory Control Updated? <input type="checkbox"/> YES <input type="checkbox"/> NO	Released by <i>(initial):</i>	Witnessed by <i>(initial):</i>		
	Batch Potency:	Batch Purity:	Batch expiration date data/support:	Notes/Details:				

























# Attachment 4.11

	<h2 style="margin:0;">Marijuana Product Transport Manifest</h2>	<b>Transfer Identification #:</b>	<i>Test results included for ALL products being shipped?</i> <input type="checkbox"/> YES <input type="checkbox"/> NO	
<i>*This form must be completed prior to the shipping of any marijuana or manufactured marijuana products. This Record for Transfer must be present along with the Transportation/Trip Manifest Form with ALL shipments of marijuana and/or manufactured marijuana products from the Licensed Premise.</i>				
Date Package/Shipment Sealed:		Time Package/Shipment Sealed:		
		License # of Originating Entity:		
Name of Registered Employee who prepared and sealed the package:				
Signature of Registered Employee who prepared and sealed the package:				
Name of Originating Entity: Blue Planet Healing LLC				
Address of Originating Entity:			Phone #:	
			Email:	
<i>*If you are delivering more than fifteen (15) products to one stop, use a second form to list the additional product(s).</i>				
<input type="checkbox"/> Check Here if multiple pages are used      List the total number of pages in the Manifest here _____.				
Receiving Retail Dispensary Location Information		Marijuana/Product(s) within the Shipment	Quantity/Weight	Attribute #/Product ID #
Stop Number on Route:		1)		
Name of Receiving Party:	Blue Planet Healing LLC	2)		
License # of Retail Dispensary Location:		3)		
Address of Receiving Retail Dispensary Location:		4)		
		5)		
Phone # of Receiving Dispensary:		6)		
Date and Approximate Time of Departure:		7)		
Date and Approximate Time of Arrival:		8)		
Route to be Traveled:		9)		
		10)		
		11)		
		12)		
		13)		
		14)		
		15)		
Additional Description: <i>(add description/details about the marijuana products and/or manufactured marijuana product(s))</i>				
<b>PRODUCT REJECTION</b> <i>(if only a portion of the shipment is rejected, circle that portion above.)</i>				
Name of Person Receiving or Rejecting Product(s):			Date:	
<i>I confirm that the contents of this shipment match the weight records above, and I agree to the custody of those portions of this shipment NOT circled above. Those portions that ARE circled above were returned to the individual delivering this shipment.</i>				
Signature:		Signature of Individual Taking Receipt of Rejected Portion of this Shipment:		
Name of Person Transporting Product(s):		Signature of Person Transporting Product(s):		
Make, Model, License Plate #:			Date of Signature:	

## Medical Cannabis Transport Manifest Form



*\*All sales transactions are to be completed prior to transportation of ANY marijuana or manufactured marijuana products. The receiving entity may reject the product being delivered, but the amount delivered must be limited to the amount which was agreed upon in the prior sales transaction.*

<b>Fax Form to:</b>		<b><u>OR</u> Email to:</b>	
Date Manifest Completed:		License # of Originating Entity:	
Name of Originating Entity:			
Address of Originating Entity:		Phone #:	
		Email:	

**Email Address or Fax Number to Which Approved Manifest Copy is to be Sent:**

**Phone # Can Call with Questions:**

*\*If you are delivering more than fifteen (15) products to one stop, use a second form to list the additional product(s).*

Check Here if multiple pages are used      *List the total number of pages in the Manifest here \_\_\_\_\_.*

Trip/Manifest Plan	Marijuana Product Name	Attribute # and Batch #	Quantity/Weight
Stop Number on Route:	1)		
Name of Destination Entity:	2)		
License # of Destination Entity:	3)		
Address of Destination Entity:	4)		
	5)		
Phone # of Destination Entity:	6)		
Date and Approximate Time of Departure:	7)		
Date and Approximate Time of Arrival:	8)		
Route to be Traveled:	9)		
	10)		
	11)		
<i>*If any other person had custody or control of this shipment, document that person's identity, the circumstances, duration, and disposition here.</i>	12)		
	13)		
	14)		
	15)		

Notes: <i>(add details for extenuating circumstances such as road closures, flat tire, etc.)</i>	Handeling and/or storage instructions:
--	--

**PRODUCT REJECTION** *(if only a portion of the shipment if rejected, circle that portion above.)*

*I confirm that the contents of this shipment match the weight records above, and I agree to the custody of those portions of this shipment **NOT** circled above. Those portions that **ARE** circled above were returned to the individual delivering this shipment.*

Name of Person Accepting or Rejecting Product(s):		Date:	Time:
Signature:		Signature of Individual Taking Receipt of Rejected Portion of this Shipment:	
Name of Person Transporting Product(s):		Signature of Person Transporting Product(s):	
Make, Model, License Plate #:		Date of Signature:	









## Emergency Situation Documentation



Date:	Reporting Employee:	Manger on Duty:
-------	---------------------	-----------------

Type of Emergency:  Robbery of Theft    Fire Emergency    Chemical Spill    Medical Emergency    Other Emergency

Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO	Which Authorities:
--	--------------------

Description of the Incident:

Date:	Reporting Employee:	Manger on Duty:
-------	---------------------	-----------------

Type of Emergency:  Robbery of Theft    Fire Emergency    Chemical Spill    Medical Emergency    Other Emergency

Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO	Which Authorities:
--	--------------------

Description of the Incident:

Date:	Reporting Employee:	Manger on Duty:
-------	---------------------	-----------------

Type of Emergency:  Robbery of Theft    Fire Emergency    Chemical Spill    Medical Emergency    Other Emergency

Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO	Which Authorities:
--	--------------------

Description of the Incident:

Date:	Reporting Employee:	Manger on Duty:
-------	---------------------	-----------------

Type of Emergency:  Robbery of Theft    Fire Emergency    Chemical Spill    Medical Emergency    Other Emergency

Authorities Notified: <input type="checkbox"/> YES <input type="checkbox"/> NO	Which Authorities:
--	--------------------

Description of the Incident:

## Deviation/Material Change to SOP's



<b>Date:</b>	<b>Registered Employee:</b>	<b>Deviation in Production:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Reason for the deviation</b> ( <i>identify and describe in detail the deviation from the SOP</i> ):		
<b>SOP requiring material change:</b>		
<b>Material Change made to the SOP</b> ( <i>please describe in detail</i> ):		
<b>SOP Updated?</b> <input type="checkbox"/> YES	<b>Date Updated:</b>	<b>Update By:</b>
<b>Manager/Supervisor Awareness and Approval:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Manager/Supervisor Signature:</b>	
<b>Sample of producton batch with deviation sent to independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Sample of producton batch with deviation determined to meet specifications for the variety by BPH and the independent testing laboratory?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>Medical Cannabis Batch Released for Distribution?</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	<b>Additional Notes/Comments:</b>	
<i>After documentation of a material change to a standard operating procedure, registered employees will be required to maintain the record of material change within a limit-access and secured area of the Licensed Premise.</i>		



MIP Log Sheets











Retail Log Sheets








Date:	Employee:	Register:
-------	-----------	-----------

<b>Cash</b>	\$ _____
	+
<b>Credit Cards</b>	\$ _____
	+
<b>Checks</b>	\$ _____
	+
<b>Payouts</b>	\$ _____
	=
<b>Total On Hand</b>	\$ _____
	-
<b>Less Starting Cash Balance</b>	\$ _____
	=
<b>Daily Total</b>	\$ _____
	X
<b>Tax Rate</b>	\$ _____
	=
<b>Daily Sales</b>	\$ _____
	-
<b>Daily Total</b>	\$ _____
	=
<b>Daily Tax</b>	\$ _____





**Record of Distributed Medical Cannabis Products**



**Retail Dispensary Location License #:**

**Dispensary Phone #:**

**Location Address:**

**Qualified Patient Name:**

**Patient Address** (*street, city, state, ZIP*):

**DOB:**

**Patient Registry ID #:**

**Patient Sex:**     Male     Female     Transgender

***Fill Out Caregiver Information IF Applicable***

**Designated Caregiver Name:**

**DOB:**

**Caregiver Registry ID #:**

**Dispensing Information**

Date Marijuana Product was Dispensed:

Quantity of Medical Marijuana Product(s):

Marijuana Product Attribute #:

Number of Days Supply that was Dispensed:

Product Batch #:

Date Distributed:

Payment Method:     Cash     Credit     Other

Payment Amount: \$





# Patient Feedback Evaluation Form

*The purpose of this form is to evaluate data on patient's reactions to the marijuana and/or manufactured marijuana products dispensed. Patient feedback is critical in order to supply patients with needed and required medications to treat specific ailments.*

## Patient Information

Qualified Patient Name:

DOB:

Patient State Registry Number:

Expiration Date:

Marijuana Product(s) Dispensed:

Date Marijuana Products Dispensed:

Quantity Dispensed:

Route of Administration/Consumption Method:

- Smoke/Vaporize/Inhalation    Ingestion--Tincture/Capsule/Pill    Topical Product    Other

## Patient Qualifying Condition

- Cachexia    Wasting syndrome    Severe nausea    Severe or Persistent Muscle Spasms    PTSD    Other  
 Anorexia    Severe or chronic pain    Seizures    Glaucoma    Hospice Care

**Patient Ailments, etc.** (please write any ailments or side effects, etc. that you may be suffering from or noticed in relation to your medical condition)

## General Questions

Did patient experience relief after using the marijuana product?    YES    NO

(please describe your reactions (positive or negative) you may have experienced with the marijuana product.)

Did patient experience any unforeseen side effects from the marijuana product?    YES    NO

(please describe any unforeseen side effects (positive or negative) you may have experienced with the marijuana product.)

Will patient continue using the marijuana product to treat your medical condition?    YES    NO    Undecided

(do you have any additional comments or thoughts about marijuana products as a treatment option?)

## Additional Comments:



<i>Customer Complaint Form</i>	
<b>Date:</b>	<b>Location:</b>
<b>Customer Name:</b>	
<b>Employee Documenting Complaint:</b>	<b>Supervisor on Duty:</b>
<b>Description of Complaint:</b>	
<b>Corrective Action to be Taken:</b>	
<b>Customer Comments:</b>	
<i>Customer Signature:</i>	<i>Date:</i>
<i>Employee Signature:</i>	<i>Date:</i>

# Notice of Disciplinary Action

<b>Employee Name:</b> _____		<b>Date of Notice:</b> _____	
<b>Supervisor Name:</b> _____		<b>Employee Job Position:</b> _____	
<b>Type of Problem or Violation:</b>			
<input type="checkbox"/> Tardiness	<input type="checkbox"/> Quantity of Work	<input type="checkbox"/> Carelessness	
<input type="checkbox"/> Absenteeism	<input type="checkbox"/> Neatness	<input type="checkbox"/> Policy Violation	
<input type="checkbox"/> Insubordination	<input checked="" type="checkbox"/> Safety Issue	<input type="checkbox"/> Other _____	
<input type="checkbox"/> Quality of Work	<input type="checkbox"/> Drug or Alcohol Abuse	<input type="checkbox"/> Date of Occurance _____	
<b>DETAILS OF OCCURANCE</b> <i>(Include the impact on the Company):</i>			
_____			
_____			
_____			
_____			
<b>CORRECTIVE ACTION TO BE TAKEN:</b>			
<b>Suspension:</b> <input type="checkbox"/> With Pay <input type="checkbox"/> Without Pay		<b>Job Suspension:</b>	
<b>Job Termination:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		First Day: _____	
<b>Other:</b> _____		Last Day: _____	
<b>EXPECTED IMPROVEMENT</b> <i>(Include a clear statement as to the consequences of failing to improve):</i>			
_____			
_____			
_____			
<b>EMPLOYEE'S STATEMENT</b> <i>(Use additional paper if necessary)</i>			
_____			
_____			
_____			
_____			
By signing this notice, I am acknowledging that I have been counseled about my inappropriate conduct and informed of consequences if improvements are not made.			
<b>Employee Signature:</b> _____		<b>Date:</b> _____	
<b>Supervisor Signature:</b> _____		<b>Date:</b> _____	

<u>Cultivation Facility Hours of Operation</u>			<u>Processing Facility Hours of Operation</u>			<u>Dispensary Hours of Operation</u>		
	Open	Close		Open	Close		Open	Close
<i>Monday</i>	5:00	8:00	<i>Monday</i>	8:00	8:00	<i>Monday</i>	8:00	8:00
<i>Tuesday</i>	5:00	8:00	<i>Tuesday</i>	8:00	8:00	<i>Tuesday</i>	8:00	8:00
<i>Wednesday</i>	5:00	8:00	<i>Wednesday</i>	8:00	8:00	<i>Wednesday</i>	8:00	8:00
<i>Thursday</i>	5:00	8:00	<i>Thursday</i>	8:00	8:00	<i>Thursday</i>	8:00	8:00
<i>Friday</i>	5:00	8:00	<i>Friday</i>	8:00	8:00	<i>Friday</i>	8:00	8:00
<i>Saturday</i>	5:00	8:00	<i>Saturday</i>	8:00	8:00	<i>Saturday</i>	8:00	8:00
<i>Sunday</i>	5:00	8:00	<i>Sunday</i>	8:00	8:00	<i>Sunday</i>	CLOSED	CLOSED

## Year 2016 HAWAII STATE HOLIDAYS

<u>(Hawaii Rev. Statutes, Sec. 8-1)</u>	<u>Day Observed in 2016</u>	<u>Official Date Designated in Statute/Constitution</u>
New Year's Day.....	Jan. 1 Friday.....	The first day in January
Dr. Martin Luther King, Jr. Day.....	Jan. 18 Monday.....	The third Monday in January
Presidents' Day.....	Feb. 15 Monday.....	The third Monday in February
Prince Jonah Kuhio Kalaniana'ole Day.....	Mar. 25 Friday.....	The twenty-sixth day in March
Good Friday.....	Mar. 25 Friday.....	The Friday preceding Easter Sunday
Memorial Day.....	May 30 Monday.....	The last Monday in May
King Kamehameha I Day.....	June 10 Friday.....	The eleventh day in June
Independence Day.....	July 4 Monday.....	The fourth day in July
Statehood Day.....	Aug. 19 Friday.....	The third Friday in August
Labor Day.....	Sept. 5 Monday.....	The first Monday in September
General Election Day.....	Nov. 8 Tuesday.....	The first Tuesday in Nov. following the first Monday of even-numbered years. ( <i>Hawaii State Constitution, Article 2 – Section 8</i> )
Veterans' Day.....	Nov. 11 Friday.....	The eleventh day in November
Thanksgiving.....	Nov. 24 Thursday.....	The fourth Thursday in November
Christmas.....	Dec. 26 Monday.....	The twenty-fifth day in December



## **REGISTERED DISPENSARY FACILITY SECURITY PLAN**

Blue Planet Healing's facility management is committed to ensuring all facilities are accessed only by authorized personnel, secured against loss or theft of medical marijuana or plant material; as well as, the diversion or potential diversion of medical marijuana or marijuana plant material. To fulfill these objectives, the facility will contract with a Hawaii-licensed and insured security company for the implementation of the electronic security systems.

### **SECURITY SURVEILLANCE SYSTEM**

**Video Surveillance System.** Securitas will design video surveillance systems at each of BPH's RDLs and PCs that will allow for twenty-four hour continuous video monitoring and recording of those facilities. All video equipment will have back up capability and all recorded images will clearly and accurately display the time and date of the recording. The surveillance system storage device and cameras will be internet protocol (IP) compatible. All video surveillance cameras will be of professional quality with minimum resolution to allow for the clear and certain identification of any person or activity in any area of a Dispensary Facility where marijuana and manufactured marijuana products are produced, moved or stored including: all point of sale areas; all rooms used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; all rooms or areas which store a surveillance system storage device; and all exits and entrances to a Dispensary Facility from both indoor and outdoor locations. Each surveillance system video recording storage device will be secured within a limited or restricted access area and inside a locked box, cabinet, closet or secured by other means to protect the system from tampering and theft. BPH will make all video recordings available to DOH upon request.

**Alarm System.** Each RDL and PC operated by BPH will feature an alarm system, installed by Securitas, which will detect unauthorized entry and send notification to law enforcement in the



## **Security Plan**

event of an emergency. The alarm system will be electronic and equipped with a backup power source that will provide power for a minimum of eight (8) hours. Backup power supply will be provided by battery storage. The system will be connected to a professional alarm monitoring company (and to law enforcement if so directed by DOH) and will be activated twenty-four hours a day, seven (7) days a week. The professional monitoring company will respond to alarm activity and notify BPH (and law enforcement if so directed by DOH).

**System Failure.** In the event of a failure, or breach of a security system, BPH will immediately suspend operations and secure the affected Dispensary Facility until the security system is fully operable. BPH will notify DOH immediately upon a breach or failure and again when it resumes operations all as required by HAR §11-850-51.

## **Video Monitoring System**

**Surveillance System:** The cultivation facility will utilize an advanced “Internet Protocol” (IP), day/night video surveillance and recording system is installed prior to the first day of operation. The IP system will be installed in a secure location within the building to provide 24 hour surveillance of the interior and exterior of the establishment. The cameras will have the following specifications: Indoor and Outdoor Domes, with 3MP/1080p, H264, 6mm, Day/Night, IR (30m), IP66, PoE/12VDC to provide clear and certain identification of the persons in view. All recorded images will clearly and accurately display the time and date and will be recorded at least three frames per second during alarm or motion based recording.

The Video Management Software and Access Control Software will be fully integrated into a single platform which will manage both the access control and the surveillance equipment, thus allowing the system to create not only a digital record of the image as detailed above, but to tie those images to any location where a person has accessed a controlled area, and to activate the respective camera whenever an intrusion alarm had been triggered in order to transmit verification images to the monitoring center.





## **Security Plan**

All cameras will be monitored locally and remotely, recorded on a 24/7 schedule, and stored at the permitted dispensary site for a period of 90 days. Video recordings will be archived in a format that ensures authentication of the recording as legitimately-captured video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. All recordings shall be erased or destroyed prior to disposal. The system will also have a video printer capable of producing a clear still photo from any video camera image in an industry standard image format, including .jpg, .bmp and .gif as well as the capability to export any recording and turn over to the commissioner of local law enforcement upon request. Further, the system will be able to produce a digital video disk using an installed media recording drive, and the video will be viewable in any standard computer operating system.

There will be at least one onsite, desktop viewing station (minimum of 19 inches) that will have a live-feed to monitor all entry points, vulnerable and restricted areas. This monitoring station will only be accessible to authorized personnel and law enforcement. Playback quality will be suitable for viewing as the surveillance equipment is capturing the identity of all individuals and activities in the monitored areas.

All video surveillance systems will be equipped with a failure notification system that provides prompt notification to the cultivation security director of any prolonged surveillance interruption and/or the complete failure of the surveillance system.

### **Locations and Coverage**

BPH's production center(s) and retail dispensary location(s) licensed premises will be properly secured with required professional security alarms and video surveillance as dictated by Hawaii regulations. The diagrams below are floor plans for BPH's production center and retail dispensary location as well as additional security overlays displaying all the security features to be installed and utilized. *\*The floor plans and security overlays can be viewed in their original document format and provided upon request.*



## Security Plan

### Production Center Security Overlay



### Retail Dispensary Security Overlay





## Security Plan

**Interior Coverage:** All interior cameras will be either ceiling- or wall-mounted depending on the physical structure and strategic location to provide the best angles, facial and operational identification and unobstructed fullness of coverage. There will be camera coverage that will provide clear view of activity without sight blockage from lighting hoods, fixtures, or other equipment, for all areas inside the facility except restrooms and management offices.

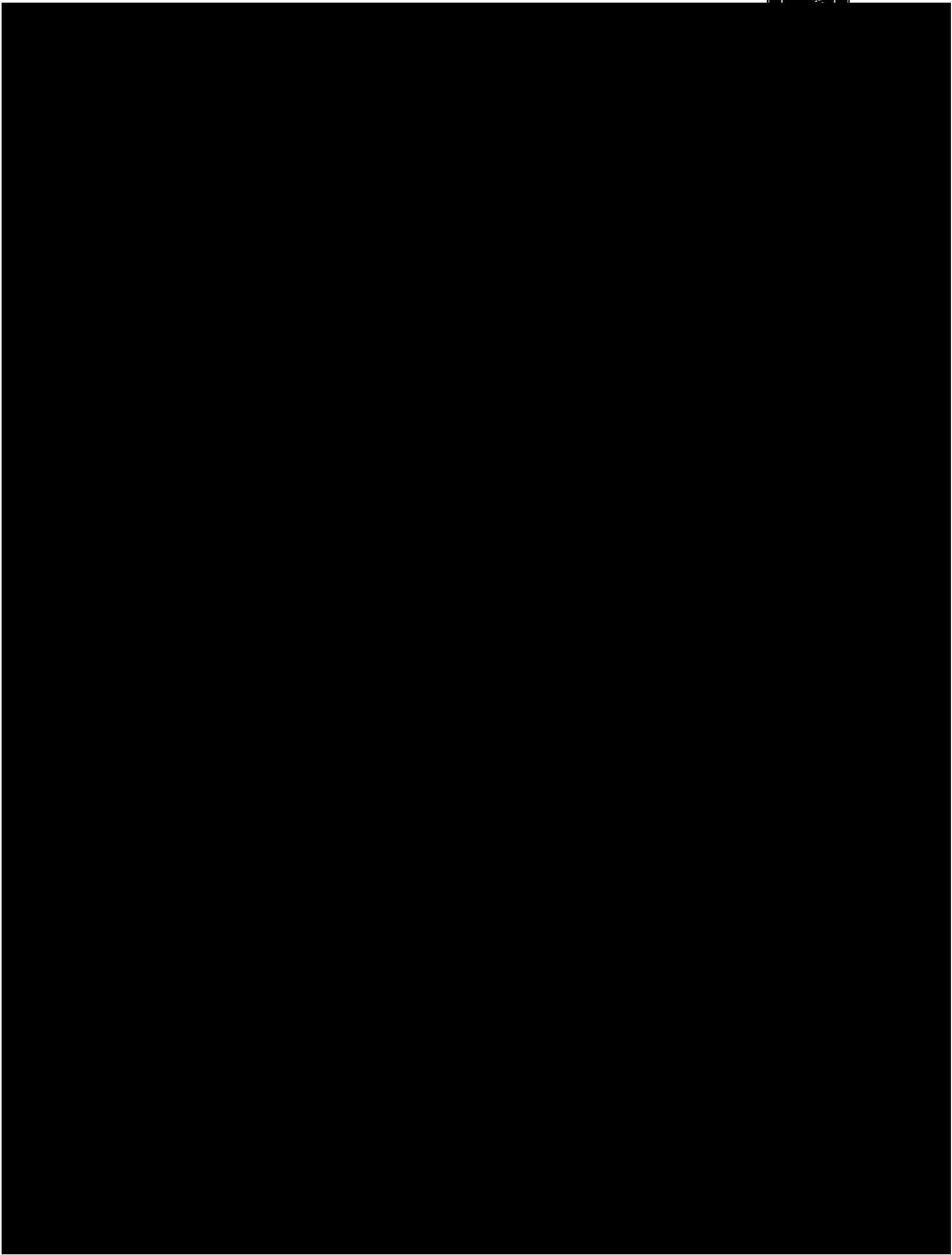
**Signage:** Blue Planet Healing will post two signs in conspicuous locations all entrances of the facility that read:

- 1) **"PERSONS UNDER TWENTY-ONE YEARS OF AGE NOT PERMITTED ON THESE PREMISES."**
- 2) **"THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."**

**Power:** Cameras are powered and communicate through a "Power over Ethernet" (PoE) switch. These switches do not have on board battery backup. The switches will be plugged into an Uninterruptable Power Supply (UPS) with battery backup. The UPS will plug into a circuit tied to the backup generator. The UPS will keep power to the cameras in the event of a power failure until the backup generator starts producing power. This prevents any downtime or equipment shutdown during the time there is no power and before the generator starts. However, should all regular plus backup and mitigating measures fail and a catastrophic failure occur, the dispensary shall not operate if the video surveillance equipment is inoperative. A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system will be implemented.

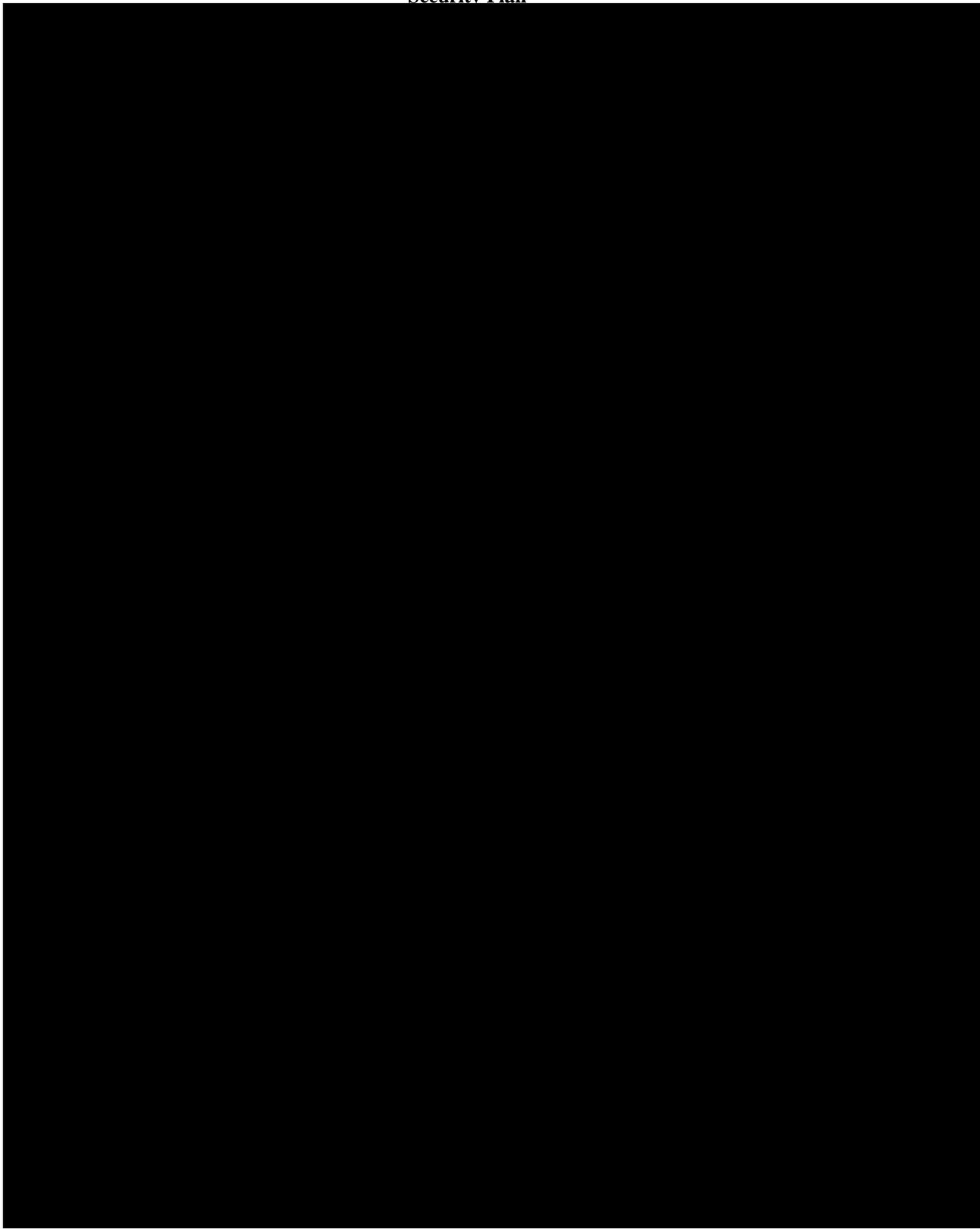
**Monitoring and Recording:** BPH will ensure that the surveillance system is monitored and recorded 24 hours per day, 7 days per week, via an on-site DVR system as well as off-site through secure web-based portal.

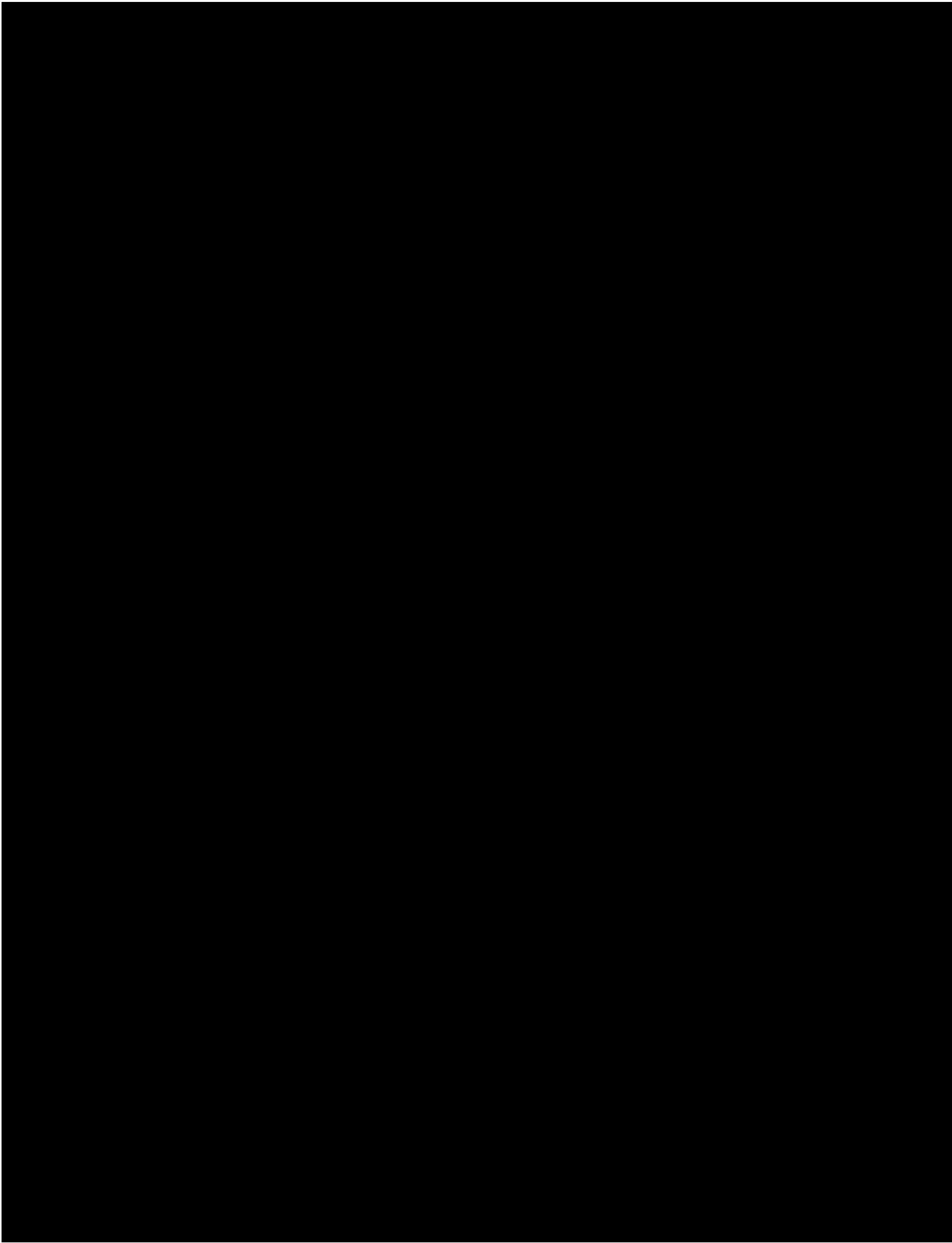
**Head-End Equipment:** All head-end (digital or network video recorders, digital archiving devices, etc.) equipment will be installed in a secure, limited-access location within the licensed premise. This location will consist of a locked cabinet/rack inside a secured and monitored room to protect from employee or third party tampering or criminal theft. Access to this room will be

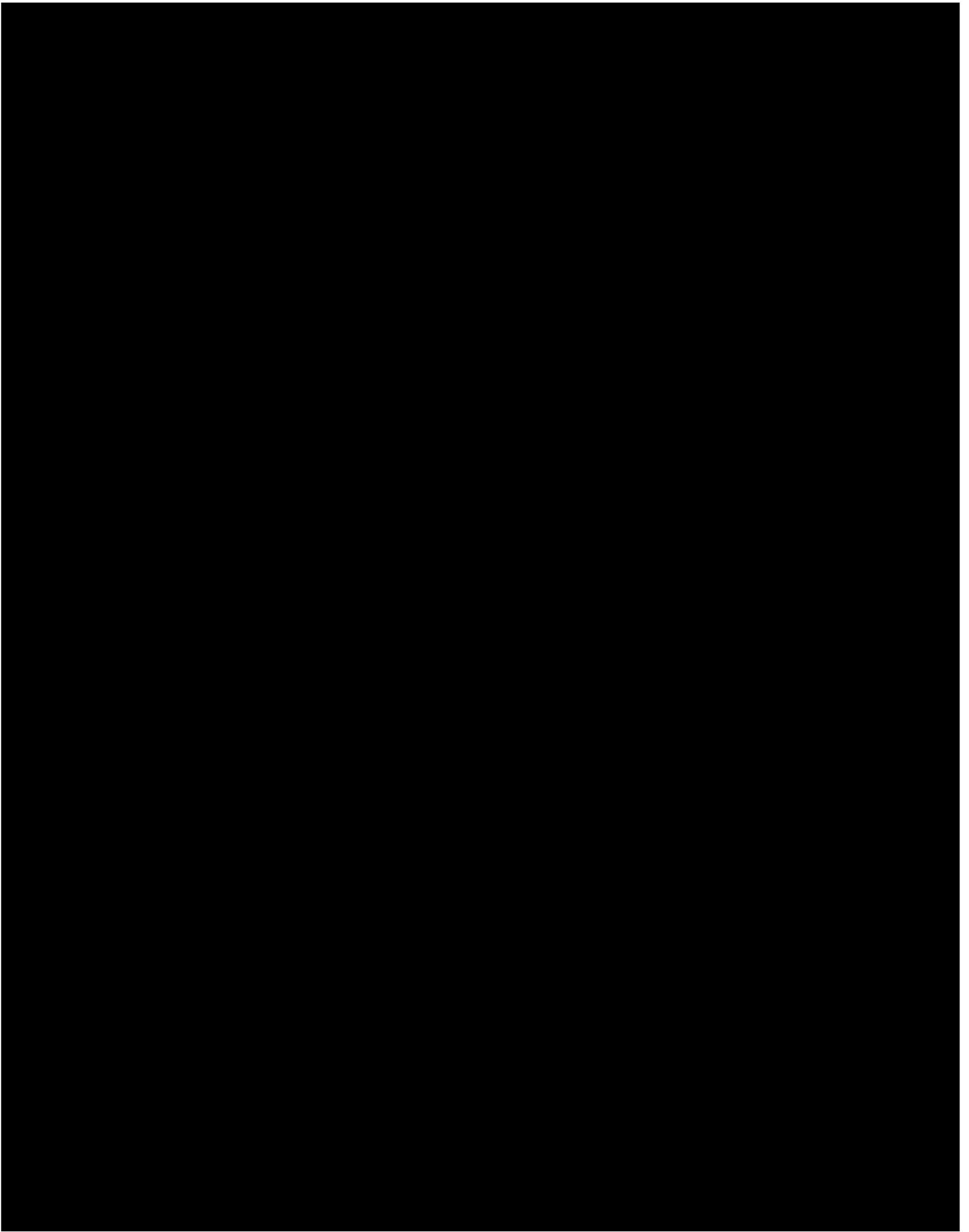


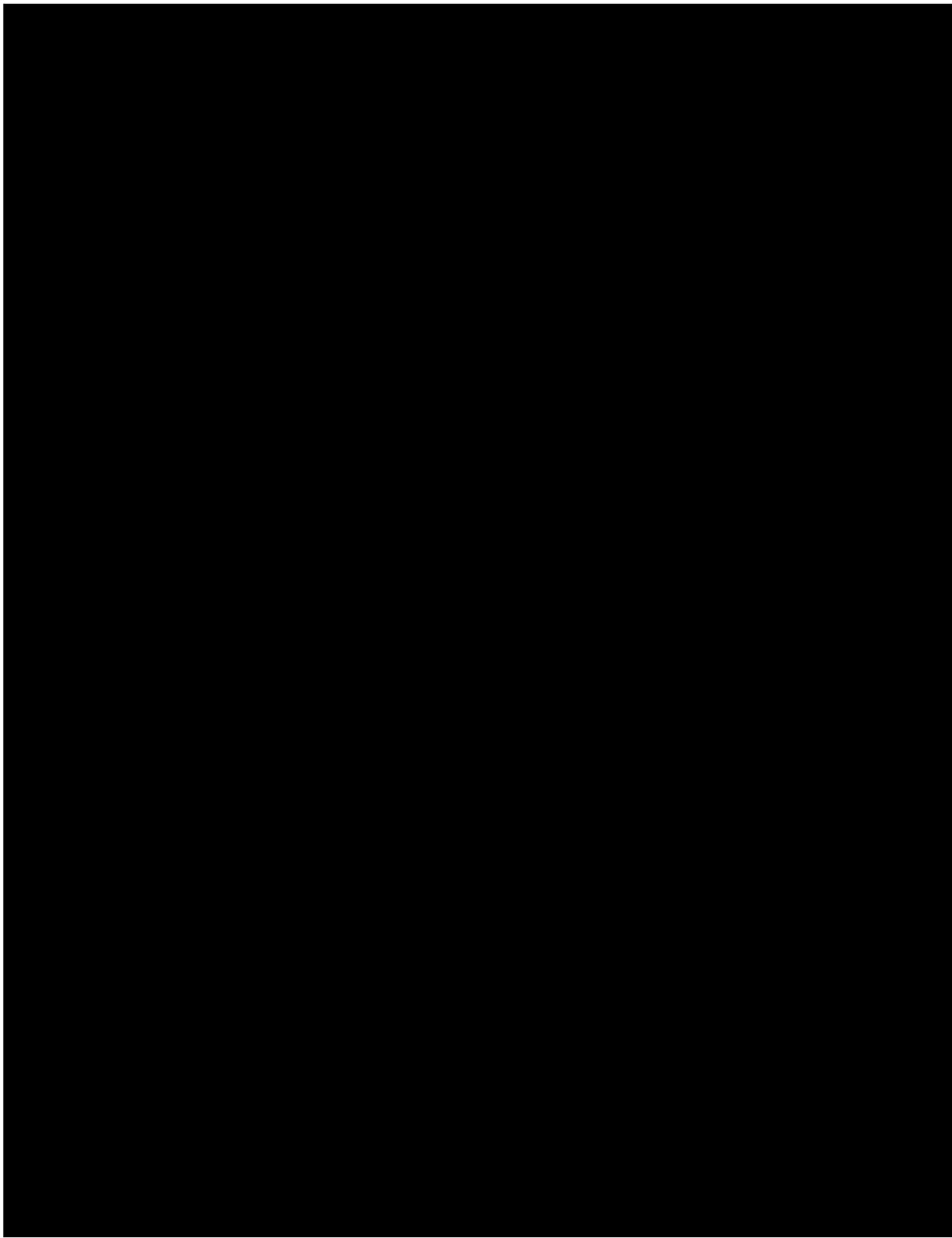


## Security Plan





































































### Application Response: Question 8

Patient confidentiality will be a top priority of Blue Planet Healing, LLC (“BPH”). As such, BPH will maintain secure, confidential patient records properly stored on the retail dispensary locations (“RDL”) premise in compliance with all required laws and regulations including HAR §11-850-40 as well as the specifications of BPH’s written patient confidentiality Standard Operating Procedures (“SOP”) that are attached hereto as “8.1”. To ensure compliance, BPH has retained medical professionals with abundant knowledge and experience maintaining patient confidentiality to serve on BPH’s advisory board and to work at the RDL. These medical professionals will include a Chief Medical Officer, a Registered Nurse and a Pharmacist to help guide BPH in establishing and maintaining registered patient information confidential, as well as providing training in confidentiality policies and procedures and helping educate registered employees on the importance of patient confidentiality and best practices in connection therewith.

BPH will implement policies prohibiting photography or video recording inside any dispensary facility by anyone not authorized under HAR §11-850-40 (b). BPH’s written SOPs require all registered patient records or files that are maintained as a “hard” or physical document be properly stored in a locked file cabinet within a limited or restricted access area of BPH’s RDL. If registered patient records or files are maintained electronically, said records or files will be maintained on a secure, BioTrackTHC™ Health Insurance Portability and Accountability Act (“HIPAA”) compliant computer server which will be stored securely within a limited or restricted access area of the premise. The computer will be secure from physical theft but also electronic theft of records through the use of virus protection and secured servers. Access to confidential patient records and files will be limited to BPH registered employees with proper clearance.

BPH will utilize BioTrackTHC™ seed-to-sale software system for all operations including cultivation, processing/manufacturing operations, and retail dispensing operations. The



### Application Response: Question 8

BioTrackTHC™ system will be used to create and maintain a patient database that will include sensitive and confidential information and records. In addition, the system will be used on designated computers for sales procedures, inventory control and tracking, and other core operations. BioTrackTHC™ Point-of-Sale (“POS”) computer systems are HIPAA compliant and as such will protect and maintain the confidentiality of a registered patient’s medical conditions, health status, and purchases of marijuana or manufactured marijuana products. All RDLs will ensure that computer networks are HIPAA-compliant to protect sensitive and confidential patient information. BioTrackTHC™ is the software platform used by both of BPH’s industry consultants, High Country Healing’s Colorado facilities as well as within American Cannabis Company’s client’s facilities in various states. Having consultants with intimate knowledge of this software platform will further ensure that BPH is able to successfully meet its patient information confidentiality requirements. All BioTrackTHC™ systems utilize a secured program that is password protected and can also be set for Biometric Fingerprint scanning to ensure only authorized personnel will be able to access secure documentation within the system. (See Attachment “8.3”)

#### **General HIPAA policies to be implemented by BPH will include the following:**

All registered employees that will have direct contact with confidential patient information will complete basic HIPAA training; Upon acceptance of new registered patient records, registered employees will provide a verbal disclosure statement to the registered patient explaining that confidential records will be maintained in such a way that information will remain confidential and kept from public view or oversight; Access to confidential patient records will be limited to registered employees with proper clearance; BPH will keep all hard-copy registered patient records in a secure locking file cabinet or lockable filing system within a limited or restricted access area



Application Response: Question 8

of the dispensary facility premise; When registered patient records are initially gathered, registered employees will be required to create a new patient folder and place the newly created and future patient records within said folder. All folders will be marked confidential and placed in a secured, fire proof and lockable file cabinet within a limited or restricted access area of the dispensary facility; Registered employees will receive training to never disclose the names of registered patients with non-employees or parties outside BPH; Registered employees will be trained to never leave registered patient records unattended or unsecured; BPH will host periodic meetings with all registered employees to go over privacy and confidentiality policies, procedures and measures. This will provide further accountability on all staff levels to make sure confidentiality and privacy/legal compliance are met.

BPH's policies and procedures pertaining to the confidentiality of a qualifying patient's medical conditions, health status and purchases of marijuana and/or manufactured marijuana products can be seen in detail within the patient confidentiality and HIPAA compliance written SOPs. (See Attachment "8.1" and Attachment "8.2")



## Attachment 8.1

### Standard Operating Procedure: Patient Confidentiality

**Purpose:**

To explain the steps involved for handling patient confidentiality.

**Scope:**

Covers the steps involved to protect patient confidentiality.

### The Principles of Protecting Patient Confidentiality

This section will cover the best practices in patient privacy and confidentiality. When operating a business within the marijuana industry it is important to ensure that your patient's records and information are secured and kept private. A breach in such privacy can result in HIPAA violations, legal ramifications and a potential cease and desist order. Below you will find some helpful tips in keeping patient information private.

#### **Patient Record Privacy & Confidentiality Tips**

- 1) Keep all patient records in a secure lockbox or lockable cabinet. Having these records all in one place can help to ensure that no patient records are being kept in exposed areas where it is possible for an information breach.



- 2) When patient records are gathered for the first time, be sure to place the information in a secured and lockable location.
- 3) Upon acceptance of new patient records, provide a verbal disclosure statement to the patient. This verbal statement should make the patient aware that their records are being kept per state law and that they will be maintained in such a way that their information will remain confidential and kept from public view or oversight.
- 4) Have only employees who can be trusted and held responsible work with and maintain patient records.
- 5) Train ALL employees never disclose the specific names of patients with non-employees. It is important that the names of patients not be shared with the public in any way, as this would result in a HIPAA violation.
- 6) Store patient records in a secure place that is away from any cash or inventory vault. By keeping this location separate and secured you will minimize the chance that records could potentially go missing, get stolen, etc.



## Attachment 8.1



- 7) NEVER leave patient records out on a receptionist's desk or patient intake desk while the station is unattended.
- 8) Get HIPAA trained! It would be beneficial to have all employees' complete basic HIPAA training. This training will provide employees with HIPAA compliance training and ensure patients with more peace of mind knowing that the employees understand HIPAA privacy rules and procedures. See <http://www.hipaatraining.com/>
- 9) Host a monthly or bi-monthly meeting with all employees to go over privacy and confidentiality measures. This will provide further accountability on all staff levels to make sure privacy/legal compliance is met.
- 10) Designate record maintaining/record processing employees and limit patient records access. By doing this you will limit the potential for complications within your internal operations.



## Attachment 8.2

### Standard Operating Procedure: HIPAA Compliance Training

**Purpose:**

To explain the steps involved with becoming HIPAA-compliant trained.

**Scope:**

Covers the steps involved to obtain certified HIPAA training.

The primary goal of the federal Health Insurance Portability and Accountability Act (“HIPAA”) law is to make it easier for people to keep health insurance, protect the confidentiality and security of healthcare information and help the healthcare industry control administrative costs. **HIPAA** provides for the protection of individually identifiable health information that is transmitted or maintained in any form or medium. The privacy rules affect the day-to-day business operations of all organizations that provide medical care and maintain personal health information, this includes medical marijuana businesses and establishments.

Patient confidentiality will be of utmost importance during operations and maintaining patient records as confidential and properly stored and secured on the premise will be done according to requires laws and regulations.



All patient records or files that are maintained as a “hard” or physical document will be properly stored in a locking file cabinet within a limited or restricted access area of the premise. If patient records or files are maintained electronically, said records or files will be maintained on a secure, HIPAA-compliant computer which will also be stored securely within a limited or restricted access area of the premise. The computer will be secure from physical theft but also electronic theft of records through the use of virus protection and secured servers on other security measures. Access to confidential patient records and files will be limited to SFN employees with proper clearance levels.

**General HIPAA Policies:**

- All employees that will have direct contact with confidential patient information will complete basic HIPAA training. This training will help employees understand HIPAA privacy rules and procedures. Visit the website: <http://www.hipaatraining.com/>



- Upon acceptance of new patient records, provide a verbal disclosure statement to the patient. This verbal statement should make the patient aware that their records are being kept per State law and that they will be maintained in such a way that their information will remain confidential and kept from public view or oversight.
- Access to confidential patient records will be limited to employees with the proper clearance level. These records will be accessible only by ownership, management and patient advocates. Limiting employee access



## Attachment 8.2

to confidential patient records will help reduce the risk to exposure. Additional employees may be granted the proper clearance level to access confidential patient records as needed in the future.

- Keep all patient records in a secure locking file cabinet or lockable filing system within a limited or restricted access area of the premise. Having all confidential patient files centrally located in can help ensure that no confidential patient records are being kept in exposed areas where it is possible for an information breach.



- When patient records are initially gathered, be sure to create a new patient folder and place the patient records within said folder. All folders should be marked confidential and place in a secured and lockable file cabinet within a limited or restricted access area of the facility (e.g. general manager's office).



- ALL employees will receive training to never disclose the specific names of patients with non-employees or parties outside the organization. It is important that the names of patients not be shared with the public in any way, as this would result in a HIPAA violation.
- NEVER leave patient records unattended or unsecure within the file cabinet.
- Organization will host a monthly or bi-monthly meeting with all employees to go over privacy and confidentiality policies, procedures and measures. This will provide further accountability on all staff levels to make sure privacy/legal compliance is met.



## Attachment 8.3



1/22/2016  
Maya Rogers  
Blue Planet Healing LLC.

Reference: BioTrackTHC Support Document

Dear Maya,

BioTrackTHC provides effective cutting edge technology solutions for the emerging legal marijuana industry. Solutions that not only prevent product theft, but assist business owners in running their cultivation, processing, packaging, and retail operations more profitably and more legally compliant. Furthermore, this is all done without leaving sensitive business and consumer data vulnerable in the cloud. Specifically, BioTrackTHC is the industry's only true seed-to-sale software system with enterprise resource planning, complete inventory tracking, point-of-sale, marketing, financial reporting and regulatory compliance features. Subsequently, because it is a server based system with advanced security features, customers can rest assured that no one, not even the BioTrackTHC team, can access their business or consumer information without their permission.

This document confirms BioTrackTHC's intentions to enter into a formal agreement with Blue Planet Healing LLC. to provide software solutions guaranteed to meet published Hawaii Department of Health reporting, regulation, and compliance guidelines for cannabis production facilities in the event that an authorized license is obtained.

Thank you for your consideration of BioTrackTHC. We are eager to assist you in your efforts to acquire a license and look forward to entering into a software solution agreement with you upon receipt of that license.

Best Regards,



Moe Afaneh  
Chief Operating Officer



## Attachment 8.3

### Hawaii HB 321

- (A) Secure inventory tracking and control;
- (B) Protecting confidential customer information;
  - (1) Ability to comply with the requirements in this chapter and chapters 329 and 3290, HRS, for inventory tracking, security, and sales limits for qualifying patients;
    - (1) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;
  - (2) Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 3290-7 and 3290-8, HRS;
  - (3) Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;
  - (4) A plan for secure disposal or destruction of marijuana and manufactured marijuana products;

***BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.***

- (a) A dispensary licensee shall not transfer any marijuana or manufactured marijuana products to any other dispensary.
- (b) A dispensary licensee shall not accept any marijuana or manufactured marijuana products from any other dispensary.

**NO pre-rolls, no samples, no paraphernalia**



## Attachment 8.3

### §11-850-35 Employee records

(a) A dispensary licensee shall have available at each dispensary facility a time clock or other adequate method to record the month, day, year, and time that each employee arrives at and leaves the facility.

(b) Time record entries shall be made at the time an employee reports for duty and again when the employee goes off duty and at any time the employee leaves and returns to the premises for any reason.

(c) A dispensary licensee shall maintain all employee records, including the specific employee training provided and hours worked.

***The Time Clock function within BioTrackTHC records the date and time that every employee clocks into and out of the system. A manager can be granted the permission within the system to modify the clock in/out times for an employee in the event of an error or someone forgetting to clock out.***

### §11-850-36 Transport

(a) A dispensary may transport marijuana and manufactured marijuana products between its facilities, and between its facilities and a laboratory for testing.

(b) Only employees designated by the dispensary licensee, who are trained and knowledgeable on the transportation protocols required by this chapter, shall transport marijuana and manufactured marijuana products. Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.

(c) Each time marijuana and manufactured marijuana products are transported, the dispensary licensee shall prepare a manifest on a form prescribed by the department that lists the elements required by the department's tracking system. A dispensary licensee shall only transport marijuana or manufactured marijuana products that are listed on the manifest. A dispensary licensee shall transport marijuana or manufactured marijuana products in secured containers. The dispensary licensee shall include a copy of the manifest in the interior and on the exterior of the container.

(b) Upon receipt of marijuana and manufactured marijuana products the dispensary licensee or the laboratory shall immediately report to the department any discrepancies between what is received and what is on the manifest.

(c) The designated employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest.

(d) The dispensary licensee shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion.

(e) A dispensary licensee shall not transport marijuana or manufactured marijuana products:



## Attachment 8.3

- (1) Off site to qualifying patients or to primary caregivers;
- (2) To another county or another island within the same county; or
- (3) To, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

***BioTrackTHC provides functionality for Cultivators, Processors and Dispensary Licensees to create transfer manifest documents. Transfer manifests will be stored and tracked by the System. Input data may include, but is not limited to, the following fields: ship from name, license number and route description. For each item include destination address, destination name, license number, address, product description, product ID and lot number, quantity and units of measure. Transfer manifests will be used as shipping documents for transfers between locations within an organization or sales between Licensees.***

- (b) A dispensary licensee shall give the department access to all parts of the dispensary property, equipment, records, documents, and any other substance, material, or information relevant to ensure the dispensary licensee's compliance with this chapter, upon request.

***BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.***

### §11-850-38 Reports.

- (a) A dispensary licensee shall submit quarterly reports on January 15, April 15, July 15, and October 15.

If the due date for submitting a quarterly report falls on a Saturday, Sunday, or State holiday, the report will be on time if it is submitted on the next day that is not a Saturday, Sunday, or State holiday. Reports shall be submitted on a form and in a manner prescribed by the department.

- (b) Reports shall include but not be limited to:
1. Records of entry and exit for all individuals who entered a dispensary facility;
  2. Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
  3. Amounts by category of marijuana and manufactured marijuana products sold;
  4. A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
  5. A summary financial statement;
  6. Laboratory results of all tests conducted;
  7. Description of any breach or halt in its security system and tracking system; and
  8. Any other information requested by the department.



## Attachment 8.3

*BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.*

### §11-850-39 Audits

- (a) A dispensary licensee shall obtain an independent financial audit annually, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.
- (b) The report shall be completed and submitted to the department no later than sixty days prior to the end of the license expiration date, or at another time as the department may direct.
- (c) When a license is revoked, suspended, surrendered, or expires, a dispensary licensee shall file a final report thirty days following revocation, suspension, surrender, or expiration.

*In the course of doing business, a user can perform inventory audits to confirm or adjust what's showing in your inventory and what the user actually has on hand. After clicking on the Inventory Audit icon a list will populate showing all of the items for inventory in the current inventory room. If the user wishes to run a "Blind Audit" this will prevent the employee from seeing the original weights or any differences. The Inventory Shrinkage report allows you to total loss across various products for a given time period with a threshold to ignore adjustments outside of a certain increment (mistakes).*

### §11-850-41 Record retention.

(a) A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:

- (1) Inventory tracking including transport of marijuana and manufactured marijuana products;
- (2) Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
- (3) Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
- (4) Logs of entry and exit for dispensary facilities; and
- (5) Employee records.

(b) A dispensary licensee shall retain for a minimum of one year all security recordings.

*BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity. All inventory records, patient records, recall reports, sales/transaction records, product disposal records, and all scanned documents can be accessed at any time (real time), either in-system or through the report creation tool. Though system actions can be adjusted or voided, at no time is any data ever fully*



## Attachment 8.3

*deleted as BioTrackTHC™ maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.*

### §11-850-42 Allowed quantities for dispensing.

- (a) A dispensary licensee may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four ounces of marijuana during a period of fifteen consecutive days, and shall not exceed eight ounces of marijuana during a period of thirty consecutive days .
- (b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter.

*Within "Sales Limits" a user can regulate the permissible quantities allotted to a patient or caregiver.*

### §11-850-43 Disposal or destruction.

- (a) A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.
- (b) A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.
- (c) A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired marijuana and manufactured marijuana products.

*During or after a Harvest or Cure, a user would create a batch for the "green waste" which would include broad leaf trim, and stems that weren't going to be converted into a concentrated format. All waste would be weighed, given it's own 16-digit barcode, which is permanently stored in the system prior to it being destroyed. When a BioTrackTHC user sends a sample for Quality Assurance testing and the sample does not meet minimum standards, a user may; 1) Place the product into quarantine*



## Attachment 8.3

*for destruction, or, 2) Convert the product into a different format. If the user converts the non-conforming sample and originating lot, the new converted product must be retested.*

### §11-850-61 Tracking requirements

- (a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.
- (b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.
- (c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.
- (d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable . The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

***BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.***

## PRODUCTS AND PRODUCT STANDARDS

### §11-850-71 Marijuana.



## Attachment 8.3

(a) A dispensary licensee may dispense marijuana only in the form of dried matured processed flowers of female cannabis plants.

### §11-850-72 Manufactured marijuana products.

(a) A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

### §11-850-74 Equivalent weights for manufactured marijuana products.

(a) A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.

(b) A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale.

***BioTrackTHC is a complete inventory control system that also creates a searchable, secure, tamper-evident record of each and every action performed within the system. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.***

## LABORATORY CERTIFICATION, TESTING, AND STANDARDS

### §11-850-81 Laboratory testing required.

A dispensary licensee shall not dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter.

### §11-850-85 Laboratory standards and testing

(a) A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-proof manner a similar sample from the same batch, for verification testing as directed by the department.

(a) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things for which it is certified. The certificate of analysis shall include the results with supporting data for the following:

- (1) The chemical profile of the batch for the following compounds:
  - (A) 9 (delta 9) - Tetrahydrocannabinol (THC)
  - (B) Tetrahydrocannabinol Acid (THCA)
  - (C) Cannabidiol (CBD)



## Attachment 8.3

- (D) Cannabidiolic Acid (CBDA)
- (E) Cannabigerol (CBG)
- (F) Cannabinol (CBN)
- (2) The presence of the following contaminants, which shall not exceed the following levels:
  - (A) Heavy metals:
    - (i) Arsenic 10.0 ppm
    - (ii) Lead 6.0 ppm
    - (iii) Cadmium 4.0 ppm (iv) Mercury 2.0 ppm
  - (B) Pesticides regulated by the U.S. Environmental Protection Agency: 1.0 ppm
  - (C) Solvents:
    - (i) Butanes 800 ppm
    - (ii) Heptanes 500 ppm (iii) Benzene\*\* 1 ppm
    - (iv) Toluene\*\* 1 ppm (v) Hexane\*\* 10 ppm
    - (vi) Total Xylenes (m,o,p-xylene) 1 ppm

\*\* Contaminants in solvents
  - (D) Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;
  - (E) Moisture content of plant material <15%
  - (F) Microbiological impurities, including but not limited to:
- 1. Total Viable Aerobic Bacteria:
  - a. Unprocessed and Processed Materials: 105 Colony Forming Unit (CFU)/g
  - b. C02 and Solvent Based Extracts: 104 CFU/g
- 2. Total Yeast and Mold:
  - (i) Unprocessed and Processed Materials: 104 CFU/g
  - (ii) C02 and Solvent Based Extracts: 103 CFU/g
  - (iii) Total Coliforms:
    - (a) Unprocessed and Processed Materials: 103 CFU/g
    - (b) C02 and Solvent Based Extracts: 102 CFU/g
  - (iv) Bile-tolerant Gram Negative Bacteria:
    - (a) Unprocessed and Processed Materials: 103 CFU/g
    - (b) C02 and Solvent Based Extracts: 102 CFU/g
  - (v) *E. coli* (pathogenic strains) and *Salmonella spp.*: Not detected in 1 g
  - (vi) *Aspergillus fumigatus*, *Aspergillus flavus*, *Aspergillus niger*: <1 CFU/g;
  - (vii) Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and



## Attachment 8.3

- (3) Additional testing requested at the discretion of the department.

***The above information can all be generated within BioTrackTHC and reflected on the label for each product.***

- (d) The certified laboratory may retest or reanalyze the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense.
- (e) The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of marijuana or manufactured marijuana products that remain after testing and analysis are completed.
- (f) A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana products, including but not limited to:
1. The time and date the sample was obtained;
  2. A description of the sample, including the amount;
  3. What tests were conducted on each sample;
  4. The results of the tests including the certificate of analysis; and
  5. Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount;
  6. and shall make all the records available to the department upon request.
- (g) A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection (c), and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.
- (h) A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.
- (i) The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.
- (j) A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c).

***BioTrackTHC automatically syncs testing data upon receipt from a certified testing location. Testing will ensure the product is free of contaminants with consistent THC and/or CBD levels. Furthermore,***



## Attachment 8.3

*every plant interaction is recorded, including but certainly not limited to what additives are used and when, allowing cultivators to replicate results or make applicable changes to increase plant quality and consistency. BioTrackTHC syncs testing data to the applicable plant batch or barcode for easy display and retrieval. To simplify the process that information can be directly ported onto the associated product labels.*

*All aspects of the marijuana plants, byproduct wastes, weights, ID numbers and associated data is stored in the system indefinitely. Destruction event information and explanations are also documented and stored within the BioTrackTHC system. This data cannot be modified or deleted by the cultivation center employees or even by BioTrackTHC.*

*BioTrackTHC records manual inventory adjustments through a detailed notes section. The reason for disposal and, if applicable, disposal company are recorded and archived to the 16 digit barcode associated with the disposed cannabis. As with all transactions in the BioTrackTHC system, the employee responsible for the transaction is required to enter a PIN number or biometric fingerprint recording the date, time, and reason for the transaction.*

§11-850-92 Packaging and labeling for retail sale.

(b) Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:

1. Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
  - (A) Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;
  - (B) The concentration of tetrahydrocannabinol or 9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;
- (2) The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;
- (3) The batch number and date of packaging;
- (4) Includes a computer tracking inventory identification number barcode generated by tracking software;
- (5) Date of harvest or manufacture and "Use by date";
- (6) Instructions for use;
- (7) The phrases "For medical use only" and "Not for resale or transfer to another person";
- (8) The following warnings:
  - (A) "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";



## Attachment 8.3

- (B) "This product has intoxicating effects and may be habit forming";
- (C) "Smoking is hazardous to your health";
- (D) "There may be health risks associated with consumption of this product";
- (E) "This product is not reconunended for use by women who are pregnant or breast feeding";
- (F) "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
  - (6) A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
- (9) The name of the laboratory that performed the testing;
  - provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
    - (c) A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.

***BioTrackTHC™'s label creation tool enables licensed producers to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale.***



### Application Response: Question 9

Blue Planet Healing LLC (“BPH”) will ensure compliance with all pertinent state laws and regulations (HRS §329D-7 and §329D-8, and HAR §11.850-81 and §11-850-85) pertaining to the requirements for the use of a certified laboratory to perform content, contamination, and consistency testing on all marijuana or manufactured marijuana products. BPH will ensure that no marijuana or manufactured marijuana products will be dispensed or made available for dispensing unless and until a laboratory certified by the Department of Health (“DOH”) has tested and certified that the marijuana and manufactured marijuana products meet the requirements set out in HAR Chapter 11-850. As detailed in BPH’s written Standard Operating Procedures (“SOP”) (See Attachments “9.1” and “9.2”), BPH will select and utilize a DOH-certified independent testing laboratory that has adopted a complaint protocol to test marijuana and manufactured marijuana products. When selecting a laboratory, BPH will review the laboratory’s procedures for effective, validated, accurate and precise measurement of  $\Delta^9$ -Tetrahydrocannabinol (“THC”), Tetrahydrocannabinolic Acid (“THCA”), Cannabidiol (“CBD”), Cannabidiolic Acid (“CBDA”), Cannabinol (“CBN”), Cannabigerol (“CBG”), and terpenes, to ensure that BPH’s marijuana and manufactured marijuana products are free from contaminants and any other criteria the DOH or BPH deems necessary. It will be BPH’s policy to routinely test marijuana plant material, cannabinoid concentrates, and in-process materials and finished packaged product to assure they meet all specifications and requirements established by DOH to identify the chemical profile of the batch and to ensure the products are not contaminated with any of the following:

1. Residual solvents, processing chemicals or pesticides as defined by the state;
2. Foreign material such as hair, insects, or any similar or related adulterant;
3. Heavy metals as defined by the state
4. Any microbiological impurity as defined by the state.



### Application Response: Question 9

Each product manufactured in a BPH production center will be tested for shelf stability. An ISO accredited testing laboratory will test marijuana product and manufactured marijuana products to determine the shelf life and stability of all final products. The tests will include but not be limited to pH, Water Activity ( $a_w$ ), and accelerated stability tests at high heat and humidity. The packaging for final marijuana and manufactured marijuana products will be designed to support and ensure the designated shelf life of the marijuana product. A batch will only be assigned an expiration date after the testing laboratory issues an authoritative Certificate of Analysis that meets all required marijuana product specifications. Data derived from the lab tests and ongoing stability testing will determine the shelf life and the expiration date will be determined using the shelf life in conjunction with the date of production.

### Collecting Test Samples.

Unless a State of Hawaii Department of Health (“DOH”) approved lab’s protocol requires 3<sup>rd</sup> party sampling, a registered employees of BPH will collect and send a random, statistically representative sample from each batch of marijuana and/or manufactured marijuana products to an independent, DOH-certified laboratory for testing. In addition, BPH will retain an equal sample, in sufficient quantity for verification testing, from the same batch of marijuana and manufactured marijuana products released for distribution, and store it in a secure, tamper-proof container with a tamper-evident seal for further verification testing as directed by the DOH.

### Certificate of Analysis.

As detailed in BPH’s written SOPs, BPH’s registered employees will coordinate with the independent testing laboratory(s) to issue a certificate of analysis for each batch of marijuana or manufactured marijuana products tested. Each certificate of analysis will include sample test results that show the sample meets all specifications set forth in HAR §11-850-85. The testing



### Application Response: Question 9

laboratory will also supply supporting data such as graphs and charts that display test results signifying batch purity, strength, consistency, and contaminants or lack thereof. BPH will retain all certificates of analysis within a secure, lockable file cabinet located in an office in a limited access area of the licensed premise and make all certificates of analysis readily available to the DOH upon request.

BPH will require all batches of marijuana and manufactured marijuana products to be segmented in secure storage until the batch sample passes all required testing and the sample is determined to meet all specifications set forth in HAR §11-850-85. At that point, the independent testing laboratory will produce a certificate of analysis and supporting data for the sample tests. Once BPH is in possession of the certificate of analysis for a particular batch, then that particular batch may be released for packaging, distribution and shipment to the retail dispensary facilities. The process for releasing a batch for packaging and transporting is detailed in BPH's SOPs attached as "9.3". As part of this procedure BPH will require registered employees to revise and update the status of the batch within the BioTrackTHC™ inventory control system with its appropriate stage in the chain of custody e.g., "in cure, in batch hold for testing, awaiting delivery".

### **Transportation Procedures.**

BPH will ensure compliance with HAR §11-850-36 by following written standard operating procedures for the transportation of all marijuana and manufactured marijuana products to DOH-approved testing laboratories. BPH will employ specifically trained and designated registered employees responsible for transporting marijuana and manufactured marijuana products from its production center to a certified testing laboratory. BPH's written transportation SOP has been included as an additional attachment to its application. (See Attachment "9.3")



## Attachment 9.1

<b>Standard Operating Procedure:</b> Cultivated Marijuana Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Cultivation Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

### Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

### State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)
  - Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.



## Attachment 9.1

- If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the *Marijuana Waste SOP* upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

### Preparation of Medical Marijuana Samples to be Tested

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Flower/bud—ensure adequate quantity from batch for sampling (~7-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# MIP001 → Create new ‘Sample Package’: MIPT101
- Fill out all required documentation/log sheets
  - *Samples for Laboratory Testing*
  - *Marijuana Product Shipping Manifest*

<u>Marijuana Samples for Laboratory Testing</u>					
Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:



## Attachment 9.1

- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow *Shipping, Transferring/Transporting SOP*

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show medical marijuana potency, cannabinoid profiles, terpene profiles, and contaminants (if any present). The testing laboratory will provide BPH test results from each batch and lot tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meet all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**—there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm$  90-100% of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating

It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.



## Attachment 9.1

- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<b><u>Marijuana Batch Samples for Laboratory Testing</u></b>						
<b>Date Sample Prepared:</b>	<b>Grower Agent #1:</b>	<b>Grower Agent #2:</b>	<b>Product Attribute ID #, Batch# and Strain/Variety</b>	<b>Sample Quantity/Weight:</b>	<b>Test Sample ID # (NEW) :</b>	<b>Receiving Laboratory:</b>
<b>Date Sample Shipped:</b>	<b>Sample Pass Testing</b>	<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>If sample failed testing, will batch be reprocessed or destroyed?</b>		<b>Licensed Processor to Send Batch to:</b>	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed			
<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>			<b>Notes/Details:</b>	
<b>Date of 6-month interval test:</b>	<b>Sample Pass Testing</b>	<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
<b>Notes/Comments:</b>						

### **Release for Distribution**

All batches of marijuana are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH’s registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.

- This process will be completed by two (2) registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

### **Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.



## Attachment 9.2

<b>Standard Operating Procedure:</b> Manufactured Marijuana Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana and manufactured marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Manufactured Marijuana Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

### **POLICY**

To submit medical marijuana for lab testing.

### **RESPONSIBILITY**

Production Manager, Extraction Manager or their designee.

### **RECORDS**

BioTrackTHC™ Seed-to-Sale Inventory Tracking System and physical documentation log sheets

### **PROCEDURES**

Any medical marijuana sample is tested at the lab for the required cannabinoid profile, contaminants, any pesticide/herbicide/fungicide used during production of the medical marijuana product, and any growth regulator used during production of the medical marijuana product. Test results will be transmitted directly from the Testing Lab to the Extraction Manager. The Extraction Manager will assign the test results to the extraction batch number and document results in inventory tracking software. The accurate cannabinoid profile information will be utilized in the production formulations and standard operating procedures for medical marijuana product production to ensure safe, secure, accurate and consistent cannabinoid dosing and labeling

#### **1. Post-Harvest:**

- a. The first phase of quality control consists of visually inspecting the leaves and flowers of harvested and cured marijuana. Upon approved inspection, samples of the leaves and flowers will be sent to a lab to test for potency and contaminants. A medical marijuana “leaves and flowers sample collection” SOP will be followed. Lab test results will be used:
  - i. to compare against post extraction results
  - ii. to ensure the cultivated and cured marijuana plants are of consistent quality and THC/CBD concentrations
  - iii. to create concentrates of consistent quality.
- b. Uniform and homogenous leaves and flowers samples will be placed within sealed, child-resistant containers. One sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the



## Attachment 9.2

sample to the testing lab. Remaining samples will be kept securely stored for future testing as required.

### 2. Post Processing:

- a. The second phase of quality control will test the extract produced from the leaves and flowers of the marijuana plant. A sample from each lot of extract will be tested to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. A uniform and homogenous sample will be placed within a sealed, child-resistant container. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab.

### 3. Finished Product:

- a. A number of samples, which accurately represent the production lot of the final medical marijuana product, will be selected for lab testing. Cannabinoid profile and contaminant testing will be performed to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. “Final medical marijuana product samples” will be submitted to the testing lab facility, sealed, packaged and labeled exactly as they will be delivered to a patient obtaining the product at a dispensing facility.
- c. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab. All final medical marijuana products will be kept secured in a limited access area until approved test results are received. No final medical marijuana product will be shipped to a dispensing facility until approved lab test results are received and the final marijuana product is labeled with test results.

### Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

### State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)



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- Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.
  - If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the ***Marijuana Waste SOP*** upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

### Preparation of Medical Marijuana Samples to be Tested

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Manufactured marijuana products—ensure adequate quantity from batch for sampling (~2-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# MIP001 → Create new ‘Sample Package’: MIPT101
- Fill out all required documentation/log sheets
  - ***Samples for Laboratory Testing***
  - ***Marijuana Product Shipping Manifest***



## Attachment 9.2

<u>Marijuana Samples for Laboratory Testing</u>					
Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:



- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow *Shipping, Transferring/Transporting SOP*

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show marijuana product potency, cannabinoid profiles, terpene profiles, contaminants (if any present). The testing laboratory will provide BPH test results from each batch tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meets all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**— there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm 90-100\%$  of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating



## Attachment 9.2

It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.

- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<u><b>Marijuana Batch Samples for Laboratory Testing</b></u>						
Date Sample Prepared:	Grower Agent #1:	Grower Agent #2:	Product Attribute ID #, Batch# and Strain/Variety	Sample Quantity/Weight:	Test Sample ID # (NEW) :	Receiving Laboratory:
Date Sample Shipped:	Sample Pass Testing		Certificate of Analysis Provided w/ Supporting Data?	If sample failed testing, will batch be reprocessed or destroyed?		Licensed Processor to Send Batch to:
	<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed		
Batch Potency	Batch Purity		Batch expiration date data/support:		Notes/Details:	
Date of 6-month interval test:	Sample Pass Testing	Certificate of Analysis Provided w/ Supporting Data?		Batch Potency	Batch Purity	Batch expiration date data/support:
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
Notes/Comments:						

### Release for Distribution

All batches of marijuana products are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH's registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.



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- This process will be completed by two (2) register registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

### **Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.



## Attachment 9.3

<b>Standard Operating Procedure:</b> Transferring/Transporting Marijuana Products
<b>Purpose:</b> To explain the steps required to be followed to ship marijuana and manufactured marijuana products to BPH retail dispensary locations.
<b>Scope:</b> Covers the training required and procedures for registered employees covering the shipping/transporting of marijuana and manufactured marijuana products.
<b>Initial Training:</b> 2-4 hours

### The Principles of the Shipping Procedure, Transferring/Transporting

The facility will transport marijuana and manufactured marijuana products to BPH retail dispensary locations and/or Department-approved testing laboratories.

#### **The Shipping Process:**

- 1) New Shipping Order
- 2) Fulfillment
- 3) Create Manifest/Trip Plan
- 4) Transportation
- 5) Delivery
- 6) Post-Delivery

#### **1) New Shipping Order**

- 1) Fill out *Marijuana Products Shipment (Outgoing)* log sheet
- 2) Create a new invoice for shipping order
  - a. Date that order is placed
  - b. Products and quantities ordered
  - c. Prices of products
  - d. Estimated delivery date

#### **2) Fulfillment**

- 1) Collect products needed for shipping order
- 2) Take ordered/collected products out of the inventory control system
- 3) Package the order of products into a container that is constructed on tamper-evident, opaque material
  - a. The use of tamper-evident cardboard boxes, hard plastic opaque cases that can be locked with tamper-evident seals or locks, or a similar shipping package that will meet Hawaii requirements
  - b. Seal said tamper-evident package with tamper-evident tape.
  - c. If shipping multiple packages to the same recipient, the packages will need to be shipped within one large opaque tamper-evident container.
- 4) **Repackaging**—if necessary, registered employees may have to repackage the shipment into a container that is constructed of tamper-evident opaque materials and sealed with tamper-evident tape
  - a. This will typically only happen if the original packaging is defective or gets destroyed.
  - b. Medical marijuana will need to be repackaged if not originally packaged in an opaque container.
  - c. Repackaging may be required if multiple packages are identified as being shipped to the same recipient
    - i. If this is the case, then the packages will need to be repackaged into one large opaque tamper-evident container and sealed with tamper-evident tape
      1. Ensure package is sealed with tamper-evident tape; seal all entry/access points
- 5) Complete the *Marijuana Products Daily Transfer/Shipping* log sheet
  - a. Example of *Marijuana Products Daily Transfer/Shipping* log sheet can be seen below:



## Attachment 9.3

<u>Marijuana Products Daily Transfer/Shipping</u>					
<u>Date:</u>	<u>Employee preparing Shipment:</u>	<u>Marijuana Product Name/Batch ID #/Strain:</u>	<u>Quantity Shipped:</u>	<u>Receiving Retail Dispensary Location:</u>	<u>Receiving Employee:</u>

- 6) Create new record within the inventory control system for the products being shipped—registered employees will need to create a record of the products prior to shipping any marijuana products.
  - a. Information required on record:
    - i. Date and time of the sealing of the package for shipment
    - ii. Name a signature of the registered grower agent who prepared and sealed the package
    - iii. Name and address of BPH
    - iv. Shipment identification number
    - v. A description of the package being shipped including the weight of each item
    - vi. The name and address of the party receiving the shipment

### **3) Manifest/Trip Plan Creation**—See *Marijuana Product Shipping Manifest SOP*

Prior to the transportation of any marijuana products or marijuana-infused products a facility agent will generate a manifest/trip plan including at a minimum:

- 1) The name of the agent(s) who will be transporting;
- 2) The automobile license plate, make and model;
- 3) The date, start time of the trip and estimated delivery time;
- 4) A description including the exact amount, type and batch of any marijuana products and marijuana-infused products being transported; and
- 5) The intended route of transportation.

Facility management shall maintain a copy of the manifest/trip plan document at the location of departure, record the manifest/trip plan with any needed authorities, and the transporting employees will maintain a copy of the manifest/trip plan during the transportation.

### **4) Transportation/Shipping**

This section covers how to transport the wholesale order to the purchasing organization/facility. All applicable state and local laws/regulations pertaining to transportation of medical marijuana products will need to be strictly adhered to by all organization team members. All transportation/shipping to be done in-house by BPH registered employees and/or transportation agents. BPH does not intend to use a secure transportation company unless deemed absolutely necessary.

**Transportation Vehicle Requirements**—all agents responsible for transporting medical marijuana must:

- 1) Use of an unmarked, unidentifiable vehicle
  - a. Vehicle should not have any BPH markings, logos or identifiers on the vehicle
  - b. Vehicle should not raise awareness that it may be transporting medical marijuana and/or medical marijuana products of any kind



## Attachment 9.3

- 2) Ensure the vehicle has current, valid registration from the State
  - a. Registration paperwork should be located in vehicle glovebox
  - b. Vehicle license plate should have current, valid registration sticker
- 3) Ensure the vehicle has current valid proof of insurance
  - a. Proof of insurance paperwork should be located in the glovebox

**Transportation Agent Requirements**—all agents responsible for transporting medical marijuana must:

- 1) There will be at minimum two registered employees and/or transportation agents for every product shipment. Each transportation agent will play a separate and vital role.
  - o One transportation agent will be required to drive the transportation vehicle and to remain with the transportation vehicle at all times.
  - o The second transportation agent is to remain with the medical marijuana product be shipped at all times and to ensure that the product is secure at all times during transport.
- 2) Wearing appropriate work attire
  - o Work attire for BPH transportation agents will be plain with no company logos, brands or identification.
  - o BPH transportation agents should not appear to indicate ownership or possession of marijuana.
    - Plain polo shirt
    - Plain khakis/jean pants
    - Plain dress/tennis shoes
  - Failure to arrive to a scheduled shift with proper attire will result in not being able to make transports, incident noted in personal file and possible disciplinary action.
- 3) Possess a current and valid State-issued marijuana industry worker license;
- 4) Possess a current and valid State-issued driver's license;
- 5) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or marijuana-infused products pursuant to regulation, all transporting agents shall:

- 1) Carry a copy of the manifest/trip plan with him or her for the duration of the trip;
- 2) Wear their agent card and/or have Commission approved identification readily available;
- 3) Use a vehicle without any medical marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or marijuana-infused products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation as well as a back-up emergency cell phone; and
- 5) Ensure that the medical marijuana is not at all visible to the public.

### 5) Delivery

- 1) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the shipping manifest/trip plan
- 2) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

### 6) Post-Delivery

**Post-Delivery Protocol**—after transporting marijuana products or marijuana-infused products, pursuant to the regulations the employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.



## Attachment 9.3

**Documentation of Delivery**—both the transporting dispensing facility and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Division agents for review upon request.

**Deviations from Transportation Plan**—the transporting agent shall immediately report all diversion due to loss or theft of marijuana or marijuana-infused products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the state licensing authorities as required per state regulations. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



## Application Response: Question 10

### **Signage.**

If awarded a license, Blue Planet Healing, LLC (“BPH”) will fully comply with HAR §11-850-91. BPH will ensure that the only sign visible from the exterior of each of its retail dispensing locations (“RDL”) are one single sign no greater than 1,600 square inches that bears only the name “Blue Planet Healing” in text without pictures or illustrations. BPH will comply with any more restrictive signage requirements imposed by the City and County of Honolulu.

### **Packaging.**

BPH will comply with HAR §11-850-92 and package all medical marijuana products in child resistant packaging in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act. All medical marijuana products will be packaged in opaque packaging that ensures the product cannot be seen unless the package is opened. Packaging will also protect the product from contamination and will not impart any toxic or harmful substance to the marijuana product. BPH’s marijuana product packages will not contain more than 10 milligrams of Tetrahydrocannabinol (“THC”) for one dose, serving, or single wrapped item; with a limit of a maximum of 100 milligrams of THC per child safe pack or container for manufactured marijuana products sold in a pack of multiple doses.

Before transporting to RDLs for sale to registered patients, all marijuana and manufactured marijuana products will be unit-packaged at the production center. Per BPH procedures, once packaged, the marijuana or manufactured marijuana product will remain sealed throughout the chain of custody until dispensed or destroyed. BPH will seal every bulk package of final medical marijuana products and manufactured marijuana products designated for transport with tamper-evident tape that will ensure the original seal is not broken except for testing performed by a



### Application Response: Question 10

laboratory certified by the State of Hawaii Department of Health (“DOH”), dispensing or destruction.

BPH may utilize ‘exit packaging’ at its RDLs. Purchased products will be placed in exit packaging at the RDL prior to registered patients and/or caregivers exiting the facility. Exit packaging is child-resistant, opaque, and conceals the contents. Exit packaging minimizes the risk of marijuana product diversion or accidental ingestion by a child or pet.

### **Labeling.**

BPH will comply with the labeling regulations set forth at HAR §11-850-92(b) in connection with all packages containing marijuana or manufactured marijuana products. BPH will affix each package of marijuana or manufactured marijuana product with a product label and will ensure all marijuana product labels include advisories, warnings and other information required under HAR §11-850-92. BPH’s labels will use black lettering only on a white background with no pictures or graphics. (See Attachment “10.1”)

All BPH product labels will contain the information required by HAR §11-850-92(b) regarding the contents and potency of the marijuana product. All BPH labels will also contain the phrases “For medical use only” and “Not for resale or transfer to another person” along with and the following warnings:

(A) “This product may be unlawful outside of the State of Hawai‘i and is unlawful to possess or use under federal law”; (B) “This product has intoxicating effects and may be habit forming”; (C) “Smoking is hazardous to your health”; (D) “There may be health risks associated with consumption of this product”; (D) “This product is not recommended for use by women who are pregnant or breast feeding”; (E) “Marijuana can impair concentration, coordination, and



**Application Response: Question 10**

judgement. Do not operate a vehicle or machinery under the influence of this drug”; and (F)

“When eaten or swallowed, the effects of this drug may be delayed by two or more hours.”

BPH’s labeling requirements and procedures are detailed within its written SOPs. (See Attachment “10.2”)

**Chain of Custody.**

BPH will ensure that there will be plans, procedures and systems adopted, implemented, utilized and maintained to safeguard and protect the chain of custody of all medical marijuana, and for inventory tracking, record keeping, record retention, and surveillance systems relating to medical marijuana at every stage of BPH’s operations including cultivating, processing and manufacturing of marijuana products, transporting, sale and dispensing of marijuana products and manufactured marijuana products. BPH will use the BioTrackTHC™ inventory control computer system in accordance with BPH’s inventory tracking, monitoring operations and to document the chain of custody for all marijuana product or manufactured marijuana product while in BPH’s possession at any of its facilities or while in transport or during testing. BPH will employ written physical documentation via log sheet or manifest for all shipping and transporting of marijuana products and manufactured marijuana products from its production centers to its RDLs or to Department-approved testing laboratories. (See Attachment “10.3”) All written documentation must be signed by the generating employee and his/her direct manager or manager with equivalent authority. This written documentation provides and added reference point in our chain of custody with the dual sign-off further mitigating risk of employee based diversion. This will additionally be controlled with access permission, both physically within the building but also within the BioTrackTHC™ inventory control computer system.

# Attachment 10.1

## SAMPLE PRODUCT LABEL: LOTION

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <table border="1"><tr><td><b>INDEPENDENT TESTING LABORATORY</b></td></tr><tr><td><b>IDENTIFICATION</b></td></tr></table> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p>  <p>0 123456 789012</p> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>	<b>INDEPENDENT TESTING LABORATORY</b>	<b>IDENTIFICATION</b>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div data-bbox="934 592 1228 885"></div> <p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Manufacture: _____</p> <p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p> <p>Net Wt: _____</p>	<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>						
<b>INDEPENDENT TESTING LABORATORY</b>										
<b>IDENTIFICATION</b>										
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PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: SALVE

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <table border="1"><tr><td>INDEPENDENT TESTING LABORATORY</td></tr><tr><td>IDENTIFICATION</td></tr></table> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p>  <p>0 123456 789012</p> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>	INDEPENDENT TESTING LABORATORY	IDENTIFICATION	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div data-bbox="934 592 1228 885"></div> <p>FOR MEDICAL USE ONLY SMOKING IS HAZARDOUS TO YOUR HEALTH.</p> <p>Date of Manufacture: _____</p> <p>Net Wt: _____</p> <p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p>	<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>						
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Cannabinoid Profile _____										

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: SERUM

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <table border="1"><tr><td><b>INDEPENDENT TESTING LABORATORY</b></td></tr><tr><td><b>IDENTIFICATION</b></td></tr></table> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p>  <p>0 123456 789012</p> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>	<b>INDEPENDENT TESTING LABORATORY</b>	<b>IDENTIFICATION</b>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div style="text-align: center;"><p><b>SERUM</b></p></div> <p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Manufacture: _____</p> <p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p> <p>Net Wt: _____</p>	<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>						
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Cannabinoid Profile _____										

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: GEL

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

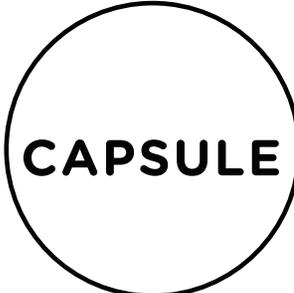
<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p><b>INDEPENDENT TESTING LABORATORY</b></p> <hr/> <p><b>IDENTIFICATION</b></p> </div> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p> <div style="display: flex; align-items: center;">  <div style="font-size: small;"> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p> </div> </div>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div style="font-size: 2em; font-weight: bold; margin: 20px 0;">GEL</div> <p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Manufacture: _____</p>	<p style="text-align: center;"><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p> <p>Net Wt: _____</p>
<div style="border: 1px solid black; padding: 5px; font-size: x-small;"> <p>Dispensary License Number _____</p> <p>The date of packaging _____ Use By date _____</p> <p>Production Batch Number _____</p> <p>Marijuana Concentrate Batch Number _____</p> <p>The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____</p> <p>Cannabinoid Profile _____</p> </div>	<p><b>NAME OF PRODUCTION CENTER</b></p>	
<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>		

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: CAPSULE

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

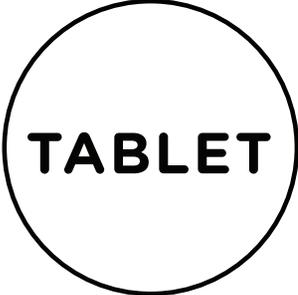
<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <table border="1"><tr><td><b>INDEPENDENT TESTING LABORATORY</b></td></tr><tr><td><b>IDENTIFICATION</b></td></tr></table> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p>  <p>0 123456 789012</p> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>	<b>INDEPENDENT TESTING LABORATORY</b>	<b>IDENTIFICATION</b>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div data-bbox="934 592 1228 885"><p><b>CAPSULE</b></p></div> <p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Manufacture: _____</p> <p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p> <p>Net Wt: _____</p>	<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>						
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Marijuana Concentrate Batch Number _____	The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____									
Cannabinoid Profile _____										

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: TABLET

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

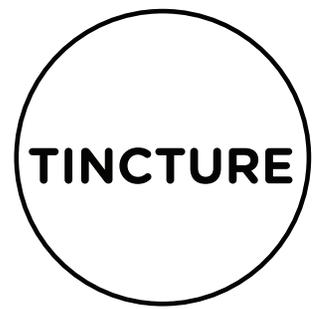
<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <table border="1"><tr><td><b>INDEPENDENT TESTING LABORATORY</b></td></tr><tr><td><b>IDENTIFICATION</b></td></tr></table> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p>  <p>0 123456 789012</p> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>	<b>INDEPENDENT TESTING LABORATORY</b>	<b>IDENTIFICATION</b>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div data-bbox="936 594 1234 889"></div> <p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Manufacture: _____</p> <p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p> <p>Net Wt: _____</p>	<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>								
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The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____												
Cannabinoid Profile _____												

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: TINCTURE

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <table border="1"><tr><td><b>INDEPENDENT TESTING LABORATORY</b></td></tr><tr><td><b>IDENTIFICATION</b></td></tr></table> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p> <div data-bbox="441 974 609 1088"><p>0 123456 789012</p></div> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>	<b>INDEPENDENT TESTING LABORATORY</b>	<b>IDENTIFICATION</b>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div data-bbox="924 584 1239 893"></div> <p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Manufacture: _____</p> <p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p> <p>Net Wt: _____</p>	<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>
<b>INDEPENDENT TESTING LABORATORY</b>				
<b>IDENTIFICATION</b>				
<table border="1"><tr><td data-bbox="420 1104 882 1266">Dispensary License Number _____ The date of packaging _____ Use By date _____ Production Batch Number _____ Marijuana Concentrate Batch Number _____ The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____ Cannabinoid Profile _____</td><td data-bbox="882 1104 1743 1266"><b>NAME OF PRODUCTION CENTER</b></td></tr></table>			Dispensary License Number _____ The date of packaging _____ Use By date _____ Production Batch Number _____ Marijuana Concentrate Batch Number _____ The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____ Cannabinoid Profile _____	<b>NAME OF PRODUCTION CENTER</b>
Dispensary License Number _____ The date of packaging _____ Use By date _____ Production Batch Number _____ Marijuana Concentrate Batch Number _____ The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____ Cannabinoid Profile _____	<b>NAME OF PRODUCTION CENTER</b>			

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: CO<sub>2</sub> OIL

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/> <p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p> <table border="1"><tr><td><b>INDEPENDENT TESTING LABORATORY</b></td></tr><tr><td><b>IDENTIFICATION</b></td></tr></table> <p>There may be health risks associated with consumption of this product.</p> <p>This product is not for resale or transfer to another person.</p>  <p>0 123456 789012</p> <p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>	<b>INDEPENDENT TESTING LABORATORY</b>	<b>IDENTIFICATION</b>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p> <div data-bbox="934 592 1228 885"></div> <p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Manufacture: _____</p> <p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p> <p>Net Wt: _____</p>	<p><b>INSTRUCTIONS FOR USE:</b></p> <p>Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.</p> <p><b>ALLERGEN LABELING:</b></p> <p>This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.</p>						
<b>INDEPENDENT TESTING LABORATORY</b>										
<b>IDENTIFICATION</b>										
<table border="1"><tr><td>Dispensary License Number _____</td><td>Use By date _____</td></tr><tr><td>The date of packaging _____</td><td>Production Batch Number _____</td></tr><tr><td>Marijuana Concentrate Batch Number _____</td><td>The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____</td></tr><tr><td>Cannabinoid Profile _____</td><td></td></tr></table> <p><b>NAME OF PRODUCTION CENTER</b></p>		Dispensary License Number _____	Use By date _____	The date of packaging _____	Production Batch Number _____	Marijuana Concentrate Batch Number _____	The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____	Cannabinoid Profile _____		
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Cannabinoid Profile _____										

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

# SAMPLE PRODUCT LABEL: Marijuana

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

<p>THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING.</p> <hr/> <hr/>	<p>Contains no more than 10mg THC for one dose, no more than 100mg THC in container.</p>						
<p><i>When eaten or swallowed, the effects of this drug may be delayed by two or more hours.</i></p>							
<table border="1"><tr><td><b>INDEPENDENT TESTING LABORATORY</b></td></tr><tr><td>IDENTIFICATION</td></tr></table>		<b>INDEPENDENT TESTING LABORATORY</b>	IDENTIFICATION				
<b>INDEPENDENT TESTING LABORATORY</b>							
IDENTIFICATION							
<p>There may be health risks associated with consumption of this product.</p>	<p><b>THIS PRODUCT IS NOT RECOMMENDED FOR USE BY WOMEN WHO ARE PREGNANT OR BREASTFEEDING.</b></p>						
<p>This product is not for resale or transfer to another person.</p>							
 <p>0 123456 789012</p>	<p><i>Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.</i></p>						
<table border="1"><tr><td>Dispensary License Number _____</td></tr><tr><td>The date of packaging _____ Use By date _____</td></tr><tr><td>Production Batch Number _____</td></tr><tr><td>Marijuana Concentrate Batch Number _____</td></tr><tr><td>The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____</td></tr><tr><td>Cannabinoid Profile _____</td></tr></table>	Dispensary License Number _____	The date of packaging _____ Use By date _____	Production Batch Number _____	Marijuana Concentrate Batch Number _____	The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____	Cannabinoid Profile _____	<p><b>FOR MEDICAL USE ONLY</b></p> <p><b>SMOKING IS HAZARDOUS TO YOUR HEALTH.</b></p> <p>Date of Harvest: _____</p> <p>Net Wt: _____</p> <p><b>NAME OF PRODUCTION CENTER</b></p>
Dispensary License Number _____							
The date of packaging _____ Use By date _____							
Production Batch Number _____							
Marijuana Concentrate Batch Number _____							
The pre-mixed total weight (in ounces or grams) of usable cannabis in the package _____							
Cannabinoid Profile _____							

PRODUCTION BATCH STICKER  
UNIQUE TO EACH BATCH

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**INSTRUCTIONS FOR USE:**

Type of extraction method used including solvents, gases or other chemicals or compounds used to produce the marijuana product. All ingredients of the item, including any colors, artificial flavors and preservatives, listed in descending order by predominance of weight shown with common or usual names.

**ALLERGEN LABELING:**

This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law.

## Attachment 10.2

<b>Standard Operating Procedure:</b> Packaging and Labeling
<b>Purpose:</b> to educate and train registered employees on BPH packaging and labeling requirements within the production center
<b>Scope:</b> Covers the packaging and labeling activities within the production center.
<b>Initial Training:</b> TBD

- 1) **Weighing and Packaging Medical Marijuana**—is the process of accurately weighing the medical marijuana to be put into packages for distribution. Packaging regulations and requirements may vary, so it is essential to reference the state and local laws and regulations pertaining to packaging requirements for medical marijuana business. Use of NTEP certified scales for the weighing of all marijuana products is mandatory.
- All BPH packing will be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
  - Packaging must be opaque so that the product cannot be seen from outside the packaging;
  - The packaging must be constructed to protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.
  - Packages must not contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; providing that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
  - Marijuana will be carefully weighed and packaged at the production center. All products will be packaged, recorded into the inventory system, and labeled per Hawai'i regulations.



- Upon marijuana being weighed and packaged registered employees are required to document the marijuana weight associated to the product with a unique attribute number and batch number. This documentation must be done with two registered employees, one employee to make the record in the inventory control system and a second to witness the record.
- Ensure inventory control system is updated to show the packaged marijuana weights and specifications.

### *Examples of Child-Resistant Packaging:*



- 2) **Labeling**—all packages of medical marijuana will require a label to be conspicuously placed on the package.



## Attachment 10.2

- Labels must be made of weather resistant and tamper-evident material
- As a redundancy, registered employees will be required to recheck each package for a label prior to shipping and package containing medical marijuana from the Licensed Premise.
- **Hawaii specific labeling requirements:**
  - Labels must use black lettering only on a white background with no pictures or graphics
  - Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
    - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
    - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
  - The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
  - The batch number and date of packaging;
  - A computer tracking inventory identification number barcode generated by tracking software;
  - Date of harvest or manufacture and a "use by date";
  - Instructions for use;
  - The phrases "For medical use only" and "Not for resale or transfer to another person";
  - The following warnings:
    - "This product may be unlawful outside of the State of Hawai'i and is unlawful to possess or use under federal law";
    - "This product has intoxicating effects and may be habit forming";
    - "Smoking is hazardous to your health";
    - "There may be health risks associated with consumption of this product";
    - "This product is not recommended for use by women who are pregnant or breast feeding";
    - "Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug"; and
    - "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"
  - A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
  - The name of the laboratory that performed the testing

### Equivalent Weights for Manufactured Marijuana Products

#### **Assessment of the pre-mixed total weight (in ounces or grams) of usable marijuana contained within in an extract, oil, or infused product.**

The pre-mixed total weight of usable marijuana contained in an extract, oil or infused product is determined by the amount of marijuana plant material used to make the marijuana extract or oil. To determine the amount of usable marijuana in an infused product the additional step of determining the amount of extract or oil used to make an infused product is necessary.

Equivalency of marijuana flower or trim to extract, oil or infused product can vary due to several variables;

1. The tetrahydrocannabinol (THC) content of the marijuana flower or trim.
2. The THC content of the extract or oil produced from marijuana flower or trim.
3. The amount of THC infused into the infused product.

The average tetrahydrocannabinol (THCa) percentage of medical marijuana flower ranges from 15 - 19%. THCa is the form of THC found within the marijuana plant material. THCa is the non-psychoactive bio-synthetic precursor to THC. THCa must be decarboxylated to become bioavailable to the human body and is done so in the production of some extracts an oil and with all infused product production. During decarboxylation the THCa loses carbon and oxygen molecules, and about 12.3 percent of its weight. This must be taken into account when determining the usable weight of marijuana found in extract, oil, or infused products.

Extraction efficiency for CO2 Sub/Supercritical Extract and Oil average from an average between 60% - 80%. This range provides an estimated average total of 70% of the total THC milligrams available within the plant will be



## Attachment 10.2

extracted. The oil or extract is then lab tested to determine the exact amount of active cannabinoids in the product. These lab results are then used to determine how much in weight or volume of the extract or oil is to be used in the infused product formulation. Infused products are measured in activated milligrams of THC. No more than 10 milligrams THC per dose. No more than 100 total THC milligrams per package.

Projected extracted milligrams of THC per gram of plant material based on average extraction efficiencies of yield and THC percentage:

1. Beginning plant material THC % is 15%.
2. Extraction efficiency is 70%.
3. Infused Product is to contain 10 milligrams of active THC

Example: of 1 gram of medical marijuana = 1000mg Total Weight

- A. The medical marijuana is 15% THC the total available THC milligrams within that one gram is 150 milligrams. ( $1000\text{mg} \times 15\% = 150\text{mg}$ )
- B. The CO2 Extraction efficiency is equal to 70% total amount of THC milligrams extracted 105 mg THC per gram of plant material.
- C. 105 mg of THC will produce 10.5 units of 10 mg THC infused products.
- D. 1/10 gram would be the pre mixed total weight of usable marijuana contained within the infused product.



## Attachment 10.3

<b>Standard Operating Procedure:</b> Transferring/Transporting Marijuana Products
<b>Purpose:</b> To explain the steps required to be followed to ship marijuana and manufactured marijuana products to BPH retail dispensary locations.
<b>Scope:</b> Covers the training required and procedures for registered employees covering the shipping/transporting of marijuana and manufactured marijuana products.
<b>Initial Training:</b> 2-4 hours

### The Principles of the Shipping Procedure, Transferring/Transporting

The facility will transport marijuana and manufactured marijuana products to BPH retail dispensary locations and/or Department-approved testing laboratories.

#### **The Shipping Process:**

- 1) New Shipping Order
- 2) Fulfillment
- 3) Create Manifest/Trip Plan
- 4) Transportation
- 5) Delivery
- 6) Post-Delivery

#### **1) New Shipping Order**

- 1) Fill out *Marijuana Products Shipment (Outgoing)* log sheet
- 2) Create a new invoice for shipping order
  - a. Date that order is placed
  - b. Products and quantities ordered
  - c. Prices of products
  - d. Estimated delivery date

#### **2) Fulfillment**

- 1) Collect products needed for shipping order
- 2) Take ordered/collected products out of the inventory control system
- 3) Package the order of products into a container that is constructed on tamper-evident, opaque material
  - a. The use of tamper-evident cardboard boxes, hard plastic opaque cases that can be locked with tamper-evident seals or locks, or a similar shipping package that will meet Hawaii requirements
  - b. Seal said tamper-evident package with tamper-evident tape.
  - c. If shipping multiple packages to the same recipient, the packages will need to be shipped within one large opaque tamper-evident container.
- 4) **Repackaging**—if necessary, registered employees may have to repackage the shipment into a container that is constructed of tamper-evident opaque materials and sealed with tamper-evident tape
  - a. This will typically only happen if the original packaging is defective or gets destroyed.
  - b. Medical marijuana will need to be repackaged if not originally packaged in an opaque container.
  - c. Repackaging may be required if multiple packages are identified as being shipped to the same recipient
    - i. If this is the case, then the packages will need to be repackaged into one large opaque tamper-evident container and sealed with tamper-evident tape
      1. Ensure package is sealed with tamper-evident tape; seal all entry/access points
- 5) Complete the *Marijuana Products Daily Transfer/Shipping* log sheet
  - a. Example of *Marijuana Products Daily Transfer/Shipping* log sheet can be seen below:



# Attachment 10.3

<u>Marijuana Products Daily Transfer/Shipping</u>					
<u>Date:</u>	<u>Employee preparing Shipment:</u>	<u>Marijuana Product Name/Batch ID #/Strain:</u>	<u>Quantity Shipped:</u>	<u>Receiving Retail Dispensary Location:</u>	<u>Receiving Employee:</u>

- 6) Create new record within the inventory control system for the products being shipped—registered employees will need to create a record of the products prior to shipping any marijuana products.
  - a. Information required on record:
    - i. Date and time of the sealing of the package for shipment
    - ii. Name a signature of the registered grower agent who prepared and sealed the package
    - iii. Name and address of BPH
    - iv. Shipment identification number
    - v. A description of the package being shipped including the weight of each item
    - vi. The name and address of the party receiving the shipment

### **3) Manifest/Trip Plan Creation**—See *Marijuana Product Shipping Manifest SOP*

Prior to the transportation of any marijuana products or marijuana-infused products a facility agent will generate a manifest/trip plan including at a minimum:

- 1) The name of the agent(s) who will be transporting;
- 2) The automobile license plate, make and model;
- 3) The date, start time of the trip and estimated delivery time;
- 4) A description including the exact amount, type and batch of any marijuana products and marijuana-infused products being transported; and
- 5) The intended route of transportation.

Facility management shall maintain a copy of the manifest/trip plan document at the location of departure, record the manifest/trip plan with any needed authorities, and the transporting employees will maintain a copy of the manifest/trip plan during the transportation.

### **4) Transportation/Shipping**

This section covers how to transport the wholesale order to the purchasing organization/facility. All applicable state and local laws/regulations pertaining to transportation of medical marijuana products will need to be strictly adhered to by all organization team members. All transportation/shipping to be done in-house by BPH registered employees and/or transportation agents. BPH does not intend to use a secure transportation company unless deemed absolutely necessary.

**Transportation Vehicle Requirements**—all agents responsible for transporting medical marijuana must:

- 1) Use of an unmarked, unidentifiable vehicle
  - a. Vehicle should not have any BPH markings, logos or identifiers on the vehicle
  - b. Vehicle should not raise awareness that it may be transporting medical marijuana and/or medical marijuana products of any kind



## Attachment 10.3

- 2) Ensure the vehicle has current, valid registration from the State
  - a. Registration paperwork should be located in vehicle glovebox
  - b. Vehicle license plate should have current, valid registration sticker
- 3) Ensure the vehicle has current valid proof of insurance
  - a. Proof of insurance paperwork should be located in the glovebox

**Transportation Agent Requirements**—all agents responsible for transporting medical marijuana must:

- 1) There will be at minimum two registered employees and/or transportation agents for every product shipment. Each transportation agent will play a separate and vital role.
  - o One transportation agent will be required to drive the transportation vehicle and to remain with the transportation vehicle at all times.
  - o The second transportation agent is to remain with the medical marijuana product be shipped at all times and to ensure that the product is secure at all times during transport.
- 2) Wearing appropriate work attire
  - o Work attire for BPH transportation agents will be plain with no company logos, brands or identification.
  - o BPH transportation agents should not appear to indicate ownership or possession of marijuana.
    - Plain polo shirt
    - Plain khakis/jean pants
    - Plain dress/tennis shoes
  - Failure to arrive to a scheduled shift with proper attire will result in not being able to make transports, incident noted in personal file and possible disciplinary action.
- 3) Possess a current and valid State-issued marijuana industry worker license;
- 4) Possess a current and valid State-issued driver's license;
- 5) Report all vehicle accidents that occur during the transportation directly to management and the required authorities within two hours of the incident.

**Transportation Protocol**—during the transportation of marijuana products or marijuana-infused products pursuant to regulation, all transporting agents shall:

- 1) Carry a copy of the manifest/trip plan with him or her for the duration of the trip;
- 2) Wear their agent card and/or have Commission approved identification readily available;
- 3) Use a vehicle without any medical marijuana identification or relation to the industry
  - a. The vehicle must be equipped with a secure lockbox or locking cargo area that will be used to maintain sanitary and secure transportation of the marijuana products or marijuana-infused products;
- 4) Have a cellular phone as a means of communicating with the establishment for which the agent is providing the transportation as well as a back-up emergency cell phone; and
- 5) Ensure that the medical marijuana is not at all visible to the public.

### **5) Delivery**

- 1) Receiving facility/organization inspects the delivered products
  - a. Ensure delivered products are indeed the order that was placed
  - b. Weigh incoming delivery packages to verify stated weights and to ensure no diversion occurred
  - c. Ensure quantities delivered are identical to products/items on the shipping manifest/trip plan
- 2) Receiving facility either ACCEPTS or REJECTS the delivery
  - a. ACCEPT—if delivered package is what was ordered and quantities match quantities stated on manifest/trip plan
  - b. REJECT—if delivered packages NOT what was ordered and/or the quantities delivery do NOT match quantities stated on the manifest/trip plan

### **6) Post-Delivery**

**Post-Delivery Protocol**—after transporting marijuana products or marijuana-infused products, pursuant to the regulations the employee will complete the trip plan by entering the end time of the trip and any necessary alterations to the trip plan.



## Attachment 10.3

**Documentation of Delivery**—both the transporting dispensing facility and the receiving dispensary shall maintain all documents required by regulation and provide copies of such documents to Division agents for review upon request.

**Deviations from Transportation Plan**—the transporting agent shall immediately report all diversion due to loss or theft of marijuana or marijuana-infused products that occur while transporting to management and to all required authorities. The dispensary facility management shall ensure all such occurrences are reported to the appropriate law enforcement agency and to the state licensing authorities as required per state regulations. Dispensary facility management shall maintain a log of all reports received pursuant to the regulations.



### Application Response: Question 11

Blue Planet Healing, LLC (“BPH”) will comply with all applicable law including HAR §11-850-43 and HRS §329D-7 and employ Standard Operating Procedures (“SOP”) for the destruction and disposal of all unused, unsold, contaminated or expired marijuana, marijuana infused products, marijuana plants, and waste products resulting from the cultivating or manufacturing process. This will also include any inventory existing in the event of revocation or surrender of BPH’s license. As part of this SOP, BPH will require registered employees of the dispensary to weigh, document, and render all marijuana waste products as unusable, unrecognizable and unrecoverable and then to destroy and dispose of all marijuana waste. The SOPs will be utilized within all BPH operations including, but not limited to, cultivation operations, processing and manufacturing operations and retail dispensing operations. BPH management will ensure proper training and implementation of the Marijuana Waste Destruction and Disposal Procedures. Registered employees will record all required information in the inventory control system as well as on a physical marijuana waste log sheet witnessed and signed by his/her manager or a manager with equivalent authority. An example of a physical log sheet has been included as an attachment (See Attachment “11.1”).

BPH will utilize a cannabis industry specific inventory control system, BioTrackTHC™, to track all marijuana products and inventory throughout the product lifecycle, including destruction and disposal. BioTrackTHC™’s inventory management tools track unusable marijuana products (e.g., outdated, damaged, deteriorated, mislabeled, or contaminated) and marijuana waste by weight and barcode throughout the chain of custody of marijuana production. Upon destruction, the inventory tracking system will generate a destruction report. The system also allows for the electronic authentication of the witnesses to the destruction process through either a four-digit pin number or a biometric scan. BioTrackTHC™ does not delete the data related



### Application Response: Question 11

to the waste; rather, the system evidences the lifecycle of every original plant barcode with an auditable trail to either retail dispensing or verified destruction. In addition to the electronic chain-of-custody procedure, BPH will maintain a physical Waste Destruction Log Sheet as an additional reference point. All destruction of waste will be witnessed by two employees and documented in BioTrackTHC™ as well as recorded on the physical Waste Destruction Log Sheet to further mitigate risk of employee based diversion.

### **Daily Inventory Inspection.**

On a daily basis, BPH will audit and inspect all medical marijuana product inventory in each facility and functional area including cultivation operations, processing/manufacturing operations and retail dispensing operations. As part of the daily inventory audit, all medical marijuana products will be inspected and any marijuana products that are outdated, damaged, deteriorated, mislabeled, or contaminated will be segregated from the main inventory and evaluated for destruction and disposal. Marijuana products will be destroyed and disposed of according to BPH's SOPs regarding Marijuana Waste Destruction and Disposal. (See attachment "11.2")

### **Marijuana Waste Storage.**

BPH will have a separate secure area within the production center for the temporary storage of any returned or recalled marijuana products, quarantined marijuana material and/or products in need of destruction. After marijuana products have entered the separate secure storage area, they will remain there until being documented for destruction per BPH's Marijuana Waste Destruction and Disposal SOP. BPH will hold all marijuana waste in the secure, segregated storage area, until the proper destruction and disposal of the medical marijuana waste by a registered employee and witnessed by a second registered employee. This secure, segregated storage area will promote



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biosecurity and good handling practices within all BPH facilities and limit the potential for product diversion. The location of the separate secure area for marijuana products in need of destruction and disposal can be seen on the production center floor plan that is attached as “Attachment 11.3”.

### **Product Recall.**

As a manufacturer and retailer of consumer goods, i.e. medical marijuana products, BPH may be liable for defective products provided to consumers and may face the potential of a product recall for potentially dangerous or hazardous marijuana products. If BPH ever has the need to issue a product recall for any marijuana product, BPH will utilize the inventory control and point-of-sale system to determine exactly where such products are in the supply chain, or if already dispensed, which registered patients purchased the affected product(s). BPH will immediately notify any patients potentially in possession defective of and coordinate the retrieval for destruction. The dispensary will also have a secure storage area of the handling of any recalled products returned by patients or removed from inventory. Upon receiving recalled marijuana products, registered employees will record the data in the inventory control system and place products in secure storage to await destruction and disposal.

### **Standard Operating Procedure.**

BPH will adopt in-use, industry best practices from its consultant HCH for the proper destruction and disposal of marijuana waste products. BPH will establish a compliant SOP for the destruction and disposal of marijuana waste. The waste destruction and disposal SOP to be utilized was developed in Colorado’s regulated marijuana industry, one of the nation’s most mature markets with well-developed regulations for the destruction and disposal of marijuana. Proper destruction and disposal of marijuana waste within all BPH facilities will ensure no marijuana products are being diverted to unregistered and/or unauthorized parties.



### Application Response: Question 11

In line with best practices for Marijuana Waste Destruction and Disposal, all BPH marijuana waste will be rendered unrecoverable, unusable and unrecognizable, and the destruction and disposal will be carried out and verified by two registered dispensary agents and documented in the inventory control system and on the Waste Log Sheet. This is achieved by first grinding the marijuana waste with a commercial grinder or wood chipper in preparation to mix and incorporate the same with non-marijuana waste in order to make the marijuana waste unrecognizable, unrecoverable and unusable. Once the waste has been ground, the ground marijuana waste material will be mixed by a 50/50 ratio (by weight) with some other waste, such as soil or dirt. The written SOP (See Attachment “11.2”) will include the following:

1. Segregation - Location within facility designated for waste storage. Access will be limited to authorized personnel.
2. Disposal by authorized personnel - Supervisory approval will be required for all marijuana waste and products designated for disposal. These segregated inventories are clearly identified with a label that includes the signature of supervisory personnel.
3. Render substance unusable - A clear description of waste-handling procedures including protocols for rendering the substance unusable prior to disposal. This will include mixing waste with non-consumable solid-wastes such that the resulting mixture is at least 50-percent non-cannabis waste.
4. Procedures will be performed in view of video surveillance security equipment with multiple people involved to provide witnesses to the disposal process.
5. Documentation of disposal in inventory control system - Supervisory sign-off will include certifying waste has been entered into the inventory control system.



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6. Location of disposal - Identification of approved solid waste site and disposal facility.
7. Documentation retained for six (6) years.

### **Disposal.**

Upon successfully grinding and incorporating the marijuana waste with non-marijuana waste, the material will be ready for proper disposal by a means prescribed by the DOH or the Department of Public Safety Narcotics Enforcement Division administrator per HAR §11-850-40.

Only authorized registered employees will have access to destroy product and ensure the destroyed weight and document the reason for destruction via BioTrackTHC™ which will generate reports on the number and/or weight of destroyed material at any point in the process. Every action in the chain of custody will be recorded with a date/timestamp and the username of the employee performing the action. BPH will maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of marijuana and/or manufactured marijuana products. This information will be retained in the business records of the Company for a period of six (6) years.





## Attachment 11.2

<b>Standard Operating Procedure:</b> Marijuana Waste Destruction and Disposal
<b>Purpose:</b> To explain required and proper disposal processes for marijuana waste.
<b>Scope:</b> Covers marijuana waste grinding, mixing and disposal measures within the retail dispensing facility.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Marijuana Waste Disposal Log

### Equipment/Tools Required

- 1) Wood chipper/plant grinder
- 2) Mixing material (material to mix marijuana waste with at 50/50 ratio)
- 3) Trash bags
- 4) Dumpster/trash compactor

### Requirements of Marijuana Waste Disposal

All marijuana waste, byproducts, undesired materials, green waste and returned/recalled marijuana will be destroyed by rendering the waste unrecognizable, unusable and unrecoverable.

BPH will require registered employees to weigh, document, record and destroy all marijuana waste according to the written standard operating procedures. All marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated will be destroyed and disposed of according to the written SOP.

**Secure, Segregated Storage**—all medical marijuana waste will be stored in secure, segregated storage at the production center until the proper destruction and disposal of the marijuana waste. This segregated storage will be isolated from the main inventory.

- The secure, segregated storage will promote good growing and handling practices.

**Marijuana Waste Disposal**—all medical marijuana waste, byproducts and undesired products will be destroyed and disposed of according to all applicable state and local regulations. Facility management will ensure proper training and implementation of destruction and disposal procedures and protocols. Documentation will be recorded and maintained at the facility location for a period determined by state regulations. Record all required information on the *Marijuana Waste Log Sheet*.

**Disposal**—Disposal of any marijuana product waste must be rendered unrecognizable, unusable and unrecoverable through grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty (50%) percent non-marijuana waste:

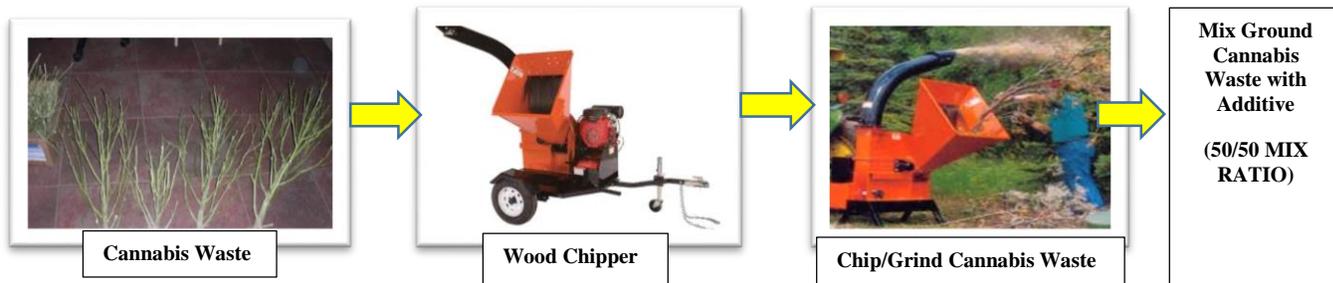
- 1) Paper waste;
- 2) Plastic waste;
- 3) Cardboard waste;
- 4) Food waste;
- 5) Grease or other compostable oil waste;
- 6) Bokashi, or other compost activators;
- 7) Other wastes approved by the State Licensing Authority that will render the medical marijuana waste unusable and unrecognizable as marijuana; and
- 8) Soil.

# Attachment 11.2

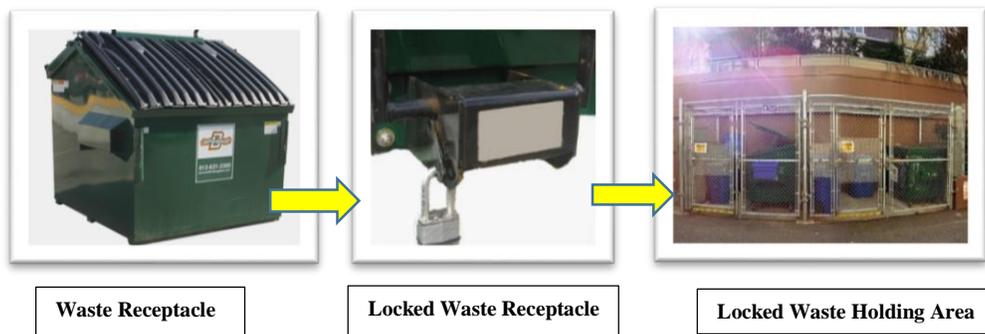
Cannabis Stalks (waste)



## Grinding Marijuana Waste (Stalks, Stems, Leaves and Other Material)



**\*\*BPH shall not dispose of marijuana product waste in an unsecured waste receptacle not in possession and control of the licensed premise. It is recommended to have a lock on the physical dumpster as well as the area where the dumpster is maintained.**



*Example of Marijuana Waste Documentation Log Sheet (see below):*







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Blue Planet Healing's ("BPH") top priority is to provide registered patients with safe access to quality medical marijuana ("MM") that will alleviate their pain and suffering. BPH will ensure product safety by utilizing organizational plans and policies, training programs and written Standard Operating Procedures ("SOP") developed by BPH's consultant, High Country Healing ("HCH"). HCH will provide operational experience which will prove critical in helping BPH to establish best practices for marijuana product safety. In addition, BPH will test all marijuana products to determine and show the chemical profile of the test sample and to ensure the products are consistent and free from contamination as is required by HRS §329D-8 and HAR §11-850-85. Finally, BPH will adopt a Quality Management System ("QMS") (See Attachment "12.1") to ensure that product safety and quality remains the core focus of BPH's daily operations.

**Product Safety through Types of Manufactured Marijuana Products.** BPH will ensure compliance with HRS §329D-10 and only manufacture marijuana products allowed under applicable law. BPH will only manufacture capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, skin lotions and other products as specified by State of Hawai'i Department of Health ("DOH"). BPH's manufacturing licensing partner, UNDRNWMNGMNT, LLC ("UNM"), has developed a list of proposed products to be manufactured and has included this product list with specifications as an additional attachment. (See Attachment "12.2")

**Manufacturing Standard Operating Procedures.** Each manufactured marijuana product will have a separate written SOP based on the production processes specific to that product. The written SOP's have been included as an attachment to our application. (See Attachment "12.3") The system will be online to facilitate managing document control, change control, and employee training processes. BPH will document every step of the process, from the inputs used, the sanitation procedures performed, the persons responsible for each phase, quality control



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review, temperature, humidity, and testing. Every movement or manipulation of ingredients and personnel will be documented in detail to ensure consistency in production. BPH will take advantage of legacy SOPs provided by BPH's consultant HCH and from BPH's manufacturing licensor UNM, both of which have extensive, refined and tested written SOPs for manufacturing processes and operations. BPH will designate a quality control manager in charge of manufactured marijuana product quality and safety which involves various stages in the production process as follows: (1) SOPs which adhere to Good Manufacturing Practice ("GMP"), Hazard Analysis Critical Control Point ("HACCP") plan, Federal Drug Agency ("FDA") and regulatory guidelines including chain of custody, testing and sanitation; (2) Formal validation of all manufacturing processes to ensure product purity and consistent results; (3) Selection of ingredients (including marijuana and non-marijuana) and vetting suppliers for quality and purity; (4) Strict sanitation guidelines for facility, production line and storage; (5) Product testing during and post production; (6) Quarantine of products prior to testing and strict guidelines for releasing product for commercial distribution; (7) Strict inventory control to allow for tracking of all batches and lots; (8) Child resistant packaging and regulatory compliant labeling; and (9) Recall and rework policies and procedures. Additionally, BPH will implement a HACCP Plan for the production center to manage critical control points of possible contamination. HACCP is a management system in which product safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing and distribution. All registered employees will be trained in HACCP procedures.

**Product Safety through Laboratory Testing.** BPH will comply with all pertinent state laws and regulations pertaining to requirements for the use of a certified laboratory to perform content, contamination, and consistency testing on all marijuana products. BPH will ensure that no



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marijuana or manufactured marijuana products will be dispensed until a laboratory certified by the DOH has tested and certified that the marijuana products meet all specifications required by state law. As detailed in BPH's written SOPs, BPH will select and utilize a DOH-certified independent testing laboratory that has adopted a compliant protocol to test marijuana products. When selecting a laboratory, BPH will review the laboratory's procedures for effective, validated, accurate and precise measurement of  $\Delta$ 9-Tetrahydrocannabinol ("THC"), Tetrahydrocannabinolic Acid ("THCA"), Cannabidiol ("CBD"), Cannabidiolic Acid ("CBDA"), Cannabinol ("CBN"), Cannabigerol ("CBG"), and terpenes to ensure that our marijuana and manufactured marijuana products are free from contaminants and any other criteria the DOH or BPH deems necessary. See attachments "12.4" and "12.5" for laboratory testing SOPs.

**Product Safety through Packaging and Labeling.** As one measure of product safety, BPH will comply with HRS §329D-11 and HAR §11-850-92 and package all medical marijuana products in child-resistant packaging in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act. All packaging will be opaque to ensure the product cannot be seen unless the package is opened. Packaging will also protect from contamination and will not impart any toxic or harmful substance to the product. BPH's marijuana product packages will not contain more than 10 milligrams of  $\Delta$ 9-Tetrahydrocannabinol ("THC") for one dose, serving, or single wrapped item; with a maximum of 100 milligrams of THC per pack or container for manufactured marijuana products sold in a pack of multiple doses.

Before transporting to its retail dispensing locations ("RDL") for dispensing to registered patients, all BPH marijuana products will be unit-packaged at the production center ("PC"). Consumer products being produced will be packaged in U.S. Consumer Product Safety Commission ("CPSC") recognized child-resistant packaging. Per BPH procedures, once



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packaged, the marijuana or manufactured marijuana product will be bulked packaged and remain sealed by tamper evident tape throughout the chain of custody until dispensed or destroyed. All packaging will include a barcode generated by the BioTrackTHC™ inventory tracking system, which will link the package to the original production center. As an additional product safety measure, BPH may utilize ‘exit packaging’ at all retail dispensary facility locations. Purchased products may be placed in exit packaging at the RDL prior to registered patients and/or caregivers exiting the facility. Exit packaging will be child-resistant and opaque, concealing the contents. Exit packaging will also minimize the risk of marijuana product diversion or accidental ingestion by a child or pet. BPH will utilize marijuana industry specific exit packaging that meets child-safety requirements of the CPSC. BPH will label all packages with the required advisories, recommendations and warnings as described in HRS §329D-11 and HAR §11-850-92. All marijuana product packages will be labeled at the PC with a product-specific label. The product-specific labels will include, but not be limited to: the required advisories, recommendations and warnings; information about the contents and potency of the product; weight of the marijuana or in the case of manufactured marijuana products a listing of equivalent physical weight of the marijuana used to manufacture the amount of the product; and identification of the PC where the product was produced including the batch number and date of packaging. See attachment 12.6 for the detailed SOP.

**Product Safety through Inventory Control and Proper Storage.** The tracking of all marijuana and manufactured marijuana products from “seed-to-sale” will be done through the BioTrackTHC™ inventory control system which will help BPH manage all marijuana product inventory and allow for easy identification of an inventory discrepancy. BPH will store all



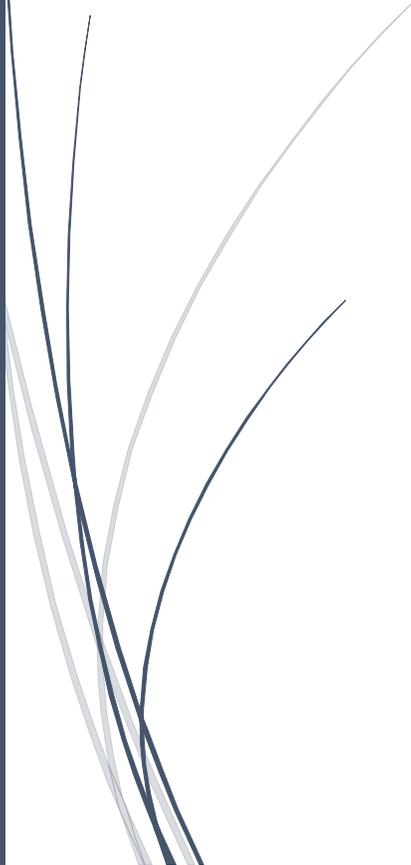
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marijuana products in a locked room, or locked container securely affixed to a wall or floor with limited permission based access.

**Manufacturing Permits and Licenses.** BPH will be required to obtain a Food Establishment Permit to produce manufactured marijuana products that are intended to be ingested orally, including capsules, lozenges, pills, oils, oil extracts, and tinctures. HRS § 11-850-73. The requirements may vary slightly depending on whether the building used is a new or converted building, or is an existing food establishment that changes ownership. To obtain a permit for a newly constructed or converted food establishment, BPH will submit an Application for Food Establishment Permits along with the plans and specifications of the establishment, a list of food items to be produced and other information that may be required by the Department. HRS § 11-50-54(b). The Department may also require a HACCP Plan, specifications regarding the anticipated volume of product to be stored, prepared or stored, or other information. HAR 11-50-4(i) (8). An HACCP plan is required if a food establishment requires a variance (aka a modification or waiver of a requirement in 11-50), and the variance has been deemed to not present a health hazard or nuisance. HAR 11-50-13. Prior to commencement of operations, the DOH will conduct a preoperational inspection of the food establishment to verify that the facility is constructed in accordance with the plans, has established operating procedures, and is in compliance with Chapter 11-50. BPH will comply with all applicable provisions of HAR Chapter 11-50 including roles govern personnel procedures and requirements, raw ingredient and food production procedures and requirements, equipment requirements, plumbing requirements, and building design and construction requirements.



# **Quality Management Plan**





To ensure employee and public safety, Blue Planet Healing LLC (“BPH”) is committed to establish, document, implement and maintain an appropriate Quality Management System.

To this end, BPH is committed to the following Quality Management Principles:

- Customer Focus
  - Leadership
- Involvement of People
  - Process Approach
- System Approach to Management
  - Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships

To assure adequate establishment, implementation, documentation and maintenance of their Quality Management System, the applicant has taken guidance from ISO 9001 (see below) and has *budgeted to hire a full-time Director of Quality Management who is certified as a Manager of Quality and Organizational Excellence by the American Society of Quality*. The Director of Quality Management shall be responsible for using the guidance from ISO 9001 to develop the appropriate Quality Management System for the applicant in accordance with Hawaii state regulations.

[http://www.iso.org/iso/home/standards/management-standards/iso\\_9000.htm](http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm)

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

**Plan:** establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies

**Do:** implement the processes.

**Check:** monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

**Act:** take actions to continually improve process performance.

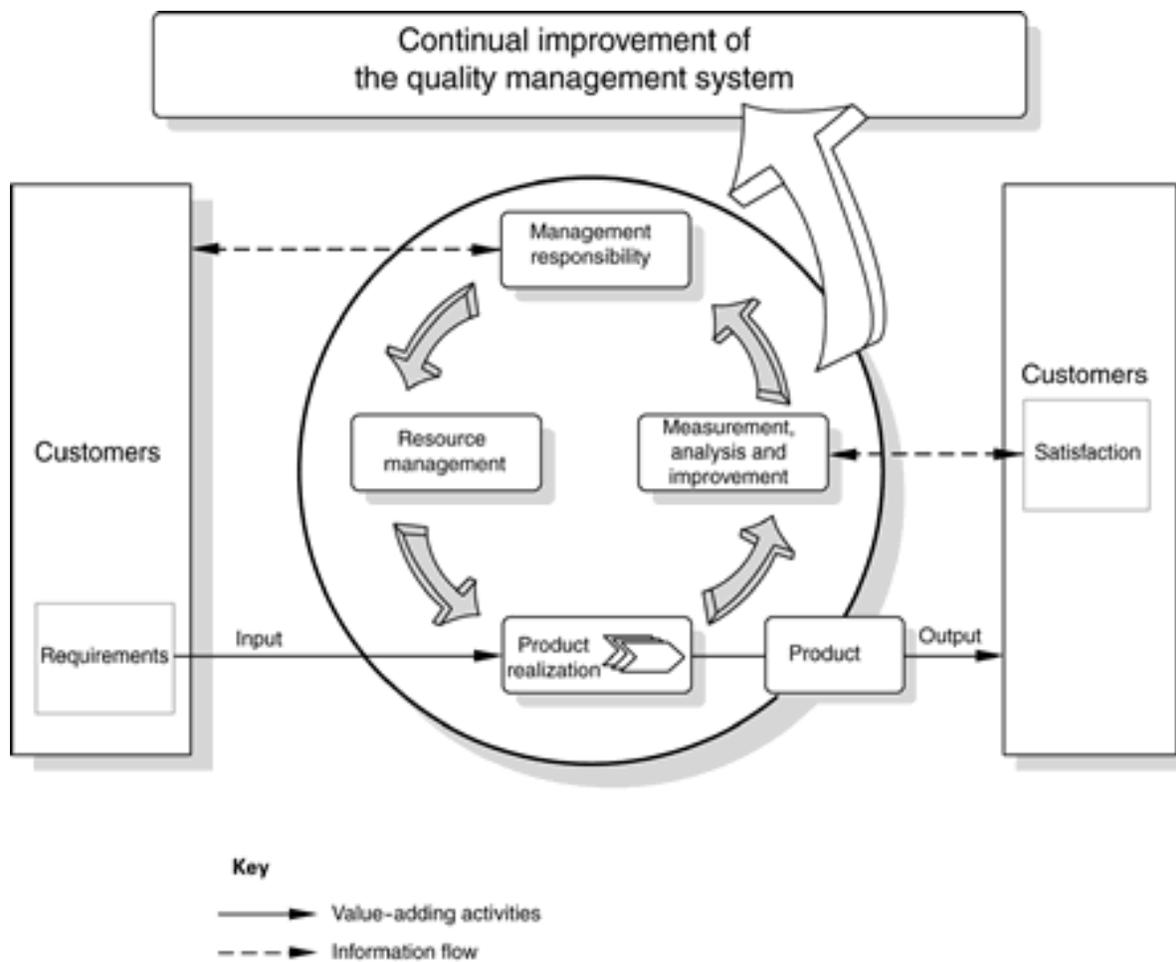




Figure 1 — Model of a process-based quality management system

*NOTE-Sections 1, 2 and 3 are not included because they are not directly pertinent to the establishment, implementation application and maintenance of a Quality Management System.*

## **4. Quality Management System**

### **4.1 General Requirements**

Establish, document, implement, and maintain a quality management system. Continually improve its effectiveness in accordance with ISO 9001 requirements. Implement the system to:

- Determine processes needed for the quality management system (and their application throughout the organization)
- Determine process sequence and interaction
- Determine criteria and methods for process operation and control
- Ensure resources and supporting information are available
- Monitor, measure where applicable, and analyze these processes
- Implement actions to achieve planned results and continual process improvement
- Manage these processes in accordance with ISO 9001 requirements. Define the type and extent of control applied to any outsourced processes that affect product conformity to requirements.

NOTE 1: Processes needed for the quality management system include the processes for management activities (see 5), provision of resources (see 6), product realization (see 7), and measurement, analysis, and improvement (see 8).

NOTE 2: An outsourced process is a process the organization needs for its quality management system, and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve your organization of the responsibility to conform to all customer, statutory, and regulatory requirements. The type and extent of control applied to an outsourced process can be influenced by factors such as:

- Potential impact of the outsourced process on your organization's capability to provide product that conforms to requirements.
- Degree to which the control for the process is shared
- Capability of achieving the necessary control through the application of 7.4

### **4.2 Documentation Requirements**

#### **4.2.1 General Requirements**

Include in the quality management system documentation:



- Documented statements of a quality policy and quality objectives
- A quality manual
- Documented procedures and records required by ISO 9001
- Documents and records determined by the organization to be necessary for the effective planning, operation, and control of its processes

NOTE 1: Where “documented procedure” appears within the Standard, this means that the procedure is established, documented, implemented, and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The extent of the quality management system documentation can differ from one organization to another due to:

- Size of the organization and type of activities
- Complexity of processes and their interactions
- Competence of personnel

NOTE 3: The documentation can be in any form or type of medium.

#### **4.2.2 Quality Manual**

Establish and maintain a quality manual with:

- Scope of the quality management system
- Details and justification for any exclusions
- Procedures or references to the procedures
- Description of interaction between processes

#### **4.2.3 Control of Documents**

Control the documents required by the quality management system. Records are a special type of document and must be controlled as required by clause 4.2.4.

Establish a documented procedure to:

- Approve documents for adequacy prior to issue
- Review, update as necessary, and re-approve documents
- Identify the changes and current document revision status
- Make relevant documents available at points of use
- Ensure the documents remain legible and readily identifiable
- Identify external documents and control their distribution
- Prevent obsolete documents from unintended use



- Apply suitable identification if obsolete documents are retained

#### **4.2.4 Control of Records**

Establish and control records as evidence of conformity to requirements and to demonstrate the effective operation of the quality management system.

Establish a documented procedure to define the controls needed for record:

- Identification
- Storage
- Protection
- Retrieval
- Retention
- Disposition
- Keep records legible, readily identifiable, and retrievable.

### **5. Management Responsibility**

All requirements in clause 5 are the responsibility of top management.

#### **5.1 Management Commitment**

Provide evidence of management commitment to develop and implement the quality management system, as well as, continually improve its effectiveness by:

- Expressing the importance of meeting requirements
- Establishing the quality policy and quality objectives
- Conducting management reviews
- Ensuring the availability of necessary resources

#### **5.2 Customer Focus**

Ensure customer requirements are determined and met in order to improve customer satisfaction.

#### **5.3 Quality Policy**

Ensure the quality policy is:

- Appropriate to the purpose of the organization
- Focused on meeting requirements and continual improvement
- Used as a framework for quality objectives
- Communicated and understood at appropriate levels



- Reviewed for continuing suitability

## **5.4 Planning**

### **5.4.1 Quality Objectives**

Ensure quality objectives, including those needed to meet product requirements, are established at the relevant functions and levels within the organization. Ensure quality objectives are measurable and consistent with the quality policy.

### **5.4.2 Quality Management System Planning**

Ensure that planning for the quality management system:

- Meets the general requirements (4.1), as well as, quality objectives (5.4.1)
- Maintains the system integrity when changes are planned and implemented

## **5.5 Responsibility, Authority, and Communication**

### **5.5.1 Responsibility and Authority**

Ensure responsibilities and authorities are defined and communicated within the organization.

### **5.5.2 Management Representative**

Appoint a member of your management who, irrespective of other duties, has the responsibility and authority to:

- Ensure the needed processes are established, implemented, and maintained
- Report to top management on quality management system performance
- Report to top management on any need for improvement
- Ensuring the promotion of awareness of customer requirements

NOTE: The responsibility of a management representative can include being the liaison with external parties on matters relating to the quality management system.

### **5.5.3 Internal Communication**

Ensure the appropriate communication processes are established and carried out within the organization regarding the effectiveness of the system.

## **5.6 Management Review**



### **5.6.1 General**

Review the quality management system at planned intervals to:

- Ensure a suitable, adequate, and effective system
- Assess possible opportunities for improvement
- Evaluate the need for any changes to the system
- Consider the need for changes to the quality policy and objectives
- Maintain records of the management reviews.

### **5.6.2 Review Input**

Inputs for management review must include information on:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from earlier reviews
- Changes that could affect the quality system
- Recommendations for improvement

### **5.6.3 Review Output**

Outputs from the management review must include any decisions and actions related to:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

## **6. Resource Management**

### **6.1 Provision of Resources**

Determine and provide the resources necessary to:

- Implement and maintain the quality management system
- Continually improve the effectiveness of the system
- Enhance customer satisfaction by meeting customer requirements

### **6.2 Human Resources**

#### **6.2.1 General**



Ensure people performing work affecting conformity to product requirements are competent based on the appropriate education, training, skills, and experience.

NOTE: Conformity to product requirements can be affected directly, or indirectly, by personnel performing any task within the quality management system.

## **6.2.2 Competence, Training, and Awareness**

The organization must:

- Determine the competency needs for personnel
- Provide training (or take other actions) to achieve the necessary competence
- Evaluate the effectiveness of the actions taken
- Inform employees of the relevance and importance of their activities
- Ensure they know their contribution to achieving quality objectives
- Maintain education, training, skill, and experience records

## **6.3 Infrastructure**

Determine, provide, and maintain the necessary infrastructure to achieve product conformity.

Infrastructure includes, as applicable:

- Buildings, workspace, and associated utilities
- Process equipment (both hardware and software)
- Supporting services (such as transport, communication, or information systems)

## **6.4 Work Environment**

Determine and manage the work environment needed to achieve product conformity.

NOTE: The term “work environment” relates to those conditions under which work is performed, including physical, environmental, and other factors such as noise, temperature, humidity, lighting, or weather.

## **7. Product Realization**

### **7.1 Planning of Product Realization**

Plan and develop the processes needed for product realization. Keep the planning consistent with other requirements of the quality management system and document it in a suitable form for the organization. Determine through the planning, as appropriate, the:



- Quality objectives and product requirements
- Need for processes, documents, and resources
- Verification, validation, monitoring, measurement, inspection, and test activities
- Criteria for product acceptance
- Records as evidence the processes and resulting product meet requirements

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes), and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2: The organization can also apply the requirements given in 7.3 to the development of product realization processes.

## **7.2 Customer-Related Processes**

### **7.2.1 Determination of Requirements Related to the Product**

Determine customer requirements:

- Specified for the product (including delivery and post-delivery activities)
- Not specified for the product (but needed for specified or intended use, where known)

Determine:

- Statutory and regulatory requirements applicable to the product
- Any additional requirements considered necessary by the organization

NOTE: Post-delivery activities include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

### **7.2.2 Review of Requirements Related to the Product**

Review the product requirements before committing to supply the product to the customer in order to:

- Ensure product requirements are defined
- Resolve any requirements differing from those previously expressed
- Ensure its ability to meet the requirements
- Maintain the results of the review, and any subsequent follow-up actions. When the requirements are not documented, they must be confirmed before acceptance.
- If product requirements are changed, ensure relevant documents are amended and relevant personnel are made aware of the changed requirements.



NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information such as catalogs or advertising material.

### **7.2.3 Customer Communication**

Determine and implement effective arrangements for communicating with customers on:

- Product information
- Inquiries, contracts, or order handling (including amendments)
- Customer feedback (including customer complaints)

## **7.3 Design and Development**

### **7.3.1 Design and Development Planning**

Plan and control the product design and development. This planning must determine the:

- Stages of design and development
- Appropriate review, verification, and validation activities for each stage
- Responsibility and authority for design and development
- The interfaces between the different involved groups must be managed to ensure effective communication and the clear assignment of responsibility. Update, as appropriate, the planning output during design and development.

NOTE: Design and development review, verification, and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as deemed suitable for the product and the organization.

### **7.3.2 Design and Development Inputs**

Determine product requirement inputs and maintain records. The inputs must include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Applicable information derived from similar designs
- Requirements essential for design and development
- Review these inputs for adequacy. Resolve any incomplete, ambiguous, or conflicting requirements.

### **7.3.3 Design and Development Outputs**

Document the outputs of the design and development process in a form suitable for verification against the inputs to the process. The outputs must:



- Meet design and development input requirements
- Provide information for purchasing, production, and service
- Contain or reference product acceptance criteria
- Define essential characteristics for safe and proper use
- Be approved before their release

NOTE: Information for production and service can include details for product preservation.

#### **7.3.4 Design and Development Review**

Perform systematic reviews of design and development at suitable stages in accordance with planned arrangements (see 7.3.1) to:

- Evaluate the ability of the results to meet requirements
- Identify problems and propose any necessary actions

The reviews must include representatives of the functions concerned with the stage being reviewed. Maintain the results of reviews and subsequent follow-up actions.

#### **7.3.5 Design and Development Verification**

Perform design and development verification in accordance with planned arrangements (see 7.3.1) to ensure the output meets the design and development input requirements. Maintain the results of the verification and subsequent follow-up actions.

#### **7.3.6 Design and Development Validation**

Perform validation in accordance with planned arrangements (see 7.3.1) to confirm the resulting product is capable of meeting the requirements for its specified application or intended use, where known. When practical, complete the validation before delivery or implementation of the product. Maintain the results of the validation and subsequent follow-up actions.

#### **7.3.7 Control of Design and Development Changes**

Identify design and development changes and maintain records. Review, verify, and validate (as appropriate) the changes and approve them before implementation. Evaluate the changes in terms of their effect on constituent parts and products already delivered. Maintain the results of the change review and subsequent follow-up actions.

### **7.4 Purchasing**

#### **7.4.1 Purchasing Process**



Ensure that purchased product conforms to its specified purchase requirements. The type and extent of control applied to the supplier and purchased product depends upon the effect of the product on the subsequent realization processes or the final product. Evaluate and select suppliers based on their ability to supply product in accordance with the requirements. Establish the criteria for selection, evaluation, and re-evaluation. Maintain the results of the evaluations and subsequent follow-up actions.

#### **7.4.2 Purchasing Information**

Ensure the purchasing information contains information describing the product to be purchased, including the requirements for:

- Approval of product, procedures, processes, and equipment
- Qualification of personnel

(Also include quality management system requirements in the purchasing information)

Ensure the adequacy of the specified requirements before communicating the information to the supplier.

#### **7.4.3 Verification of Purchased Product**

Establish and implement the inspection or other necessary activities for ensuring the purchased products meet the specified purchase requirements. If the organization or its customer proposes to verify the product at the supplier location, state the intended verification arrangements and method of product release in the purchasing information.

### **7.5 Production and Service Provision**

#### **7.5.1 Control of Production and Service Provision**

Plan and carry out production and service provision under controlled conditions to include, as applicable:

- Availability of product characteristics information
- Availability of work instructions, as necessary
- Use of suitable equipment
- Availability and use of monitoring and measuring equipment
- Implementation of monitoring and measurement activities
- Implementation of product release, delivery, and post-delivery activities

#### **7.5.2 Validation of Processes for Production and Service Provision**

Validate any production or service provision where subsequent monitoring or measurement cannot verify the output. This validation includes processes where deficiencies may become apparent only after product



use or service delivery. Demonstrate through the validation the ability of processes to achieve the planned results.

Establish validation arrangements including, as applicable:

- Criteria for process review and approval
- Approval of equipment
- Qualification of personnel
- Use of defined methods and procedures
- Requirements for records
- Re-validation

### **7.5.3 Identification and Traceability**

Identify, where appropriate, the product by suitable means during product realization. Identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, control the unique identification of the product and maintain records.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.

### **7.5.4 Customer Property**

Exercise care with any customer property while it is under the control of, or being used by, the organization. Identify, verify, protect, and safeguard customer property provided for use, or for incorporation into the product. Record and report any lost, damaged, or unsuitable property to the customer.

NOTE: Customer property can include intellectual property and personal data.

### **7.5.5 Preservation of Product**

Preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes:

- Identification
- Handling
- Packaging
- Storage
- Protection
- Also apply preservation to the constituent parts of the product.

## **7.6 Control of Measuring and Monitoring Equipment**



Determine the monitoring and measurements to be made, and the required equipment, to provide evidence of product conformity. Use and control the monitoring and measuring devices to ensure that measurement capability is consistent with monitoring and measurement requirements.

- Where necessary to ensure valid results:
- Calibrate and/or verify the measuring equipment at specified intervals or prior to use
- Calibrate the equipment to national or international standards (or record other basis)
- Adjust or re-adjust as necessary
- Identify the measuring equipment in order to determine its calibration status
- Safeguard them from improper adjustments
- Protect them from damage and deterioration
- Assess and record the validity of prior results if the device is found to not conform to requirements. Maintain records of the calibration and verification results.
- Confirm the ability of software used for monitoring and measuring for the intended application before its initial use (and reconfirmed as necessary).
- NOTE: Confirming the ability of software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

## **8. Measurement, Analysis, and Improvement**

### **8.1 General**

Plan and implement the monitoring, measurement, analysis, and improvement processes needed to:

- Demonstrate conformity to product requirements
- Ensure conformity of the system
- Continually improve effectiveness
- Determine through planning the need for, and use of, applicable methods, including statistical techniques, as well as, the extent of their use.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

Monitor information on customer perception as to whether the organization is meeting requirements (as one of the performance measurements of the quality management system).

Define the methods for obtaining and using this information.

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and dealer reports.



### **8.2.2 Internal Audit**

Conduct internal audits at planned intervals to determine if the quality management system:

- Conforms to planned arrangements (see 7.1)
- Conforms to requirements of ISO 9001
- Is effectively implemented and maintained

The organization must:

- Plan the audit program
- Consider the status and importance of the audited areas
- Consider the results of prior audits
- Define the audit criteria, scope, frequency, and methods
- Select and use impartial and objective auditors (not audit their own work)

Establish a documented procedure to address responsibilities and requirements to:

- Plan audits and conduct audits
- Establish records and report results
- Maintain records of the audits and their results.
- Ensure management of the audited areas takes actions without undue delay to eliminate detected nonconformities and their causes. Verify through follow-up actions the implementation of the action and report the results.

NOTE: See ISO 19011 for audit guidance.

### **8.2.3 Monitoring and Measurement of Processes**

Apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. Confirm through these methods the continuing ability of each process to satisfy its intended purpose. When the planned results are not achieved, take correction and corrective action, as appropriate.

NOTE: When determining “suitable” methods, consider the type and extent of monitoring or measurement for each process in relation to its impact on product conformity and on the effectiveness of the quality management system.

### **8.2.4 Monitoring and Measurement of Product**

Monitor and measure product characteristics to verify product requirements are being met. Carry out the monitoring and measuring at the appropriate stages of product realization in accordance with planned arrangements (see 7.1). Maintain evidence of conformity with the acceptance criteria.



Record the person responsible for authorizing release of product for delivery to the customer. Product release and service delivery cannot proceed until all planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, the customer.

### **8.3 Control of Nonconforming Product**

Ensure any nonconforming product is identified and controlled to prevent its unintended use or delivery. Establish a documented procedure to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, deal with the nonconforming product by one or more of the following ways:

- Take action to eliminate the detected nonconformity
- Authorize its use, release, or acceptance by concession
- Take action to preclude its original intended use or application
- Take action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started
- Maintain records of the nature of the nonconformity, and any subsequent actions, (including any concessions). When the nonconformity is corrected, re-verify it to show conformity.

### **8.4 Analysis of Data**

Determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system, as well as, evaluate where continual improvement of the effectiveness of the quality management system can be made. Include in the analysis the data generated by monitoring and measuring activities and from other relevant sources. Analyze this data to provide information on:

- Customer satisfaction (see 8.2.1)
- Conformity to product requirements (see 8.2.4)
- Characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3, 8.2.4, and 8.5.3)
- Suppliers (see 7.4)

### **8.5 Improvement**

#### **8.5.1 Continual Improvement**

Continually improve the effectiveness of the quality management system through:

- Quality policy
- Quality objectives



- Audit results
- Analysis of data
- Corrective and preventive action
- Management review

### **8.5.2 Corrective Action**

Take corrective action to eliminate the causes of nonconformities and prevent recurrence.

Corrective action must be appropriate to effects of the problem.

Establish a documented procedure for corrective action that defines requirements to:

- Review nonconformities (including customer complaints)
- Determine the causes of nonconformities
- Evaluate the need for actions to prevent recurrence
- Determine and implementing the needed action
- Maintain records of the results of the action taken
- Review the effectiveness of corrective action taken

### **8.5.3 Preventive Action**

Determine the action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Ensure preventive actions are appropriate to the anticipated effects of the potential problem.

Establish a documented procedure for preventive action to define requirements to:

- Determine potential nonconformities and their causes
- Evaluate the need for actions to prevent occurrence
- Determine and implementing the needed action
- Maintain records of the results of the action taken
- Review the effectiveness of preventive action taken



## Attachment 12.2

### -----Blue Planet Healing LLC Manufactured Marijuana Product Descriptions-----

#### **1. Medical Marijuana Sublingual Tincture**

Medical Marijuana Sublingual Tinctures are administered sublingually by the use of a measured dropper. Sublingual tinctures shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The droppers have measurement demarcations as to provide safe and easy dosing levels. Sublingual Tinctures offer patients the ability to ‘micro-dose’ cannabinoids in measurements of 2-3 mg of active cannabinoids. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana Sublingual Tinctures will be labeled and packaged in ASTM certified child resistant re-sealable dropper caps that will maintain the child resistant effectiveness for multiple openings.

#### **2. Medical Marijuana Infused Sublingual Tablet**

Medical Marijuana Infused Sublingual Tablets are designed to dissolve slowly in a patient’s mouth making an effective sublingual administered product. Each individual Sublingual Tablet shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. The product will be lab tested for accurate active cannabinoid profile. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana infused sublingual tablets will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **3. CO2 Medical Marijuana Concentrate**

A concentrated extract of cannabinoids, including but not limited to THC, CBD, and CBN created using a Closed-Loop Sub/Supercritical CO2 Extraction. CO2 is a non-polar solvent, which is efficient at extracting the Cannabinoids, Terpenes, and Flavonoids from Medical Marijuana plant matter. This concentrated form of Medical Marijuana can have up to a 90% concentration of cannabinoids. The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **4. Medical Marijuana Infused Lotion**

Medical Marijuana Infused Lotion products are an oil based lotion to be applied directly to the skin, not meant for oral consumption. Infused Lotions shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Marijuana infused lotions will be packaged in squeeze tubes with an ASTM certified child resistant re-sealable cap that will maintain the child resistant effectiveness for multiple opening.

#### **5. Medical Marijuana Infused Salve**

The Medical Marijuana Infused Salve is an ointment, not meant for oral consumption, to promote the healing of the skin and muscles. The Salve provides gentle relief for abrasions, sores, dry, cracked or chapped skin. Infused Salves shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The unique formulation of active cannabinoids and all natural soothing and plant based pain relief provides convenient and fast acting relief for patients. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **6. Medical Marijuana Infused Serum**

The Medical Marijuana Infused Serum, not meant for oral consumption, is a water based formulation of active cannabinoids, antioxidants, all natural ingredients to provide patient relief. It is a fast absorbing active ingredients that penetrate the skin faster than lotions or gels. Serums are super-efficient delivery methods as small amounts are absorbed into the skin quickly and deeply. Infused Serums shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and



## **Attachment 12.2**

packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **7. Medical Marijuana Infused Gel**

The Medical Marijuana Infused Gel, not meant for oral consumption, is a Aloe based gentle moisturizer, with a proprietary formulation of herbs, essential oils and active cannabinoids. The Gel provides fast and long lasting muscle relief for patients. Infused Gels shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **8. Medical Marijuana Infused Capsule**

Medical Marijuana Infused Capsules are a blend of active cannabinoids and all natural ingredients within a gelatin capsule. The gelatin capsule dissolves in the stomach of the patient releasing the cannabinoids and ingredients. Each individual Capsule shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. Medical Marijuana Capsules will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.



## Attachment 12.3

<b>Standard Operating Procedure:</b> Manufacturing Operations
<b>Purpose:</b> To explain post-harvest activities, procedures and protocols. Including: manufacturing, processing, weighing, packaging and labeling.
<b>Scope:</b> Covers the manufacturing activities within the cultivation facility.
<b>Initial Training:</b> TBD

### -----UNM EXTRACTION AND PRODUCTION GENERAL OPERATIONS-----

#### Overview

The extraction and production area of the production center will manage and produce the extraction of cannabinoids from the leaves and flowers of the female marijuana plant and the production of these extractions into medical marijuana products. The extraction and production area shall meet or exceed requirements set forth by the State of Hawaii. All extraction, packaging and labeling of medical marijuana products will comply with all state and local laws. All local and state fire, safety and building codes will be followed and internal manufacturing systems will be approved before operation.

The medical marijuana product extraction and production area will be physically separated from the other areas within the manufacturing facility and shall be considered a Limited Access Area. Only employees designated to work within the area will be permitted access. The extraction and production area will have designated areas for: Production, Packaging and Labeling, Climate Controlled Storage (walk-in coolers, reach-in coolers and freezers), Secured Storage and Toxic and/or Flammable Materials Storage. The area for the extraction and production of medical marijuana products will have mechanical ventilation of sufficient capacity as necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke and fumes.

The extraction and production area will have independent exhaust vents respectively in addition to the facility HVAC system. Equipment and surfaces used throughout the areas of extraction, manufacturing, processing and packaging of medical marijuana products will be constructed of NSF certified stainless steel. All equipment and utensils used will be lab grade or of commercial kitchen standards and meet or exceed State of Hawaii requirements. The extraction and production areas will be open and free as to provide ample space for preparation and sanitation.

#### Extraction

Marijuana concentrate is extracted from raw, cured marijuana by the use of:

- CO2 Sub/Super-Critical Extraction provides pure, solvent-free extracts by utilizing carbon dioxide. CO2 is a green alternative to solvent-based extraction techniques. The properties of a supercritical fluid can be altered by varying the pressure and temperature, allowing selective extraction. The low viscosity of supercritical carbon dioxide allows it to penetrate into the material more easily while its diffusivity allows for faster extractions. CO<sub>2</sub> is an environmentally friendly solvent that leaves no residue. Known as the “Entourage Effect” these “Whole Plant Extractions” are known to be more effective medicinally by four unique qualities:
  - Ability to affect multiple targets within the body
  - Ability to improve the absorption of active ingredients
  - Ability to overcome bacterial defense mechanisms
  - Ability to minimize adverse side effects.

CO2 extractions will be performed in a professional-grade, closed- loop extraction system, rated to minimum 900 pounds per square inch.

All solvents will be stored in secure and approved flammable materials storage containers. All MSDS sheets will be displayed along with emergency procedures to provide proper response to an accident involving a solvent.



## Attachment 12.3

Employees will be trained by the industries best practices and company extraction Standard Operation Procedures (SOPs) Marijuana flower and trim is cured in the Cultivation Area of the Manufacturing Facility. After the curing process, cured flower and trim will be delivered securely to the Extraction Area of the Manufacturing Facility and prepared for the extraction process. Marijuana from the cultivation area will be delivered securely to the extraction area when after properly cured and ready to be extracted. The chain of custody of the marijuana plant material from cultivation to extraction will be documented within the Seed-to-Sale Inventory Tracking Software. The extraction staff will properly and securely store the marijuana leaves and flowers until the cannabinoids are processed and extracted. Marijuana extract shall be assigned a lot number immediately upon creation. Extraction employees will be trained in the best practices of all emergency procedures.

The extraction area ventilation system will be spark-resistant and separate from the main manufacturing HVAC system. All employees working in the Extraction and Production Area will be trained in Standard Operating Procedures, Good Manufacturing Practices and Emergency Procedures.

### CHEMICAL HANDLING

#### **Material Safety Sheets:**

Safety data sheets (SDS), material safety data sheets (MSDS), and product safety data sheets (PSDS) are an important component of product stewardship and occupational safety and health. They are intended to provide workers and emergency personnel with procedures for handling or working with that substance in a safe manner, and include information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment, and spill-handling procedures.

Our standard operating procedures will include reference to relevant safety data sheets applicable to that specific process documented in the SOP. In addition the Company will maintain a comprehensive database of all safety data sheets in hard copy and electronic scanned copies on site. The Company will ensure the SDSs are readily accessible to employees for all hazardous chemicals in their workplace. We will also designate a person responsible for obtaining and maintaining the SDSs and contacting the manufacturer to obtain one.

Employees will be trained with regard to the use of safety data sheets as part of the orientation process as well as the specific training provided by their supervisor in the performance of their duties. OSHA has published a “brief” describing the “Hazard Communication Standard: Safety Data Sheets”. Section 7 of this brief covers the Handling and Storage of chemicals and outlines the type of information that will be included in the SDS for a chemical. This brief will be provided to all employees in the training process to provide guidance to help workers who handle hazardous chemicals to become familiar with the format and to understand the contents of the SDSs. It will also be included in relevant SOPs as a clickable link.

#### **OSHA Protocols for handling and storage of chemicals:**

The safety of our employees and the public is our foremost business consideration. The prevention of accidents and injuries takes precedence over expedience. In the conduct of our business, every attempt will be made to prevent accidents from occurring. The Company’s safety SOPs address both OSHA regulations and good laboratory practice. Key laboratory personnel will be required to participate in OSHA Certification in Health and Safety educational classes. All employees will be fully trained in the safe and efficient use of chemicals, tools, and machinery.

There are several key safety precautions necessary for extraction operations:

The room must be well ventilated and separate from all other processes. The area will have a CO2 monitor as a safety precaution designed to sound when the level of CO2 in the room nears an unsafe level. Equipment safety features must be maintained so that in the event of a leak, pressure will no longer be maintained by the system and the pump will shut off.

Standards will be established, documented and followed for chemical receiving, tracking, storage, and disposal. The General Manager and department supervisors will implement and maintain the PPE program. The program will be compliant with OHSA and EPA standards and address:

1. Hazards present;
2. Selection, maintenance, and use of PPE;
3. Training; and



## Attachment 12.3

### 4. Monitoring.

Personnel will be required to wear protective clothing, chemical resistant gloves and goggles when handling hazardous chemicals.

For each of the chemicals we are using in our production process we will determine the appropriate OSHA protocols. OSHA has defined specific protocols for handling and storage of chemicals in their CFR regulations. These are included in OSHA CFR 29, Standard number 1910, subpart H. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

All employees will be appropriately trained on spill response. Every employee is responsible for participating in spill response activities. A fully stocked spill kit will be maintained in the processing and laboratory facilities.

Our batch processing for extraction generally uses CO<sub>2</sub>, though other chemicals may be used for processing and sanitation. Hence we will adopt, CFR 29 H 1910.101 which concerns the general requirement for Compressed Gases. This will apply to our use of CO<sub>2</sub> in extraction during the chemical processing stage of production. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

Another example is CFR 29 H 1910.106 which concerns the requirements for Flammable liquids. This OSHA protocol will also be applicable to certain of our processes for production, such as those processes which use ethanol, and for sanitation where flammable liquids or aerosols are used. We are subject to or will voluntarily adopt these OSHA standards in our storage and handling procedures.

### **MANUFACTURING PROCESS VALIDATION**

GMP defines Validation as: “Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting predetermined specifications and quality attributes.”

These production runs will be of limited units, produced under routine conditions and the number of production runs and observations made will be sufficient to allow for the normal extent of variation and trends to be established and provide sufficient data for evaluation. This will include at a minimum, 10 batches of any new concentrate, product or process. A state of control will be maintained with the use of procedures for monitoring and control systems for process performance and product quality. The facility will utilize an ISO9001 ‘Process Approach’ Quality-Management System to analyze hazards and place managerial controls on each process.

Before any batch or lot is commercially-distributed, we will have gained a high-degree of assurance that processes will consistently produce products meeting attributes of identity, strength, quality, purity, and potency. Additionally, FDA211.180 (e) states the quality standards of each product will be evaluated “annually” to determine the need for changes in product specifications, manufacturing or control procedures.

The FDA describes process-validation in three stages:

- (1) Process Design: The commercial-manufacturing process is defined during this stage.
- (2) Process Qualification: The process design is evaluated to determine if the process is capable of reproducible, commercial manufacturing.
- (3) Continued Process Verification: Ongoing assurance is gained during routine production that processes remains in a state of control.

The following are examples of circumstances requiring validation:

1. Major site changes
2. Major changes to equipment
3. Major Changes in Composition and Components:
  - a. addition of a new product
  - b. addition of a new dietary ingredient to a formulation;
  - c. changes to excipient concentration that are likely to have detectable impact on formulation quality and performance.
4. Major Process Changes: Changes to the type of process used in the manufacturing of the product, such as change from wet granulation to direct compression of dry product.
5. Major Changes to Specification: usually as a result of a formulation change;



## Attachment 12.3

6. When an adverse event is experienced where a process has failed to provide the desired result, such as contamination, and the process must be re-evaluated.

### **VALIDATION MASTER PLAN:**

The Company will create an SOP to document our master plan and standard protocols for validation, summarized as follows:

1. Establish predetermined specifications that define a successful validation result.
2. Determine appropriate resources and assign responsibilities for the project.
3. Define equipment and instruments to be used.
4. Define ingredients and chemicals to be used.
5. Establish review team.
6. Establish time-line and number of production runs included in the test.
7. Determine number of units or volume of production in each run.
8. Define test protocols (number of units in each lot to be “sampled”, sampling methods, testing protocols and laboratories).
9. Documents used:
  - a. Validation plan
  - b. Validation report
  - c. Discrepancy forms
  - d. SOPs
  - e. System-change request forms
  - f. Test results
10. Perform validation on a minimum of 10 lots produced according to a single manufacturing order during the same cycle of manufacture.
11. Acceptance. All documentation obtained and filed in the established Validation Filing System.

### **VARIATION**

During Production of validation Lots employees will identify sources of variation affecting process performance and product quality for improvement to reduce or control variation. Scrutiny of intra-batch and inter-batch variation is part of a comprehensive process-verification program under 21CFR§211.180(e). Control Procedures shall be established to monitor the output and validate performance of manufacturing processes that may be responsible for variability in the characteristics of in-process material and the drug product.

Sources of Variation include:

Employees -Employees will be trained to analyze parameters and attributes identified in the control strategy to verify continued operation within a state of control. Employees will provide feedback on product quality from both internal and external sources (e.g., complaints, product rejections, non-conformances, recalls, deviations, audits and regulatory inspections). Employees will be provided proper tools to perform their duties and receive ongoing education and training. Supervisors will perform Direct Observation of SOPs during Process-Validation runs.

Raw Materials - Strict SOPs of sourcing raw ingredients will be followed. Specifications of quality for suppliers have been developed to limit the variability of raw materials and packaging. We have the advantage of purchasing raw material from suppliers with existing strategic partnerships with our consultants. All suppliers have proven cGMP and tested product. Product received into the facility will be inspected upon arrival, recorded, refused or received, and stored in accordance with FDA cGMP Sec.211.80, 211.82 and 211.86. These controls are a foundation of the validation process by limiting the variable of compromised or inconsistent packaging and raw-materials entering the facility. We will source our marijuana from our own vertically-integrated cultivation facility located contiguous to our processing operation. In addition to a lab-testing facility we will utilize in-house testing at critical control points (including: raw marijuana, marijuana concentrate, marijuana infused final product) throughout the production facility to control intrinsic variables.

Equipment - Equipment used in production will be used for its intended use and will be of “appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.” (FDA cGMP Sec211.63) All equipment will be regularly maintained and documented. (FDA cGMP Sec211.67) Employees will be properly trained and certified on equipment.



## Attachment 12.3

Measurement Systems -Acceptance criteria for sampling and testing conducted by the quality control unit shall be adequate to assure the batches meet each appropriate specification and appropriate quality control criteria as a condition for their approval and release.

SOP– SOPs are discussed in detail in other sections of the application and will document every movement and method in the process.

Environment -Managerial control measures will be implemented in all phases of the operation. Controls of critical control-points will be supported with proper documentation in accordance to FDA cGMP Sec.211.100. Data collection of the production process is ongoing with direct-observation documentation of all critical control-points throughout receiving, extraction, production, storage, sample collection, and lab testing. Documentation provides a record that appropriate corrective actions were taken when critical limits were not met due to internal or external variables.

The validation process will allow us to:

1. Understand the sources of variation
2. Detect the presence and degree of variation
3. Understand the impact of variation on the process and ultimately on product attributes
4. Control variation in a manner commensurate with the risk it represents to the process
5. Judge whether we have gained sufficient understanding to provide a high degree of assurance in our manufacturing process to justify commercial distribution.

### **DOCUMENTATION**

All Validation Protocols, final Validation Reports and associated testing results required by this procedure shall be retained for at least five years after distribution of the product manufactured, processed or packaged utilizing that that process or equipment.

### **-----Blue Planet Healing Manufactured Marijuana Product Descriptions-----**

#### **1. Medical Marijuana Sublingual Tincture**

Medical Marijuana Sublingual Tinctures are administered sublingually by the use of a measured dropper. Sublingual tinctures shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The droppers have measurement demarcations as to provide safe and easy dosing levels. Sublingual Tinctures offer patients the ability to ‘micro-dose’ cannabinoids in measurements of 2-3 mg of active cannabinoids. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana Sublingual Tinctures will be labeled and packaged in ASTM certified child resistant re-sealable dropper caps that will maintain the child resistant effectiveness for multiple openings.

#### **2. Medical Marijuana Infused Sublingual Tablet**

Medical Marijuana Infused Sublingual Tablets are designed to dissolve slowly in a patient’s mouth making an effective sublingual administered product. Each individual Sublingual Tablet shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. The product will be lab tested for accurate active cannabinoid profile. The medical benefits of sublingual Medical Marijuana products have the benefit of a faster onset due to a more direct ingestion method. These products bypass the liver and GI tract and as a result are a great benefit to patients with medical conditions, such as autoimmune diseases and Crohn’s disease, which affect the GI tract and/or the liver and kidneys. Medical Marijuana infused sublingual tablets will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

#### **3. CO2 Medical Marijuana Concentrate**

A concentrated extract of cannabinoids, including but not limited to THC, CBD, and CBN created using a Closed-Loop Sub/Supercritical CO2 Extraction. CO2 is a non-polar solvent, which is efficient at extracting the Cannabinoids, Terpenes, and Flavonoids from Medical Marijuana plant matter. This concentrated form of Medical Marijuana can



## **Attachment 12.3**

have up to a 90% concentration of cannabinoids. The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **4. Medical Marijuana Infused Lotion**

Medical Marijuana Infused Lotion products are an oil based lotion to be applied directly to the skin, not meant for oral consumption. Infused Lotions shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Marijuana infused lotions will be packaged in squeeze tubes with an ASTM certified child resistant re-sealable cap that will maintain the child resistant effectiveness for multiple opening.

### **5. Medical Marijuana Infused Salve**

The Medical Marijuana Infused Salve is an ointment, not meant for oral consumption, to promote the healing of the skin and muscles. The Salve provides gentle relief for abrasions, sores, dry, cracked or chapped skin. Infused Salves shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. The unique formulation of active cannabinoids and all natural soothing and plant based pain relief provides convenient and fast acting relief for patients. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **6. Medical Marijuana Infused Serum**

The Medical Marijuana Infused Serum, not meant for oral consumption, is a water based formulation of active cannabinoids, antioxidants, all natural ingredients to provide patient relief. It is a fast absorbing active ingredients that penetrate the skin faster than lotions or gels. Serums are super-efficient delivery methods as small amounts are absorbed into the skin quickly and deeply. Infused Serums shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **7. Medical Marijuana Infused Gel**

The Medical Marijuana Infused Gel, not meant for oral consumption, is a Aloe based gentle moisturizer, with a proprietary formulation of herbs, essential oils and active cannabinoids. The Gel provides fast and long lasting muscle relief for patients. Infused Gels shall contain no more than 100 milligrams of tetrahydrocannabinol (THC). The product will be lab tested for accurate active cannabinoid profile. Labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

### **8. Medical Marijuana Infused Capsule**

Medical Marijuana Infused Capsules are a blend of active cannabinoids and all natural ingredients within a gelatin capsule. The gelatin capsule dissolves in the stomach of the patient releasing the cannabinoids and ingredients. Each individual Capsule shall contain no more than 10 milligrams of tetrahydrocannabinol (THC). With no more than 100 milligrams of tetrahydrocannabinol per package. Medical Marijuana Capsules will be labeled and packaged in ASTM certified child resistant packaging that will maintain the child resistant effectiveness for multiple openings.

## **-UNM MANUFACTURING PRODUCTION STANDARD OPERATING PROCEDURES-**

### **PRODUCTION OF SALVE**

#### **PRODUCT DESCRIPTION**

1oz Medical Marijuana Infused Salve

#### **POLICY**

To prepare and package Topical salve in child resistant packaging. All production will be documented.

#### **RESPONSIBILITY**

Production Manager or their designee.



## Attachment 12.3

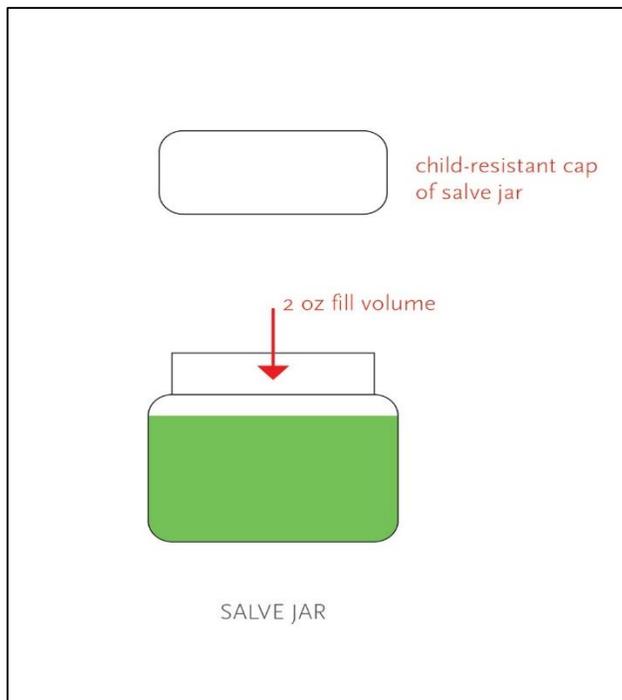
### RECORDS

Production Log  
Inventory Tracking Software

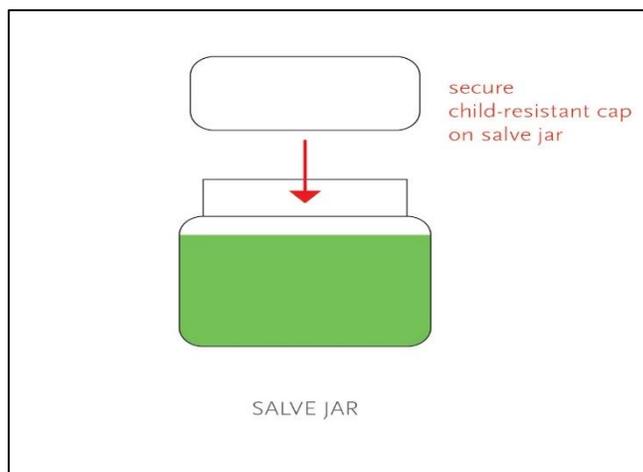
### PROCEDURE

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers, caps or droppers. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers, caps or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$
  - o **divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.
  - o  $(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Fill Topical salves to the 1 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.

## Attachment 12.3

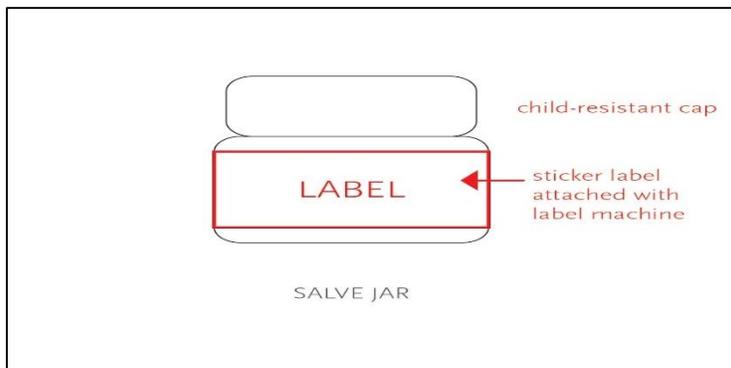


13. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
14. Apply the child resistant cap to the jar. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



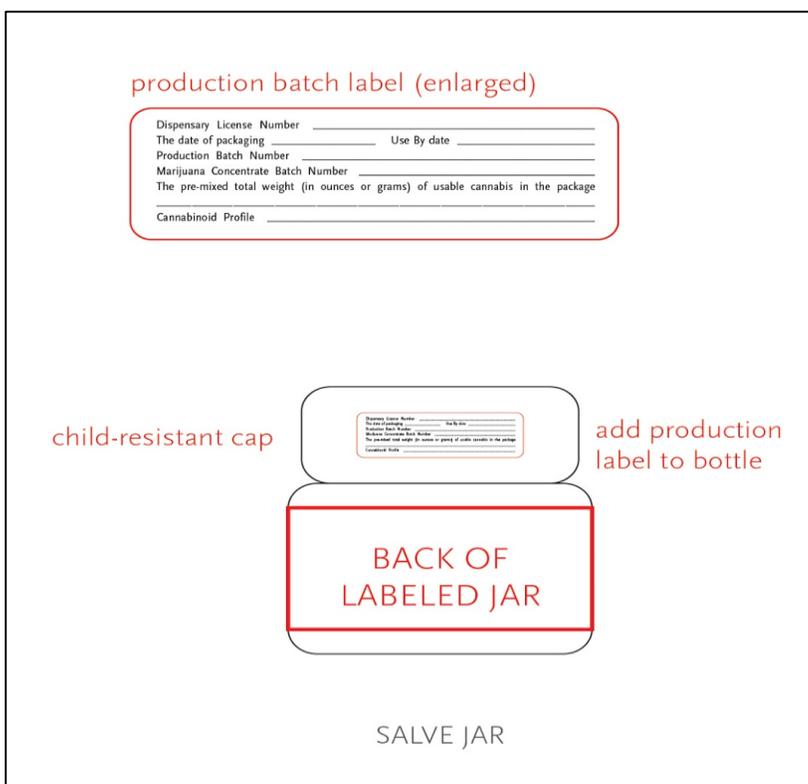
15. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Salve package properly so that front of label is centered on front of the package.

## Attachment 12.3



16. Apply the Production Batch Sticker which will contain the following information:

- Dispensary License Number
- The date of packaging and “use by” date
- Production Batch Number
- Marijuana Concentrate Batch Number
- The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
- A list of cannabinoid content by weight.



17. Final Quality Control Inspection of product includes:

- proper label applied correctly
- proper production batch label applied correctly
- dropper cap is applied correctly
- package is clean and dry

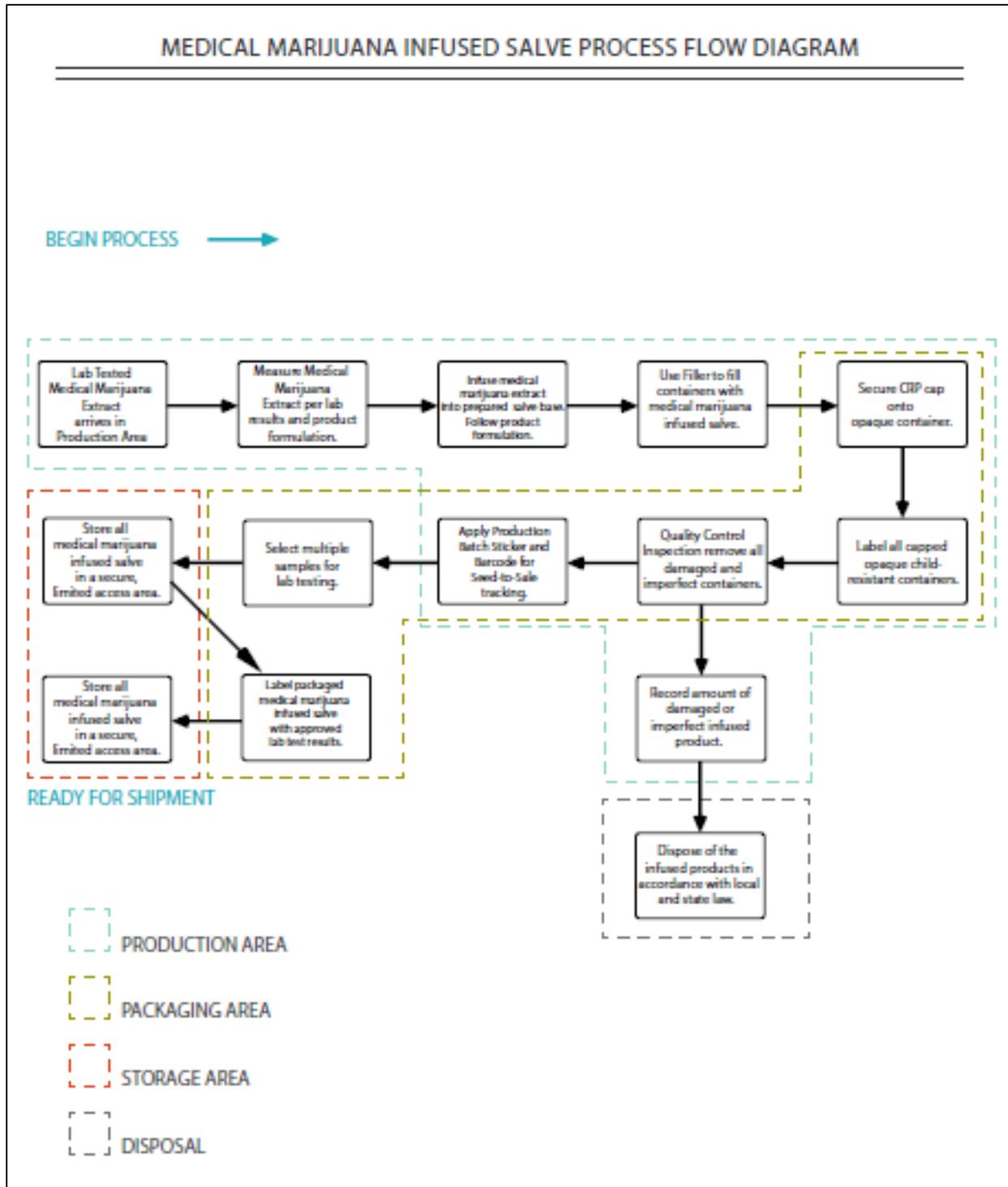


## Attachment 12.3

18. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
19. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
20. Complete the Production Form and enter information into Inventory Tracking Software.
21. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
22. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
23. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Salve can be seen below:*

# Attachment 12.3





## Attachment 12.3

### PRODUCTION OF INFUSED TOPICAL SERUM

#### PRODUCT DESCRIPTION

1oz Medical Marijuana Infused Topical Serum

#### POLICY

To prepare and package Topical Serum in child resistant packaging. All production will be documented.

#### RESPONSIBILITY

Production Manager or their designee.

#### RECORDS

Production Log

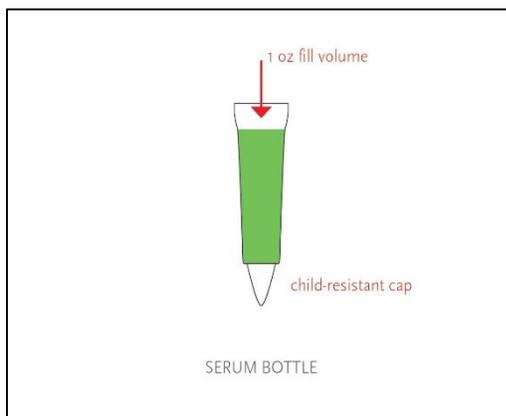
Inventory Tracking Software

#### PROCEDURE

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' Fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply the mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\#)\text{mg/THC} = (\#) \text{ total mg needed}$

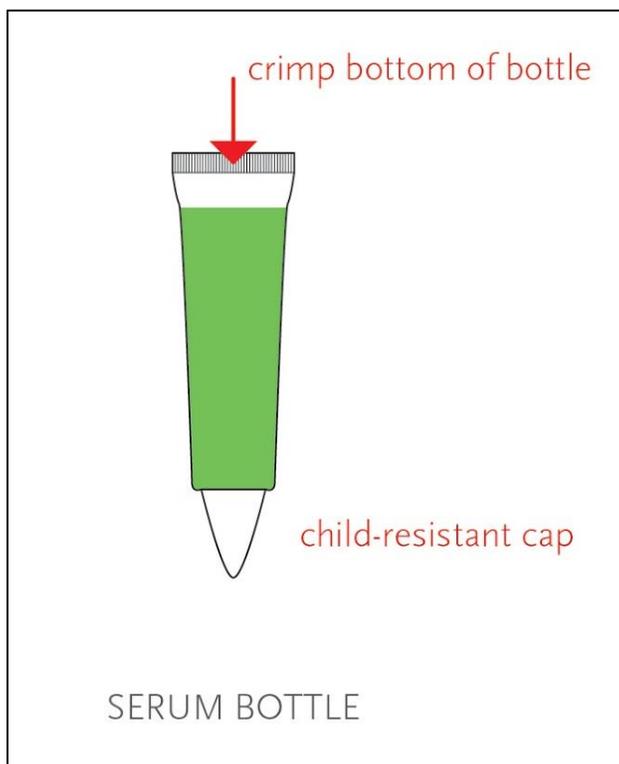
## Attachment 12.3

- **divide the total mg needed by the mg of THC per gram of the concentrate.**
  - **(#) total mg needed/(#) mg THC per gram = grams of concentrate to use in production**
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
  11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
  12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
  13. Fill Topical Serums to the 1 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

## Attachment 12.3

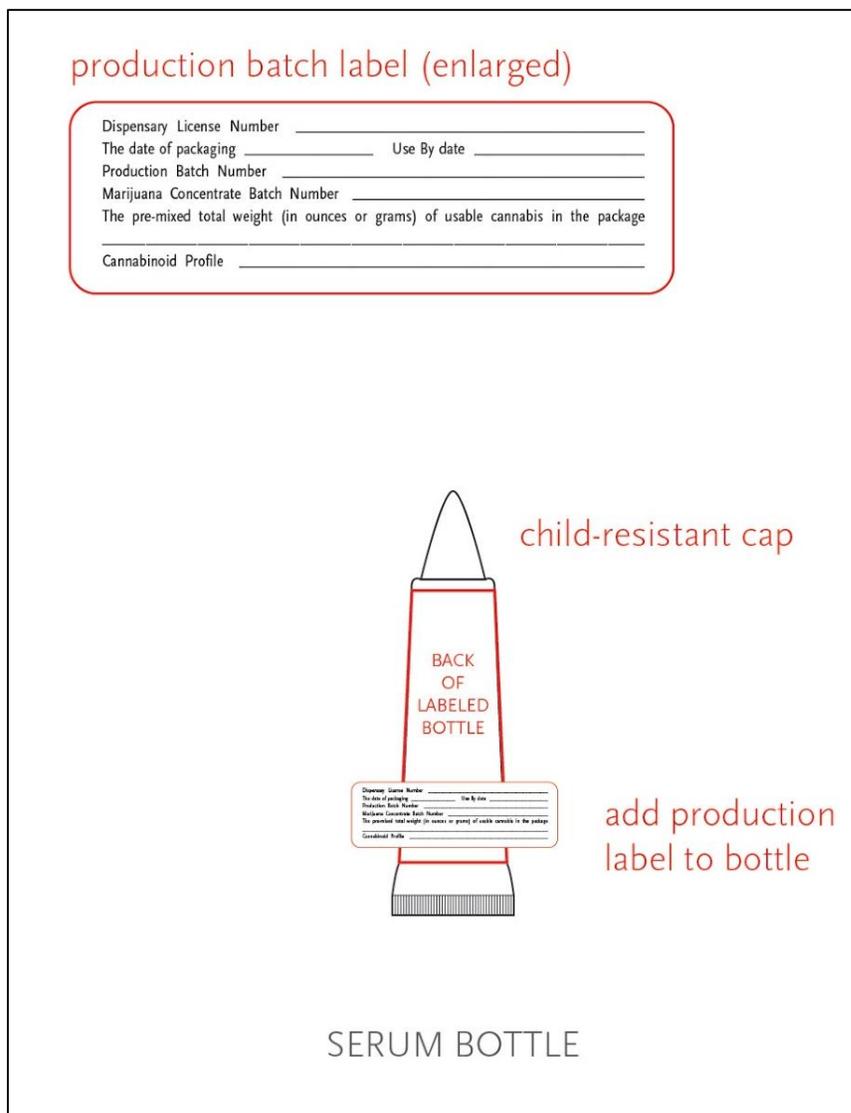


16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Serum package properly so that front of label is centered on front of the package.



17. Apply the Production Batch Sticker which will contain the following information:
1. Dispensary License Number
  2. The date of packaging and "use by" date
  3. Production Batch Number
  4. Marijuana Concentrate Batch Number
  5. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  6. A list of cannabinoid content by weight.

## Attachment 12.3



18. Final Quality Control Inspection of product includes:
  1. proper label applied correctly
  2. proper production batch label applied correctly
  3. dropper cap is applied correctly
  4. package is clean and dry
  
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
  
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
  
21. Complete the Production Form and enter information into Inventory Tracking Software.
  
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the



## Attachment 12.3

consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
24. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
25. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Serum can be seen below:*

### **PRODUCTION OF TOPICAL GEL**

#### **PRODUCT DESCRIPTION:**

3oz Medical Marijuana Infused Gel

#### **POLICY:**

To prepare and package Topical Gel in child resistant packaging. All production will be documented.

#### **RESPONSIBILITY**

Production Manager or their designee.

#### **RECORDS**

Production Log  
Inventory Tracking Software

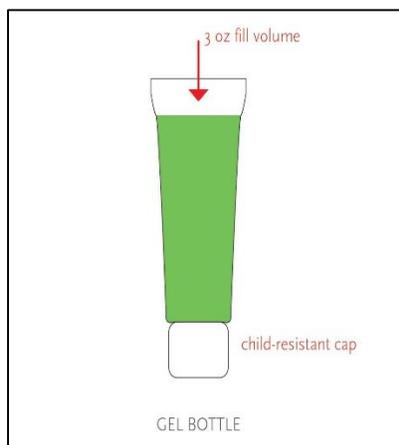
#### **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.



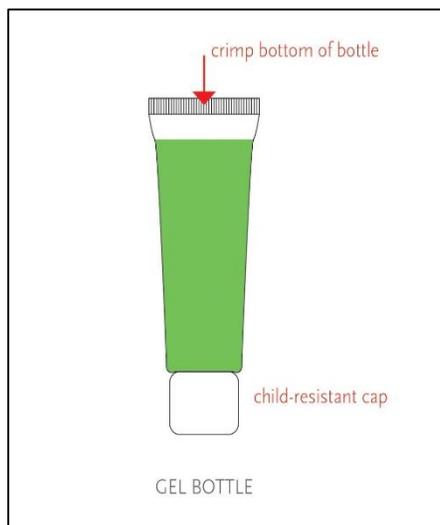
## Attachment 12.3

5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - o **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - o  $(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$
  - o **divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.
  - o  $(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
13. Fill Topical Gels from the open tube side with the child resistant cap facing down. Fill to the 3oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



## Attachment 12.3

14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube closed. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

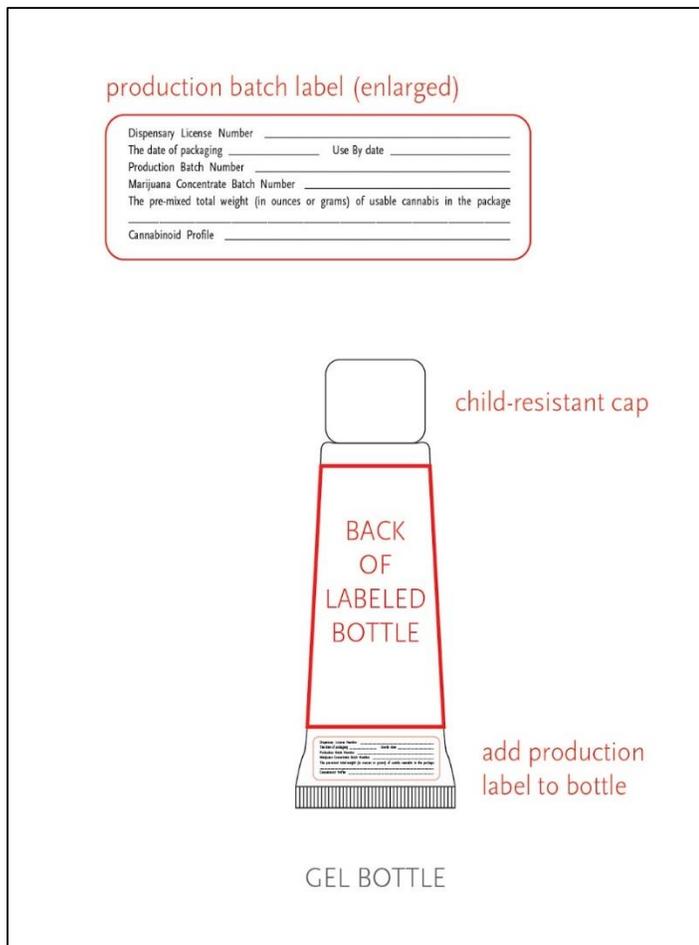


16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Gel package properly so that front of label is centered on front of the package.



17. Apply the Production Batch Sticker which will contain the following information:
  1. Dispensary License Number
  2. The date of packaging and "use by" date
  3. Production Batch Number
  4. Marijuana Concentrate Batch Number
  5. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  6. A list of cannabinoid content by weight.

## Attachment 12.3



18. Final Quality Control Inspection of product includes:
  1. proper label applied correctly
  2. proper production batch label applied correctly
  3. dropper cap is applied correctly
  4. package is clean and dry
  
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, Reason for disposal, and Quantity of the marijuana product to be disposed of.
  
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
  
21. Complete the Production Form and enter information into Inventory Tracking Software.
  
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.



## Attachment 12.3

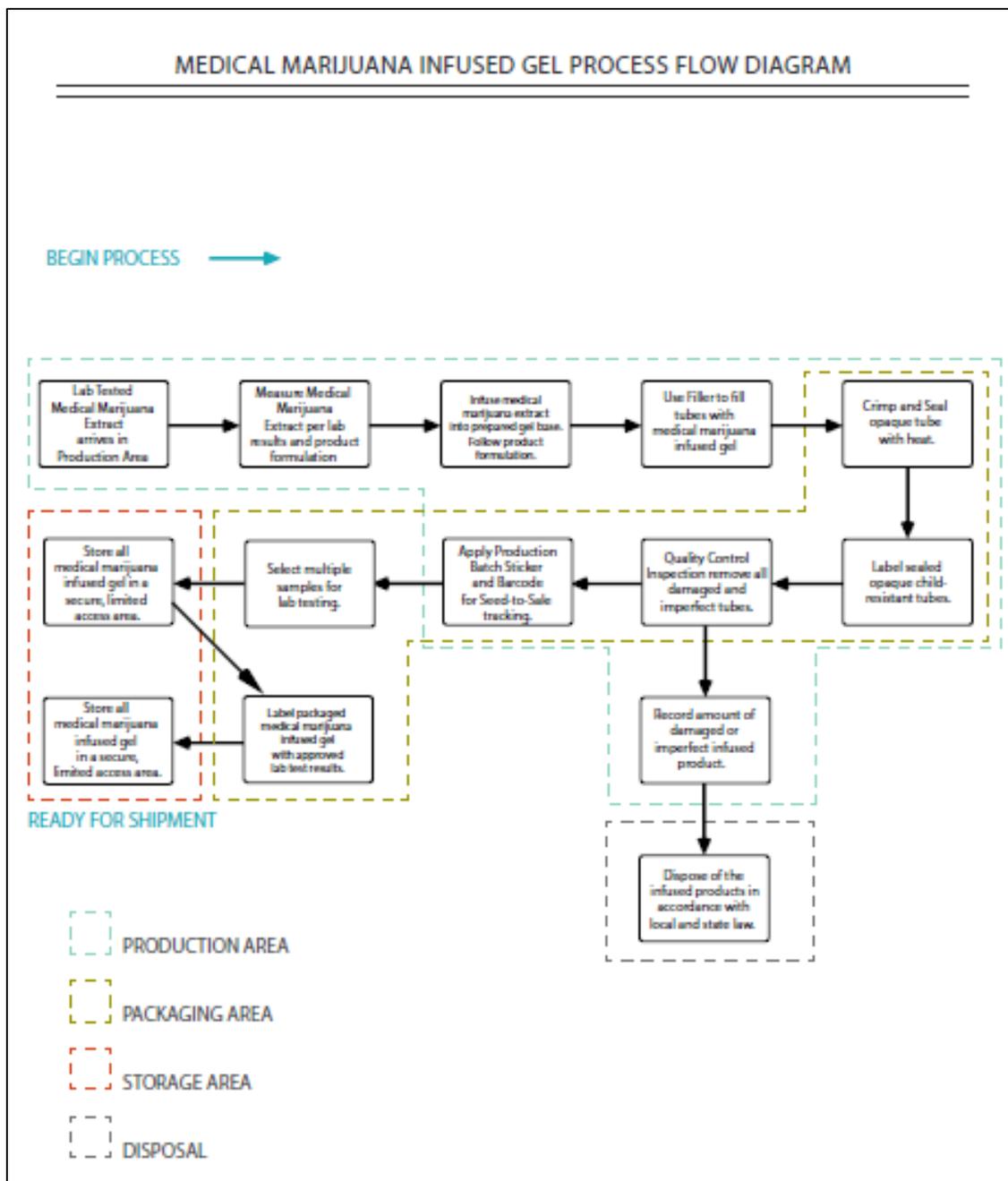
23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.

Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.

24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Gel can be seen below:*

## Attachment 12.3



### PRODUCTION OF SUBLINGUAL MARIJUANA TINCTURES

#### PRODUCT DESCRIPTION

2oz Sublingual Medical Marijuana Tincture. 2ml Dropper for Metered Dosing.

#### POLICY

To prepare and package sublingual marijuana tinctures in child resistant packaging. All production will be documented.

#### RESPONSIBILITY

Production Manager or their designee.



## Attachment 12.3

### RECORDS

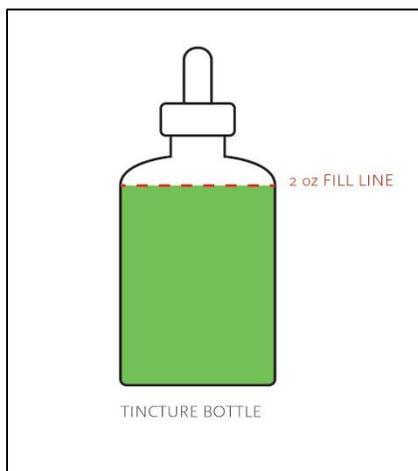
Production Log  
Inventory Tracking Software

### PROCEDURE

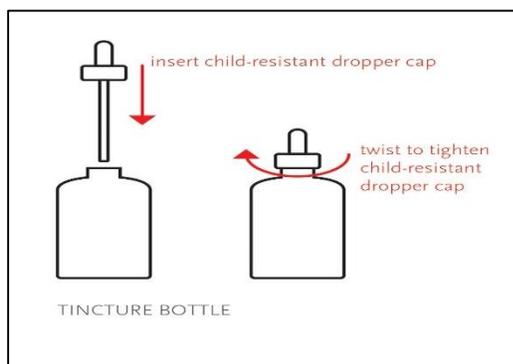
1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all containers and droppers. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers, caps or droppers. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.
  - a. **multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run
  - b.  $(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$
  - c. **divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.
  - d.  $(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} = \text{grams of concentrate to use in production}$
10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.

## Attachment 12.3

12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
13. Fill Tinctures to the 2 oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.

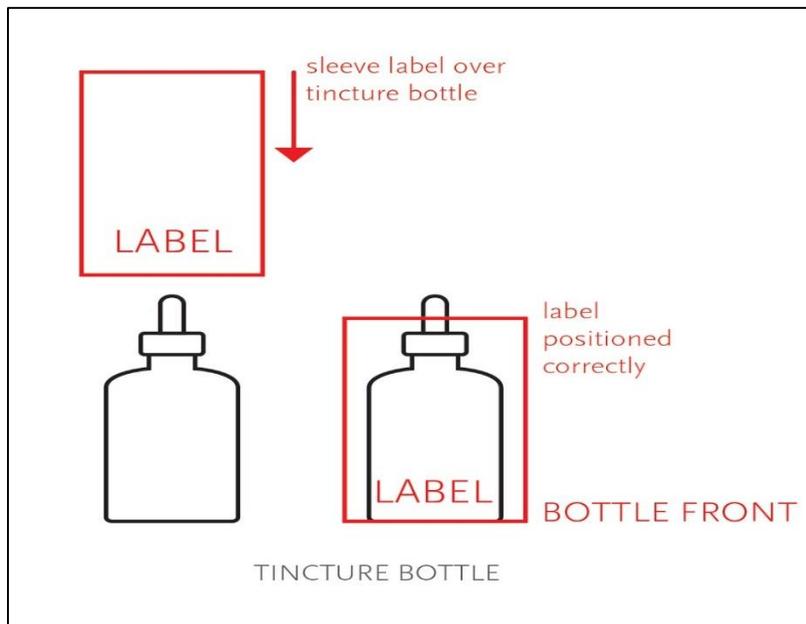


14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Secure and seal child resistant dropper cap. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



16. Turn power on to the Heat Shrink Tunnel. Set speed control to '3' and Heat control to 180F. For tincture labeling close top 4 heat tunnel vents, leaving only the bottle 2 vents open. Allow 15 minutes for Heat Tunnel to reach temperature. If applicable turn on exhaust fan to remove hot air from production area.
1. Label with tamper evident, opaque shrink-wrap label. Perform and document Direct Observation Quality Control that labels contain all required information. "Sleeve" the bottled product. -- Place shrink wrap label onto every filled and capped tincture bottle by sliding the label over the container and positioning the label properly so that front of label is centered on front of bottle.

## Attachment 12.3



2. Run Sleeved product through the heat tunnel. Carefully place each unit onto the conveyor belt so that the Tincture bottle stays upright. Bottle placement should be so that the front of the bottle faces the left side of the Heat Tunnel. As tincture bottles exit the Heat Tunnel each unit should be Quality Control inspected for tearing, wrinkling, stretching, or improper label placement. Adjust Heat Tunnel controls if necessary. Next, Label products with Production Batch Label.

Apply the Production Batch Sticker which will contain the following information:

- a. Dispensary License Number
- b. The date of packaging and “use by” date
- c. Production Batch Number
- d. Marijuana Concentrate Batch Number
- e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
- f. A list of cannabinoid content by weight.



## Attachment 12.3



Final Quality Control Inspection of product includes:

- proper label applied correctly
- proper production batch label applied correctly
- dropper cap is applied correctly
- package is clean and dry

Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.

Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.

Complete the Production Form and enter information into Inventory Tracking Software.

Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab



### Attachment 12.3

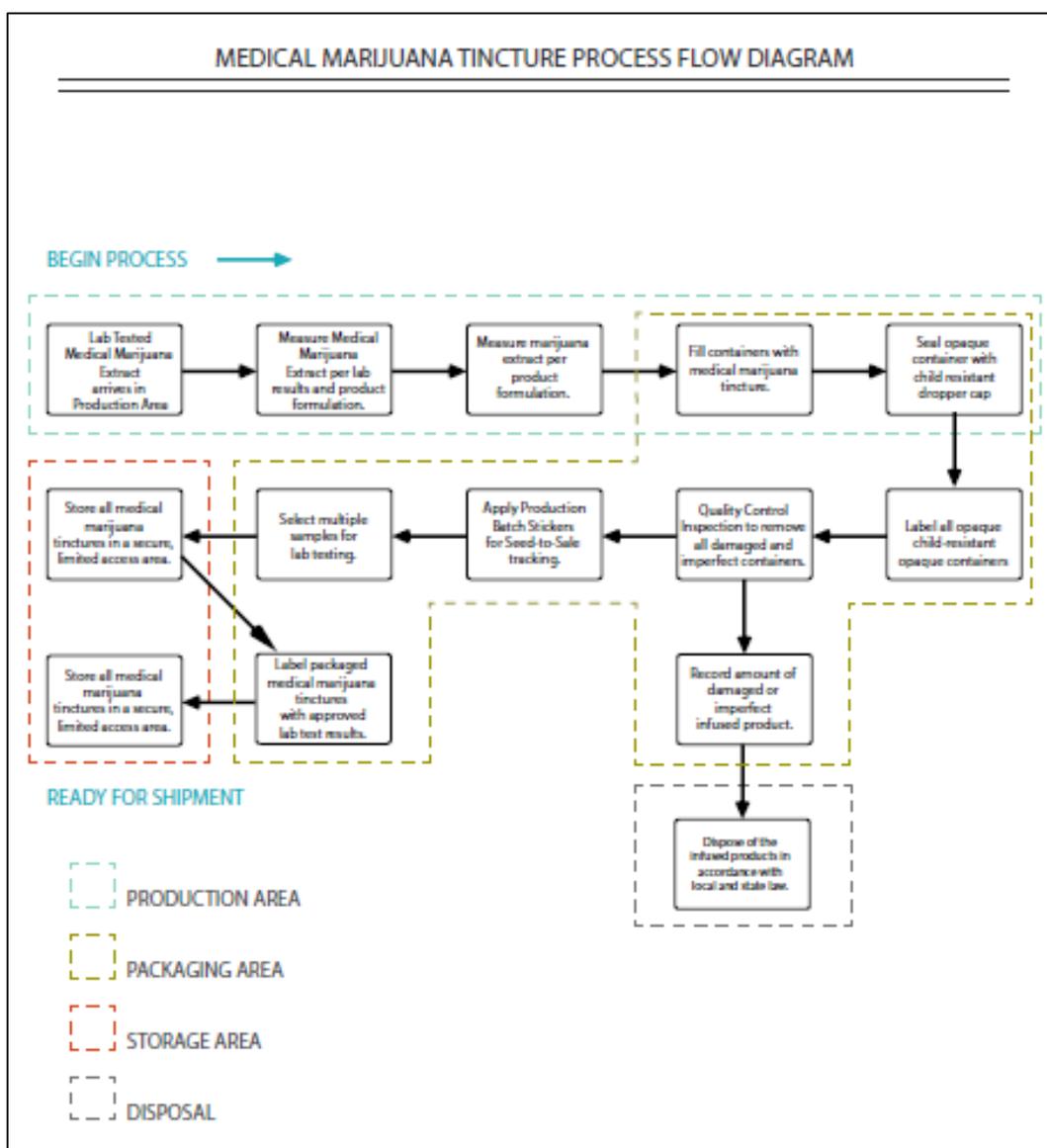
facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.

Move all final marijuana products to a secure storage area within the Production Area to await lab test results.

Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.

Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Infused Tincture can be seen below:*



### PRODUCTION OF MARIJUANA SUBLINGUAL TABLET



## Attachment 12.3

### PRODUCT DESCRIPTION

Medical Marijuana Sublingual Tablet

### POLICY

To prepare and package marijuana concentrate into accurately dosed sublingual Tablets.

### RESPONSIBILITY

Production Manager or their designee.

### RECORDS

Production Log

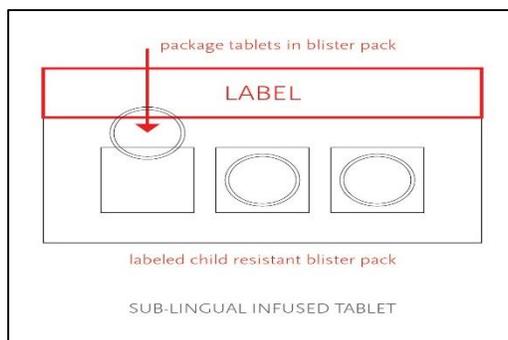
Seed-to-Sale Inventory Tracking System

### PROCEDURE

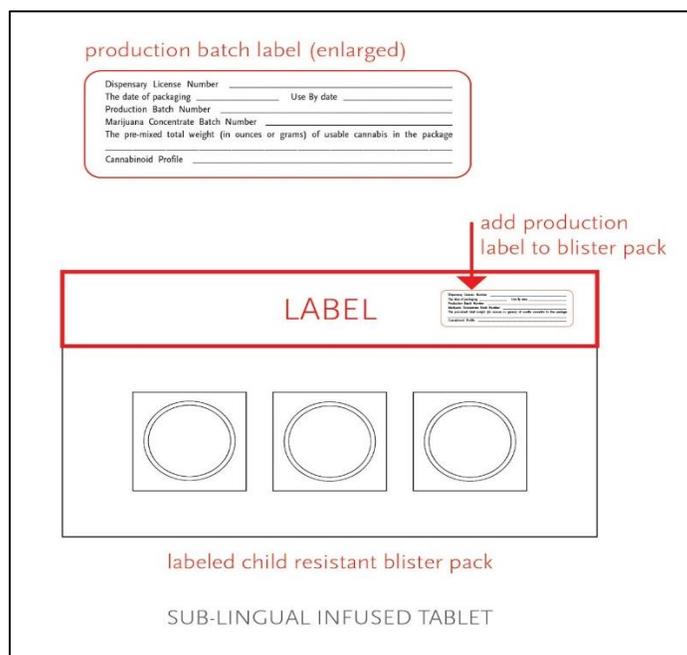
1. Before daily processing begins, sanitize work surface with 50 - 200 ppm sanitizer solution.
2. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level.
3. Wipe all work surfaces with bleach solution, allow to air dry
4. Ensure that all utensils are cleaned and sanitized.
5. Have a container with sanitizer on the table at all times.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form by assigning a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name. The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form Inventory Tracking Software Inventory Tracking software will be used to track all medical marijuana products.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a State certified testing lab ensure consistent and metered medical marijuana products.
9. Use a NTEP approved scale to measure an accurate amount of marijuana extract per medical marijuana product formulation.
10. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Use the assembled and sanitized equipment to form the tablets. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of medical marijuana product. Quality Control Direct Observation of the tablets to provide a safe and consistent medical marijuana product.

## Attachment 12.3

13. Operate the packaging equipment to package tablets in child resistant packaging. The packaging provides a consistent and recognizable child resistant packaging to provide safety for the patient.



14. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information.



15. Final Quality Control Inspection of product.
16. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
17. Once documented render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
18. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch.

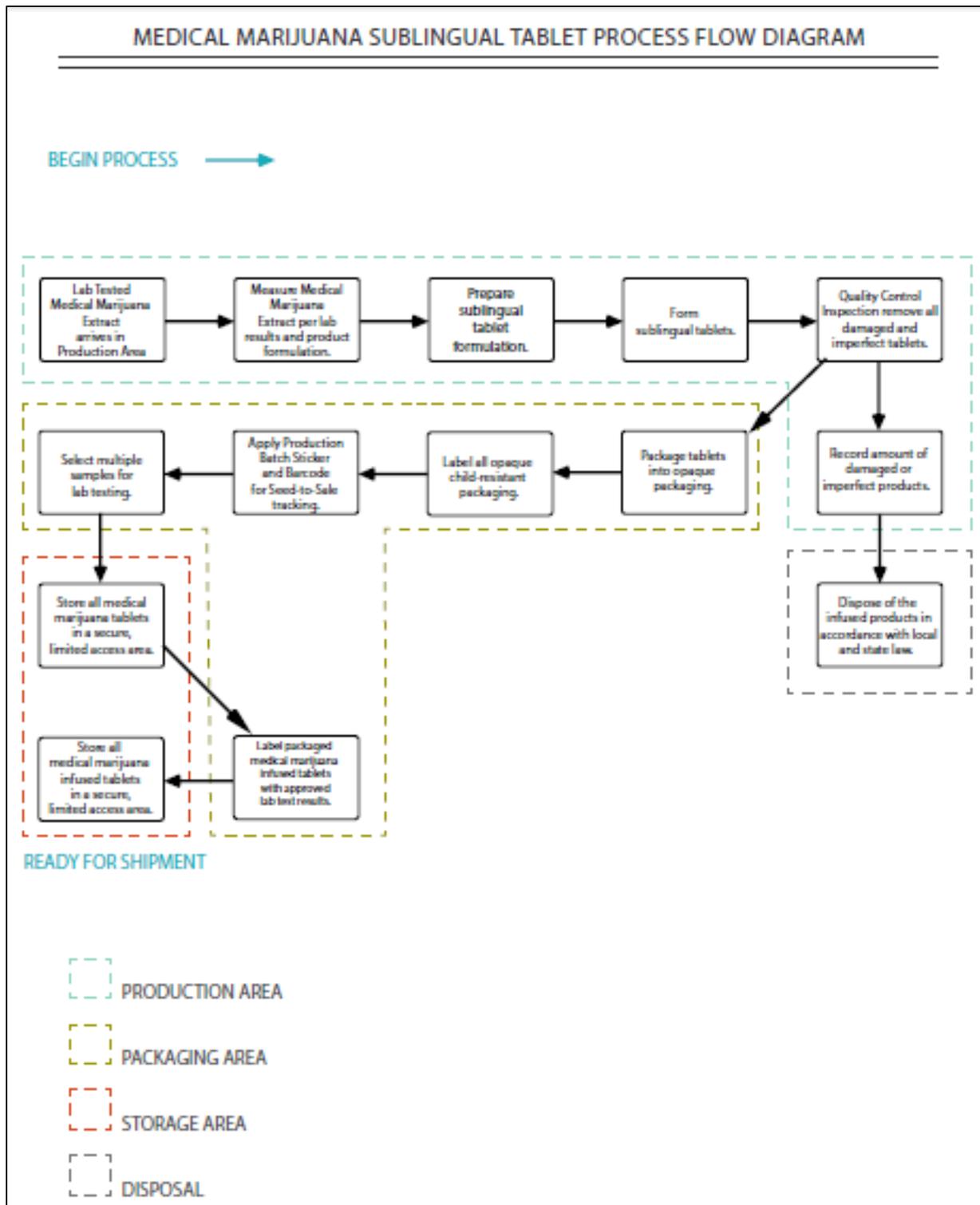


## Attachment 12.3

19. Enter Batch Number, quantity produced, date of production, and marijuana extract Batch information into Inventory Tracking Software.
20. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
21. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
22. Upon receiving approved test results for the marijuana product Production Batch, apply Production Batch Sticker to the final product. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
23. Apply the Production Batch Sticker which will contain the following information:
  - a. Dispensary License Number
  - b. The date of packaging and “use by” date
  - c. Production Batch Number
  - d. Marijuana Concentrate Batch Number
  - e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - f. A list of cannabinoid content by weight.
24. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

***The Process Flow Diagram for Marijuana Infused Sublingual Tablet can be seen below:***

# Attachment 12.3



## PRODUCTION OF INFUSED TOPICAL LOTION

### PRODUCT DESCRIPTION

6oz Medical Marijuana Infused Lotion

### POLICY



## Attachment 12.3

To prepare and package Infused Topical Lotion in child resistant packaging. All production will be documented.

### RESPONSIBILITY

Production Manager or their designee.

### RECORDS

Production Log

Inventory Tracking Software

### PROCEDURE

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all packaging. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with packaging. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized packaging into dry food grade plastic container and cover with plastic wrap. Place container of sanitized packaging on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a state certified testing lab ensure consistent and metered medical marijuana products.
9. Formulation for amount of marijuana concentrate to be used: begin by determining total mg of THC needed for production run.

**multiply** the **mg/THC** of each unit by the **number of units** to be produced to find the **total mg THC needed** for production run

$(\# \text{ units}) \times (\#) \text{mg/THC} = (\#) \text{ total mg needed}$

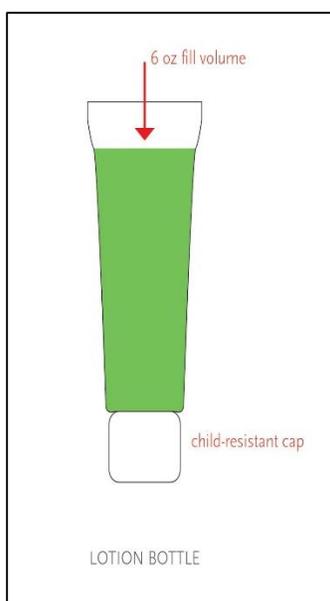
**divide** the **total mg needed** by the **mg of THC per gram** of the concentrate.



## Attachment 12.3

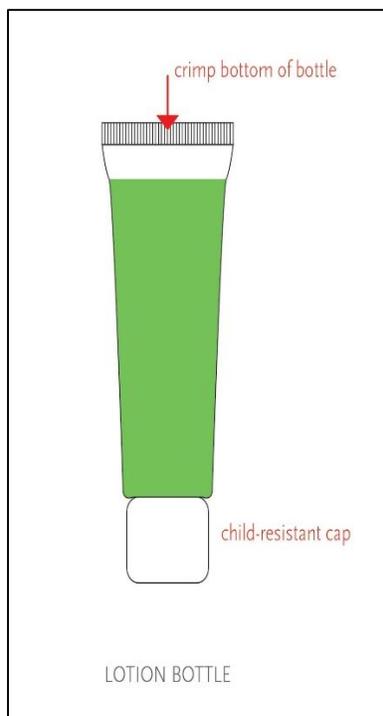
$(\#) \text{ total mg needed} / (\#) \text{ mg THC per gram} =$   
grams of concentrate to use in production

10. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
11. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
12. Follow product formulation to create a homogenous and consistent Form of marijuana infused product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
13. Fill Topical Lotions to the 6oz line using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.

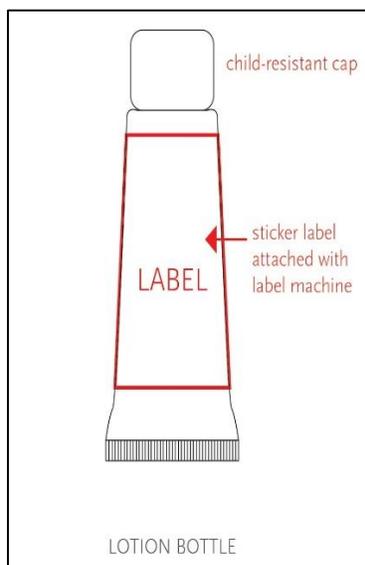


14. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.
15. Heat seal the tube. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.

## Attachment 12.3



16. Apply label. Perform and document Direct Observation Quality Control that labels contain all required information. Apply the label onto every filled and sealed Topical Lotion package properly so that front of label is centered on front of the package.



18. Apply the Production Batch Sticker which will contain the following information:
- Dispensary License Number
  - The date of packaging and "use by" date
  - Production Batch Number
  - Marijuana Concentrate Batch Number
  - The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - A list of cannabinoid content by weight.

## Attachment 12.3



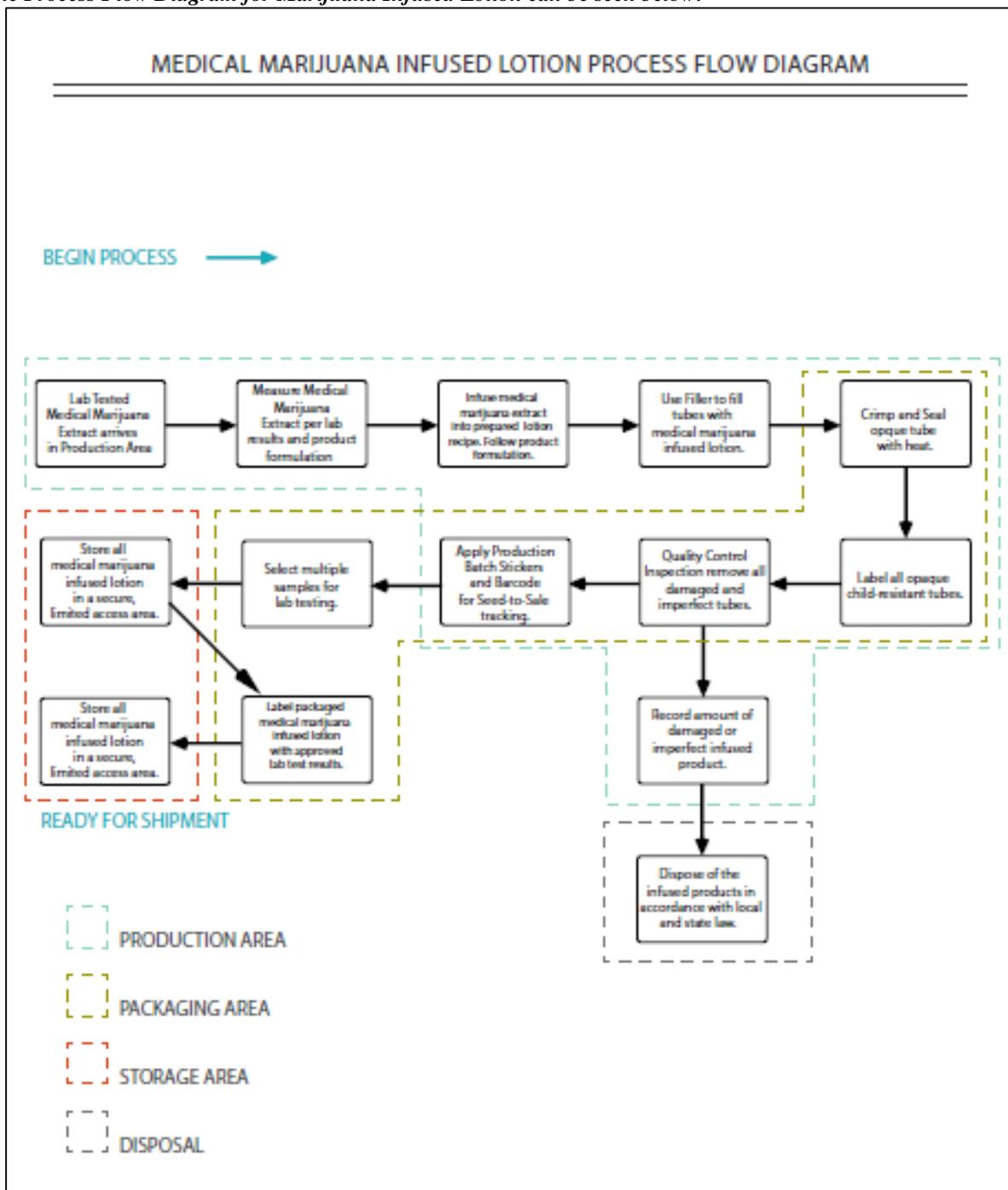
19. Final Quality Control Inspection of product includes:
  - a. proper label applied correctly
  - b. proper production batch label applied correctly
  - c. dropper cap is applied correctly
  - d. package is clean and dry
  
20. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for disposal, and Quantity of the marijuana product to be disposed of.
  
21. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
  
22. Complete the Production Form and enter information into Inventory Tracking Software.
  
23. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
  
24. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
  
25. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.



## Attachment 12.3

26. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

The Process Flow Diagram for Marijuana Infused Lotion can be seen below:



### PRODUCTION OF MARIJUANA CAPSULE

#### PRODUCT DESCRIPTION

Medical Marijuana Infused Capsule



## Attachment 12.3

### **POLICY**

To prepare and package marijuana concentrate into consistent and metered capsules.

### **RESPONSIBILITY**

Production Manager or their designee.

### **RECORDS**

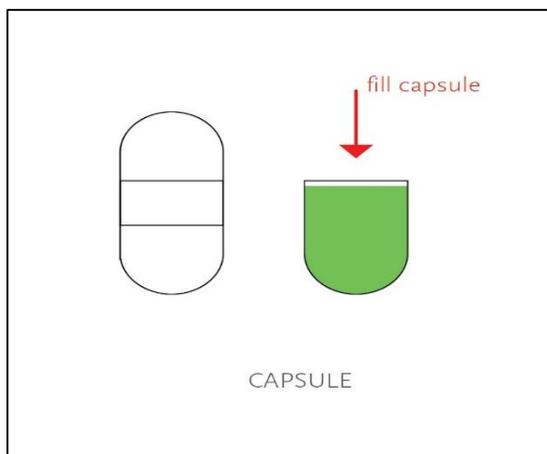
Production Log

Seed-to-Sale Inventory Tracking System

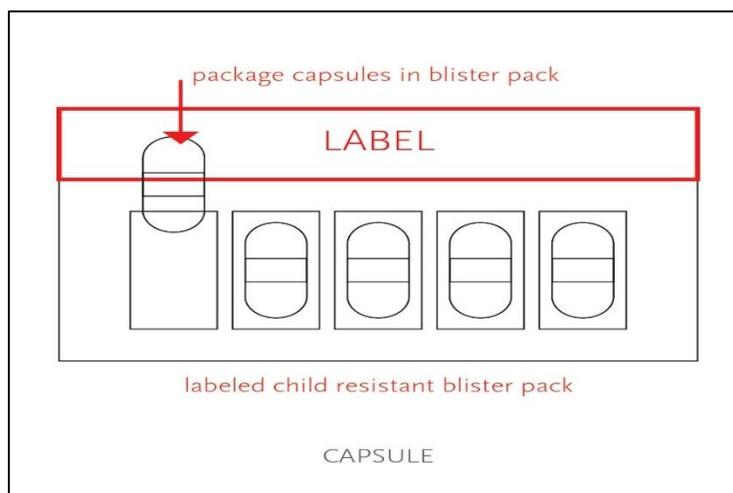
### **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50 - 200 ppm sanitizer solution.
2. Mix 5 gallons of water with 1 teaspoon full of unscented bleach in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level.
3. Wipe all work surfaces with bleach solution, allow to air dry.
4. Ensure that all utensils are cleaned and sanitized.
5. Have a container with sanitizer on the table at all times.
6. A designated employee shall retrieve marijuana extract from the secure storage area and bring to the Production Area.
7. Begin the Production Form by assigning a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Extract Batch Number, Date, and Product Name. The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form Inventory Tracking Software Inventory Tracking software will be used to track all medical marijuana products.
8. Use the approved lab test results for cannabinoid profile associated with the Marijuana Extract Batch to determine the amount of Marijuana Extract to be utilized for the Production Batch. Accurate test results from a State certified testing lab ensure consistent and metered medical marijuana products.
9. Use a NTEP approved scale to measure an accurate amount of marijuana extract per medical marijuana product formulation.
10. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
11. Follow product formulation to create a homogenous and consistent Form of marijuana product. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the production of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to ensure safe and consistent medical marijuana products.
12. Using the assembled and sanitized packaging equipment to fill and seal Capsules. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product. Quality Control Direct Observation of the filled and sealed containers will document proper quantity amounts and sealing of each container to provide a safe and consistent marijuana product.

## Attachment 12.3



13. Operate the packaging equipment to package and label capsules in child resistant packaging. The packaging provides a consistent and recognizable child resistant packaging to provide safety for the patient.



14. Final Quality Control Inspection of product.

15. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, Reason for disposal, and Quantity of the marijuana product to be disposed of.

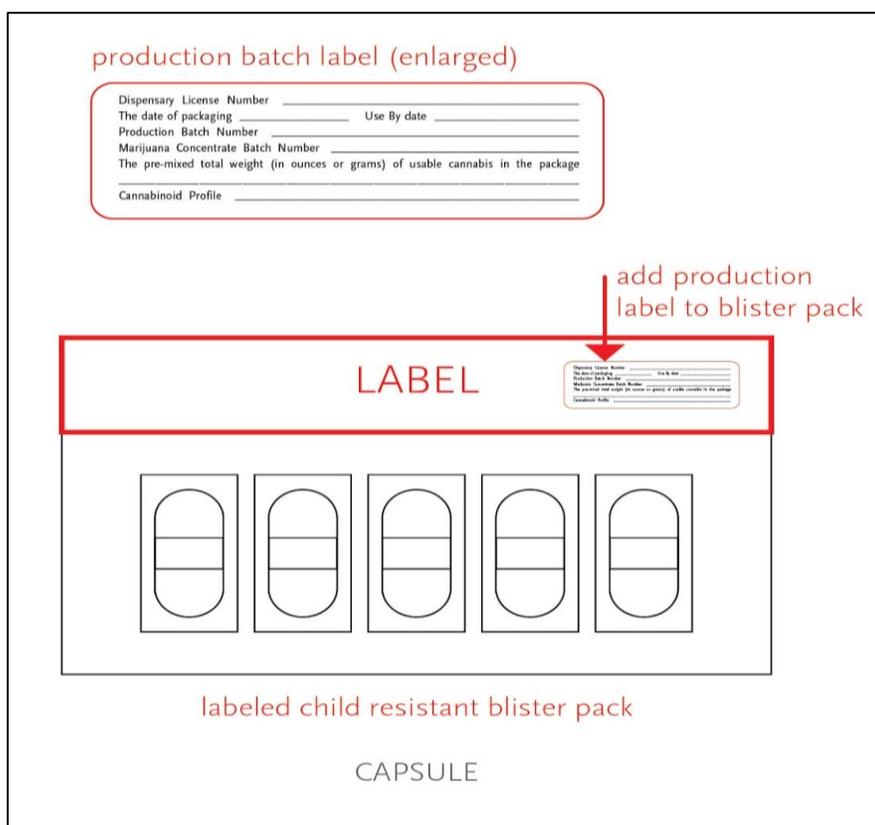
16. Once documented render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.

17. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch.

18. Enter Batch Number, quantity produced, date of production, and marijuana extract Batch information into Inventory Tracking Software.

## Attachment 12.3

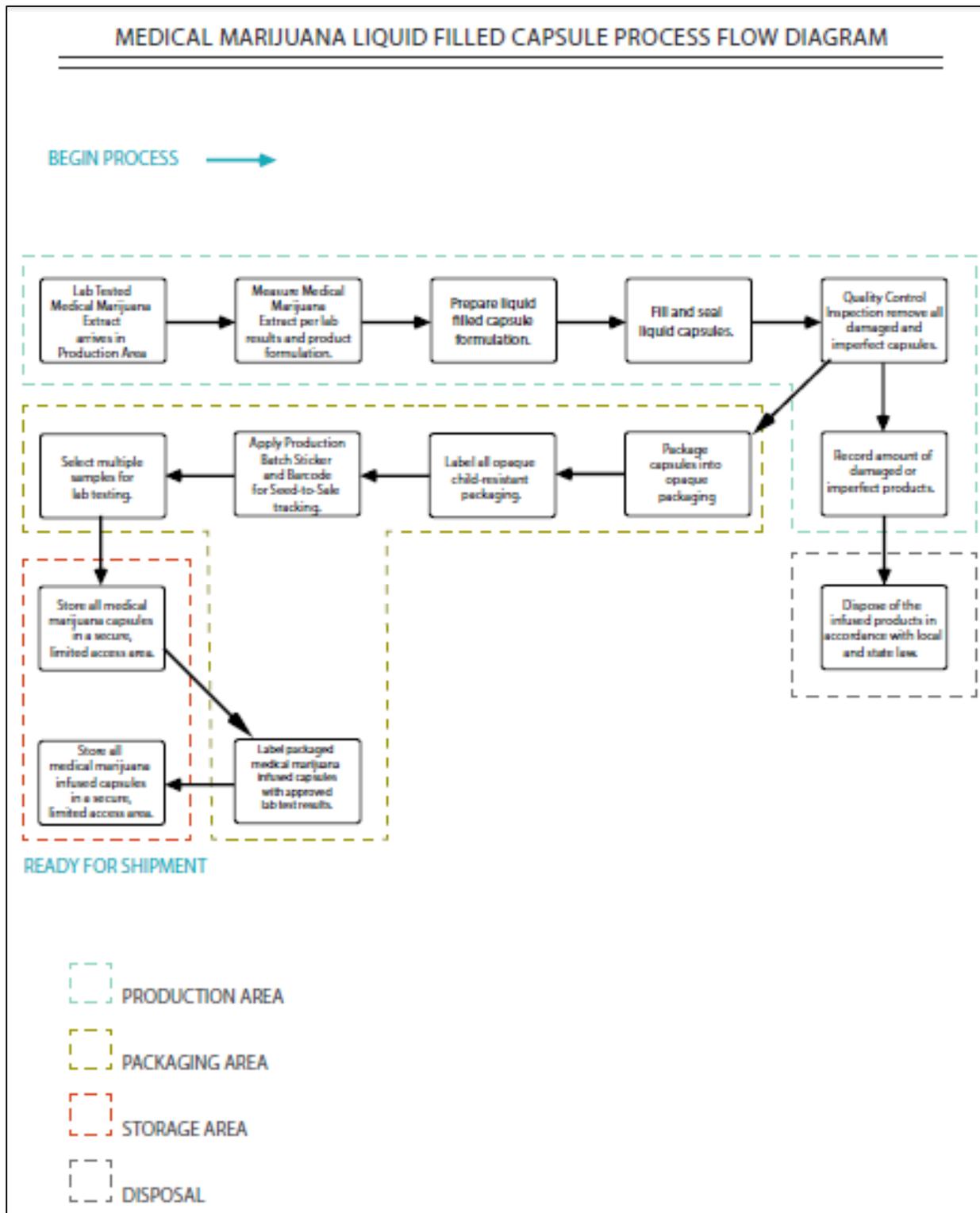
19. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
20. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
21. Upon receiving approved test results for the marijuana product Production Batch, apply Production Batch Sticker to the final product. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and consistent.
22. Apply the Production Batch Sticker which will contain the following information:
  - a. Dispensary License Number
  - b. The date of packaging and “use by” date
  - c. Production Batch Number
  - d. Marijuana Concentrate Batch Number
  - e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - f. A list of cannabinoid content by weight.



23. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

*The Process Flow Diagram for Marijuana Liquid Filled Capsule can be seen below:*

# Attachment 12.3





## Attachment 12.3

### -----CLOSED LOOP SUB AND SUPERCRITICAL CO<sub>2</sub>-----

#### **EXTRACTION**

##### **PRODUCT DESCRIPTION**

A concentrated extract of cannabinoids including but not limited to THC, THCA, THCV, CBD, CBDA, CBDV, CBN, CBG, and CBC derived from the leaves and flowers of the female marijuana plant.

##### **EXTRACTION METHOD**

CO<sub>2</sub> has a polarity that is compatible for the solubilization of lipophilic compounds such as lipids and essential oils. The low polarity index makes SFE CO<sub>2</sub> highly advantageous during medical marijuana extraction. Closed-Loop Sub/Supercritical CO<sub>2</sub> and Co-Solvent Introduction. CO<sub>2</sub> is a non-polar solvent. We utilize the latest Subcritical (17 MPa / 2500 PSI and below) and Supercritical (above 17 MPa/ 2500 PSI) Fluid Extraction (**SFE**) technologies and combine them with our own proprietary processes, formulas and equipment. SFE allows the processing of our medical grade marijuana at low temperatures limiting thermal degradation while preserving the most vital medicinal components of the plant.

##### **POLICY**

To follow all company standard operating procedures and sanitation protocols while manufacturing marijuana extract in compliance with Hawaii State and local law.

##### **RESPONSIBILITY**

Lab Manager or their designee.

##### **RECORDS**

Seed-to-Sale Inventory Tracking Software

##### **EQUIPMENT**

- 1) One extraction vessel 5000 mL in size.
- 2) Two separators each 1500 ML in size.
- 3) Temperature range maintained between 40 and 50 °C.
- 4) Pressures are created to subject the marijuana flowers to either a subcritical extraction process or a supercritical extraction process.

Pressure variance applied to each process:

- subcritical extraction process pressures: (17 MPa\* and below)
- supercritical extraction process pressures: (above 17 MPa to 69 MPa)

\* MPa: 1 megapascal (MPa) = 145.037738 pound-force/square inch (PSI)

##### **Our Sub/Supercritical Extraction Process is illustrated in 8 procedures:**

2. Penetration of matrix (marijuana plant matter).
3. SCF solubilizes the solutes inside the pores.
3. Intra-particle (or internal) diffusion of the solutes takes place until the external surface is fully saturated with solvent.
4. External (or film) diffusion of the solutes from solid-fluid interface to the SCF bulk.
5. Precipitation of target solutes in the trapping system by changing the pressure and/or temperature of the fluid.
6. Apply proprietary formulas that vary time intervals and solvent quantities to control and output the anticipated extraction grade and type.



## Attachment 12.3

7. Apply proprietary extract refinement processes to complete the end product output.
8. Based on the final extract output selected, Co-solvents are sometimes introduced at different phases of the extraction process.

### **(8a) CO-SOLVENT Introduction:**

Co-solvents are introduced at different time phases of the extraction process based on the desired final product. Primary intervals are 25%, 50%, and 75% time interval to completion of the extraction process.

Additional Extraction Runs, Matrix Disposal and further Solvent Reclaim:

Due to our closed-loop extraction equipment, all solvents are reclaimed for re-use or disposed per State of Hawaii solvent removal procedures. Due to the primary extraction process achieving a greater than 90% efficiency very little extract potential resides within the marijuana plant matter. The remaining extract potential of the marijuana is subjected to a primary ethanol solvent rinse to capture all remaining marijuana extract. The exhausted post extract marijuana plant matter is then classified as “unusable” and packaged for safe removal and disposal from the lab.

#### A) Subcritical extraction process (17 MPa and below)

Time Interval to completion of process is related to the percentage (%) of co-solvent introduced of total solvent in system at a temperature range: 40- 50 °C.

- 25% / 10%
- 50% / 5%
- 75% / 2%

#### B) Supercritical extraction process (above 17 MPa to 69 MPa)

Time Interval to completion of process is related to the percentage (%) of co-solvent introduced of total solvent in system at a temperature range: 40- 50 °C

- 25% / 10%
- 50% / 5%
- 75% / 2%

### **Extraction Process Yield:**

Yields utilizing our proprietary CO<sub>2</sub> and co-solvent methods are expected to be greater than **90+%**.

The remaining extract potential of the marijuana is subjected to a primary food-grade ethanol solvent rinse to capture all remaining marijuana extract from the plant matter.

The extraction equipment schematic is illustrated in **Diagram Two:**

First, the liquid carbon dioxide is pumped through a heat exchanger to reach the system at supercritical state. Next, the SC CO<sub>2</sub> is uniformly pumped into the extractor where the dry and ground plant material forms a fixed bed of solid matrix. The extraction can be performed in static (with no follow-through) or dynamic (with follow-through) mode or in a mixed approach. During extraction, the supercritical solvent passes through the plant matrix bed and dissolves the soluble compounds. The mixture solvent-plant solutes are separated in flash tanks (cyclonic and gravimetric separators) usually changing drastically the solvent power of CO<sub>2</sub> by depressurization or temperature change or both. Then, CO<sub>2</sub> is cooled at liquid state and compressed to return to the extractor.

# Attachment 12.3



# Attachment 12.3

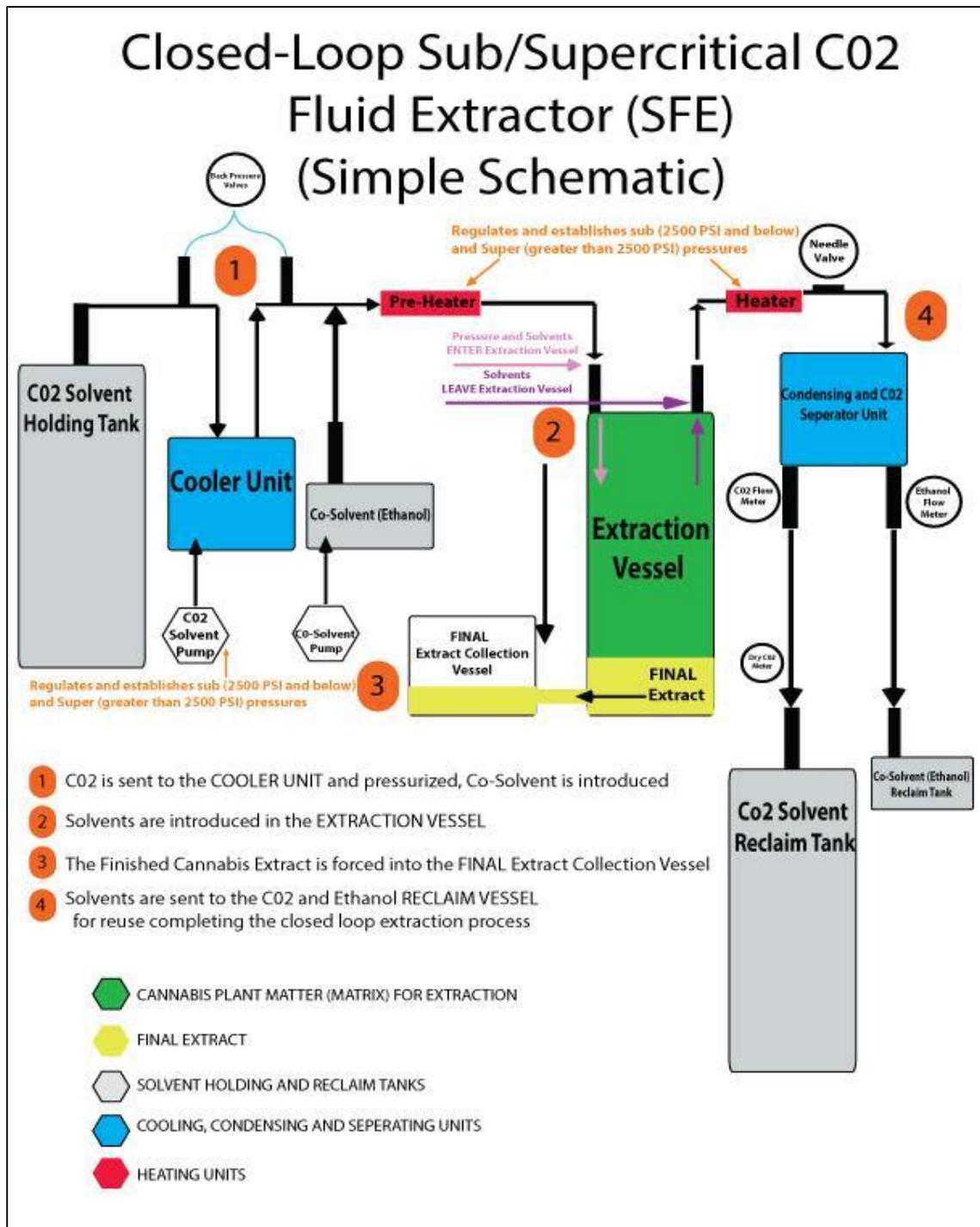
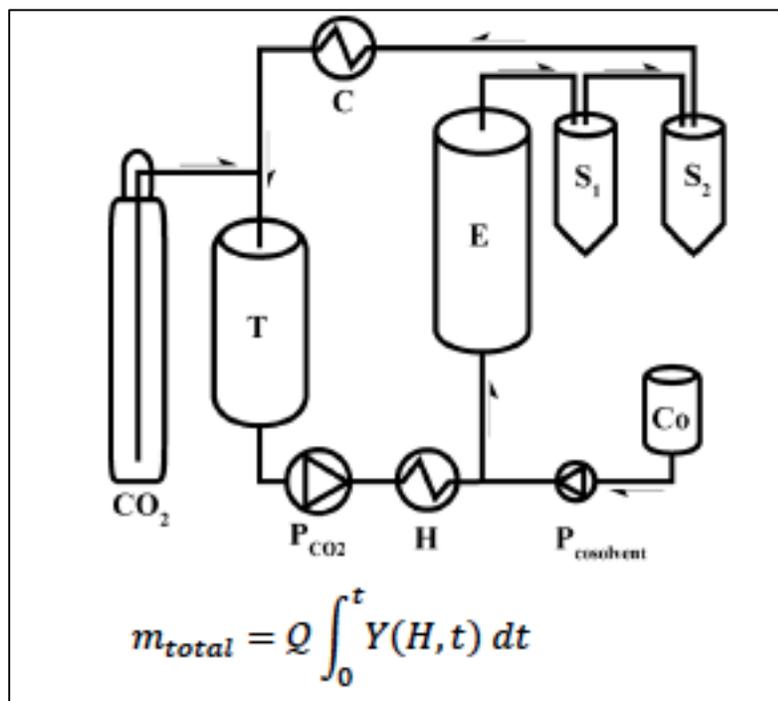


Diagram Three:

## Attachment 12.3

Raw Diagram of the supercritical fluid extraction process:



Legend Descriptor for Supercritical Extraction machine:

- (T): Storage Tank
- (P<sub>CO2</sub>): CO<sub>2</sub> Pump
- (H): Heat exchanger
- (Co): Solvent Pump
- (E): Extraction vessel
- (S1-S2): Separation cells
- (C): Condenser

The versatility of SC CO<sub>2</sub> as extraction technology utilizes the solvent's efficiency through the simple change of pressure and temperature. The range of variation of SC CO<sub>2</sub> density is relatively wide, from 0.2 g cm<sup>-3</sup> at 8 MPa and 40 °C to 1.0 g cm<sup>-3</sup> at 69 MPa and 50 °C. Furthermore, the increase of temperature leads to reduction of density of supercritical fluids but, on the other hand, the increase of temperature affects the volatility of target compounds. For volatile marijuana oil extraction through SC CO<sub>2</sub>, small changes in temperature cause significant changes in solubility with a non-linear relationship. The operative pressure is one of the primary parameters we utilize to influence the fluid density and therefore the solvent power of supercritical fluid and co-solvent. We also utilize the effects of temperature depends on the nature of plant material and has to be determined case by case.

For the analysis of solubility of target compounds and for the design of extraction process, four parameters are extremely helpful in the understanding of solute behavior in supercritical fluids. The miscibility or threshold pressure, that is the pressure at which the solute starts to be transferred into the supercritical fluid; the pressure of maximum solubility of solute; the fractionation pressure range, that is the pressure region between the miscibility and maximum solubility pressures and; the physical properties of the solute, particularly its melting point. The determination of the last two parameters allows us to define the best conditions for solubility and selectivity, because these compounds diffuse better above their melting points and an operative pressure between miscibility and maximum solubility increases the selectivity of extraction.



## Attachment 12.3

By closely monitoring, utilizing and adjusting the pressure and temperature during extraction, the global yield of the marijuana plant matter is determined and maintained. Global yield refers to a single target compound or to the global mixture of compounds. This parameter is closely related to the solubility of the solute in the supercritical fluid. Moreover, the solubility of target compounds can be determined also from the slope of the linear portion of the extraction curve in the stage of constant-extraction rate period (CER).

Beyond the extraction parameters related to the engineering aspects such as pressure, temperature and flow rate, other factors related to the nature of plant material can influence the SFE. The particle size, shape, surface area, porosity, and moisture level of extractable solutes are variables that depend on the nature of the matrix or pretreatment of the plant material. As a rule, the smaller the particle size of the marijuana plant material, the more exposed surface for SC CO<sub>2</sub> penetration and solute heat transfer. However, the excessive grinding of the material might produce an extraction bed extremely thick and the SC CO<sub>2</sub> could find fast tracks inside the extractor (fluid channeling effect), thus reducing the contact with the plant material. This is closely monitored during our extraction phase to negate this occurring since it reduces the overall efficiency of the extraction process.

Moreover, the moisture content of the solid material influences not only the extraction quality and yield but also the fluid dynamics of the solvent. Water can act as co-solvent by interacting with the supercritical solvent and by changing the overall polarity of the fluid. However, extracted water can increase the formation of ice blockages. Therefore, drying the raw material is recommended in order to have a water content of around 4–14%.

Co-solvents act through two hypothetical mechanisms: solute-co-solvent interaction, and matrix swelling which facilitates the contact of the solutes with the solvent. The co-solvents do not have absolute mechanism of action; their effects are related to the type of co-solvent, plant material and target compounds. Studies about the effects of co-solvents at constant pressure and temperature evaluated the extraction efficiency of different modifiers at increasing percentages for volatile marijuana oil extractions. The addition of ethanol decreases the number of extracted terpenes with respect to pure SC CO<sub>2</sub> but increases the overall “whole plant” being extracted given the polarity of stated co-solvent.

We use co-solvents, especially at high percentages to change the critical parameters of the solvent mixture. Our co-solvent is food grade ethanol added in a percentage that varies from 1% to 15%

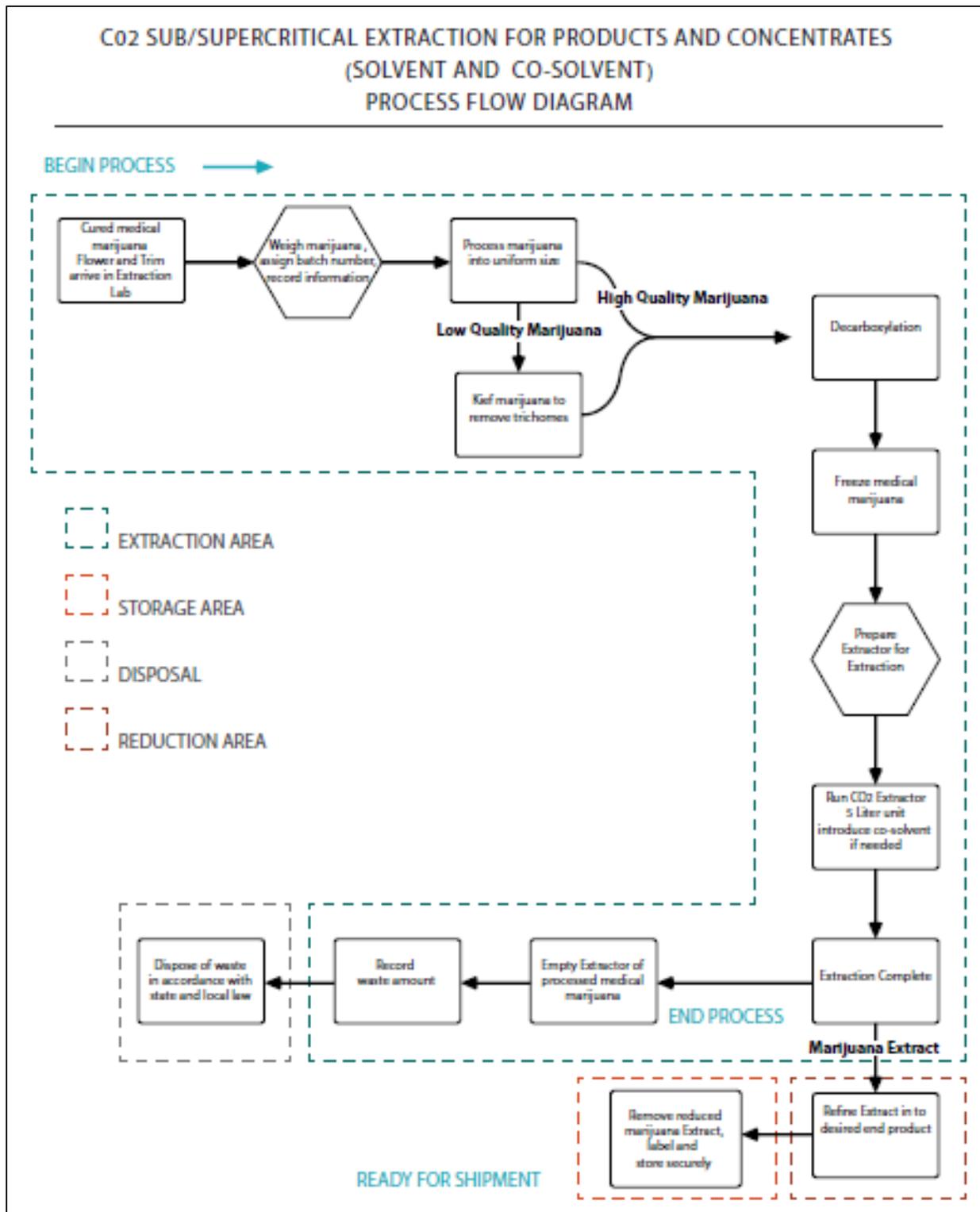
### 4) ADVANCEMENT OF SFE EXTRACTION TECHNOLOGY:

SFE is a technology that allows extraction of a wide range of diverse compounds. Our focus on utilizing, refining and expanding its use insures the best possible medical grade marijuana extracts available in the market.

By focusing our efforts on natural solvents such as CO<sub>2</sub> and food grade ethanol we will continue to provide the most environmentally friendly, medically centered medicinal-grade marijuana extracts to patients. With our focus on “whole plant” extracts we continue to advance the accepted medical focus on the entourage effect, namely that the sum of the plant together offers far more medicinal benefits than a strict isolation and assimilation of any one component of the marijuana plant. Additionally, since SFE adds a new dimension to the pharmaceutical and nutraceutical medicine advancement, its potential technologically and economy provides new, sustainable, and safe marijuana extract based medicine to patients.

*The Process Flow Diagram for Marijuana CO<sub>2</sub> Oil can be seen below:*

# Attachment 12.3





## Attachment 12.3

### -----PACKAGING OF CO<sub>2</sub> OIL-----

#### **PRODUCT DESCRIPTION**

CO<sub>2</sub> Oil packaged in child resistant containers

#### **POLICY**

To prepare and package CO<sub>2</sub> Oil packaged in child resistant containers. All production will be documented.

#### **RESPONSIBILITY**

Production Manager or their designee.

#### **RECORDS**

Production Log

Inventory Tracking Software

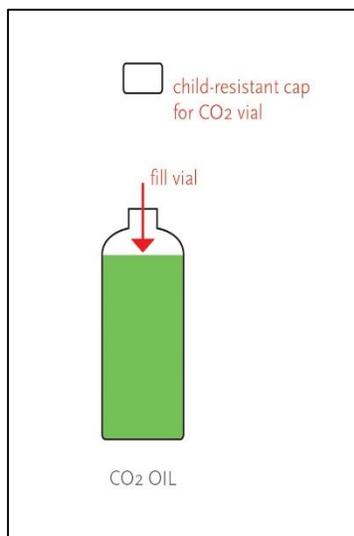
#### **PROCEDURE**

1. Before daily processing begins, sanitize work surface with 50-200 ppm sanitizer solution. Mix 5 gallons of water with 1 teaspoon full of sanitizer in a five gallon bucket. Check the bleach solution with tester strips to ensure proper ppm level. Fill Spray bottle with solution and label as 'Sanitizer' fill a 1 quart sized bucket with sanitizer solution, label as 'Sanitizer' and set a bucket at every workstation. Wipe all work surfaces with sanitizer solution, allow to air dry. Ensure that all utensils are cleaned and sanitized.
2. Assemble filling machine per instructions.
3. Sanitize all containers and droppers. Fill the food grade plastic container with sanitizer solution. Fill perforated insert for food grade plastic container. Fill with containers and caps. Submerge into sanitizer solution for five minutes. After five minutes, remove perforated insert and let drain over plastic container. Move sanitized containers or droppers into dry food grade plastic container and cover with plastic wrap. Place container of sanitized containers, caps or droppers on production line.
4. Sanitize filling machine.
5. Fill an 8 quart container with sanitizer solution and place Small Immersion Blender in sanitizer. NOTE: DO NOT submerge motor.
6. A designated employee shall retrieve CO<sub>2</sub> Oil from the secure storage area and bring to the Production Area.
7. Begin the Production Form - The Production Form is a hard copy record that tracks the marijuana extract, approved non-marijuana ingredients, employees involved, quantity produced and verifies multiple quality control inspections of the medical marijuana product during the production process. In addition to this form, Inventory Tracking software will be used to track all medical marijuana products. To begin: print the production form and fill out manually during production run, enter into digital format by end of production day. Assign a Medical Marijuana Product Batch Number to the production run. Fill in remaining information before beginning the production run: Date and Product Name.
8. Use a NTEP approved scale to measure an accurate amount of marijuana concentrate needed for production.
9. Record in the Production Form and Inventory Tracking Software the amount of marijuana extract used per production run.
10. Quality Control Direct Observation of a Production Tech and Production Manager to be performed and recorded on the Production Form throughout the packaging of the marijuana product. Quality Control Direct Observation provides an ongoing and documented inspection of all products being produced to

## Attachment 12.3

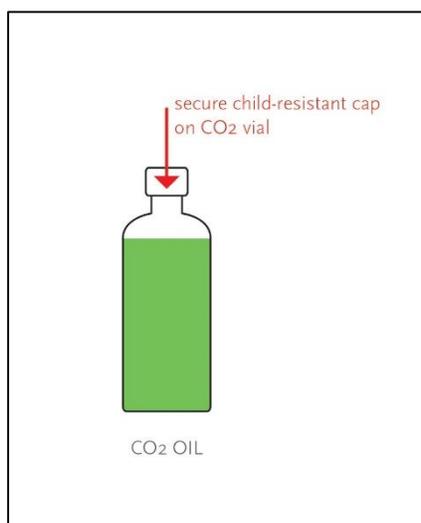
ensure safe and consistent medical marijuana products.

11. Fill CO<sub>2</sub> oil vial using the assembled and sanitized Filler. Proper equipment maintenance and operation will ensure an accurate and consistent quantity of marijuana product.



12. Quality Control Direct Observation of the filled containers will ensure proper quantity amounts of each container to provide a safe and consistent marijuana product.

13. Secure and seal child resistant cap. This step seals the marijuana product ensuring no contamination of the product. Perform and document Direct Observation Quality Control that all marijuana products are properly sealed.



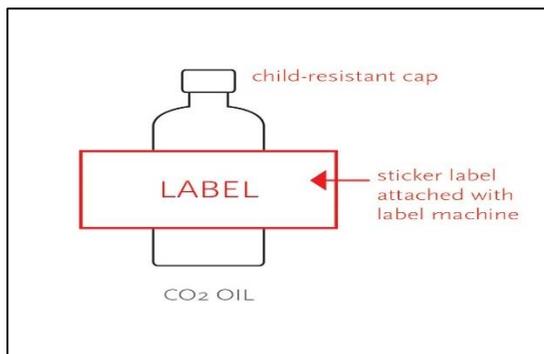
14. Turn power on to the Heat Shrink Tunnel. Set speed control to '3' and Heat control to 180F. For CO<sub>2</sub> oil vial labeling close top 4 heat tunnel vents, leaving only the bottle 2 vents open. Allow 15 minutes for Heat Tunnel to reach temperature. If applicable turn on exhaust fan to remove hot air from production area.

15. Label with tamper evident, opaque shrink-wrap label. Perform and document Direct Observation Quality Control that labels contain all required information. "Sleeve" the bottled product. -- Place shrink wrap label onto



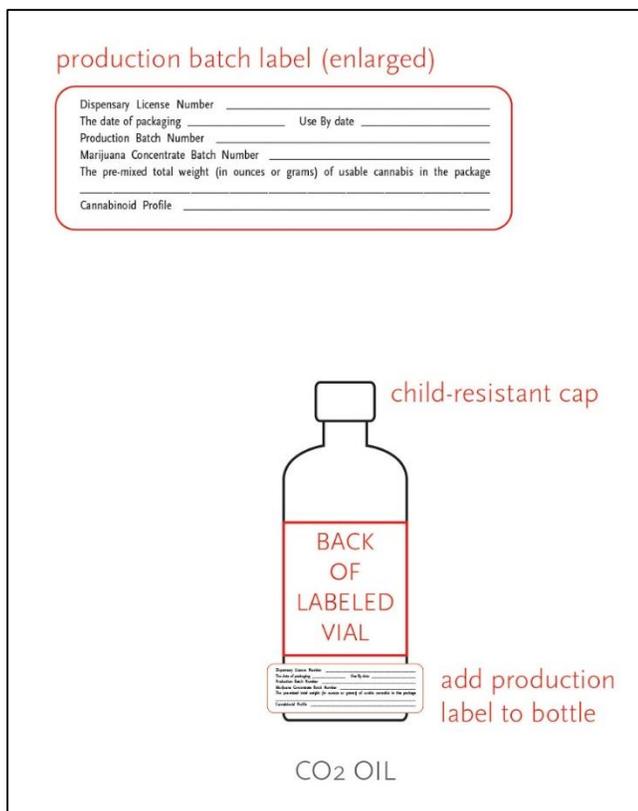
## Attachment 12.3

every filled and capped CO<sub>2</sub> oil vial by sliding the label over the container and positioning the label properly so that front of label is centered on front of bottle.



16. Run Sleeved product through the heat tunnel. Carefully place each unit onto the conveyor belt so that the CO<sub>2</sub> oil vial stays upright. Bottle placement should be so that the front of the bottle faces the left side of the Heat Tunnel. As CO<sub>2</sub> oil vial exit the Heat Tunnel each unit should be Quality Control inspected for tearing, wrinkling, stretching, or improper label placement. Adjust Heat Tunnel controls if necessary. Next. Label products with Production Batch Label.
17. Apply the Production Batch Sticker which will contain the following information:
  - a. Dispensary License Number
  - b. The date of packaging and “use by” date
  - c. Production Batch Number
  - d. Marijuana Concentrate Batch Number
  - e. The pre-mixed total weight (in ounces or grams) of usable marijuana in the package.
  - f. A list of cannabinoid content by weight.

## Attachment 12.3



18. Final Quality Control Inspection of product includes:
  - a. proper label applied correctly
  - b. proper production batch label applied correctly
  - c. dropper cap is applied correctly
  - d. package is clean and dry
  
19. Segregate products found to be damaged and imperfect from the Production Batch. Document the Product Name, Production Batch, Extract Batch, Date, and Reason for Disposal, and Quantity of the marijuana product to be disposed of.
  
20. Once documented, render damaged or imperfect marijuana products unusable and unrecognizable as a marijuana product and dispose of in accordance with state law.
21. Complete the Production Form and enter information into Inventory Tracking Software.
  
22. Select three products from the Production Batch to be sent to a state certified Testing Lab facility for required cannabinoid and contaminant testing. Select one unit that was produced at the beginning of production, one unit towards the middle of production and one unit at the end of production, to accurately represent the consistency of the Production Batch. Provide samples for testing to Shipping Dept. to schedule and deliver samples to the testing lab facility. Final medical marijuana product samples will be submitted to the testing lab facility sealed, packaged and labeled exactly as they will be delivered to a patient from a dispensing facility.
  
23. Move all final marijuana products to a secure storage area within the Production Area to await lab test results.
  
24. Upon receiving approved test results for the marijuana product Production Batch, apply a label to the final product providing the cannabinoid profile. All test results will be recorded in Inventory Tracking Software and associated with the Production Batch. Accurate cannabinoid test results ensure marijuana product is safe and

## Attachment 12.3

consistent.

25. Store the marijuana products in the secure storage area. Products should be stored off the ground, in an organized and clean manner. The secure storage area is to be climate controlled. Use the Refrigerator/Freezer Monitoring Form to record storage area temperature throughout the day.

### -----PACKAGING AND LABELING MANUFACTURED MARIJUANA PRODUCTS-----

**Weighing and Packaging Medical Marijuana**—is the process of accurately weighing the medical marijuana to be put into packages for distribution. Packaging regulations and requirements may vary, so it is essential to reference the state and local laws and regulations pertaining to packaging requirements for medical marijuana business. Use of NTEP certified scales for the weighing of all marijuana products is mandatory.

- All BPH packing will be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
- Packaging must be opaque so that the product cannot be seen from outside the packaging;
- The packaging must be constructed to protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.
- Packages must not contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; providing that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
- Marijuana will be carefully weighed and packaged at the production center. All products will be packaged, recorded into the inventory system, and labeled per Hawai'i regulations.



- Upon marijuana being weighed and packaged registered employees are required to document the marijuana weight associated to the product with a unique attribute number and batch number. This documentation must be done with two registered employees, one employee to make the record in the inventory control system and a second to witness the record.
- Ensure inventory control system is updated to show the packaged marijuana weights and specifications.

It is important for qualifying, registered patients' to understand the importance of packaging and labeling medical marijuana products. Proper packaging and labeling will achieve two primary objectives; 1) the medical marijuana product will be properly labeled to identify who the product is intended for, dosage rates and instruction and other important information pertaining to the patient or the medical marijuana derivative products, and 2) proper child-resistant packaging will help to ensure children cannot easily access the medical marijuana derivative product(s).

#### *Examples of Child-Resistant Packaging:*



## Attachment 12.3

Child Resistant Packaging to be used for pill-form edibles (*capsules*)



Child Resistant Packaging to be used for oils (*for sublingual administration*)



Metered Dosage Packaging to be used for oils (*vaporization administration*)



Tamper-Evident Packaging to be used for pill-form edibles (*capsules*)



Tamper-Evident Packaging to be used for oils (*for sublingual administration*)



Tamper-Evident Packaging to be used for oils (*for vaporization*)



**Labeling**—all packages of medical marijuana will require a label to be conspicuously placed on the package.

- Labels must be made of weather resistant and tamper-evident material
- As a redundancy, registered employees will be required to recheck each package for a label prior to shipping and package containing medical marijuana from the Licensed Premise.
- **Hawaii specific labeling requirements:**
  - Labels must use black lettering only on a white background with no pictures or graphics
  - Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
    - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
    - The concentration of tetrahydrocannabinol or  $\Delta^9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
  - The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
  - The batch number and date of packaging;
  - A computer tracking inventory identification number barcode generated by tracking software;
  - Date of harvest or manufacture and a "use by date";
  - Instructions for use;
  - The phrases "For medical use only" and "Not for resale or transfer to another person";
  - The following warnings:
    - "This product may be unlawful outside of the State of Hawai'i and it is unlawful to possess or use under federal law";
    - "This product has intoxicating effects and may be habit forming";



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- “Smoking is hazardous to your health”;
  - “There may be health risks associated with consumption of this product”;
  - “This product is not recommended for use by women who are pregnant or breast feeding”;
  - “Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug”;
  - “When eaten or swallowed, the effects of this drug may be delayed by two or more hours”
- A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
  - The name of the laboratory that performed the testing

## Examples of manufactured marijuana product labels:

**SAMPLE PRODUCT LABEL: LOTION**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product.

This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**LOTION**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_

DATE OF MANUFACTURE: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: This product may be unsealed outside of the State of Hawaii and is unsealed for possession or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: SALVE**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product.

This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**SALVE**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_

DATE OF MANUFACTURE: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: This product may be unsealed outside of the State of Hawaii and is unsealed for possession or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: SERUM**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product.

This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**SERUM**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_

DATE OF MANUFACTURE: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: This product may be unsealed outside of the State of Hawaii and is unsealed for possession or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

**SAMPLE PRODUCT LABEL: GEL**

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

**INDEPENDENT TESTING LABORATORY IDENTIFICATION**

There may be health risks associated with consumption of this product.

This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

**GEL**

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_

DATE OF MANUFACTURE: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: This product may be unsealed outside of the State of Hawaii and is unsealed for possession or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.



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### SAMPLE PRODUCT LABEL: CAPSULE

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

INDEPENDENT TESTING LABORATORY IDENTIFICATION

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Type of active ingredient (including strength), name of other ingredients, and the amount of each ingredient in the container. List the name of the manufacturer, distributor, and packager. List the name of the state of manufacture. List the name of the state of distribution. List the name of the state of sale.

ALLERGEN LABELING: This product may be packaged outside of the State of Hawaii and is subject to process or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

### SAMPLE PRODUCT LABEL: TABLET

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

INDEPENDENT TESTING LABORATORY IDENTIFICATION

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Type of active ingredient (including strength), name of other ingredients, and the amount of each ingredient in the container. List the name of the manufacturer, distributor, and packager. List the name of the state of manufacture. List the name of the state of distribution. List the name of the state of sale.

ALLERGEN LABELING: This product may be packaged outside of the State of Hawaii and is subject to process or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

### SAMPLE PRODUCT LABEL: TINCTURE

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

INDEPENDENT TESTING LABORATORY IDENTIFICATION

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Type of active ingredient (including strength), name of other ingredients, and the amount of each ingredient in the container. List the name of the manufacturer, distributor, and packager. List the name of the state of manufacture. List the name of the state of distribution. List the name of the state of sale.

ALLERGEN LABELING: This product may be packaged outside of the State of Hawaii and is subject to process or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

### SAMPLE PRODUCT LABEL: CO<sub>2</sub> OIL

The label example shown here is for a child-resistant, tamper-proof/tamper-evident, light-resistant, and resealable packages that minimizes oxygen exposure.

THIS PRODUCT HAS INTOXICATING EFFECTS AND MAY BE HABIT FORMING. Contains no more than using THC for one dose, no more than using THC in container.

When eaten or swallowed, the effects of this drug may be delayed by two or more hours.

INDEPENDENT TESTING LABORATORY IDENTIFICATION

There may be health risks associated with consumption of this product. This product is not for resale or transfer to another person.

Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.

FOR MEDICAL USE ONLY  
SMOKING IS HAZARDOUS TO YOUR HEALTH.

Net Wt: \_\_\_\_\_  
Date of Manufacture: \_\_\_\_\_

NAME OF PRODUCTION CENTER

PRODUCTION BATCH STICKER UNIQUE TO EACH BATCH

INSTRUCTIONS FOR USE: Type of active ingredient (including strength), name of other ingredients, and the amount of each ingredient in the container. List the name of the manufacturer, distributor, and packager. List the name of the state of manufacture. List the name of the state of distribution. List the name of the state of sale.

ALLERGEN LABELING: This product may be packaged outside of the State of Hawaii and is subject to process or use under Federal law.

An inventory tracking barcode for use by tracking software that will match the product with a producer batch and lot number to facilitate any warnings or recalls the Department or producer deems appropriate.

- 1) **Secure, Segregated Storage**—Upon manufactured marijuana products being packaged, BPH registered employees will be required to hold the marijuana in secure, segregated storage until released for distribution
  - o The secure, segregated storage will be within the production center vault(s).



## Attachment 12.4

<b>Standard Operating Procedure:</b> Cultivated Marijuana Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Cultivation Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

### Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

### State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)
  - Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.



## Attachment 12.4

- If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the *Marijuana Waste SOP* upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

### Preparation of Medical Marijuana Samples to be Tested

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Flower/bud—ensure adequate quantity from batch for sampling (~7-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# MIP001 → Create new ‘Sample Package’: MIPT101
- Fill out all required documentation/log sheets
  - *Samples for Laboratory Testing*
  - *Marijuana Product Shipping Manifest*

<u>Marijuana Samples for Laboratory Testing</u>					
Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:



## Attachment 12.4

- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow *Shipping, Transferring/Transporting SOP*

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show medical marijuana potency, cannabinoid profiles, terpene profiles, and contaminants (if any present). The testing laboratory will provide BPH test results from each batch and lot tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meet all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**—there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm$  90-100% of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating

It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.



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- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<b><u>Marijuana Batch Samples for Laboratory Testing</u></b>						
<b>Date Sample Prepared:</b>	<b>Grower Agent #1:</b>	<b>Grower Agent #2:</b>	<b>Product Attribute ID #, Batch# and Strain/Variety</b>	<b>Sample Quantity/Weight:</b>	<b>Test Sample ID # (NEW) :</b>	<b>Receiving Laboratory:</b>
<b>Date Sample Shipped:</b>	<b>Sample Pass Testing</b>	<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>If sample failed testing, will batch be reprocessed or destroyed?</b>		<b>Licensed Processor to Send Batch to:</b>	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed			
<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>			<b>Notes/Details:</b>	
<b>Date of 6-month interval test:</b>	<b>Sample Pass Testing</b>	<b>Certificate of Analysis Provided w/ Supporting Data?</b>	<b>Batch Potency</b>	<b>Batch Purity</b>	<b>Batch expiration date data/support:</b>	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
<b>Notes/Comments:</b>						

### **Release for Distribution**

All batches of marijuana are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH’s registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.

- This process will be completed by two (2) registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

### **Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.



## Attachment 12.5

<b>Standard Operating Procedure:</b> Manufactured Marijuana Product Samples for Laboratory Testing
<b>Purpose:</b> To explain the procedures involved for preparing marijuana and manufactured marijuana product samples for laboratory testing. (Product potency, contaminants, etc.)
<b>Scope:</b> Covers the steps to prepare samples for lab testing.
<b>Initial Training:</b> 2-4 hours

### Documentation Log Sheets Required

- 1) Manufactured Marijuana Products Samples for Laboratory Testing
- 2) Manifest/Trip Plan

### Equipment/Tools Required

- 1) Certified Scale
- 2) Child-Resistant Packaging
- 3) State-Compliant Labels

### **POLICY**

To submit medical marijuana for lab testing.

### **RESPONSIBILITY**

Production Manager, Extraction Manager or their designee.

### **RECORDS**

BioTrackTHC™ Seed-to-Sale Inventory Tracking System and physical documentation log sheets

### **PROCEDURES**

Any medical marijuana sample is tested at the lab for the required cannabinoid profile, contaminants, any pesticide/herbicide/fungicide used during production of the medical marijuana product, and any growth regulator used during production of the medical marijuana product. Test results will be transmitted directly from the Testing Lab to the Extraction Manager. The Extraction Manager will assign the test results to the extraction batch number and document results in inventory tracking software. The accurate cannabinoid profile information will be utilized in the production formulations and standard operating procedures for medical marijuana product production to ensure safe, secure, accurate and consistent cannabinoid dosing and labeling

#### **1. Post-Harvest:**

- a. The first phase of quality control consists of visually inspecting the leaves and flowers of harvested and cured marijuana. Upon approved inspection, samples of the leaves and flowers will be sent to a lab to test for potency and contaminants. A medical marijuana “leaves and flowers sample collection” SOP will be followed. Lab test results will be used:
  - i. to compare against post extraction results
  - ii. to ensure the cultivated and cured marijuana plants are of consistent quality and THC/CBD concentrations
  - iii. to create concentrates of consistent quality.
- b. Uniform and homogenous leaves and flowers samples will be placed within sealed, child-resistant containers. One sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the



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sample to the testing lab. Remaining samples will be kept securely stored for future testing as required.

### 2. Post Processing:

- a. The second phase of quality control will test the extract produced from the leaves and flowers of the marijuana plant. A sample from each lot of extract will be tested to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. A uniform and homogenous sample will be placed within a sealed, child-resistant container. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab.

### 3. Finished Product:

- a. A number of samples, which accurately represent the production lot of the final medical marijuana product, will be selected for lab testing. Cannabinoid profile and contaminant testing will be performed to ensure appropriate and consistent concentrations of cannabinoids are present and identified, such that the extract may be relied upon.
- b. “Final medical marijuana product samples” will be submitted to the testing lab facility, sealed, packaged and labeled exactly as they will be delivered to a patient obtaining the product at a dispensing facility.
- c. The sample will then be transported directly to a lab testing facility. All standard operating procedures for transportation will be followed to ensure secure and safe delivery of the sample to the testing lab. All final medical marijuana products will be kept secured in a limited access area until approved test results are received. No final medical marijuana product will be shipped to a dispensing facility until approved lab test results are received and the final marijuana product is labeled with test results.

### Principles of Samples for Laboratory Testing

Samples of medical marijuana that have been cultivated/produced will need to be sent off for 3<sup>rd</sup> party laboratory testing pursuant to State of Hawaii regulations. State-licensed 3<sup>rd</sup> party laboratories will perform lab tests on provided samples to determine the content of the medical marijuana, the potency, the presence of any contaminants or health hazards, cannabinoid profile, terpene profile, etc.

### State of Hawaii Regulations

BPH will be required to select and utilize an independent testing laboratory that has adopted a standard operating procedure to test medical marijuana that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

- BPH will select an independent testing laboratory meeting the above requirements
- The Commission should have a list of licensed testing laboratories that will meet the requirements
  - BPH will select an independent testing laboratory from Commission list (*if applicable*)

BPH will select and utilize an independent testing laboratory to obtain samples of each batch. The independent testing laboratory utilized by BPH will:

- Obtain samples of a batch according to a statistically valid sampling method
  -
- BPH will require an independent testing laboratory to analyze the samples according to:
  - The most current version of the marijuana inflorescence monograph published by the American Herbal Pharmacopoeia (AHP) which can be viewed using the hyperlink provided
    - [http://www.stcm.ch/files/us-herbal-pharmacopoeia\\_marijuana-monography.pdf](http://www.stcm.ch/files/us-herbal-pharmacopoeia_marijuana-monography.pdf)



## Attachment 12.5

- Or through a scientifically valid methodology that is equal or superior to that of the AHP monograph.
- BPH will perform random audits and checks on the independent testing laboratory to ensure the lab is follow their standard operating procedure to confirm or refute the original result in the event of a test result which falls out of specification.
  - Audits of selected independent testing laboratories are to be conducted at a minimum every six (6) months
  - Audits are to be performed by BPH registered employees or retained professional audit companies with experience of this nature.
  - If the 6-month interval sample test results fall out of specification an audit and inspection of the independent testing laboratory will ensue.
- BPH will need to interact with the independent testing laboratory to issue a certificate of analysis.
  - A certificate of analysis with supporting data for each batch must be issued
    - This will include but not be limited to the sample test results showing the tests meets all specifications for the variety.
    - Certificate should indicate independent testing laboratory and registered grower agent approval for release for distribution
    - Testing laboratory should also provide supporting data for the sample test such as graph, charts and analysis of the sample showing purity and potency of the sample.
- Work with BPH to destroy the remains of the sample of medical marijuana after analysis is completed.
  - BPH will supply the independent testing laboratory with documentation log sheets and procedures for the shipment of test samples requiring destruction.
  - BPH will take possession of test samples requiring destruction and hold the samples in secure storage until receiving approval from the Commission to destruct and dispose of the test samples.
  - BPH will destroy test samples according to the ***Marijuana Waste SOP*** upon receiving Commission approval.
- Help to identify and establish expiration dates for the medical marijuana.

### **Preparation of Medical Marijuana Samples to be Tested**

BPH will send a sample of every production batch and lot to a State-licensed independent testing laboratory to perform State-required tests.

- Prepare individual samples for testing from medical marijuana
  - Collect samples for testing from each production batch
    - Manufactured marijuana products—ensure adequate quantity from batch for sampling (~2-14 grams)
    - You will need to prepare four (4) test samples per production batch
      - Two (2) samples to send to the laboratory for testing
        - One of this samples will be retained in the need of a re-test
      - Two (2) samples will be maintained at the licensed premise for potential future testing.
- Create a new ‘package’ for the test sample.
  - Create a ‘sample package’ from the original product package
  - Test sample will now have its own unique Attribute ID # that was created from the original product package with its own unique Attribute ID #
    - Original Package: Attribute ID# MIP001 → Create new ‘Sample Package’: MIPT101
- Fill out all required documentation/log sheets
  - ***Samples for Laboratory Testing***
  - ***Marijuana Product Shipping Manifest***



## Attachment 12.5

<u>Marijuana Samples for Laboratory Testing</u>					
Date:	Employee preparing Sample:	Attribute ID #/Product Batch #/Strain:	Sample Weight/Quantity:	Sample Attribute ID # (NEW):	Receiving Laboratory:



- Send test samples to the 3<sup>rd</sup> party laboratory/testing facility
  - Follow *Shipping, Transferring/Transporting SOP*

**Laboratory Test Results**—upon testing medical marijuana samples from the testing laboratory will provide the test results back to BPH. Test results will show marijuana product potency, cannabinoid profiles, terpene profiles, contaminants (if any present). The testing laboratory will provide BPH test results from each batch tested and provide graphs, charts and/or spectra from laboratory instrumentation.

**Certificate of Analysis**—the independent testing laboratory will issue a certificate of analysis with supporting data if the sample passes all required testing. This will include but not be limited to the sample test results showing the tests meets all specifications for the variety. Every certificate of analysis will need to be retained on site.

- **Expiration Date**—expiration dates are used to express the shelf life of a particular product, for BPH expiration date will need to be assigned to all medical marijuana. Upon review of the certificate of analysis and a determination that a batch meets the specification for the variety, registered employees will be required to assign an expiration date to the batch.
- **Determining Expiration Dates**— there are typically no expiration dates required by US Federal regulation, except for infant formula. There is currently also no uniform or universally accepted system for marijuana expiration dating in the US or Hawaii.
  - BPH will determine marijuana product expiration dates by first assigning an expiration date of a 1-year expiration date from the date of product packaging.
  - The expiration date will include the day, month and year of expiration.
  - Expiration date will also be followed or preceded by a statement or phrase explaining the expiration date such as “sell-by” or “use before”.
- **Evaluating Expiration Dates**—Expiration dating will be evaluated during required 6-month interval testing’s performed by an independent testing laboratory.
  - The testing laboratory will test retention samples from the production batch for purity and potency to compare against the original production batch test sample.
  - Production retention sample’s purity and potency will need to fall within a range of the original production batch test sample in order for the expiration date to be confirmed.
    - Purity and potency range for retention test sample must fall within  $\pm 90-100\%$  of the purity and potency of the original production batch test sample.
    - If the purity and potency level of the production retention sample does not fall within the required range of potency and purity of the original production test sample then the assigned expiration date will be reevaluated and re-determined.

**Frequency of Testing**—BPH will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals. This is done for two reasons:

1. To ensure product potency and purity
2. Provide support for expiration dating



## Attachment 12.5

It will be paramount to keep and properly store an adequate amount (~7-14 grams) of each released batch of medical marijuana in order to achieve this frequency of testing. See preparation of samples instructions noted in previous content.

**Sample Storage**—BPH will retain a sample from each batch released. The sample will be sufficient enough to provide for follow-up testing if necessary and the sample will need to be properly stored for a minimum of one (1) year past the date of expiration of the batch.

- Samples from each batch released to be retained for a long period of time will be vacuum-sealed to limit oxygen exposure to the medical marijuana as oxygen will degrade the sample quicker.

**Retention of Laboratory Test Results**—BPH will retain all laboratory test results for each batch and lot of medical marijuana tested for a minimum of five (5) years on-site within the Licensed Premise. Laboratory test results will be maintained within a lockable filing cabinet located in a limited-access area on the Licensed Premise.

- BPH will retain every certificate of analysis within secure storage in a limited access area of the Licensed Premise.

**Laboratory Test Results for Inspection/Review**—BPH will make all marijuana laboratory test result available for inspection and/or review to the Department upon request. BPH will produce said test results for Commission inspection/review within 48 hours of request.

<b><u>Marijuana Batch Samples for Laboratory Testing</u></b>						
Date Sample Prepared:	Grower Agent #1:	Grower Agent #2:	Product Attribute ID #, Batch# and Strain/Variety	Sample Quantity/Weight:	Test Sample ID # (NEW) :	Receiving Laboratory:
Date Sample Shipped:	Sample Pass Testing		Certificate of Analysis Provided w/ Supporting Data?	If sample failed testing, will batch be reprocessed or destroyed?		Licensed Processor to Send Batch to:
	<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Reprocessed <input type="checkbox"/> Destroyed		
Batch Potency	Batch Purity		Batch expiration date data/support:		Notes/Details:	
Date of 6-month interval test:	Sample Pass Testing	Certificate of Analysis Provided w/ Supporting Data?	Batch Potency	Batch Purity	Batch expiration date data/support:	
	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO				
Notes/Comments:						

### **Release for Distribution**

All batches of marijuana products are to remain in secure storage until the batch successfully passes all required testing, the batch is determined to meet all the specifications of the variety and BPH's registered employee has receipt of certificate of analysis and supporting data.

Upon samples passing all independent laboratory testing and the samples determined to have met the specifications of the variety, the marijuana or manufactured marijuana product batch being held will be cleared for release and distribution.

**Inventory Control Revision**—upon releasing the batch for distribution, registered employees are required to revise the status of the batch in the inventory control.



## Attachment 12.5

- This process will be completed by two (2) register registered employees for redundancy.
  - One grower agent will revise the status of the batch within the inventory control system
  - The other grower agent will witness the revision to the inventory control to ensure the record is accurate.
- Once the medical marijuana batch has been released and the status revised in the inventory control, registered employees will be authorized to distribute the medical marijuana batch.

### **Failure to pass Laboratory Testing**

Marijuana and manufactured marijuana products will not be released for distribution if the sample does not pass laboratory testing. Upon receipt of test results that do not meet specifications, BPH may choose to rework, reprocess or destroy and dispose of the batch according to standard operating procedures. Upon reworking or reprocessing the batch will be resampled and retested by an independent testing laboratory to ensure that all required specifications are met.

## Attachment 12.6

<b>Standard Operating Procedure:</b> Packaging and Labeling
<b>Purpose:</b> to educate and train registered employees on BPH packaging and labeling requirements within the production center
<b>Scope:</b> Covers the packaging and labeling activities within the production center.
<b>Initial Training:</b> TBD

- 1) **Weighing and Packaging Medical Marijuana**—is the process of accurately weighing the medical marijuana to be put into packages for distribution. Packaging regulations and requirements may vary, so it is essential to reference the state and local laws and regulations pertaining to packaging requirements for medical marijuana business. Use of NTEP certified scales for the weighing of all marijuana products is mandatory.
- All BPH packing will be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
  - Packaging must be opaque so that the product cannot be seen from outside the packaging;
  - The packaging must be constructed to protect the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product.
  - Packages must not contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; providing that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
  - Marijuana will be carefully weighed and packaged at the production center. All products will be packaged, recorded into the inventory system, and labeled per Hawai'i regulations.



- Upon marijuana being weighed and packaged registered employees are required to document the marijuana weight associated to the product with a unique attribute number and batch number. This documentation must be done with two registered employees, one employee to make the record in the inventory control system and a second to witness the record.
- Ensure inventory control system is updated to show the packaged marijuana weights and specifications.

### *Examples of Child-Resistant Packaging:*



- 2) **Labeling**—all packages of medical marijuana will require a label to be conspicuously placed on the package.



## Attachment 12.6

- Labels must be made of weather resistant and tamper-evident material
- As a redundancy, registered employees will be required to recheck each package for a label prior to shipping and package containing medical marijuana from the Licensed Premise.
- **Hawaii specific labeling requirements:**
  - Labels must use black lettering only on a white background with no pictures or graphics
  - Information on the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
    - Net weight in ounces and grams or volume; and for manufactured marijuana products, also the physical weight of the marijuana used to produce the manufactured marijuana product;
    - The concentration of tetrahydrocannabinol or  $\Delta 9$  tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A and cannabidiol;
  - The dispensary licensee's license number and the name of the production center where the marijuana in the product was produced;
  - The batch number and date of packaging;
  - A computer tracking inventory identification number barcode generated by tracking software;
  - Date of harvest or manufacture and a "use by date";
  - Instructions for use;
  - The phrases "For medical use only" and "Not for resale or transfer to another person";
  - The following warnings:
    - "This product may be unlawful outside of the State of Hawai'i and is unlawful to possess or use under federal law";
    - "This product has intoxicating effects and may be habit forming";
    - "Smoking is hazardous to your health";
    - "There may be health risks associated with consumption of this product";
    - "This product is not recommended for use by women who are pregnant or breast feeding";
    - "Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug"; and
    - "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"
  - A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
  - The name of the laboratory that performed the testing

### Equivalent Weights for Manufactured Marijuana Products

#### **Assessment of the pre-mixed total weight (in ounces or grams) of usable marijuana contained within in an extract, oil, or infused product.**

The pre-mixed total weight of usable marijuana contained in an extract, oil or infused product is determined by the amount of marijuana plant material used to make the marijuana extract or oil. To determine the amount of usable marijuana in an infused product the additional step of determining the amount of extract or oil used to make an infused product is necessary.

Equivalency of marijuana flower or trim to extract, oil or infused product can vary due to several variables;

1. The tetrahydrocannabinol (THC) content of the marijuana flower or trim.
2. The THC content of the extract or oil produced from marijuana flower or trim.
3. The amount of THC infused into the infused product.

The average tetrahydrocannabinol (THCa) percentage of medical marijuana flower ranges from 15 - 19%. THCa is the form of THC found within the marijuana plant material. THCa is the non-psychoactive bio-synthetic precursor to THC. THCa must be decarboxylated to become bioavailable to the human body and is done so in the production of some extracts an oil and with all infused product production. During decarboxylation the THCa loses carbon and oxygen molecules, and about 12.3 percent of its weight. This must be taken into account when determining the usable weight of marijuana found in extract, oil, or infused products.

Extraction efficiency for CO2 Sub/Supercritical Extract and Oil average from an average between 60% - 80%. This range provides an estimated average total of 70% of the total THC milligrams available within the plant will be



## Attachment 12.6

extracted. The oil or extract is then lab tested to determine the exact amount of active cannabinoids in the product. These lab results are then used to determine how much in weight or volume of the extract or oil is to be used in the infused product formulation. Infused products are measured in activated milligrams of THC. No more than 10 milligrams THC per dose. No more than 100 total THC milligrams per package.

Projected extracted milligrams of THC per gram of plant material based on average extraction efficiencies of yield and THC percentage:

1. Beginning plant material THC % is 15%.
2. Extraction efficiency is 70%.
3. Infused Product is to contain 10 milligrams of active THC

Example: of 1 gram of medical marijuana = 1000mg Total Weight

- A. The medical marijuana is 15% THC the total available THC milligrams within that one gram is 150 milligrams. ( $1000\text{mg} \times 15\% = 150\text{mg}$ )
- B. The CO2 Extraction efficiency is equal to 70% total amount of THC milligrams extracted 105 mg THC per gram of plant material.
- C. 105 mg of THC will produce 10.5 units of 10 mg THC infused products.
- D. 1/10 gram would be the pre mixed total weight of usable marijuana contained within the infused product.



### **Application Response Question 13**

In compliance with §11-850-20 (13), the owners of Blue Planet Healing LLC (“BPH”) have never had a business license revoked. All BPH owners enjoy business success and are role models in their respective industries as can be seen from the personal profiles provided as attachments to our application. (See Attachment “13.1”)

### **Blue Planet Healing LLC—Organization Members**

#### **Sole Applicant—Henk Rogers**

Considered one of the visionaries of computer games, Henk Rogers helped change the face of the industry when he brought the Tetris® game to the United States and world markets. Under Mr. Roger’s direct leadership, the Tetris game has become one of the world’s top-selling video game brands with hundreds of millions of products sold; after 30 years since its “birth” that number is still growing. Today, Henk serves as Managing Director of The Tetris Company, the exclusive licensor of the Tetris brand and Chairman of Blue Planet Software, the sole agent for the Tetris franchise. In addition, Henk is the founder of Blue Startups, Hawai‘i’s first venture accelerator, as well as the founder of the Blue Planet Foundation, a nonprofit clean energy advocate.

Determined to help facilitate an end to the use of carbon-based fuel on the planet, starting with fossil fuel use in Hawai‘i, his adopted home, Henk established Blue Planet Foundation, which has become the frontline organization in the fight for indigenous renewable energy in Hawai‘i. As Blue Planet Foundation's principal and visionary philanthropist, Henk is committed to the mission of stewarding the environment by developing non-carbon, clean energy sources. In 2015 Henk founded Blue Planet Energy Systems, becoming a leader in energy storage systems.



### Application Response Question 13

Henk is an Honorary Consul to the Kingdom of the Netherlands to Hawaii. He also serves as Chairman of Pacific International Space Center Exploration Systems (PISCES). Henk is also a board member of the East West Center.

### **Maya Rogers Kiyomura—Chief Executive Officer**

Maya Rogers Kiyomura is Chief Executive Officer (“CEO”) for Blue Planet Healing, LLC and President and CEO of Blue Planet Software, the sole agent for the Tetris® brand. Maya has spent the last eight years leading the Tetris brand’s worldwide business initiatives. Prior to Tetris, Maya steered cross culturalization and development efforts with Sony Computer Entertainment America and American Honda. In 2012, Maya co-founded Blue Startups, Hawai‘i’s first venture accelerator that helps early stage startups with investments and mentoring. Fifty companies have gone through the Blue Startups program, received capital from the Blue Ventures Fund, and attracted approximately [REDACTED] in funding. In March 2015, Blue Startups placed #17 in TechCrunch’s annual ranking of top US accelerators.

Maya is a board member with the American Red Cross Hawai‘i Chapter, and is a National Council Member of the Tiffany Circle Society of Women Leaders, a national Red Cross program comprised of women leaders and philanthropists. Maya also serves as a member of the advancement committee and advisory board of the Smithsonian Asian Pacific American Center. She has recently joined the board of the Women’s Fund of Hawaii, which supports the empowerment of women and is a member of the U.S.-Japan Council, which is dedicated to strengthening U.S.-Japan relations.

In January of 2015, Maya was chosen by Pacific Business News as one of the top 12 “Women to Watch” recognition, as part of the Women Who Mean Business Awards. In March 2015, Maya was awarded “20 for the Next 20” recognition by Hawai‘i Business Magazine as one



### Application Response Question 13

of 20 emerging leaders who have made major contributions to the state of Hawai‘i and are expected to have a significant impact on the state over the next two decades. Maya, a Dutch national, grew up in Japan and the US, and currently resides in Hawai‘i. She holds a B.S. in Business Administration and an MBA from Pepperdine University.

#### **Andrew Salini – Chief Compliance Officer**

Andrew has acted as the Chief Operations Officer & Chief Strategist at High Country Healing’s Retail & Cultivation Facilities from 2014 to present. Andrew’s management experiences include HCH operations, retail/cultivation/financial strategy and analytics, as well as brand and business development. Formerly, Andrew was the Chief Strategist at EMF Fixed Income Fund from 2011-2014, specializing in fixed income relative value arbitrage. He was also previously an Associate at Credit Suisse in the Fixed Income Division of the investment bank from 2010-2011 and began his career at Deutsche Bank Securities where he was an Associate Proprietary Trader and Portfolio Manager in the Global Finance & Foreign Exchange Division from 2006 to 2009. Andrew received an A.B. in Economics, a Certificate in Finance, and a Certificate in French Language & Culture from Princeton University in 2006.

#### **Bill Meyer – General Counsel**

Bill’s license to practice law has never been revoked nor suspended, nor has he been subjected to any disciplinary action. Bill has been practicing law in Hawai‘i, and has been in good standing with the Hawai‘i BAR Association since 1979. For more than three decades, Mr. Meyer has provided creative legal and business guidance to a broad spectrum of clients both in Hawai‘i and on the mainland. Mr. Meyer was selected for inclusion in “Hawai‘i Super Lawyers” in intellectual property (2008 through 2015) and is peer review rated “AV” (preeminent) by Martindale-Hubbell, the highest rating available for legal ability and professional ethics.

# **Attachment 13.1**



## **Blue Planet Healing LLC (“BPH”) Profiles**

### **Henk Rogers—Sole Applicant, Chairman & Spokesperson**

BPH’s individual applicant, Henk Rogers ("Henk") is an internationally recognized entrepreneur, philanthropist and community leader who was recognized as Hawai‘i’s 2015 CEO of the Year. A longtime resident of Hawai‘i who studied computer science at the University of Hawai‘i, Henk has skillfully assembled a dynamic group of individuals with the necessary education, training, skills and real life experience necessary and advisable to start and successfully operate a business that will accomplish the statutory goals of HRS Chapter 329D.

Considered one of the visionaries of computer games, Henk Rogers helped change the face of the industry as the entrepreneur responsible for bringing the Tetris® game to the United States and world market. Under Henk’s direct leadership, the Tetris game has become one of the world’s top-selling video game brands with hundreds of millions of products sold, and after 30 years since its “birth,” that number is still growing. Today Rogers serves as Managing Director of The Tetris Company, the exclusive licensor of the Tetris brand and Chairman of Blue Planet Software, the sole agent for the Tetris franchise, founder of Blue Planet Foundation, a nonprofit clean energy advocate, and founder of Blue Startups, Hawai‘i’s first venture accelerator.

A heart attack in 2005 gave Henk the opportunity to rethink the rest of his life and reevaluate the purpose of his life’s work. Henk is determined to end the use of carbon-based fuel on the planet, starting with fossil fuel use in Hawai‘i, his adopted home. To fulfill his mission, Henk established Blue Planet Foundation, which has become the frontline organization in the fight for indigenous renewable energy in Hawai‘i. As Blue Planet Foundation's principal and visionary philanthropist, Henk Rogers is committed to the mission of stewarding the environment through developing non-carbon, clean energy sources. He is personally devoted to helping our planet reduce and eventually eliminate its dependence on fossil fuels.

Furthermore in 2015, Henk founded Blue Planet Energy Systems, becoming a leader in energy storage solution systems home and commercial usage.

Henk’s community recognitions include:

- 2015 – Hawai‘i Business Magazine, CEO of the Year
- 2015 – Honorary Doctorate of Human Letters, University of Hawai‘i
- 2014 – Hawai‘i Institute for Publish Affairs (HIPA) Ho‘ulu Award
- 2013 – Hawai‘i Business News Business Leadership Award Finalist
- 2011 – Hawai‘i Business Innovation Showcase “City & Council of Honolulu” Finalist
- 2010 – Hawai‘i Business Magazine “Five for Today” leadership recognition
- 2009 – Hawai‘i Venture Capital Association “Entrepreneur of the Year”
- 2008 – Hawai‘i Venture Capital Association “Venture Capital Deal of the Year” Honorable Mentioned – Avatar Reality

### **Maya Rogers—Chief Executive Officer**

Maya Rogers ("Maya") will be the CEO of BPH. For the last several years she has helmed Blue Planet Software, one of Hawai‘i’s most successful high tech companies, through the highly complex and competitive high-tech world with international sophistication and a sense of local pride and style. As the Business Development Manager of Blue Startups, Hawai‘i’s premier Business Accelerator Organization and a 2015 top 20 US Accelerator, Maya assists and trains promising start-up entrepreneurs to compete on a global scale using a mentor driven model that reaches networks throughout Hawai‘i, Asia and Silicon Valley.

## **Attachment 13.1**

Maya Rogers Kiyomura is President and CEO of Blue Planet Software, the sole agent for the Tetris® brand. With a history that spans more than 30 years, Tetris is one of the leading and most distinctive video game brands and franchises in the world. Rogers has spent the last eight years leading the Tetris brand's worldwide business initiatives, including and more than 12 years in the video game industry in Japan, China and the U.S. Prior to Tetris, Rogers steered cross culturalization and development efforts with Sony Computer Entertainment America and American Honda.

In 2012, Maya co-founded Blue Startups, Hawai'i's first venture accelerator that helps early stage startups with investments and mentoring. Fifty companies have gone through the Blue Startups program and received capital from the Blue Ventures Fund, and have attracted approximately \$25 million in funding. In March 2015, Blue Startups placed #17 in TechCrunch's annual ranking of top US accelerators.

Prior to Tetris, Maya held management roles with Sony Computer Entertainment America, where she steered localization efforts for games such as the Gran Turismo and Hot Shots Golf franchises. Rogers began her career working with cars at American Honda before making the switch over to working on virtual cars at SCEA.

Maya is a board member with the American Red Cross Hawai'i Chapter, and is a member of the Tiffany Circle Society of Women Leaders, a national Red Cross program comprised of women leaders and philanthropists who dedicate their time and talents to support community Red Cross efforts. Rogers also serves as a member of the advancement committee and advisory board of the Smithsonian Asian Pacific American Center. She is also actively involved in eGlobal Family, an organization that links orphaned and vulnerable children in developing countries to compassionate and responsible supporters.

In March 2015, Maya was awarded "20 for the Next 20" recognition by Hawai'i Business Magazine as one of 20 emerging leaders who have made major contributions to the state of Hawai'i, and are expected to have a significant impact on the state over the next two decades. In 2016, Pacific Business News honored Maya with the Women to Watch recognition.

Maya grew up in Japan and the US, and currently resides in Hawai'i. She holds a B.S. in Business Administration and an MBA from Pepperdine University.



## **High Country Healing (“HCH”) Company Profile**

### **High Country Healing Overview**

- Medical Cannabis Cultivation and Dispensing since 2009
- Opened 2 of Colorado's first 20 recreational cannabis dispensaries on 1/1/2014
- Corporate mission statement is to sustainably grow some of the world's premier pharmaceutical grade cannabis for the connoisseur. Compassion, Caring, and Education are core values of High Country Healing (HCH)... as highlighted by the HCH's Free CBD oil program for those with a dire medical need, Sommelier ("Interpening") and Compliance training for all staff.
- Currently operating 3 medical and 3 recreational dispensaries: Vail, Silverthorne, Alma, and CO Springs (multiple locations)
- Currently operating 4 cultivation facilities, the largest is 22,000 square feet (organic soil and various hydroponic techniques)

## **Attachment 13.1**

- Grows over 60+ varieties of high quality pharmaceutical grade cannabis, including rare CBD-rich genetics
- CBD oil program provides free CBD-oil to cancer patients and those suffering from various forms of epilepsy, auto-immune diseases, chronic pain syndrome, PTSD etc.
- *High Times* Magazine's (leading cannabis culture magazine) most featured dispensary brand of all time (known for exceptional flower quality).
- As featured in *The Cannabist*, MSNBC's *Pot Barons*, *The Denver Post*, *The Guardian* (UK), *Skiing*, *Powder*, and *Ski Magazines*, *Yo Beat*, *Dope Directory*
- Perfect record of compliance spanning 6-years of constant and significant regulatory change with zero security issues. Certificate of good standing.
- One of Colorado's first dispensary chains to formally train staff and receive RVT (Responsible Vendor Training) Status
- Rigorously complies and exceeds all security protocol required by the state of Colorado.

### **Andrew J. Salini – Chief Operating Officer - Operations, Finance, & Strategy**

- COO & Chief Strategist at High Country Healing's Retail & Cultivation Facilities, 2014-Present
- *Management*: HCH operations, retail/cultivation/financial strategy & analytics, brand, and business development
- Formerly, Vice President, Strategist & Portfolio Management at EMF Fixed Income Fund, \$500mm AUM, 2011-2014
- Associate, Credit Suisse Fixed Income Strategy & Research, 2010-2011
- Associate, Deutsche Bank Securities, Global Finance & Foreign Exchange, Proprietary Trader & Portfolio Manager, 2006-2009
- Received a A.B. in Economics, Princeton University, 2002-2006
- Received Certificates in both Finance and French Language & Culture from Princeton University, 2002-2006
- Academic All-American in Baseball, Princeton Baseball's All-time hits leader, & 3-time Ivy League Champion
- Graduated, Phillips Academy Andover, 2002

#### **Andrew Salini Narrative Resume**

Mr. Salini graduated Princeton University in 2006 with a degree in Economics, with certificates in Finance and French Language & Culture in 2006. He was also a 4-year letterman and starter for the Varsity Baseball team, where he was part of 3 Ivy-League Championship teams ('03, '04, '06) making 3 College World Series Tournament appearances. Mr. Salini also holds the all-time record for most hits in a career in Princeton baseball history.

Following graduation, Mr. Salini started his career in investment banking as an Associate at Deutsche Bank in the Global Finance and Foreign Exchange division where he worked until 2009. His responsibilities included portfolio management and proprietary trading of fixed income derivatives and currencies. From 2010 to 2011, Mr. Salini joined the Credit Suisse Fixed Income team in their investment bank before transitioning to the hedge fund business as the lead Strategist

## **Attachment 13.1**

for EMF, a fixed income relative value fund with as much as ██████████ where he worked until 2014 before joining High Country Healing.

Mr. Salini developed a niche in finance through his ability to distill the quantitative nuances of the fixed income markets. His professional experience has thus always focused on the details and intricacies of a highly complex and highly regulated market place. This detail-orientation and meticulous approach to work made him a natural fit to step into the COO role at High Country Healing. His role has included overseeing and optimizing all operations and compliance functions and offering market analysis and strategy to help steer HCH through the tumultuous waters of ever-changing regulatory landscape of this blossoming new cannabis industry.

As a researcher by training, Mr. Salini took a deep dive into the medicinal benefits of cannabis following conversations with Mr. Brown in 2009. His resulting conviction sparked a desire to be a part of the movement to share the wonderful healing powers of this giving plant with the world to help end suffering. After losing his mother to breast cancer in 2009 after a 10 year battle, and seeing the deleterious and lingering effects of cancer on his father, he joined the HCH team in 2014 and has not looked back since.

## **William G. Meyer, III —General Counsel**

Mr. Meyer began practicing business law in Hawai`i in 1979. His practice emphasizes intellectual property law (including copyright, trademark and right of publicity licensing and registration, entertainment, trade secret, art and advertising matters); government relations; real estate matters; and related dispute resolution including litigation, arbitration and mediation.

For more than three decades, Mr. Meyer has provided creative legal and business guidance to a broad spectrum of individuals, companies and educational institutions, both in Hawai`i and on the mainland, including intellectual property owners, licensors and licensees such as artists, writers, photographers, television and film producers, composers, software and game developers, publishers, advertisers, broadcasters, art gallery owners, entertainers, recording artists, musicians, record labels, architects, scientists, apparel designers and merchandisers. Mr. Meyer's clients have included the University of Hawai`i at Mānoa, the University of Hawai`i at Hilo, national and international entertainment companies and many of Hawai`i's top recording artists, record labels and filmmakers.

Mr. Meyer's government relations work has promoted the diversification of Hawai`i's economy through the adoption of legislation which has enhanced the development of the creative and high tech industries. Mr. Meyer's real estate related practice has focused on the resolution of complex disputes involving real estate development and sales transactions, land use, eminent domain, construction defects, government bid disputes and real estate broker issues.

Mr. Meyer has taught at the William S. Richardson School of Law, University of Hawai`i at Mānoa; the Pacific New Media Workshop, University of Hawai`i at Mānoa; and the Hawai`i Music Institute at Windward Community College and served as a court appointed mediator for the United States District Court for the District of Hawai`i in connection with intellectual property issues. Mr. Meyer is past Chair of the Intellectual Property & Technology Section of the Hawai`i State Bar Association, and a frequent speaker on intellectual property, music, art, advertising, e-commerce and Internet law topics, and has authored numerous articles and other materials on these topics, including continuing legal education materials for the Hawai`i State Bar Association and other organizations and publishers. Mr. Meyer was selected for inclusion in the 2008, 2009, 2010, 2011, 2012, 2013, 2014 and 2015 "Hawai`i Super Lawyers" in intellectual property and is peer review rated "AV" (preeminent) by Martindale-Hubbell, the highest rating available for legal ability and professional ethics.

## **Attachment 13.1**

Mr. Meyer is active in community organizations dedicated to the promotion of literacy, the preservation of Hawai`i's host culture and the arts, devotes time to a pro bono practice which assists creative individuals with their legal and business issues and mentors young lawyers interested in the creative industries. Mr. Meyer has served on the Board of Governors of the Hawai`i Academy of Recording Arts, a Hawai`i non-profit organization, which each year presents the "Nā Hōkū Hanohano Awards" (which is similar to the Grammy® Awards and recognizes outstanding achievement in the recording arts in the State of Hawai`i) and the annual Lifetime Achievement Awards (which honors those who have made significant contributions to the music, culture and related arts of Hawai`i and/or the host culture of Hawai`i). See <[www.nahokuhanohano.org](http://www.nahokuhanohano.org)>. Mr. Meyer also serves on the Board of the Kaua`i Music Festival, the oldest and largest songwriters conference in the State of Hawai`i (see <[www.kauaimusicfestival.com](http://www.kauaimusicfestival.com)>) and acts as special counsel to the Hawai`i International Film Festival.