

Question E-6

As part of our continuing commitment to ensure the highest level of security for the patients, product and public, TWG will conduct due diligence on all persons defined below (See Appendix I) that are involved in any way with the company, to include initiating the required criminal background checks, fingerprinting and conducting eCrim checks. TWG will additionally conduct polygraph examinations of certain individuals as warranted to ensure that the company has received truthful responses to our requests for information.

In conformance with §11-850-17, §329D-12, §329D-15, §329D-16 and §846-2.7, HRS, TWG's Director of Security, Mr. Shannon Kawakami, a retired HPD officer (See Appendix II) will be personally responsible to TWG's CEO Robert Kauffman to:

- A. Coordinate with all those listed in Appendix I to obtain completed and signed background checks authorization documentation; completed fingerprint cards; and cause the company to pay the required applicable processing fees to the DOH or its designee.
- B. Implement and utilize TWG's internal tacking system and secure record keeping system to track and document the status of all pending background check requests, fingerprinting and payment of fees for all those listed in Appendix I to ensure adequacy of qualification under this section.
- C. Conduct and document the initial eCrim check, and quarterly checks thereafter, for all those listed in Appendix I to ensure adequacy of initial and continued qualification under this section, and report disqualification immediately in writing to the CEO and DOH within the same day.
- D. Provide a quarterly recertification authorization form to all those listed in Appendix I to ensure timely reporting of disqualifying activity.

E. Participate as Director of Security, along with the Director of Compliance & Training, Mr. James Miller, a retired U.S. Navy Master Chief (See Appendix III) as part of the human resources selection and hiring team to ensure TWG's hires the best possible and most reliable candidates to work in this highly regulated industry. TWG's security and compliance managers have extensive experience and training in conducting interviews, interrogations, investigative practices and behavioral sciences that will assist the hiring team in selecting excellent candidates to minimize the threat of infiltration of the criminal element and ensure security for the company, its employees, patients and the public.

F. Conduct periodic, but at least semi-annually, informational training in coordination with TWG's Director of Compliance to: (1) advise all those listed in Appendix I of the requirement to immediately report disqualifying activity to the Director of Security or the CEO; (2) educate TWG personnel and consultants on the requirements of §329D-15 and §329D-16 for the access to the production centers and retail dispensing locations and for maintaining required record keeping, among many other requirements specified in the sections; (3) conduct other periodic compliance and security training for new and onboard employees and consultants. Training will be comprehensive to include all security policies, such as those security SOPs related to background investigations, the safe transportation of product or currency, armed takeover or robbery of facilities or personnel, detection of fraud, theft and diversion of product. Security and Compliance personnel will train retail dispensary employees to ensure that State regulations regarding facility/dispensary admittance, usage, authorization, etc. are followed and will ensure employees understand how to act immediately to terminate any illegal or improper activity. TWG security employees will also receive training and mentorship by members of the ABcann/UB team who have a long and successful record of experience and excellence in the

management and implementation of security requirements and regulations that are extremely extensive in the Canadian regulatory system. ABcann/UB will further assist TWG in creating additional security SOPs, policies and procedures.

In conclusion, TWG is profoundly aware of the extensive and detailed requirements that the DOH expects in the area of security, and in particular the stringent requirements for background checks. TWG's Board of Managers and the CEO, Robert Kauffman, a retired FBI executive (See Appendix IV), have in fact already implemented a higher standard than the regulations require and we have rejected the request for ownership from five investors who had State of Hawaii criminal misdemeanor and petty misdemeanor convictions for such offenses as criminal contempt of court and driving under the influence of liquor or had a pending misdemeanor or other charge. TWG is committed to upholding the highest standards in conducting a medical marijuana dispensary in Hawaii. TWG has secured exceptionally qualified management personnel and has aligned itself with strong and knowledgeable international consultants to incorporate best practices to ensure the safety and well-being of our patients, employees, consultants, shareholder/owners and the general public.

SECTION E
QUESTION 6
APPENDIX I
Background Checks



Appendix I - Question E-6

(a) The following are subject to **background checks** conducted by the department or its designee:

- (1) The individual applicant or licensee;
- (2) All officers, directors, shareholders with at least twenty-five percent ownership interest or more, members, and managers of an entity applicant or licensee;
- (3) Each employee of a dispensary;
- (4) Each subcontractor of a dispensary;
- (5) All officers, directors, shareholders with at least twenty-five per cent ownership interest or more, members, and managers of a subcontracted production center or retail dispensing location;
- (6) Each employee of a subcontracted production center or retail dispensing location;
- (7) Any person permitted to enter or remain in dispensary facilities pursuant to sections 3290-6, 3290-15, and 3290-16, HRS; and
- (8) Agents of any of the above persons.

(b) A person subject to background checks as provided in subsection (a) shall be disqualified as an individual applicant or licensee, be disqualified as an entity applicant or licensee, be prohibited from entering a dispensary, and be prohibited from having any responsibility for operating a dispensary if the person:

- (1) Has a felony conviction

- (2) Has a conviction related to use, possession, or distribution of drugs or intoxicating compounds;
 - (3) Has a conviction for a crime involving violence;
 - (4) Has a conviction for a crime involving a firearm;
 - (5) Has a conviction for a crime involving theft, or business or commercial fraud; or
 - (6) Has any other background history that the department finds would pose a risk to the health, safety, or welfare of the public or a qualifying patient, considering the nature of the offense, the time elapsed since the offense occurred, and evidence of rehabilitation.
- (c) Each person undergoing a background check shall provide written consent and all applicable processing fees to the department or its designee to conduct the background check.
- (d) All dispensary licensees shall have written policies and procedures on conducting and maintaining current background checks on all of the persons listed in subsection (a) which shall include but not be limited to notifying the department immediately of any arrest or conviction for an offense listed in subsection (b).

SECTION E
QUESTION 6
APPENDIX II

Shannon Kawakami - CV



Shannon Kawakami

- *Field Supervisor and Desk Sergeant, Honolulu Police Department*
- *Marijuana enforcement, regulation and site safety expert*

A 29-year veteran of the Honolulu Police Department, with numerous written commendations, Shannon Kawakami has been recognized as a highly specialized expert in the area of marijuana regulations, site safety, and enforcement.

During his career with HPD, Kawakami has spent 18 years working on plainclothes criminal investigations, often targeting drugs and narcotics. From 2005 to 2012, he was specifically assigned to HPD's Narcotics/Vice Division, as head of the Marijuana Eradication Team, the only law enforcement team in the state dedicated solely to marijuana enforcement. In this capacity, he worked directly in the investigation and prosecution of illegal marijuana cultivation, possession and distribution, and oversaw compliance with rules governing medical marijuana.

As HPD's top marijuana officer, Kawakami developed an intimate knowledge of state and federal marijuana and drug laws. He was also responsible for the department's presence on marijuana issues at the state legislature, a role that required him to closely monitor all proposed marijuana bills, draft HPD's response, and be available to provide expertise to lawmakers and respond to questions.

Kawakami has also worked closely with all county police departments, the state Department of Land and Natural Resources, and the state Narcotics Enforcement Division, and collaborated on drug cases with the federal Drug Enforcement Agency the Federal Bureau of Investigation. He served on the multi-agency Statewide Marijuana Eradication Task Force and the DEA-funded Domestic Cannabis Eradication/Suppression Program.

Kawakami's specialized skills include safety certifications for working in and around indoor grow operations. This training teaches law enforcement officers to spot dangerous conditions in grow houses, such as elevated levels of carbon dioxide, electrical and chemical hazards, and toxic mold. Kawakami is recognized as an expert on the subject, and has provided training on grow house and lab safety to law enforcement groups across the state. He also helped develop and run HPD's training program for helicopter safety and wilderness medical response. The program initially provided training to all of Honolulu's marijuana officers, and was eventually expanded to include all county police departments and the DLNR.

Outside of his work in marijuana enforcement, Kawakami has given drug awareness and prevention talks to numerous schools and community groups.

SECTION E
QUESTION 6
APPENDIX III

James Miller - CV



James Miller

- *Training Officer, Commander Submarine Force U.S. Pacific Fleet*
- *Former U.S. Navy Command Master Chief*
- *Thirty-year Navy veteran serving aboard and supporting submarine missions*

In his 30-year career in the U.S. Navy, James Miller has gravitated toward human resources roles, finding his calling in helping sailors succeed in the challenging job of working aboard submarines.

In his new role as the training officer of the Commander Submarine Force U.S. Pacific Fleet, Miller oversees training programs for more than 12,000 Navy personnel on 52 nuclear powered submarines. He is responsible for determining what training is needed for each vessel, ensuring that the correct number of crew members receive the training that is required for their specific mission and equipment, and monitoring training programs to ensure they are teaching exactly the skills that are needed. He also administers a \$2.6 million annual training budget, and is responsible for ensuring the funds are spent appropriately.

Miller previously served as a U.S. Navy Command Master Chief (CMC), where he was responsible for the administrative, medical, maintenance, logistical, legal, religious and personal support for the crews of 19 fast-attack submarines based at Pearl Harbor, as well as all visiting foreign, ballistic-missile and guided-missile submarines. During his tenure from 2012 to 2015, Miller developed and executed a program to monitor and ensure that all submarines were appropriately staffed to cover all required job skills. He also conducted drop-in evaluations of submarines at sea to review their operations and make sure they were following correct procedures and complying with the directives of their missions.

From 2009 to 2012, he served aboard the USS OHIO (SSGN 726(B)) as Chief of the Boat (COB). In this role, a seasoned enlisted sailor serves as advisor to a submarine commander who may have less sea time. Miller worked closely with his commanding officer to develop plans for the execution of their mission, participated in troubleshooting, oversaw employee and training programs, managed a training budget of over \$100,000, and was especially responsible for monitoring and advocating for the morale and welfare of up to 300 enlisted sailors. Miller previously served as Chief of the Boat (COB) for the USS PASADENA (SSN 752) from 2002 to 2006

As force career counselor for the Commander Submarine Force U.S. Pacific Fleet, Miller led a team of 76 human resource managers and oversaw human resources programs for 16,000 personnel in eight locations around the world. Improving employee retention was a major initiative during his 2006-2009 tenure. Miller developed an Unplanned Loss Program to reduce the number of employees leaving their positions early. By creating stress management programs, changing

orientation programs to better prepare sailors for life at sea, and pairing sailors new to submarines with seasoned mentors, the program reduced employee losses by 3 percent.

Miller joined the U.S. Navy in 1985. With the exception of a tour as chief recruiting officer at Bryan-College Station in Houston, Texas, he served most of his early career as a junior enlisted man with submarine sonar crews, culminating with a position as sonar Chief of an 18-man division aboard the USS OLYMPIA (SSN 717). In 2000, he accepted a position as sonar evaluator and ARCI development team member for the COMSUBPAC TRE team at Pearl Harbor. In this role, he was responsible for the development and implementation of training programs for the Navy's new sonar system. He developed a certification program for all Pacific Fleet submarines, created a course to train employees to maintain and troubleshoot the equipment, oversaw a \$100,000 training budget, and developed employee guidelines for the system.

Outside of his professional life, he is active in the community, serving on the board of the Hawaii LGBT Legacy Foundation and chairing the Honolulu Pride and Corporate Sponsor Committees.

SECTION E
QUESTION 6
APPENDIX IV

Robert Kauffman - CV



Robert Kauffman

- *Founder and consultant, Robert Kauffman Consulting, LLC*
- *Twenty-three year Federal Bureau of Investigation (FBI) veteran*
- *Experienced in investigation, operations, security and compliance*

A 23-year FBI veteran who oversaw field office operations and the review and update of agency investigative policies, Robert Kauffman is now a consultant who advises companies on operations, security, compliance, and law-enforcement issues.

Kauffman received his law degree from Thomas M. Cooley Law School in Lansing, Michigan, in 1987, and joined the FBI that same year. After receiving a [REDACTED]

[REDACTED] position as supervisory special agent in the FBI's Honolulu Field Office.

In this role, he supervised a squad of 14 agents, four intelligence analysts, three Hawaii National Guard counter-drug analysts, and five administrative support staff investigating Asian organized crime, drug trafficking and money laundering. He also helped organize Hawaii's first High Intensity Drug Trafficking Area Task Force, a multi-agency group that brought together the U.S. Attorney, local prosecutors, DEA, ATF, federal marshals, U.S. Coast Guard, immigration and customs enforcement, secret service, and local police, with a mission to collect intelligence and investigate organized crime, drug trafficking and gangs in Hawaii.

He moved on to a position as assistant inspector and team leader of the Inspection Division at FBI headquarters in 2000. Here he was responsible for the inspection of the operation of numerous FBI headquarters entities, field offices and legal attaché offices, to ensure they were complying with legal, regulatory, policy, and reporting requirements.

Two years later, he was promoted to assistant inspector of the Inspection and [REDACTED]

[REDACTED] was responsible for identifying and overseeing 65 special agents and other personnel; coordinating logistical support for a covert operation; managing a multi-million-dollar annual budget; and briefing senior members of the FBI, Department of Justice and the U.S. Congress. Kauffman took over management of the entire operation upon the departure of the inspector-in-charge in 2004. A year later, the team received the director's annual award for outstanding counterintelligence investigation.

As assistant special agent in charge of the Honolulu Field Office, a position to which he was promoted in 2006, Kauffman oversaw all criminal investigative and

intelligence operations, including drug trafficking, criminal enterprise, violent crime, organized crime, white-collar crime, public corruption and cyber crime. He was also responsible for the management of more than 200 employees in Honolulu, Maui, the Big Island, Guam, Saipan, and American Samoa. Kauffman managed the field office budget; was responsible for administrative matters like hiring and promotion, physical security of the office and personnel, collection and disposal of evidence, management of automobiles and aircraft, and overseeing secure and encrypted communications on three computer systems. Additional responsibilities included serving as crisis event manager, on-scene crisis manager, SWAT on-scene commander, aviation program manager and evidence response team program manager.

In 2008, Kauffman was asked to take the lead in streamlining and standardizing 15,000 pages of outdated policies guiding the FBI's investigative procedures, consolidating the confusing and sometimes contradictory mish-mash of guidelines into an 800-page policy "bible" outlining the steps for every kind of investigation, from wiretaps to obtaining bank records. As program manager assigned to the FBI director's office, Kauffman worked with the Department of the Attorney General and led a core team of eight people, supported by hundreds of subject-matter experts, to complete the policy overhaul. Kauffman continued to lead this effort as a consultant, overseeing the creation of a second and third edition of the policy, after moving to the private sector and accepting a position at Deloitte Consulting and Sava Workforce Solutions in 2011.

Since 2012, Kauffman has worked as an independent consultant as the founder of Honolulu-based Robert Kauffman Consulting LLC. Here he advises private businesses on issues including assessing and planning for the physical security of facilities and employees, fraud detection and prevention, data and information security, and compliance monitoring and oversight.

Outside of his professional life, Kauffman's community involvement includes serving as treasurer and director of the Hawaii LGBT Legacy Foundation.

Question E-7

TWG will be securing BioTrackTHC (BTT) for its seed to sale software vendor. (See Appendix I) BTT has been in the industry for over six years and has been providing a safe and secure system designed to meet the regulatory requirements set-forth by the state of Hawaii. Additionally, BTT will be user-friendly for qualified patients and employees. The system has all the necessary regulatory requirements for inventory tracking, security and sales limits for qualifying patients.

A. Secure Inventory Control and Tracking

BTT ensures all authentication is encrypted via industry standard SSL and hardware is managed and maintained internally. As with any system involving patient data, security is a top priority. Each BTT client utilizes the latest SSL encryption technology to ensure a secure operating experience. All technology supporting remote access to the BTT based solution can be described as fully secure and founded on current industry standards of strong authentication, encryption and HIPAA Compliance. Regardless of network connection type being wired/wireless or commercial/government ISP, the connection state is always encrypted end-to-end from browser to web server using SSL. Database connections are also encrypted via standard authentication + SSL. At no point in the network path will data be unencrypted.

B. Inventory Tracking

The BTT system is comprised of several components, all of which are designed to seamlessly integrate with one another. Recognized as the industry leader in seed-to-sale tracking, the BTT producer, processor and retail tracking components are completely interoperable with one another. Whether the tracking requirements include plants, trimmings, waste, conversion, dispensing or anything in between, the BTT system, in concert with its unique inventory typing system, can currently track anything the industry allows by law.

TWG will electronically track all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State. This will 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.

Within “Sales Limits” a BTT user can regulate the permissible quantities allotted to a patient or caregiver. The system stores patient purchases and cross-references with any DOH defined limits. As the system will be recording every transaction, this data can be parsed, filtered and reported against at any time. The system can also issue stop purchase alerts if a patient attempts to exceed said defined limits and disallow the completion of such a sale.

C. Real-time data Transfer

BTT’s commercial software provides seamless data exchange integration between a licensee and the state’s marijuana tracking system. There will be integration via the application program interface (API) between the registered organization’s BTT enterprise system and the state interface utilized by the DOH. This will allow data to be sent in real time, not only from the registered organization to the state, but it will allow the registered organization to retrieve transferred data by the DOH.

D. Risk Mitigation

In the event of a breach or failure of its tracking system, a TWG would suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall immediately notify the DOH upon any breach or failure and again when it resumes operations. Fortunately, in the event of a loss of internet access, BTT has the ability to operate in offline mode.

E. Patient Safety through Rigorous Product Testing and Accountability

TWG places patient safety as a top priority to ensure compliance with Chapter 11-850 and Sections 329D-8, 329D-10 and 329D-11, HRS. Specifically, after the designated validated laboratory has tested the product and the Quality Assurance (QA) person has approved the lot/product for sale, the sample test results are entered into the system and the system applies those results to the original lot from which the sample came. Only if the inventory item has a status of “Passed QA” can it be placed on a manifest. No product is sold without being released by the QA as acceptable for “sale.”

SECTION E
QUESTION 7
APPENDIX I

Bio TrackTHC
Seed to Sale Software





1/26/2016

Robert Kauffman
The Wellness Group

Reference: BioTrackTHC Support Document

Dear Robert,

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 The Wellness Group 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



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

§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:
 - (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.

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 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 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.

(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)
 - (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:
 - (a) Unprocessed and Processed Materials: 104 CFU/g
 - (b) 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
- (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, 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";
- (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 recommended 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.

Question E- 8

Protecting and safeguarding a qualifying patient's personal health information (PHI) is TWG's ethical and legal obligation. Confidentiality applies to protected patient information, including basic identifiers of the patient's past, present, or future physical or mental health conditions, including the provision of products and payment for those products. TWG respects the Federal laws outlining privacy and security regulations to protect against the improper use or disclosure of PHI and to reasonably limit uses and disclosures to the minimum necessary to accomplish their purpose (HIPAA, 2003). All employees will be required to sign a confidentiality agreement to protect PHI information to comply with TWC's privacy policy.

Under HIPAA's Security Rule, the standards for the protection of electronic information are divided into three groups: (1) Administrative safeguards (Sanction Policy and Security Awareness Training), (2) Physical safeguards and (3) Technical safeguards. TWG administration will ensure employees receive instruction regarding the disciplinary actions to occur if qualifying patients had a privacy breach, and security awareness training for all employees, agents, and contractors. Based on job responsibilities, TWG will develop a customized education program that focuses on issues regarding use of health information and responsibilities regarding confidentiality and security. From a physical and technical perspective TWG will operationalize protections by addressing the technical and non-technical safeguards for "electronic protected health information" (e-PHI).

The HIPAA privacy and security regulations require a privacy officer and security officer to be designated by the organization, and these roles will be assumed by TWG's Compliance and Security Directors. Together they will continually analyse and manage risk by thoroughly assessing potential risks and vulnerabilities and implementing related security measures.

TWG employees will understand and respect the need for patient confidentiality and only use patient's information for completing an order, obtaining payment and/or for specified operational purposes like improving the quality of service. The following steps will ensure patient confidentiality: (1) Once the product is within the automated inventory system, TWG will be ready to transfer the product to the dispensary for qualifying patients, who will have their own secured profile for ordering their marijuana products. Any documentation by third-party entities can be directly scanned into the tracking system for quick auditability and access while secured hardcopies will be stored in a locked filing cabinet in the PSR's office; (2) Discarded patient information will be shredded; (3) PSR's will have unique log in passwords required to access their patient files; (4) No unauthorized individual will have access to patient files; (5) All staff will sign a confidentiality agreement stating their obligation to protect the privacy and confidentiality of patient information including: name, physical or psychological condition, emotional status, financial situation, demographic information and ordering preferences; (6) Staff will be mindful of their surroundings when discussing patient information; (7) All confidential papers, reports and data will be maintained in a secure place; (8) Confidential papers will be retrieved immediately from fax machines, copiers, mailboxes, conference rooms and other publicly accessible locations; and (9) Technology, such as fax machines and e-mail, will be used only for patient support activities. No patient information will be sent in any form to attorneys, employers or patients absent a subpoena or court order (See Appendix I – SOP Employee Confidentiality Requirement)

TWG will use BTT for record retention of patient data including purchases and medical information that is voluntarily offered by the patient. Each patient is assigned a unique customer ID (10 hexadecimal character) for every client record when the record is created that is known

only to the PSR. The PSRs will maintain confidentiality of a qualifying patient's medical condition, health status and purchases of marijuana or manufactured marijuana products. All electronic patient information will be protected by TWG and stored in locked files in hardcopy and encrypted.

The retail dispensing operations, which have been modelled after the standards of practice for a pharmacy, will follow the same principles to protect the patient's right to confidentiality. Health related information about qualified patients, in both the electronic and paper records that carry PHI are the property of the dispensary, but will be privacy protected. TWGs dispensary pharmacist will only use or disclose PHI with the consent of the patient and will only collect and use PHI for the purposes of providing their services. Where dispensary employees have access to PHI collected and stored by the pharmacist, the pharmacist will ensure all staff are aware and trained on the dispensary privacy policies to protect the information and rights of the patient.

The dispensary's service area will be designed for privacy. The dispensary's countertop area where patients will interact with the Pharmacists will be segregated by partitions so that patients can consult and complete their medical marijuana transaction in privacy. In addition, the TWG dispensary facility will offer a separate patient education area where patients or caregivers can privately consult with dispensary representatives. The enclosed education area will be accessible from the waiting area as well as the dispensary area. When patients arrive at the dispensary they will enter the facility from one side of the building, through a secured and monitored double-door entry vestibule where TWG security personnel will record patient, caregiver or community member identification before entry into the waiting area. All persons in the waiting area will have visible identification badge distinguishing patients and caregivers.

SECTION E
QUESTION 8
APPENDIX I

Standard Operating Procedures:
Employee Confidentiality Requirements



Question E-9

TWG will use only the services of a laboratory that meets all state requirements and regulations for all required testing of materials in process or finished product intended for sale as outlined in Subchapter 7 of the Regulations. TWG's primary objectives are patient safety, product safety, and public safety and to that end TWG will only release products for sale that meet the specifications detailed in the Subchapter. Furthermore the TWG Quality Assurance Department (QAD) will ensure that the independent laboratory's state certification is current and the laboratory is ISO/IEC 17025:2005 (or a state approved equivalent) accredited for at least the scope of testing required by the state of Hawaii.

Our partner ██████████ Inc. is an ISO/IEC17025:2005 accredited laboratory currently providing independent third party testing for the dispensaries in Massachusetts and Maine. Their potency tests include eleven (11) cannabinoids and thirty (30) terpenes. Safety testing currently includes, microbiological screening including, yeast & mold, aerobic and anaerobic bacteria, *e.coli*, salmonella & listeria; Mycotoxin screening for both ochratoxin and aflatoxins; and Heavy metals and pesticide screenings are also done.

Chris Hudalla PhD, CSO has 25 years analytical chemistry and chromatography experience. The state of Maryland worked with Dr. Hudalla to write their current testing and sampling protocols. These are being reviewed by an FDA working group as a model of national standards. We have developed validated methods for our marijuana tests and use calibration curves and reference standards, maintenance and calibration schedules and detailed record keeping.

We understand and currently work with the realities of the details of release testing requirements, methods, equipment, limits of detection, statistically valid sampling, the complexity of different matrices, stability and shelf life studies along with appropriate sample methods and packaging that ensures the integrity of the sample, its condition and protection from subsequent contaminations. The assessment experience will ensure that the lab we work with will have the highest standards.

██████████ has developed chain of custody documents and protocols as a mission critical process of sample testing and have successfully implemented the Commonwealth of Massachusetts requirements for medical marijuana dispensaries and laboratory use. Every dispensary sample goes through an acceptance protocol including verification of weights under video observation and then update the manifest and chain of custody documents. Both the party giving up the sample and party receiving the sample are identified, and those employees must complete, sign and date the chain of custody documents. Copies of the completed transaction documents are made for each party. The form must accompany any sample until the sample is tested. Completed chain of custody documents are then filed.

After the samples are tested, Certificates of Authenticity will be returned. It is imperative all test results numbers be verified with the physical sample. Those results need to be interpreted correctly and with a critical eye to ensure the certificate matched the sample.

TWG advisory team through TWG partner ABCann/UB based in Canada includes QA personnel familiar with cGMP, GLP, and ISO/IEC 17025:2005. Under the Canadian regulations the licensed producer's Quality Assurance Person must ensure that the laboratory the producer uses for its finished product testing must have validated methods and essentially show evidence of Good Laboratory Practices (See Appendix I – SOP Supplier Selection).

The experiences of both [REDACTED] and ABcann/UB uniquely give TWG a complete understanding of the workings of ISO 17025 laboratory requirements and practices in medical marijuana testing.

SECTION E
QUESTION 9
APPENDIX I

Standard Operating Procedures:
Supplier Selection



Question E-10

A. Signage: No signage will be visible from the exterior other than a single sign no greater than one thousand six hundred square inches that bears only the business name in text without any pictures or illustrations. If any other ordinance restriction outdoor signage is more restrictive, that law or ordinance shall govern.

B. Packaging: The external packaging will have convenient sizes available to allow for immediate identification and tracking purposes. The packages containing all products will be packed to avoid any stresses during transportation, protect the product and be in compliance based on current regulations. Characteristics of the packaging (external and immediate) include:

- 1) Child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
- 2) Opaque outer packaging so the product contents are not visible;
- 3) Protects the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product;
- 3) Contains no more than ten (10 mg) milligrams tetrahydrocannabinol for one dose, servicing, or single wrapped item/ provided 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 (100 mg) of tetrahydrocannabinol per pack or container;
- 4) Maintains the integrity of the product during shipping;
- 5) Provides the ideal storage conditions for the product; and
- 6) Contains the required information on the label.

C. Labelling: TWG has chosen BioTrackTHC (BTT) for its seed to sale software. BTT's label creation tool enables TWG to create custom container-client labels with any fields necessary to comply with state law. All aforementioned required fields can be added as

variables. In addition to this we can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale. The name and address of the recipient, the quantity purchased, the product name, potency, batch number, and lot number of the product can all be recorded for each distribution. Packaging will include: 1) Information about the contents and potency of the marijuana and manufactured marijuana product will include: (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; and (b) The concentration of tetrahydrocannabinol or $\Delta 9$, tetrahydrocannabinol, total, tetrahydrocannabinol and activated, tetrahydrocannabinol-A and cannabidiol; 2) The dispensary licensee's license number and the name of the production centre where marijuana in the product was produced; 3) The batch number and date of packaging; 4) The package includes a globally unique and non-repeatable 16-digit barcode number to ensure the batch can be tracked by the facility 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 the State of Hawaii 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"; (e) "This product is not recommended for use by women who are pregnant or breastfeeding"; (f) "Marijuana can impair concentration, coordination and judgement. Do not operate a vehicle or machinery under the influence of this drug"; and (g) "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"; 9) A disclosure of the type of extraction

manufactured marijuana product; and 10) The name of the laboratory that performed the testing. (See Appendix I – SOP Printed Materials Label Development).

Labels for medical marijuana and medical marijuana products will contain only black lettering on a white background with no pictures or graphics and will include the information noted in paragraphs 1-7 will appear on the package and the remainder 8-10 will appear on a package and/or label insert. No marijuana or manufactured marijuana product will be labelled organic unless permitted by the U.S. Department of Agriculture in accordance with the Organic Foods Production Act. The labels for each package of products containing marijuana will be printed using a thermal transfer printer. The thermal transfer process occurs not on the substrate, but on the ribbon. Heat from the print head melts the ink in the ribbon and transfers the indelible ink directly onto the substrate. The labels will be water-resistant and ideal for packaging designed to contain medical marijuana, and tamper-evident material prevents removal.

D. Chain of Custody of Products: TWG will utilize BTT to electronically track 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 production facilities, dispensary facilities and between all production and/or dispensary facilities and a third-party State authorized laboratory. The BTT system is comprised of several components, all of which are designed to seamlessly integrate with one another. BTT producer, processor and retail tracking components are completely interoperable with one another.

Whether the tracking requirements include plants, trimmings, waste, conversion, dispensing or anything in between, the BTT system, in concert with its unique inventory typing system, can currently track anything the industry allows by law.

SECTION E

QUESTION 10

APPENDIX I

Standard Operating Procedures:
Printed Materials Label Development



Question E-11

TWG will adhere to all requirements regarding secure disposal and destruction of marijuana and marijuana products as the DOH or other state departments issue them and will establish standard operating procedures (SOP's) for all aspects of their destruction and disposal activities as outlined in Subchapter 3 11-850-43 of the regulations. TWG will also comply with any Drug Enforcement Administration (DEA) requirements issued to them for the disposal of marijuana or marijuana products. Security measures will include: storage of waste marijuana and waste marijuana products in areas with video surveillance, controlled access to those areas, the keeping of waste inventories and tracking of waste movement and transport through chains of custody and shipping manifests. TWG will also ensure proper training of all employees with regard to all SOPs and security measures necessary for avoiding diversion during all stages of waste handling and processing. TWG will track waste inventories using BioTrackTHC (BTT) that allows for inventory adjustment resulting from both non-sales operational activities (such as disposal, wastage, moisture loss, mistakes and inventory audits) and external factors (such as testing and seizure by law enforcement).

Additionally TWG will employ a waste management plan that includes: identifying and sorting of waste streams, recycling and reuse of supplies as appropriate, using local service providers for disposal of certain types of waste and employing on-site facilities for destruction of marijuana and marijuana products. While not operating a waste facility for outside clients TWG will nonetheless abide by the directives and intentions of HAR 58.1 and specifically develop its plan in such a way to ensure: a) there is no pollution of the drinking water supply or waters of the state; (b) no air pollution or nuisances occur and no diseases are spread; (c) the public's and

employees' health and safety are protected; (d) natural resources are conserved and beauty and the quality of the environment are enhanced where possible



Waste marijuana material will originate from various activities and locations. The bulk of waste will be generated at the production buildings and to a lesser degree waste due to product failure or product expiry will be generated at the dispensaries. Waste marijuana may also be returned to TWG from independent laboratories. All marijuana waste once generated will be recorded by (weight) and type in the BTT system in the same manner as any other marijuana inventory until it is destroyed.



determined (e.g. personnel not trained properly, SOP not clear, employees too rushed).

Subsequent corrective and preventative actions (CAPA) will then be taken to resolve the

problem and avoid future occurrences. Any discrepancies indicating diversion will be reported immediately to the appropriate state and federal authorities. Containers for transporting waste marijuana material will be uniformly colored or marked for easy identification as waste marijuana containers and they must also be labeled with a permanent unique identifier for tracking and linking to content lists on the COC's and manifests. They must be able to be securely closed during transport and as per regulations regarding shipping, only appropriately security cleared personnel working in pairs are allowed to transport these containers. Marijuana wastes generated in the production facility will be collected and weighed in the collection containers (also uniquely identified for tracking).

All marijuana waste is taken to the Waste Processing Room and special refrigerated, secured storage bins under video surveillance are available if waste cannot be processed immediately; waste weights must still tracked in BTT. In the case of packaged marijuana material (e.g. moldy flowers) contents can be dumped into the bins at this point and the packaging material sorted into the appropriate waste stream

mechanically shredded and/or otherwise prepared for acidic anaerobic fermenting (digesting) all in the designated area after which it is added to the digesters (that are also uniquely identified for tracking purposes). The digesters are securely closed and may be stacked as necessary in the designated area. The weight of the waste marijuana added to the digesters is recorded in the BTT system as Digesting Waste. Waste marijuana is designated as Destroyed and removed from the TWG marijuana inventory after the approximately two-week fermentation period.

B. Waste Management Plan summary for TWG: A comprehensive waste management plan will be developed by TWG to deal with all types of wastes generated by its operations. Given the number of uncertainties inherent in a new industry, the likelihood of legislative changes and new consumer demands, this plan must allow for flexibility, contain viable options, and room for innovation. Nevertheless key considerations and practices will be maintained to ensure compliance with state rules and achieve the best possible waste management solutions. Moreover where possible TWG will endeavor to reuse materials and supplies to reduce its waste generally.

One of the first steps in waste management is to identify and sort waste streams. Waste generated by TWG and its operations can be roughly divided into the following 4 categories:

1. Common recyclable (paper, glass, plastics, cans, etc.) sorted at source and processed by a local recycling facility;
2. Non-recyclables and general trash requiring disposal by non-specialized service providers;
3. Special or hazardous wastes requiring disposal by specialized service providers (a. laboratory wastes including sharps, glass and metals, b. waste solvents and other chemicals, c. computer and digital technology waste, and d. production/industrial and construction wastes); and
4. Compostable materials including marijuana waste that can be fully processed by TWG or partially processed and sent to a green waste composting service provider for finishing.

TWG has obtained lists of local providers for the first three streams of waste and will accordingly establish accounts with the providers as we goes into operation. It intends to handle the fourth waste stream internally and has considered options such as vermiculture and aerobic

composting. However, its current plan is to use mechanical shredding (as applicable) followed by acidic anaerobic fermentation known as the Bokashi-cycle System (See Appendix I – Bokashi MMJ Waste Bokashi Protocol). This system has a good history with the medical marijuana industry and large scale production facilities: the fermenting process can be accomplished indoors, is relatively odour free, and safe from methane or other noxious gas buildup such as H₂S. The biochemical action is essentially one of pickling so putrefaction does not take place. Regardless, TWG will conduct air quality tests, take all necessary measures (including obtaining necessary permits from the DOH Clean Air Branch) and implement mitigations as necessary. However, it is our understanding that mitigation is not needed provided that chemical fertilizers and petroleum pesticides are not used on the source material. TWG will not be using chemical fertilizers, pesticides or synthetic excipients for its product lines.

After two weeks the fermented material is exposed to air and mixed with soil where it finishes. If local composting service providers are allowed to accept the material TWG may enter into an agreement with one of them. Alternatively, TWG may finish the waste on its property, and in that case would again obtain any permit deemed necessary and implement all necessary testing and mitigation measures such as: routine monitoring and testing to ensure no local water reserves or waterways would be contaminated; monitoring for nuisance odor and other off gasses and mitigating appropriately (adding more soil, additional amendment, liming etc.) or alternatively enclosing the process and implementing appropriate scrubbers or air filters. If TWG is unable to use the composted product internally and choses to sell the finished product or offer it to the community as a soil amendment it will participate in the US Composting Council's STA Program to ensure the product meets the required specifications for mature and safe compost.

SECTION E
QUESTION 11
APPENDIX I

Bokashi Marijuana
Waste Disposal Protocol

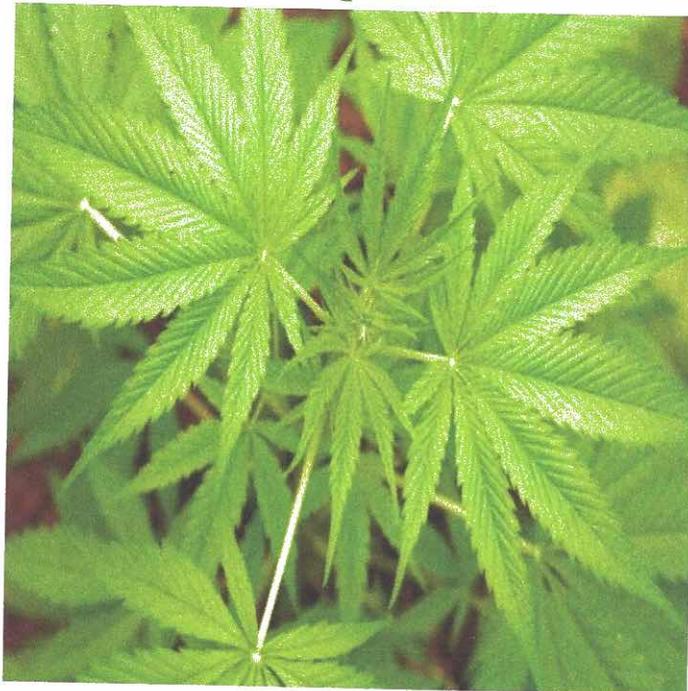


bokashicycle

7506 69th Ave SW
Lakewood, WA 98498

Protocol

Cost Effective and Efficient On-site Marijuana Waste Disposal



Lawrence R. Green MD PhD

December 2014

Contents

Cost Effective and Efficient On-site Marijuana Waste Disposal.....	1
Bokashi Fermenting solves the MMJ Dispensary and Grower Waste Disposal Problem ..	3
Bokashi Fermenting Advantage:	3
Destroy MMJ Waste On-site and Eliminate Transport Problems and Expenses ...	4
Simplify waste disposal and eliminate the expense of off-site disposal.....	5
Bokashi Composting is Very Easy and Fast	6
Equipment Requirements for On-Site MMJ Waste Cycling (Disposal):	7
Shredding Units:	8
Bokashi Culture Mix:	8
Space Requirements:.....	9
Industrial Scale Waste Disposal Protocol:.....	9
Bamboo Granulater Test Results:	10
Granulating MJ Waste:	10
Bokashi Fermenting MJ Waste:	10
Inoculating the MJ Waste with Bokashi Culture Mix:	11
How Much Culture Mix and Accelerant is Required?.....	11
What size and how many fermenters are needed?.....	11
Table 1: Number of Fermenters and Consumable Requirements for a fixed volume of marijuana waste disposal per month.	13
What is needed to Ferment Marijuana Waste?	13
Table 2: List of essential materials to properly process marijuana waste.....	14
Step by Step Protocol for Processing Marijuana Waste:	14
What about Pathogens and other un-wanted chemical bi-products?	16
What is the starting basic system for waste processing?	16
Getting Started with a Quote:.....	16

Bokashi Fermenting solves the MMJ Dispensary and Grower Waste Disposal Problem

Many states have approved medical marijuana. They are putting in place stringent regulations on how growers and dispensaries must comply with the law.

Medical marijuana waste must be properly handled.

Disposing of waste can be expensive. Dispensaries are not allowed to place waste materials in the trash containers available to the public for obvious reasons.

Regulatory agencies want to be certain that the waste materials are not left unattended or available to the public in dumpsters or containers that could be opened off site.

The growers and dispensaries are struggling to cost efficiently solve the waste disposal problem.

Waste produced at a dispensary or by a grower must be rendered unusable before it leaves the facility and then it must be transported to a properly licensed facility for composting but there are few approved available sites for composting and every step in this process is expensive and time consuming.

A chain of custody must be established for the transporting of waste from its on-site location to the approved composting site. Security must be in place. Properly approved and licensed transport services are required.

Accurate account records are required to establish that the mass of material leaving the facility is identical to the mass of material accepted at the composting site.

All of these measures add significantly to the cost and make handling the waste by either a dispensary or grower less efficient, especially if off-site waste disposal is implemented.

Waste has value. It can be recycled on-site.

Bokashi Fermenting Advantage:

- On site rapid disposal of all organic waste
- Far more efficient than composting – takes only 7 days to ferment
- Biopulp mixed with soil results in highly enriched soil, improved microbial flora and enriched organic content soil
- Conserves water
- Requires no additional machinery or effort to process

- Eliminates odors and does not attract vermin or pests
- Fermenting is phytotoxic killing weeds and their seeds
- May combine all waste in a single operation
- Eliminates expense of pick-up and transport
- For MMJ – no chain of custody additional tracking is required because waste is processed on site
- Eliminates greenhouse gas production in processing waste
- Bokashi culture mix costs are about \$25 per ton of waste processed – least expensive of all waste processing methods
- Fermenting waste is the most sustainable agricultural method of waste management

Destroy MMJ Waste On-site and Eliminate Transport Problems and Expenses

There is a better way to handle the waste. Composting the waste in a bokashi fermenting system on-site solves the problem for dispensaries and growers.

This process can accommodate any size operation. Waste is degraded and rendered useless in as little as 10 days in specially designed fermenters. The bio pulp produced can be recycled in soil maintained on the premises.

A smaller dispensary may have a few pounds to several hundred pounds of waste per month. Waste is placed in the fermenter with the culture mix and allowed to be degraded to a bio pulp.

The bio pulp is then mixed with soil on the premises. The enriched soil is used to support new plants and in so doing reduces dependency on fertilizers and other nutrients that contribute to water polluting disposal problems.



Dispensary MMJ Waste Processing Cyclettes

Simplify waste disposal and eliminate the expense of off-site disposal.

A standard residential food waste fermenting system will handle 40 pounds of waste every 2 weeks. A single 55 gallon HDPE commercial fermenter handles 450 pounds every 2 weeks. A single 2 ton capacity industrial grade fermenter can handle 2 tons of waste every 2 weeks.

At the end of each cycle in processing waste the bio pulp obtained is mixed with soil to support plants eliminating the need to purchase expensive fertilizers.

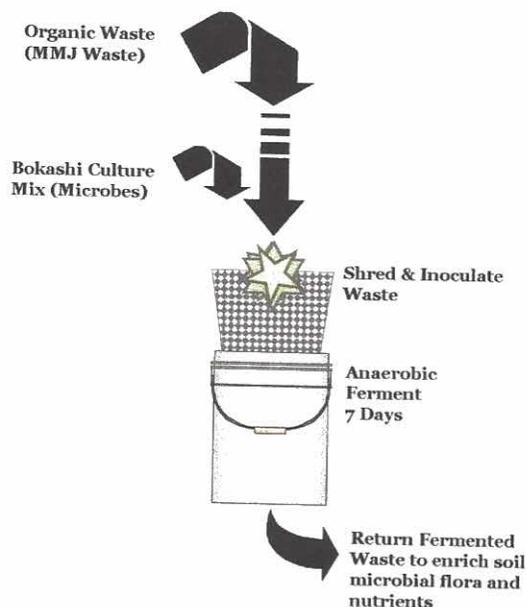
Waste is no longer a problem. It is a valuable resource cycled back to soil. Biologic soils are supported simply and easily by recycling waste to the soil.



HDPE 55 gallon fermenters with band clamp and cassette seals will handle 0.5 to 12 tons of waste per month.

Bokashi Composting is Very Easy and Fast

What is Bokashi Fermenting?



Bokashi fermenting is a method of rapidly metabolizing all organic waste with naturally occurring soil microbes. It is 10 times faster than composting, produces no greenhouse gases, produces no heat, and takes only 7 days. The “pickled” waste material is then mixed with soil to return all the nutrients and microbes to soil.

Bokashi fermenting is an approved method for disposing of MMJ waste.¹

All organic waste will rapidly decompose and noxious odors, putrefaction, and gases are eliminated. No insects or rodents are attracted to the end product. It is accomplished in a remarkably small amount of space and requires no turning, mixing, aerating, or additional materials to complete.

When processing MMJ waste, an accelerant is combined with the microbes to increase the speed of processing because the cellulose content of waste is very high. The liquid accelerant is sprayed onto the waste with each addition of culture mix and the system is then closed to exclude oxygen.

¹ <http://www.colorado.gov/cs/Satellite?blobcol=urlldata&blobheadname1=Content-Disposition&blobheadname2=Content-Type&blobheadvalue1=inline%3B+filename%3D%22Current+Set+of+Rules%2C+Effective+July+1%2C+2011.pdf%22&blobheadvalue2=application%2Fpdf&blobkey=id&blobtable=MungoBlobs&blobwhere=1251781468397&ssbinary=true>

Bokashi fermenting is very scalable. You can mix weeds, plant debris, food scraps including meat and dairy products, and any other organic material with no concerns about the carbon to nitrogen ratio.

You simply shred the material and place it in a proper fermenter. During the shredding operation you add a powder (wheat bran base inoculants) which is dispersed in the shredding step and then leave the material alone for 7 to 14 days in a sealed fermenter.

The fermenting conditions kill seeds and pathogens including E. coli and Salmonella. No methane is produced because the pH shifts to a mildly acidic profile as material is metabolized. Methanogens, the organisms that produce methane can't survive under these conditions.

For more information, on bokashi fermenting visit our WEB site at www.bokashicycle.com or call us at 800.714.2130.

Equipment Requirements for On-Site MMJ Waste Cycling (Disposal):

Operators will be provided with a package and instructions on processing waste fitting their specific needs. We provide on-site supervision and instructions for those who need assistance in getting started. Shredding units can easily handle tons per hour.

A dedicated area for processing should be established. A shredding unit will be put into position so that all inoculated shredded material ideally falls directly into the fermenter. The fermenter is then set aside with a sealed lid equipped with a safety pressure release valve cassette. The minimum number of fermenters is two per site as one fermenter is completing the pickling process while the second is being filled. This allows the operator to continuously run and process waste without any interruptions.

Granulating Units:



Bokashi Culture Mix:

Bokashi culture mix can be obtained in bulk. It is one of the consumables used in the recycling process and it is inexpensive. The general formula for processing is 25 pounds of culture mix per ton of waste processed.

Bokashi culture mix will cost approximately \$25 per ton of mmj waste processed. Waste recycled through soil quickly returns nutrients and microbes to feed new plants and the savings in a grow operation are substantial.

The bio pulp cycled through soil re-establishes nutrients so efficiently that little additional fertilizing will be required. Operators should experience vibrant active growth and will note less watering is required due to the increased soil organic content that avidly retains water where it is needed.

Space Requirements:

The area designated for processing is remarkably small. Fermenters have a small foot print as does the shredder. We recommend processing on a cement floor.

After the fermenters have reached the end point at 7 – 10 days, growers will then need to mix that bio-pulp with soil. This is normally done by applying it to the surface at a rate up to 10 pounds per square foot and tilling it so that it is mixed with soil and covered with a few inches of soil. The soil can then be used for planting after 14 days.

The 55 gallon HDPE fermenters measure 23 inches in diameter and stands 36 inches in height. A number of compact dollies are available making moving a full fermenter a simple task.

The 2 ton capacity fermenters measure 50 inches by 80 inches and stands 48 inches in height. They can be moved on a pallet or with attached wheels on a cement floor.

The number of fermenters required will be determined by the volume of waste being processed. For example, in processing 4 tons of waste per month, 18 fermenters (see Table 1) are needed and each occupies a space of about 4 square feet. All of the fermenters could be stored in a space less than 10 feet by 10 feet.

Industrial Scale Waste Disposal Protocol:

Growers have many options in handling MJ waste. Some growers simply prefer to render the waste in a form that can be sent off-site to a private contractor for subsequent handling. It may be sent for composting, or mixed with an approved inert material like cat litter for off-site disposal depending on local and regional regulatory requirements.

Other growers may want to recycle the material on site by either composting or fermenting the waste material saving in off-site disposal costs.

A common requirement to accomplish any of these options is the need to granulate or pulverize the material so that it can then be properly processed. Bokashicycle's MJ Granulating machine accomplishes this task efficiently and quietly in a small space. The machine was specifically designed to mince and granulate waste including root balls. All waste should be properly reduced in size before composting or fermenting or rendering inert.

The MJ Granulator minces and granulates material delivering it directly into 55 gallon barrels or cartons placed below the machine and can handle high volume waste cycling greater than 1 ton per hour.

Bamboo Granulator Test Results:

The MJ Granulating machine has been tested and proven to consistently mince and granulate long strands of bamboo up to 1 inch in diameter and can handle larger diameter product if it is cut into shorter strands. Bamboo is far stronger than MJ waste and is a good quality control standard.

High throughput is maintained with a 1 inch grate.



Bamboo Test Material - 1 inch diameter bamboo stock material ranging in size up to 1 inch in diameter, dry and wet granulated in a single pass



Bamboo Grate Single Pass Test Results - 1 inch diameter bamboo stock rapidly minced and granulated with shredded leaves ready for composting or fermenting

Granulating MJ Waste:

All waste can be handled easily by passing it through the granulating machine. There is no requirement for wetting or soaking this material before feeding it into the hopper however a light misting or wetting of the material will reduce the potential for dust scatter.

Bokashi Fermenting MJ Waste:

MJ waste can be fermented and returned to soil and it is an approved waste disposal process in most jurisdictions. It is a two stage process that is far faster than composting and returns to the soil the many needed nutrients that would otherwise be discarded.

Disposing of waste is a two stage process.

1. In the first stage the waste is destroyed by fermenting. It is inoculated and placed in an anaerobic fermenter for approximately 2 weeks at room temperature.
2. The end product is metabolized material that is then mixed with soil to improve the soil organic content. The metabolized waste may be

repeatedly cycled by mixing with soil. New plants may be placed in this soil 10 days after the bio pulp is mixed with soil.

Inoculating the MJ Waste with Bokashi Culture Mix:

The easiest way to efficiently inoculate the waste is to add the bokashi culture mix to the waste as it passes into the granulating machine. This spreads the inoculants uniformly throughout the waste as it exits into a standard 55 gallon fermenter.

If the waste is acquired in bins that are then dumped into the hopper, a cup of bokashi culture mix in each bin at the time it is dumped will ensure uniform distribution of the culture mix in the minced and granulated waste.

If long strands and root balls are being granulated, the easier route of inoculating is to collect all of the minced and granulated waste in a 55 gallon fermenter. The operator will then add to the 55 gallon fermenter 15 gallons of water to which is added 750 mL of accelerant and 5 pounds of bokashi culture mix.

In summary, inoculating the waste is accomplished by adding 5 lbs of culture mix for each 55 gallon filled fermenter along with 15 gallons of water and 750 mL of accelerant. Minced and granulated waste must be wet and sealed in a fermenter excluding oxygen in order to properly ferment.

How Much Culture Mix and Accelerant is Required?

A 25 pound bulk pack of bokashi culture mix and a gallon of accelerant is enough material to process 1 ton of marijuana waste.

Fermenters should be packed tightly with inoculated waste and then sealed. Inoculated waste can be added incrementally until the fermenter is filled to the top. It should then be set aside for a full 10 days at which time fermenting will be complete.

What size and how many fermenters are needed?

Dispensaries and small volume waste producers do not need to shred or pulverize waste materials. They can process waste in a standard cyclette system by wetting it down, spritzing with accelerant and adding the bokashi culture mix every couple of inches as they fill the fermenter. The fermented end product is mixed with soil at the end of the process. Standard cyclettes for processing are easy to obtain by an on-line order.

Standard Cyclette Processing unit:

http://store.bokashicycle.com/Bokashi-Fermenting-System-with-Dispensing-Unit-and-12-months-supply-of-Bokashi-Culture-Mix_p_22.html

Industrial scale fermenters come in two sizes.

1. A 55 gallon HDPE open top band clamp seal fermenter equipped with a cassette and safety pressure release valve will when tightly packed hold up to 450 pounds of end product. The cassette acts as a filter so that the liquid acquired in the fermenting process can be drained and collected if the processor wants to use it diluted 1:50 with water in drip irrigating plants. The “tea” is rich in metabolic products, trace nutrients and microbes and will improve the plant performance if applied on a regular bases.

http://store.bokashicycle.com/Bokashi-Yard-Waste-Fermenting-System-55-Gallon-Capacity_p_23.html

2. 2 ton capacity large scale fermenters with an anaerobic seal. These large scale fermenters are used to advantage when the volume of waste is greater than 6 tons per month.

http://store.bokashicycle.com/15-ton-Capacity-Food-Waste-Fermenting-Bin_p_53.html

3. Value pack Bokashi Culture Mix and Accelerant is available for growers who process a lot of waste and want to take advantage of discount pricing.

http://store.bokashicycle.com/Marijuana-Waste-Disposal-Value-Pack_p_50.html

Table 1: Number of Fermenters and Consumable Requirements for a fixed volume of marijuana waste disposal per month.

Per Month Waste Volume (tons)	Fermenter Size		Per Month Required Consumables	
	55 Gal HDPE	2 ton Cap	# BCM 25Lbs	Gals Accel
1	5		1	1
2	9		2	2
3	14		3	3
4	18		4	4
5	23		5	5
6		3	6	6
7		4	7	7
8		4	8	8
9		5	9	9
10		5	10	10
11		6	11	11
12		6	12	12
13		7	13	13
14		7	14	14
15		8	15	15

The amount of material required to process a fixed amount of waste per month is easily calculated using the figures from Table 1. For example, if the producer is generating 4 tons of waste each month, then 18 55 gallon capacity fermenters are needed to process waste. Each month 100 pounds of bokashi culture mix and 4 gallons of accelerant are needed. The operator would fill 9 fermenters in the first 2 weeks setting them aside for an additional 2 weeks while filling the other 9 fermenters.

Every 2 weeks thereafter, 9 of the fermenters are emptied. The bio pulp is mixed with soil which can be used over and over again or cycled back through the grow operation. The emptied fermenters return to be filled again and again in a continuous recycling operation.

What is needed to Ferment Marijuana Waste?

Table 2 provides a list of the needed equipment and materials for waste processing.

If the waste pH in the fermenter after adding the culture mix and accelerant with water has a pH that is greater than 6.0, the operator should adjust the pH to a level below 6.0 to be assured that fermenting will be efficient. Although this is

not a common experience, it may be essential if a lot of ammonia fertilizers are used in a grow operating.

Vinegar is a simple and effective way of lowering the pH if it is required. It is inexpensive, non-toxic, and easy to use. Any kind of vinegar can be used as it is only used to lower the pH. Depending on how much ammonia or other basic materials are in the waste the operator will add vinegar to the fermenter to bring the pH into a range between 4.0 and 6.0. If the pH is above this level fermenting will be less efficient and likely will not work if it is greater than 6.5.

Table 2: List of essential materials to properly process marijuana waste.

Materials Required for Waste Processing:

Vinegar	Use to adjust fermenter only if the pH >6.0
Bokashi culture mix	25 lbs will process 1 ton of waste
Accelerant	1 gallon will process 1 ton of waste
MJ Granulating Machine	Directs waste to fermenters, inoculates waste
Fermenters	HDPE 55 gal band clamp/safety pressure release cassette

Step by Step Protocol for Processing Marijuana Waste:

Activity	Comment
1. Locate the MJ Granulating machine in a flat working area along with the stair platform access	Lock the wheels and attach the stair platform to the machine with the hinge gate locking unit
2. Plug the machine into a 220 volt outlet	The 3 HP Teco Westinghouse is well built and rugged. It requires single phase 220 v 50 – 60 Hz power
3. Gather MJ waste in bins or as stocks including root balls	Rocks or heavy clay materials should be removed from root balls. Remove as much soil as possible and cut to size to fit the hopper
4. Wear eye and ear protection	Operators should read the operator's manual before engaging the machine
5. Place the fermenting barrel or carton to collect minced and granulated waste below the machine stand	The stand is designed to fit 55 gallon barrels. Push the barrel so that the curtain on the stand is centered over the barrel
6. Start the machine and granulate all waste filling to within 4 inches of the top of the barrel or carton	
7. Replace a filled container with an empty container	Label each granulated container by time and date

Activity	Comment
8. Bokashi Fermenting, Composting, On-site or Off-site Disposal	Arrange for off-site handling or on-site composting. If Bokashi fermenting advance to activity # 9
9. Waste collected in 55 gal size fermenters	Filled to within 4 inches of the top
10. Add 1.6 Lbs of culture mix and 250 mL of accelerant to a 5 gallon bucket	
11. Fill the bucket with 5 gallons of water	
12. Pour the liquid slurry of culture mix, water and accelerant over the minced material in the barrel	The objective is to wet all material and inoculate as the solution travels through the waste
13. Repeat Activity 10 – 12 twice so that 15 gallons of slurry have been put into the fermenter	
14. Confirm the pH is below 6.0	Obtain a small amount of fluid from the fermenter and test with a pH meter or tape.
15. Seal the fermenter using the band clamp lock and check that the safety pressure valve is in place	The safety valve fits in the top of the cassette attached to the lid for the fermenter
16. Record the ID for the fermenter in a log book and the date fermenting started	Each barrel lid has its own ID number or label
17. Allow at least 10 to 14 days at room temperature	
18. After fermenting check the pH to be certain it is below 6.0	
19. Drain liquids from the fermenter by tipping on its side and removing the safety valve	This liquid can be used to water plants. It is rich in nutrients.
20. The entire fermented material including liquids can be mixed with soil	Tilling the fermented material into normal soil or mixing into a pile of soil will result in its rapid further incorporation into the soil
21. Allow a few weeks for the soil with fermented end product to mature	Soil with end product can be recycled or sent off site for use in gardens

You may throw any food scraps into the granulating machine hopper when the marijuana waste is being minced and granulated. The food scraps will ferment and accelerate marijuana waste processing.

What about Pathogens and other un-wanted chemical bi-products?

Bokashi fermenting is a very efficient way of killing pathogens including *E. coli* and *Salmonella*. The enzymatic activity in the fermenting process will break down most chemical compounds into basic simple molecules and it will kill most seeds. Do not add petroleum products or oils as they will interfere in efficient fermenting.

Wear gloves when handling the end products as they are mildly acidic (like vinegar) and wash your skin or eyes with copious amounts of water if you accidentally splash the material on the skin or eyes. We recommend wearing safety goggles in addition to gloves as a common sense precaution.

What is the starting basic system for waste processing?

Bokashicycle recommends for all growers a basic minimal system that consists of the electric 3 HP pulverizing machine on its stand with swivel wheels and 2 55 gallon yard waste fermenting systems. The yard waste fermenting systems come with enough culture mix and accelerant to process up to 2 tons of waste.

3 HP 220v 1 PH Electric Granulating Machine:

http://store.bokashicycle.com/MJ-Granulating-Machine--3-HP-Electric-single-phase-220v_p_54.html

Yard Waste Fermenting System:

http://store.bokashicycle.com/Bokashi-Yard-Waste-Fermenting-System-55-Gallon-Capacity_p_23.html

Bokashicycle offers wholesale pricing and discounts to all growers for volume orders. Bokashi culture mix kept dry and protected has a shelf life greater than 5 years as does the accelerant. A volume discount pack of 500 pounds of culture mix and 20 gallons of accelerant on a single skid is offered at \$995 plus delivery. That is enough inoculants to process 20 tons of waste.

Getting Started with a Quote:

Bokashicycle will provide to the grower a recommended set up for processing all waste based on the information provided.

The quote will include the cost of equipment, number of fermenters, and amount of culture mix needed to process all waste efficiently.

Call us for a quote at 800.714.2130 or email us at support@bokashicycle.com

Question E-12

TWG is committed to adhering to all Regulations and all pertinent sections of 329D, HRS to ensure a safe product is available for its patients. Accordingly TWG will test all finished products using an independent accredited (ISO/IEC 17025:2005 or equivalent) state approved laboratory and will only release products for sale that meet state specifications detailed in section 11-850-85 of the Regulation. TWG will ensure that manufactured medical marijuana products comply with the State requirements for product type as outlined in 329D-10, HRS and that all single dose, single serving or single wrapped items contain no more than 10 milligrams of tetrahydrocannabinol (THC) and that any containers of oil derivatives contain no more than 100 milligrams of THC. TWG will also ensure that the labelling requirements outlined in Subchapter 8 -11-850-93 of the Regulations are strictly adhered to. TWG will not advertise any of its products but will provide information on its website that is acceptable to the state.

TWG will create an independent Quality Assurance Department (QAD), reporting only to the company Chief Executive Officer (CEO), and staffed by highly trained personnel experienced with not only ISO quality systems but at least one or more personnel must have an advanced degree, quality assurance training in Current Good Manufacturing Practices (GMP, cGMP) and at least 5 years of experience in the FDA regulated pharmaceutical or health products industry (See Appendix I – Medical Marijuana: The case for stringent Quality Assurance/Control and Patient Safety).

Compliance to cGMP is mandatory for pharmaceutical manufacturing and in fact GMP for the industry was developed in response to drug failures such as Thalidomide; its primary purpose is to ensure product safety and patient safety. Medical marijuana is not currently overseen by the FDA, however, TWG will be proactive and will implement cGMP protocols and

quality practices as appropriate. In particular all processing stages and manufacturing of the finished products will conform to cGMP. Even during the cultivation of medical marijuana, equivalent sanitation protocols will be observed such as gowning requirements and the use of decontamination chambers.

In drug manufacturing the two most important objectives of cGMP are:

1) Purity of the product - Product must be free of any extraneous or foreign material and in particular of unintended active pharmaceutically ingredients (API) arising from cross contamination. It must also be free of any toxic elements such as heavy metals, solvent residues and pesticides, and additionally all products must be free of harmful microbial contaminants such as bacteria and molds, and their associated endotoxins.

2) Product conformity to the manufacturer's product line - The products and in particular the API of the products must be consistent with what has been characterized for a particular product line. In the case of medical marijuana and medical marijuana products this means that the cannabinoid profiles of the product lines must be well determined and quantified. This is necessary in order to ensure the appropriate products and dosage levels can be controlled (by the prescribing health care provider, the patient or caregiver) and that adverse reactions can be avoided.

To ensure product purity TWG will build its production facilities for ease of cleaning and sterilization of surfaces, and the buildings will be zoned internally (black, gray and white) according to increasing levels of sanitation requirements. TWG has developed and will continue to develop a Sanitation Program (See Appendix II - SOP P-03 – Sanitation Program) that details requirements and cleaning protocols: for the various areas and rooms in the facilities; for the

tools and equipment used and; it also details rules and guidance concerning the hygiene of employees. Additionally areas and processes in the facilities will be assessed for contamination risks and testing programs will be established (especially for microbial contaminants) to limit risk throughout the various production stages and validate the sanitation protocols. TWG is committed to conducting its operations without the use of harmful cleaning agents, toxic solvents, pesticides or any other chemical materials that may pose a contamination hazard and it will also carry out the required finished product testing and meet all the state specifications regarding contaminants listed in Subchapter 7, 11-850-85 of the Regulation before releasing a product; only senior Quality Assurance personnel will have signing authority to release a product for sale (See Appendix II - SOP QA-09 – Finished Product Approval Procedure and QA-09.1 Approval Checklist).

To ensure product conformity to an established product line, TWG has partnered with ISO 17025 accredited [REDACTED] Laboratories with experience in product release testing including validated potency (cannabinoid and terpene profiling) and safety testing, as well as Super Critical CO₂ extraction and products development. By incorporating a [REDACTED] Laboratory experience and methods, TWG will be able to create safe products with consistent, reliable dosing. Our product development will include standardized SOP's, quality control and stability testing. Having experience with formulation currently being successfully used for medical marijuana patients with specific conditions including pediatric and adult epilepsy, HIV, AIDs, severe pain and cancer. TWG's partnership with ProVerde will make it possible for effective medicine to be made available immediately.

Derivatives and infused products will be made using extracted marijuana. Extractions will be done in production batches and lot number assigned. Master Batch Records will be

maintained including identification of marijuana batch used to create the extract to provide traceability. Extracts will be tested as required by state law and their cannabinoid profiles used to create specific dosing and formulation requirements. All product test records will be maintained.

Extracts or combination of extracts will be used to achieve specific formulations for derived products. Our GMP production process, including a QAD, and standard operating procedures for training, calibration, maintenance and quality will ensure TWG produces quality products that are consistently dosed and repeatable. Scientific methods, such as statistical sampling, will be used in collection of data. That will allow TWG to respond according to research, customer needs and formulation requirements in creating medicine for patient's needs.

A well-known factor contributing to drug failure is improper labelling. TWG will address this known issue by use of strict protocols including the development of Master Batch Records that include the maintenance of detailed batch/ lot dossiers, checking of all analytical test results to ensure product testing specification are met, and meticulous checking of labels cross checked with analytical results to ensure the label specifications are also met for the product line. Again only senior Quality Assurance personnel will have signing authority to release the product for sale (See Appendix II - SOP QC-01 Sampling Marijuana and Products for Laboratory Testing QC-01.3 Laboratory Testing Specification Sheets).

In addition to ensure product and patient safety the TWG QAD will conduct annual product reviews and will maintain a database for reported adverse reactions. It will also create annual or biennial reports that will include analysis of the adverse reaction data and review of pertinent scientific literature using the established Periodic Safety Update Report (PSUR) format. Copies of these reports will be made available to the DOH upon request.

SECTION E

QUESTION 12

APPENDIX I

Medical Marijuana:

The case for stringent Quality
Assurance/Control and Patient Safety



Question E-13



The Wellness Group, LLC would like to close by thanking the Department of Health and all the people who made this opportunity possible and for giving TWG the opportunity to pursue its mission: **Marijuana is Medicine.**