9.3 Exhibit 3: Quality Assurance and Quality Control SOP

9.1.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawai'i Department of Health and to promote patient, product and public safety. As rule changes occur and best practices evolve, the content of this document will be reviewed and updated where appropriate. Each step in our manufacturing and distribution processes is carefully performed and controlled so that the resulting medical marijuana products possess the safety, quality, identity, purity, and potency (SQuIPP) that patients deserve.

HAR Requirement	Description
§11-850-37.a	Each dispensary licensee shall be subject to an annual announced inspection and unlimited unannounced inspections by the department, and inspections by any other government employee or official acting in an official capacity.
§11-850-37.b	A dispensary licensee shall permit entry to the department for the purposes of any inspection.
§11-850-37.c	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.
§11-850-37.d	A dispensary licensee shall not refuse to allow inspection at any of its dispensary facilities, and its employees and personnel shall not delay or interfere with any inspection.
§11-850-37.e	Upon completion of the inspection, the department shall provide written notice to the dispensary licensee of its findings and if applicable shall proceed In accordance with subchapter 9. Eff. DEC 14 2015
§11-850-38.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.
§11-850-38.b	Reports shall include but not be limited to:
§11-850-38.b.1	Records of entry and exit for all individuals who entered a dispensary facility;
§11-850-38.b.2	Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
§11-850-38.b.3	Amounts by category of marijuana and manufactured marijuana products sold.
§11-850-38.b.4	A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
§11-850-38.b.5	A summary financial statement;
§11-850-38.b.6	Laboratory results of all tests conducted;
§11-850-38.b.7	Description of any breach or halt in its security system and tracking system; and
§11-850-38.b.8	Any other information requested by the department. Eff. DEC 14 2015.
§11-850-75.a	A dispensary licensee shall ensure that all marijuana and manufactured marijuana products it dispenses are safe for use or consumption by qualifying patients.
§11-850-75.b	A dispensary licensee shall comply with State and county health, safety, and sanitation regulations and may be subject to inspection to confirm that no health or safety concerns are present which may contaminate the products.
§11-850-75.c	Any person who has or appears to have an illness, or open lesion including boils, sores, or infected wounds, or any other source of contamination, shall be excluded from any contact with a dispensary's marijuana or manufactured marijuana products until the condition is corrected.
§11-850-75.d	A dispensary shall have hand washing facilities that are adequate and convenient, furnished with running water, and provide effective hand cleaning and sanitizing preparations.
§11-850-75.e	All persons working in direct contact with marijuana and manufactured marijuana products shall conform to hygienic practices while on duty, including but not limited to:
§11-850-75.e.1	Maintaining adequate personal cleanliness; and
§11-850-75.e.2	Washing hands thoroughly in an adequate hand washing area before starting work and at any other time when the hands may have become soiled or contaminated.
§11-850-75.f	A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.
§11-850-75.g	The floors, walls, and ceilings of a dispensary facility shall be constructed in such a manner that they may be

HAR Requirement	Description
	adequately cleaned and kept clean and in good repair.
§11-850-75.h	The dispensary licensee shall ensure that there is adequate lighting in all areas where marijuana or manufactured marijuana products are stored or sold, and where equipment or utensils are cleaned.
§11-850-75.i	The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.
§11-850-75.j	The dispensary licensee shall not allow animals in dispensary facilities, except for service animals in accordance with section 347-2.5, HRS.
§11-850-75.k	The dispensary licensee shall maintain buildings, fixtures and other facilities in a sanitary condition.
§11-850-75.l	The dispensary licensee shall use and maintain any toxic cleaning compounds, sanitizing employees, and pest control measure such as bait traps, in a manner that protects against contamination of marijuana or manufactured marijuana products and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance.
§11-850-75.m	A dispensary licensee shall not alter marijuana or manufactured marijuana products to change their appearance, flavor, or smell in a way that would appeal to minors.
§11-850-81	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. Eff. DEC 14 2015

9.1.2 Local Compliance

In accordance with the requirements defined by Hawai'i Administrative Rules Chapter(s): 11-850-37, 11-850-38, 11-850-75, 11-850-81 and enforced by the Hawai'i DOH, Hale O Laulima has developed a Quality Management System that assures each step in our manufacturing and distribution processes is carefully performed and controlled. Hale O Laulima quality assurance and control activities relating to controlled substance manufacturing will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-850-37, §11-850-38, §11-850-75 and §11-850-81.

9.1.3 Definitions and Abbreviations:

Air-Conditioning ("A/C")
American National Standards Institute ("ANSI")
American Society for Testing and Materials ("ASTM")
Automated Data Processing/Point-of-Sale System ("ADP/POS")
Batch Production Record ("BPR")
BBC Research & Consulting ("BBC")
Board of Directors ("the Board")
Cannabidiol ("CBD")
Cannabidiolic Acid ("CBDA")
Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
Chief Operations Officer ("COO")
Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)

Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")
Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")
Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)
Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")
Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")
National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")
Quality Control Team ("QCT")
Quality Control Unit ("QCU")
Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")

Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

9.1.4 Quality Assurance and Quality Control

Hale O Laulima will develop, implement and maintain a Quality Management System and training modules for employees. The development of comprehensive quality assurance and quality control measures will be overseen by Hale O Laulima's Quality Control Team. ISO 9001:2008 is the International Organization for Standardization's criteria for quality management systems; these criteria, quality management principles, standards from established industries, and quality assurance and control requirements from other medical marijuana states will be the basis upon which the Hale O Laulima Quality Management System and related training modules will be built.

9.1.5 Basic Requirements

All marijuana and marijuana products will be cultivated, processed, handled, packaged, labeled, and stored in a safe and sanitary manner. Prior to transfer from the Production facility to the Retail Dispensary Facilities, the Inventory Manager will inspect marijuana source material to confirm that it is dried, cured and stored properly, and free of unusable plant material (e.g., stems, fan leaves), dirt, debris, foreign matter, and contamination (e.g., mold, rot, fungi, bacterial disease). The Inventory Manager will also inspect marijuana in bulk packaging, if applicable, to confirm that all required disclosures are provided (i.e., test results and additives), that the label is complete and accurate, and that the bulk packaging has not been tampered with or damaged in any way.

At the Production facility, processing employees will again inspect the marijuana source material prior to beginning to process it into marijuana products, if not immediately used upon acquisition. Pre-process inspection is required so that any contamination or deterioration of marijuana source material is identified prior to use in a production process and contaminated source material is quarantined in preparation for disposal, thereby preventing the contamination of sanitary work spaces and surfaces, as well as equipment and other in-process products.

Adequate sanitation procedures will be implemented at all times during the cultivation, processing, handling, and storage of marijuana, marijuana product constituents, marijuana

products in process, finished marijuana products, and products that come in contact with finished products (e.g., packaging, storage containers).

9.1.6 Quality Control Team

The COO will ensure that a Quality Control Team (QCT) is in place at all times. The QCT will be qualified to perform all duties and will be made up of more than one employee as necessary. The QCT will develop and maintain written procedures outlining responsibilities and processes approved by the Inventory Manager and COO. The QCT, at a minimum, is responsible for:

1. Approving or rejecting all components, product containers, closures, in-process materials, packaging materials, labeling and marijuana or marijuana products;
2. Reviewing production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated and resolved;
3. Approving or rejecting marijuana or marijuana products in process, finished, or packaged; and
4. Approving or rejecting all procedures or specifications, which will impact the identity, strength, quality and purity of the marijuana or marijuana products.

9.1.7 Reports and Record Keeping

A designated member of the QCT or Inventory Manager will ensure test results are recorded and attached to the appropriate batch in the electronic automatic data processing/point-of-sale ("ADP/POS") system, Biotrack. The test results must also be forwarded to the Retail Dispensary Facilities Manager, depending on whether material tested is a marijuana product or raw marijuana, in a format that cannot be altered, and maintained in the ADP/POS system and secure cloud-based recordkeeping system for a minimum of six (6) years. A quarterly report MUST be provided to the Hawai'i DOH pursuant to §11-850-38.a that includes the following:

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 Hawai'i DOH.

9.1.8 Facility Quality Control

9.1.8.1.1 Inventory Acquisition and Receiving Guidance

The Inventory Manager shall develop, implement, and maintain detailed written procedures for the receipt, identification, storage, handling, sampling, testing, and approval or rejection of

crop inputs, such as nutrients, cultivation media, and pest and disease management products. Each container or group of containers for crop inputs must be identified with a distinctive code (i.e. batch, lot, or control number) for each lot in each shipment received for traceability. This code will be used in the crop records, as described in this Plan. Each employee engaged in receiving operations shall be trained in process and confirmation of specifications to be met, including:

1. Identity;
2. Strength and composition; and
3. Purity, including limits on those types of contamination that may adulterate or may lead to adulteration of marijuana, such as filth, insect infestation, microbiological contamination, or other contaminants. The method of administration and any hazards to certain customer populations must be considered when developing specifications.

The supplier's documentation for each shipment must be reviewed to ensure the contents are consistent with what was ordered prior to entering receipts into the inventory management system. Crop inputs must be stored under quarantine until they have been checked for conformity to specifications and approved by the Inventory Manager or their designee. Re-inspection of crop inputs must be performed, as appropriate, for identity, purity, strength, and composition and approved or rejected as necessary (e.g., after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the crop input).

9.1.8.2 Retail Dispensary Sanitation and Quality Control Practices

It is Hale O Laulima policy to implement hygiene and sanitation requirements that enhance the ability to consistently produce and distribute marijuana products that conform to internal quality standards. All marijuana products packaged for distribution will have successfully passed laboratory testing and will only enter the supply chain after all quality control and assurance activities have been fulfilled. Refer to the Hygiene, Sanitation and Facility Requirements SOP for additional detail.

9.1.8.2.1 Retail Receiving Procedure

1. Examine packaged and labeled products to provide assurance that the containers and packages have the correct labels pursuant to §11-850-92 and as defined in the Packaging and Labeling SOP prior to entering them into the ADP/POS system;
2. Verify that the tamper evident features of packaged marijuana products have not been manipulated
3. Collect a representative sample of units and ensure that the samples are visually examined for correct labeling; and
4. Record the results of the examinations performed in the receiving log.

9.1.8.2.2 Testing Required for Intake

All marijuana products distributed by Hale O Laulima must be tested. No product may be accepted by the Retail Dispensary manager that is not accompanied by valid test results. Mandatory testing at a minimum includes:

1. Cannabinoid profile, and
2. Contaminant presence including, but not limited to:
    a. Mold;
    b. Mildew;
    c. Heavy metals;
    d. Plant growth regulators; and
    e. Non-organic pesticides.

9.1.8.2.3 Vendor Compliance Required

It is the policy of Hale O Laulima to verify all vendors comply with all laws and regulations, including but not limited to:

1. Testing of each batch using approved laboratories;
2. Packaging and labeling compliance;
3. Batch size; and
4. Required disclosures, such as ingredient and additive listings.

9.1.8.3 Production Facility Sanitation and Quality Control Practices

It is Hale O Laulima policy to implement hygiene and sanitation requirements that enhance the ability to consistently produce and distribute marijuana products that conform to internal quality standards. All marijuana products packaged for distribution will have successfully passed laboratory testing and will only enter the supply chain after all quality control and assurance activities have been fulfilled.

The Production Facility Manager shall implement, and maintain sanitation and quality control practices that maintain the safety and quality of crops, including purity and consistency. Current sanitation and quality control policies and measures are detailed in the Hygiene, Sanitation and Facility Requirements SOP.

9.1.8.3.1 Cultivation Environment

All necessary precautions will be taken during the cultivation and processing of marijuana to prevent contamination of marijuana and packaging materials. These safeguards include, but are not limited to:

1. Cleaning and sanitizing all equipment, containers, and other contact surfaces as necessary;
2. Controlling airborne contamination;
3. Using sanitary handling procedures and Good Handling Practices;

4. Washing or cleaning containers and packaging components that contain soil or other contaminants;
5. Using safe water in all operations;
6. Performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated ingredients in cultivation and processing operations;
7. Sterilizing, pasteurizing, freezing, refrigerating, heating, pressurizing, controlling hydrogen-ion concentration (pH), controlling humidity, controlling water activity (aw), or using any other effective means to remove, destroy, or prevent the growth of microorganisms and prevent marijuana product decomposition;
8. Storing packaging materials, in-process marijuana, and marijuana products appropriately to prevent contamination and adulteration;
9. Preventing cross-contamination and mix-ups between contaminated or adulterated marijuana and clean marijuana; and
10. Using effective measures to protect marijuana products against adulteration by plastic, glass, metal, or other foreign materials when at risk due to processing equipment or materials.

9.1.8.3.2 Pest Control Procedures

The Production facility has been designed, and will be maintained and monitored to restrict pests, including insects, rodents, and other animals. The Production Facility Manager must ensure that pest management activities comply with procedures found herein and in the Product Process Control SOP, including an Integrated Pest Management program..

9.1.8.3.3 Quality Control Measures in Production / Cultivation Operations

The Production Facility Manager will establish surveillance schedules for each crop in cultivation. Detailed visual surveillance of each crop will be performed and documented daily. Cultivation employees performing surveillance will look for and record findings for the cultivation area assigned. The following items shall be included in surveillance operations:

1. Signs of pest infestations;
2. Changes in biological colonies;
3. Mold and mildew;
4. Leaf and tip burn, discoloration, and spotting;
5. Changes in appearance of the media;
6. Changes in stalk density and branch elasticity; and
7. Regular in-house testing will be scheduled by the Production Facility Manager based on current operational needs and recorded in the Crop Maintenance Log. Tests that must be performed include:
    a. Soil pH;
    b. Nutrient pH, Total Dissolved Solids (TDS), and Electro-Conductivity (EC);
    c. Soil EC/pH testing using a saturated media extraction (1 part soil to 2 parts water filtered) or the leachate pour-through method; and
    d. Water Oxidation Reduction Potential (ORP).

9.1.8.3.4 Crop Records

Crop records are detailed in the Inventory Control and Management SOP and are compliant with Hawai'i DOH standards. Plants are assigned a batch number at time of propagation and are assigned an individual identifier that is electronically recorded in the ADP/POS system when moved to a new room, phase of growth and through post-harvest processing. All plants will be inventoried weekly, monthly, and annually, and records will be kept for a minimum of six (6) years.

9.1.8.3.5 Quality Control Measures in Post-Harvest Processing Operations

1. The Production Facility Manager will ensure that all crops are evaluated during processing and tested in accordance with the Inventory Control and Management SOP;
2. Production employees working in processing operations will be trained to identify signs of contamination and sub-standard product. The Production Facility Manager or Inventory Manager must approve the disposal of any crops prior to commencement of any disposal procedures detailed in the Marijuana Waste Disposal SOP;
3. Two or more trained employees will perform a visual microscopic and naked-eye inspection of each crop processed to determine:
    a. Organoleptic characteristics (color, texture and odor);
    b. Presentation of the material (raw, cut, crushed, compressed);
    c. The presence of admixtures, foreign matter (sand, glass particles, dirt), mold, or signs of decay;
    d. The presence of insects;
    e. The presence of foreign material originating from poor or degraded containers; and
    f. All crops will be inspected by two or more trained employees for all visible foreign matter and sub-standard material to be removed.
4. Foreign matter includes, but is not limited to:
    a. Plant material from other strains/species or from other parts of the harvested strains/species;
    b. Grow media;
    c. Insects; and
    d. Wire, glass, paper, tools or tool parts, and other man-made objects.
5. Sub-standard material includes, for example:
    a. Discolored leaves or flowers;
    b. Evidence of mildew or mold; and
    c. Any other material that would cause the crop to fail to meet its internal and required testing specifications as determined by the Production Facility Manager.
6. The inspection for foreign matter and sub-standard material will be conducted while the crop is sufficiently well displayed on a sanitary surface by two or more employees to allow for sufficient visibility;

7. Damaged and/or degraded plant material will be removed and disposed of with Production Facility Manager approval and in accordance with the Marijuana Waste Disposal SOP.

9.1.8.3.6 Master Batch Records:

1. For each extraction process and unique formulation of marijuana product, a master batch record (MBR) must be prepared by the Production Manager;
2. For a process which consists of manufacturing and bulk packaging of a marijuana product, a MBR ("manufacturing MBR") covering both manufacturing and bulk packaging must be prepared for each lot size of the product;
3. For a process which consists of retail packaging of a marijuana product, a MBR ("packaging MBR") must be prepared for retail packaging of the product;
4. For a process which consists of both manufacturing and retail packaging of a marijuana product, a MBR ("manufacturing and packaging MBR") covering both manufacturing and retail packaging may be prepared, or separate MBRs may be prepared for the manufacturing vs. the retail packaging. In either case, a separate MBR must be prepared for each lot size of the manufacturing process;
5. The MBR must include, as applicable to the process the name of the marijuana product to be manufactured and/or packaged, including its strength, grade, and/or key features of its form, composition, or functionality if applicable;
6. For manufacturing MBRs:
    a. The lot size;
    b. The weight or measure of each constituent to be used in the lot, including the unit of measure;
    c. Any acceptable range or variation in the weight or measure of a constituent must be explained and justified.
    d. A statement of any intentional overage amount of a constituent, or a cross-reference to the master formula where such information is found;
    e. The name and label quantity claim of each ingredient declared on the label for the product, or a cross-reference to the master formula where such information is found.
    f. The name of each constituent to be used in the lot, including its strength, key features of its form or composition, or grade if applicable;
    g. The name of each packaging constituent to be used, including its size, grade, or key features of its composition, construction, or functionality, if applicable;
    h. A specimen of the bulk or retail label and all other labeling to be used, or a cross-reference to each piece of labeling (such as by label number and version number);
    i. A statement of theoretical yield for each significant process step and at the end of manufacture and of packaging, including the maximum and minimum allowed percentages of theoretical yield;
    j. Written instructions, including the following:
        i. Instructions for the execution of each process step, or cross-references to the written procedures to be used at each step;

ii. Instructions for monitoring of production process specifications, or cross-references to standard procedures for such monitoring;
iii. Instructions for in-process and final product sampling, or cross-references to standard procedures for such sampling; and
iv. Instructions for in-process material testing and examination, or cross-references to standard procedures for such testing and examination.

k. Marijuana product specifications, or a cross-reference to marijuana product specification documents;
l. Instructions for marijuana product testing and examination, or cross-references to standard procedures for such testing and examination; and
m. Other notes and precautions to be followed.

7. Manufacturing MBRs must be written with the intent to provide not less than one hundred percent of the labeled or established amount of marijuana and any other ingredient for which a quantitative label claim is made; and
8. The production process described in the MBR must ensure that product specifications are consistently met and that the product is uniform from lot to lot.

9.1.8.3.7 Batch Production Records:

1. For each lot manufactured or packaged, a batch production record (BPR) must be prepared and checked for accuracy by quality control personnel;
2. The BPR must form a complete record of the manufacturing, packaging, labeling, sampling, and testing of the lot, including record of any procedure variances;
3. Each lot must be assigned a lot, lot, or control number which allows the complete history of the production and distribution of the lot to be determined. This code must be used in recording the disposition of each lot;
4. The BPR must be an accurate reproduction of the appropriate MPR. The BPR must include, as applicable to the process:
    a. The name of the marijuana product, including its strength, key features of its form or composition, or grade if applicable, and the product's item code or product number if such are used by the manufacturing, packaging, labeling or holding operation;
    b. The lot, lot, or control number of the marijuana product;
    c. For manufacturing MPRs, the nominal lot size;
    d. The name of each constituent used in production of the lot, including its strength, key features of its form or composition, or grade if applicable;
    e. The name of each packaging material used in production of the lot, including its size, grade, or key features of its composition, construction, or functionality if applicable;
    f. The lot, lot, or control number of each constituent and packaging materials used in production of the lot;
    g. The weight or measure of each lot of each constituent used in production of the lot, including the unit of measure;

h. The quantity of each lot of each packaging constituent and each label used, including the unit of measure;
i. The date(s) on which, and where applicable the time(s) at which, each step of the MPR was performed;
j. The actual results obtained during monitoring of production process parameters;
k. The identity of processing lines and major equipment used in producing the lot;
l. The date and time of the maintenance, cleaning, and sanitizing of the processing lines and major equipment used in producing the lot, or a cross-reference to records, such as individual equipment logs, where this information is recorded;
m. The date and time of the maintenance and the calibration, inspection, or other performance verification of instruments and of automated, mechanical, or electronic equipment used directly in production of the lot; or a cross-reference to records, such as individual equipment logs, where this information is recorded;
n. A statement of the actual yield and a statement of the percentage of theoretical yield at each significant process step and at the end of manufacturing and of packaging;
o. Records of any marijuana waste generated during production of the lot;
p. Records of any treatment, process adjustment, reprocessing, repackaging, relabeling, or other deviation that occurred during production of the lot;
q. An actual or representative label used in packaging of the lot, and a specimen of any other labeling used;
r. Records of the date, time where applicable, quantity, and person responsible for any sample removed during or after production;
s. The actual results of any testing or examination of in-process marijuana material, or a cross-reference to such results;
t. Documentation that the marijuana product meets its specifications for identity, purity, strength, and composition, and is packaged and labeled in accordance with the requirements of the MPR; and
u. The identity of each person involved in production of the lot, including employees who perform secondary operations.

9.1.8.3.8 Inventory and Recordkeeping Requirements:

1. The Inventory Manager must ensure proper inventory management and recordkeeping in accordance with the policies and procedures found in the Inventory Management and Control SOP; additionally, all records will be retained on the premises for a minimum of six (6) years.

9.1.8.3.9 Harvest Inspections

Each harvest shall be examined carefully by trained employees and damaged and/or degraded plant material shall be removed and disposed of in accordance with the Marijuana Waste Disposal SOP. All crops are to be inspected by two or more trained employees for all visible foreign matter and sub-standard material to be removed. Foreign matter includes plant

material from other species or from other parts of the harvested species; grow media; insects; and wire, glass, paper, tools or tool parts, and other man-made objects. Sub-standard material includes, for example, discolored leaves or flowers; or any other material that would cause the crop to fail to meet its specifications.

The inspection for foreign matter and sub-standard material will be conducted while the crop is sufficiently well displayed by two or more employees to allow for their ready visibility. Representative samples sufficient in size shall be taken from each strain and each harvest. A sample log shall be maintained to accurately reflect the origination of the sample to allow trace- back. Samples shall be labeled with the contents by the plant name and identification; the date of harvest; the identification number; and any other identifying information and stored separately from product inventories in a manner that maintains their quality and correlation in the event that assurance of accurate identity needs to be reconfirmed at a later date.

9.1.8.4 Processing Area Sanitation and Quality Control Procedures

It is Hale O Laulima policy to implement hygiene and sanitation requirements that enhance the ability to consistently produce and distribute marijuana products that conform to internal quality standards. All marijuana products packaged for distribution will have successfully passed laboratory testing and will only enter the supply chain after all quality control and assurance activities have been fulfilled. Refer to the Hygiene, Sanitation and Facility Requirements SOP for additional detail.

The Production Facility Manager must ensure all marijuana is processed in a safe and sanitary manner. Marijuana must be:

1. Well cured and free of seeds and stems;
2. Free of dirt, media, debris and other foreign matter;
3. Free of contamination by mold, rot, other fungus, and bacterial diseases;
4. Prepared and handled on food-grade stainless steel tables; and
5. Packaged in a secure area.

9.1.8.4.1 Process Monitoring During Production:

1. Process specifications will be established by the Processing Manager and other processing area resources for production process parameters at or during any point, step, or stage where control is necessary to ensure the quality of the batch of a marijuana product, and to detect any unanticipated occurrence that may result in contamination, adulteration, or a failure to meet specifications;
2. The process parameters to be monitored will include, but are not limited to, the following as appropriate:
    a. Time;
    b. Temperature;
    c. Pressure;

d. Speed; and
e. Any additional Critical Process Parameter (CPP) as defined by the Processing Manager.

3. Production process parameters will be monitored at or during any point, step, or stage where process specifications have been established; and
4. Any deviation from the specified process parameters must be approved by the Processing Manager, documented, and justified in the Procedure Variance Log.

9.1.8.4.2 Process Validation

Hale O Laulima recognizes the importance of performing process validation for quality assurance purposes. Rather than simply performing quality assurance inspection or testing of in-process and finished products, Hale O Laulima will ensure that production processes are designed and sufficiently controlled to assure that in-process materials and finished products consistently and reliably meet pre-defined quality specifications. It is Hale O Laulima policy that no product will be released for distribution until process validation is complete and provides a high level of assurance that performance of the established production process will consistently produce products that meet product specifications for identity, purity, strength, and composition.

After a process has been validated and the product is approved for distribution, Hale O Laulima will continue to require processing employees to record and enter data at key points in the production process and carry out pre-procedure, in-process, and post-procedure inspections and quality checks of random product samples for every lot. These continual control and data collection measures will be approved by the QCT and built into Hale O Laulima's standard operating procedures.

9.1.8.4.3 Process Maintenance

Once a given production process has been established and validated, Hale O Laulima must maintain control over the process, even as changes in the workforce, equipment, materials, and other similar items occur. The QCT and Facility Managers will periodically review and analyze data in production records to assess the degree of variability and whether variability is within an acceptable range for the process. In order to assure ongoing control over the production process, Hale O Laulima will:

1. Develop and implement ongoing programs in which data is collected and used to assess process control;
2. Identify problems or opportunities for improvement; and
3. Return to the core process validation activities to assess, validate, and implement modifications to the process in the interest of improving the state of control.

9.1.8.4.3.1 Core Activities

Hale O Laulima's central goals for the process validation program are to ensure homogeneity within and consistency between lots. As such, understanding, evaluating, and addressing

sources of variation in a given process are the core activities of Hale O Laulima's process validation program. Throughout process design and evaluation, Hale O Laulima will aim to:

4. Understand the sources of real and/or potential variation;
5. Collect and analyze data at various points in the process to detect the presence and degree of variation;
6. Understand the impact of variation on the process and on the final product's quality; and
7. Identify and implement measures for controlling variation that are appropriately tailored to the risk posed (i.e., a high degree of control is appropriate for components of the process that pose a greater risk).

9.1.8.4.3.2 Interdisciplinary Process Validation Team

Our team members with experience producing marijuana / marijuana products, in pharmaceutical manufacturing, and in laboratory analysis comprise Hale O Laulima's interdisciplinary process validation team. This team has already worked together to build control measures into the production processes proposed in this application, and will coordinate during process validation for each product to identify, determine the source of, and address unacceptable levels of deviation.

9.1.9 Production Failures

Any unexplained occurrence or discrepancy, and any failure of the product to meet its specifications or requirements, will be documented and investigated. The investigation will extend to any related batches that may have been associated with the same specific failure, discrepancy, or problem; this may include, but is not limited to, batches of the same marijuana product, other batches processed on the same equipment or during the same time period, other batches produced using the same lots of constituents or packaging constituents.

9.1.10 Calculation of Yield:

1. Actual yields must be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or labeling of the marijuana and marijuana product;
2. Such calculations must either be performed by one person and independently verified by a second person; or, if the yield is calculated by automated equipment, be independently verified by one person; and

9.1.11 Production and Packaging Operations

The Quality Control Team with the Inventory Manager shall ensure that all production processes utilized by Hale O Laulima are sufficient to ensure the safety, quality, identity, purity and potency of all marijuana and marijuana products sold by Hale O Laulima. The Quality Control Team with the Inventory Manager must ensure that all employees are trained to properly execute all processes that pose a risk to marijuana or marijuana products in process.

9.1.12 Inspections

The Inventory Manager must:

3. Examine packaged and labeled products during finishing operations to provide assurance that the containers and packages have the correct labels;
4. Collect a representative sample of units at the completion of finishing operations and ensure that the samples are visually examined for correct labeling; and
5. Record the results of the examinations performed in the applicable production or control records.
6. Follow the inspections / audit schedule as defined in the Inventory Control and Management SOP

9.1.13 Laboratory Testing

Pursuant to HAR §11-850-81, Hale O Laulima will not dispense marijuana or marijuana products unless a laboratory certified by the Hawai'i DOH pursuant to Subchapter 7 Laboratory Certification, Testing, and Standards; has tested the marijuana and marijuana products and they meet the requirements set out in HAR §11-850 Subchapter 7. Refer to the Sampling and Testing SOP for additional detail on Hale O Laulima's laboratory testing policies and procedures.

9.1.14 Packaging and Labeling

Pursuant to HAR §11-850-92, Hale O Laulima has developed a Packaging and Labeling SOP that is compliant with Subchapter 8 Signage, Packaging, and Labeling. Refer to the Packaging and Labeling SOP for additional detail on Hale O Laulima's packaging and labeling policies and procedures.

9.1.15 Proper Storage Required

The Inventory Manager and the Production Facility Manager, in coordination with the Quality Control Team, will ensure that marijuana or marijuana products that have been subjected to improper storage conditions, including, without limitation, extremes in temperature, humidity, smoke, fumes, pressure, age or radiation due to natural disasters, fires, accidents or equipment failures, are not salvaged and returned to the marketplace, and are instead disposed of in accordance with the Marijuana Waste Disposal SOP.

9.1.15.1 Requirements for Salvaging Operations

If the Inventory Manager and QCT believe that marijuana or marijuana products have not been damaged due to improper storage conditions, they will authorize salvaging operations only if, upon review, there is:

1. Evidence from internal and/or independent laboratory tests that the marijuana or marijuana products meet all applicable standards of identity, strength, quality and purity; and

2. Evidence from inspection of the premises that the marijuana or marijuana products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident, if any.

9.1.15.2 Salvaged Product Records

The Inventory Manager will maintain records including the name, batch number and disposition for marijuana products salvaged for a minimum of six (6) years.

9.4 Exhibit 4: Sampling and Testing SOP

9.2.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawai'i Department of Health and to promote patient, product and public safety. As rule changes occur and best practices evolve, the content of this document will be reviewed and updated where appropriate. Each step in our manufacturing and distribution processes is carefully performed and controlled so that the resulting medical marijuana products possess the safety, quality, identity, purity, and potency (SQuIPP) that patients deserve.

HAR Requirement	Description
§11-850-81	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. Eff. DEC 14 2015
§11-850-85.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-evident manner a similar sample from the same batch, for verification testing as directed by the department.
§11-850-85.b	A certified laboratory shall test and analyze samples according to standard operating procedures prepared by the laboratory based on validated methods published in peer reviewed scientific or regulatory literature, subject to approval by the department.
§11-850-85.c	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 the supporting data for the following:
§11-850-85.c.1	The chemical profile of the batch for the following compounds:
§11-850-85.c.1.A	Δ^9 (delta 9) - tetrahydrocannabinol (THC)
§11-850-85.c.1.B	Tetrahydrocannabinol Acid (THCA)
§11-850-85.c.1.C	Cannabidiol (CBD)
§11-850-85.c.1.D	Cannabidiolic Acid (CBDA)
§11-850-85.c.1.E	Cannabigerol (CBN)
§11-850-85.c.1.F	Cannabinol (CBN)
§11-850-85.c.2	The presence of the following contaminants, which shall not exceed the following levels:
§11-850-85.c.2.A	Heavy metals:
§11-850-85.c.2.A.i	Arsenic 10.0 ppm
§11-850-85.c.2.A.ii	Lead 6.0 ppm
§11-850-85.c.2.A.iii	Cadmium 4.0 ppm
§11-850-85.c.2.B	Mercury 2.0 ppm
§11-850-85.c.2.C	Solvents:
§11-850-85.c.2.C.i	Butanes 800 ppm
§11-850-85.c.2.C.ii	Heptanes 500 ppm
§11-850-85.c.2.C.iii	Benzene** 1 ppm
§11-850-85.c.2.C.iv	Toluene** 1 ppm
§11-850-85.c.2.C.v	Hexane** 10 ppm
§11-850-85.c.2.C.vi	Total Xylenes (m, o, p-xylene) 1 ppm **Contaminants in solvents
§11-850-85.c.2.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;
§11-850-85.c.2.E	Moisture content of plant material <15%
§11-850-85.c.2.F	Microbiological impurities, including but not limited to:
§11-850-85.c.2.F.i	Total Viable Aerobic Bacteria:
§11-850-85.c.2.F.i.a	Unprocessed and Processed Materials: 10^5 Colony Forming Unit (CFU)/g
§11-850-85.c.2.F.i.b	CO2 and Solvent Based Extracts: 10^4 CFU/g
§11-850-85.c.2.F.ii	Total Yeast and Mold:
§11-850-85.c.2.F.ii.a	Unprocessed and Processed Materials: 10^4 CFU/g
§11-850-85.c.2.F.ii.b	CO2 and Solvent Based Extracts: 10^3 CFU/g

HAR Requirement	Description
§11-850-85.c.2.F.iii	Total Coliforms:
§11-850-85.c.2.F.iii.a	Unprocessed and Processed Materials: 10^3 CFU/g
§11-850-85.c.2.F.iii.b	CO2 and Solvent Based Extracts: 10^2 CFU/g
§11-850-85.c.2.F.iv	Bile-tolerant Gram Negative Bacteria:
§11-850-85.c.2.F.iv.a	Unprocessed and Processed Materials: 10^3 CFU/g
§11-850-85.c.2.F.iv.b	CO2 and Solvent Based Extracts: 10^2 CFU/g
§11-850-85.c.2.F.v	E. coli (pathogenic strains) and Salmonella spp.: Not detected in 1 g
§11-850-85.c.2.F.vi	Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger:<1 CFU/g;
§11-850-85.c.2.F.vii	Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and
§11-850-85.c.3	Additional testing requested at the discretion of the department.
§11-850-85.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.
§11-850-85.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.
§11-850-85.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:
§11-850-85.f.1	The time and date the sample was obtained;
§11-850-85.f.2	A description of the sample, including the amount;
§11-850-85.f.3	What tests were conducted on each sample;
§11-850-85.f.4	the results of the tests including the certificate of analysis; and
§11-850-85.f.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; and shall make all the records available to the department upon request.
§11-850-85.g	A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection ©, and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.
§11-850-85.h	A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.
§11-850-85.i	The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection ©, 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.
§11-850-85.j	A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection © 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). Eff. DEC 14 2015

9.2.2 Local Compliance

In accordance with the requirements defined by Hawai'i Administrative Rules Chapter(s): 11-850-81, 11-850-85 and enforced by the Hawai'i DOH, Hale O Laulima has developed a Quality Management System that assures each step in our manufacturing and distribution processes is carefully performed and controlled. Hale O Laulima will subject ALL marijuana and marijuana products for laboratory analysis prior to releasing products into the dispensary supply chain to assure full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-850-81 and §11-850-85.

9.2.3 Definitions and Abbreviations:

Air-Conditioning ("A/C")
American National Standards Institute ("ANSI")

American Society for Testing and Materials ("ASTM")
Automated Data Processing/Point-of-Sale System ("ADP/POS")
Batch Production Record ("BPR")
BBC Research & Consulting ("BBC")
Board of Directors ("the Board")
Cannabidiol ("CBD")
Cannabidiolic Acid ("CBDA")
Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
Chief Operations Officer ("COO")
Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)
Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")
Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")
Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)
Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")
Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")

National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")
Quality Control Team ("QCT")
Quality Control Unit ("QCU")
Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")
Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

9.2.4 Mandatory Sampling and Testing by Independent Laboratory

9.2.4.1 Mandatory Testing Overview

As described below, Hale O Laulima will establish a relationship with a Hawai'i DOH-approved independent testing laboratory with marijuana testing protocols and methods. Upon request, the selected independent testing laboratory will send a representative to the Production Facility to collect samples of each finished batch. The samples will be transported to the independent testing laboratory and analyzed in accordance with scientifically valid methods. The analytical tests conducted will be appropriate for determining whether the batch meets specifications for the marijuana or marijuana product. The independent testing laboratory will then provide Hale O Laulima with a certificate of analysis for each batch which provides results and a statement as to whether the batch meets pre-determined specifications. A batch may not be released for distribution by the Quality Control Unit (QCT) prior to receipt and confirmation of a certificate of analysis which demonstrates conformance with specifications. All certificates of analysis will be stored and maintained for a minimum of six (6) years. Additionally, pursuant to §11-850-85.a Hale O Laulima will maintain a similar sample in a secure tamper-evident manner from the same batch for subsequent verification testing as directed by the Hawai'i DOH.

9.2.4.2 Compliance with Hawai'i DOH Testing Rules

It is the responsibility of the Production Facility Manager in coordination with the Inventory Manager and Quality Control Team to ensure compliance with all Hawai'i DOH testing rules, including but not limited to:

1. Utilization of Hawai'i DOH-registered laboratories;
2. Required testing, which includes:
    a. §11-850-85.c.1 The chemical profile of the batch for the following compounds:
    b. §11-850-85.c.1.A Δ^9 (delta 9) - tetrahydrocannabinol (THC)
    c. §11-850-85.c.1.B Tetrahydrocannabinol Acid (THCA)
    d. §11-850-85.c.1.C Cannabidiol (CBD)
    e. §11-850-85.c.1.D Cannabidiolic Acid (CBDA)
    f. §11-850-85.c.1.E Cannabigerol (CBN)
    g. §11-850-85.c.1.F Cannabinol (CBN)
    h. §11-850-85.c.2 The presence of the following contaminants, which shall not exceed the following levels:
    i. §11-850-85.c.2.A Heavy metals:
    j. §11-850-85.c.2.A.i Arsenic 10.0 ppm
    k. §11-850-85.c.2.A.ii Lead 6.0 ppm
    l. §11-850-85.c.2.A.iii Cadmium 4.0 ppm
    m. §11-850-85.c.2.B Mercury 2.0 ppm
    n. §11-850-85.c.2.C Solvents:
    o. §11-850-85.c.2.C.i Butanes 800 ppm
    p. §11-850-85.c.2.C.ii Heptanes 500 ppm
    q. §11-850-85.c.2.C.iii Benzene** 1 ppm
    r. §11-850-85.c.2.C.iv Toluene** 1 ppm
    s. §11-850-85.c.2.C.v Hexane** 10 ppm
    t. §11-850-85.c.2.C.vi Total Xylenes (m, o, p-xylene) 1 ppm
    u. **Contaminants in solvents
    v. §11-850-85.c.2.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;
    w. §11-850-85.c.2.E Moisture content of plant material <15%
    x. §11-850-85.c.2.F Microbiological impurities, including but not limited to:
    y. §11-850-85.c.2.F.i Total Viable Aerobic Bacteria:
    z. §11-850-85.c.2.F.i.a Unprocessed and Processed Materials: 10^5 Colony Forming Unit (CFU)/g
    aa. §11-850-85.c.2.F.i.b CO2 and Solvent Based Extracts: 10^4 CFU/g
    bb. §11-850-85.c.2.F.ii Total Yeast and Mold:
    cc. §11-850-85.c.2.F.ii.a Unprocessed and Processed Materials: 10^4 CFU/g
    dd. §11-850-85.c.2.F.ii.b CO2 and Solvent Based Extracts: 10^3 CFU/g
    ee. §11-850-85.c.2.F.iii Total Coliforms:
    ff. §11-850-85.c.2.F.iii.a Unprocessed and Processed Materials: 10^3 CFU/g

gg.	§11-850-85.c.2.F.iii.b	CO2 and Solvent Based Extracts: 10^2 CFU/g
hh.	§11-850-85.c.2.F.iv	Bile-tolerant Gram Negative Bacteria:
ii.	§11-850-85.c.2.F.iv.a	Unprocessed and Processed Materials: 10^3 CFU/g
jj.	§11-850-85.c.2.F.iv.b	CO2 and Solvent Based Extracts: 10^2 CFU/g
kk.	§11-850-85.c.2.F.v	E. coli (pathogenic strains) and Salmonella spp.: Not detected in 1 g
ll.	§11-850-85.c.2.F.vi	Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger:<1 CFU/g;
mm.	§11-850-85.c.2.F.vii	Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and
nn.	§11-850-85.c.3	Additional testing requested at the discretion of the department.

3. Testing of every finished Batch;
4. Contamination response plans; and
5. Scientifically valid sampling and analytical methods.

9.2.4.3 Authorized Laboratories

Samples may only be collected by an independent laboratory approved by the Production Facility Manager and Inventory Manager. The Quality Control Team must ensure that any laboratory utilized by Hale O Laulima is registered with the Hawai'i DOH, has applied to be ISO 17025 accredited in Hawai'i or is owned or operated by a laboratory that is accredited in another jurisdiction by an accreditation body whose standards are equivalent to the ISO 17025.

9.2.4.4 Quality Assurance Responsibilities

The Inventory Manager and Quality Control Team is responsible for ensuring no finished marijuana products are released for distribution until batch test results have been received that establish that the batch meets Hale O Laulima-imposed standards for purity, potency, identity, and safety (i.e., the product specifications).

9.2.4.5 Frequency of Testing

The mandatory frequency of testing is per batch. Hale O Laulima will ensure that every finished batch undergoes analytical testing. Upon completion of a batch, the entire batch will be immediately quarantined until sampling, testing, and verification of conformance to specifications is complete and documented. Additional testing may be requested as necessary or desired.

9.2.5 Product Sampling and Quarantine

9.2.5.1 Sampling Requirements:

1. A representative sample of each lot or batch of marijuana product must be collected, by removing and compositing portions of material or units from throughout the containers in the lot or batch;
2. In addition to representative samples, other samples may be taken as appropriate to ensure safe and standardized marijuana products:
    a. Monitor the quality of in-process materials during production;
    b. Examine the degree of variability of materials or products;
    c. Investigate known or suspected non-conformances; and
    d. For retention, to allow stability testing and follow-up testing in the event of a product-related complaint or adverse event;
3. The number of containers and the amount of material or units to be removed from each container must be based on tenets of statistical validity. Other appropriate criteria may be considered as well, such as the quantity needed for testing, examination, and reserve; the past quality history of the item; the expected variability of the material or units being sampled; and the degree of confidence and precision required;
4. The containers selected for sampling must be based on rational criteria such as random sampling; directed sampling may be used where appropriate;
5. Samples must be collected in accordance with the following procedures:
    a. Product containers must be opened, sampled, and resealed in a manner designed to prevent contamination of their contents or of other constituents, packaging materials, in-process materials, and marijuana products;
    b. Sterile equipment and aseptic sampling techniques must be used when necessary; and
    c. Where appropriate for the purpose and the nature of the material being sampled, sample portions should be removed from the top, middle, and bottom of containers. Such sample portions may be composited in forming the representative sample, or may be tested separately, as appropriate to the purpose.
6. Containers from which samples have been taken must be marked to show that samples have been removed from them and identified with the following information:
    a. The name of the item sampled;
    b. The lot, batch, lot, or control number;
    c. The container from which the sample was taken, or for samples taken directly from the production line, the equipment line and time at which the sample was taken;
    d. The date on which the sample was taken;
    e. The name of the person who collected the sample; and
    f. The quantity and unit of measure of the sample.
7. Each sample removed from a lot or batch must be recorded in the inventory or production records for the lot or batch;

8. The quantity of sample used for each test or examination must be of sufficient size or number to ensure the results are representative of the lot or batch;
9. Reserve samples of twice the quantity needed for testing must be prepared from the representative sample of each batch of constituent or marijuana product;
10. Reserve samples of constituents and packaging constituents should:
    a. Be stored using an appropriate container-closure to protect against contamination or deterioration during storage;
    b. Be stored under conditions consistent with the typical storage conditions for the constituent or product; and
    c. Be retained for one year past the expiration date of the last batch of marijuana product manufactured or packaged from the lot, for use in appropriate investigations.

9.2.5.2 Batch Sampling Procedure Post-Harvest:

1. Immediately after a batch of marijuana has completed drying and curing, the Inventory Manager will segregate the finished batch, place in a sterile airtight storage container, and place in quarantine storage;
    a. The batch must be marked as quarantined in the ADP/POS system, Biotrack, by placement on the quarantine storage shelf, and by application of a "QUARANTINE- DO NOT DISTRIBUTE" tag on each container;
2. The Inventory Manager will then contact the independent testing laboratory to request sampling;
3. On the agreed upon date, an employee of the independent testing laboratory will come to the facility as an approved visitor, enter the storage area and take statistically valid samples from each batch for testing, according to the sample collection procedures contained herein and sampling protocols of the laboratory;
4. The employee of the independent testing laboratory will place samples in individual, secure, tamper-evident containers that meet sample labeling requirements;
5. The Inventory Manager will also collect a similar representative sample from the same batch that will be maintained in a secure tamper-evident manner at the Production Facility for verification testing as directed by the Hawai'i DOH.
6. Hale O Laulima will request Hawai'i DOH-mandated tests as well as any additional testing procedures desired;
7. The Inventory Manager will obtain a receipt for the sample(s) taken and will enter this receipt in the electronic ADP/POS system;
8. The remainder of the batch will then be returned to quarantine storage to await test results;
9. When test results are received (in the form of a certificate of analysis), they will be attached to the batch in the ADP/POS system and stored in the secure cloud-based recordkeeping system. The test results will then be securely sent to the Production Facility Manager and Quality Control Team; and
10. Once the test results are received by all relevant persons and entered in the ADP/POS system:

a. If the sample meets specifications, the Quality Control Team and Inventory Manager will release the entire batch for distribution and physically move the batch to regular storage; and
b. If the sample fails to meet specifications, the Inventory Manager will execute the procedure for failed batches, which includes secure segregated storage until disposal in accordance with standard operating procedure.

9.2.5.3 Batch Sampling Procedure Post-Processing:

1. Immediately after a lot of finished marijuana infused product or extract is produced, the Inventory Manager will segregate the finished lot, place in a sterile airtight storage container, and place in quarantine storage;
    a. The lot must be marked as quarantined in the ADP/POS system, by placement on the quarantine storage shelf, and by application of a "QUARANTINE- DO NOT DISTRIBUTE" tag on each container;
2. The Inventory Manager will then request that a representative of the independent testing laboratory come to collect samples from each finished lot for independent testing;
3. A representative of the independent testing laboratory will come to the facility as an approved visitor and collect sample(s) of each finished lot for testing, according to the sample collection procedures contained herein and any procedures required by the independent testing laboratory;
4. The Inventory Manager will also collect a similar representative sample from the same batch that will be maintained in a secure tamper-evident manner at the Production Facility for verification testing as directed by the Hawai'i DOH.
5. The representative of the independent testing laboratory will place samples in individual, secure, tamper-evident containers that meet sample labeling and storage requirements;
6. The Inventory Manager will request that the independent laboratory conduct all mandated tests and additional testing procedures desired;
7. The Inventory Manager will obtain receipts for the samples taken and will enter these receipts in the ADP/POS system;
8. The remainder of the lot will be returned to quarantine storage to await test results;
9. When independent test results are received (in the form of a certificate of analysis), they will be attached to the lot in the ADP/POS system and stored in the secure cloud-based recordkeeping system. The test results will then be securely sent to the Production Facility Manager and Quality Control Team; and
10. Once the test results are received by all relevant persons and entered in the ADP/POS system:
    a. If the sample meets specifications, the Quality Control Team and Inventory Manager will release the entire batch for distribution and physically move the batch to regular storage; and
    b. If the sample fails to meet specifications, the Inventory Manager will execute the procedure for failed batches, which includes secure segregated storage until disposal in accordance with standard operating procedure.

9.2.5.4 Mandatory Quarantine of Product

From the time that a BATCH/LOT is finished until the independent testing laboratory provides a certificate of analysis and the Compliance and Inventory Manager approves the Batch for release, the Production Facility unit shall segregate and withhold from use the entire batch, except the samples that are removed for testing. The Production Facility Manager in coordination with the Inventory Manager and Quality Control Team must ensure:

1. The batch is maintained in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy; and
2. Under no circumstances may the batch be distributed until testing and analysis is completed, results have been provided in a certificate of analysis, and the Quality Control Team has released the batch for distribution.

9.2.5.5 Sterile and Statistically Valid Techniques Required

It is Hale O Laulima policy that the independent testing laboratory must implement sterile and statistically valid sampling techniques when collecting samples for analysis.

9.2.5.6 Special Considerations for Sampling Raw Marijuana

The medicinally effective compounds in marijuana are unevenly and non-randomly distributed throughout the marijuana plant, which makes collecting a representative sample of raw marijuana tricky. Though representative samples could be obtained by homogenizing a finished batch of marijuana, homogenization of a batch substantially damages the product. Grinding marijuana plant material for homogenization affects potency by dislodging trichomes, increases the speed of degradation, and reducing the aesthetic quality and therefore retail value as marijuana flower is typically sold in intact bud form. As such, it is in the interest of patients and licensees alike to determine alternative methods for obtaining representative samples of marijuana that are satisfactory to the Hawai'i DOH.

Upon establishing a relationship with a registered independent testing laboratory, Hale O Laulima will discuss options for collection of representative samples that do not require homogenization of every finished batch. Any alternative must be approved by the Hawai'i DOH and considered valid in the professional opinion of the independent testing laboratory operator in order to be considered satisfactory by Hale O Laulima.

9.2.5.7 Sample Handling

The independent testing laboratory must retrieve samples from the facility and transport the samples directly to the laboratory. Samples must be handled, transported, and stored in a manner that prevents contamination. A detailed chain of custody must be maintained at all times and a receipt must be provided for all samples taken.

9.2.5.8 Sample Transportation

An authorized employee of the independent testing laboratory will be granted visitor access to the Production Facility for the purpose of retrieving samples and will then securely transport the samples directly to the laboratory. All marijuana and marijuana product samples transported to a laboratory for testing purposes will be done in accordance with the procedures detailed in the Shipping and Receiving SOP:

1. The laboratory representative will fulfill all visitor requirements detailed in the Shipping and Receiving SOP and will be signed in and out of the Hale O Laulima facility Visitor Log;
2. All samples will be transported in a secured, locked container that fulfills the transportation storage requirements set forth in the Shipping and Receiving SOP;
3. A shipping manifest will be completed and securely transmitted to the laboratory receiving the samples; and

Any motor vehicle transporting the marijuana samples will travel directly from the Production Facility to the independent testing laboratory and will not make any stops en-route except to other laboratories, for refueling purposes, or in case of emergency.

9.2.6 Failure to Meet Specifications / Non-Conformance

Any batch found to be non-conforming must be rejected and disposed or destroyed in accordance with the Marijuana Waste Disposal SOP. Alternatively, if approved by the Hawai'i DOH and Quality Control Team, reworked, treated, or reprocessed according to methods contained in Hale O Laulima standard operating procedures for the Production Facility operation. At present, Hale O Laulima does not plan to rework or reprocess failed batches and accordingly has not produced procedures for doing so at time of application.

If this policy changes in the future, any treatment, reprocessing, or reworking of a failed Batch must be documented in the production logs and ADP/POS system, justified, and approved by the Quality Control Team. After reprocessing or reworking the failed batch is complete, the batch must be sampled and tested again. If the batch fails to meet specifications a second time, the entire batch must be quarantined and disposed of in accordance with marijuana waste disposal procedures.

All documentation, including analytical test results, will be maintained for a minimum of six (6) years.

9.2.7 Results May Not Be Falsified

Hale O Laulima strictly prohibits the falsification or manipulation of analytical test results. Any Hale O Laulima employee discovered falsifying test results or distributing marijuana or marijuana products that have not been released by the Quality Control Team or Inventory Manager shall be terminated immediately.

9.2.8 Sample Return or Disposal

In accordance with §11-850-85.e, the independent testing laboratory will return to Hale O Laulima or destroy in a manner approved by the Hawai'i DOH any remains of the sample once analysis is complete. All samples returned to Hale O Laulima will be disposed of in accordance with the policies and procedures defined in the Marijuana Waste Disposal SOP.

9.2.9 Additional Testing May Be Required

The Hawai'i DOH may require additional testing. The Quality Control Team must ensure that Hale O Laulima complies with all published Hawai'i DOH testing requirements.

9.2.10 In-House Analysis Program

9.2.10.1 Laboratory Director

Hale O Laulima has acquired a Laboratory Director, who will be responsible for the development and execution of all internal testing procedures and maintenance of analytical equipment, as well as all quality assurance and quality control activities. The selected Laboratory Director, PERSON, has managed analytical laboratories and produced standard operating procedures for these operations throughout the course of his career. He also has previous experience in the pharmaceutical industry and is well versed in the handling and testing of medicines. PERSON has years of experience with quality control and chain of custody procedures for regulatory samples and will utilize these skills and implement these processes in his position as Laboratory Director. PERSON's resume and biography is provided in the Staffing and Training SOP.

The Laboratory Director will be responsible for all testing activities desired by Hale O Laulima that are not required to be conducted by an independent testing laboratory per §11-850-85. This may include, but is not limited to, chromatographic analysis of in-process marijuana plants, development and verification of product specifications, analysis of in-process marijuana products for the purpose of determining compliance with in-process specifications, and analytical testing for the purposes of research and development, formulation, process and procedural validation. Internal test results will be used for internal improvement of methods and practices, as well as for further educating the managers and employees in each production area.

9.2.10.2 Laboratory Director Responsibilities

The Laboratory Director will be responsible for conducting all internal product testing and overseeing independent product testing. The Laboratory Director will be responsible for the maintenance of analytical equipment and implementation of laboratory procedures and best practices to ensure that product test results are reliable measures of the quality, safety, and composition of the marijuana and marijuana products produced by Hale O Laulima.

9.5 Exhibit 5: Marijuana Waste Disposal SOP

9.5.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawai'i Department of Health and to promote patient, product and public safety. As rule changes occur and best practices evolve, the content of this document will be reviewed and updated where appropriate. Each step in our manufacturing and distribution processes is carefully performed and controlled so that the resulting medical marijuana products possess the safety, quality, identity, purity, and potency (SQuIPP) that patients deserve.

HAR Requirement	Description
§11-58.1	"Solid Waste Management Control". 01/13/94. Note: Effective March 13, 1999, Section 54 of HAR 11-58.1 is replaced by HAR Chapter 11-279, "Standards for the Management of Used Oil"
§11-62	"Wastewater Systems" 12/09/04
§11-260	"Hazardous Waste Management". 09/22/1999
§11-850-43.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.
§11-850-43.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.
§11-850-43.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. Eff. DEC 14 2015
§11-850-61.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 ADP/POS, 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.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-75.f	A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.
§11-850-75.i	The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.
§11-850-85.f.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; and shall make all the records available to the department upon request.

9.5.1.1 Local Compliance

In accordance with applicable Marijuana waste storage and disposal requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-850 and enforced by the Hawai'i DOH, Hale O Laulima will strictly prohibit ANY activity that may deviate from the administrative rules. All Marijuana waste disposal procedures and policies implemented in Hale O Laulima's Production and Retail Dispensary Facilities will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-58.1, §11-62, §11-260 and §11-850.

9.5.2 Definitions and Abbreviations:

Air-Conditioning ("A/C")
American National Standards Institute ("ANSI")
American Society for Testing and Materials ("ASTM")
Automated Data Processing/Point-of-Sale System ("ADP/POS")
Batch Production Record ("BPR")
BBC Research & Consulting ("BBC")
Board of Directors ("the Board")
Cannabidiol ("CBD")
Cannabidiolic Acid ("CBDA")
Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
Chief Operations Officer ("COO")
Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)
Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")
Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")
Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)
Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")

Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")
National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")
Quality Control Team ("QCT")
Quality Control Unit ("QCU")
Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")
Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

9.5.3 Marijuana Waste Storage and Disposal Policies

9.5.3.1 Important Points

All waste, including waste composed of or containing finished Marijuana and Marijuana products, will be stored, secured, locked and managed in accordance with state laws and regulations as detailed in HAR §11-850. "Marijuana waste" means any part of the plant that is not usable Marijuana, or Marijuana that cannot be processed as provided in HAR §11-850.

All disposed waste will be recorded in the Waste Disposal Log with details pertaining to the date of disposal, type and quantity of waste disposed of and the manner of disposal. Additional waste disposal provisions include detailed plans for excess product disposal, liquid and solid waste disposal based on guidelines from the Hawai'i DOH, composting practices, and the disposal of expired, contaminated, or otherwise unusable Marijuana products. The Production and Retail Dispensary Facilities General Managers will also report any verifiable incident of unauthorized destruction of Marijuana to the Hawai'i DOH and law enforcement.

9.5.3.2 Marijuana Waste Storage and Disposal Procedure

1. Hale O Laulima will not produce or maintain quantities of Marijuana in excess of what is needed for normal, efficient operation and to meet the needs of the qualified registered patients who obtain their medicine from Hale O Laulima's dispensary facilities;
2. Prior to disposal, Marijuana waste will be securely stored in a locked compartment that is located in an area under video surveillance and kept quarantined from all usable Marijuana products, Marijuana source material, or Marijuana plants in order to prevent contamination;
3. Prior to disposal, Marijuana waste will be rendered unusable via the methods set forth below. All Marijuana waste will be returned to the secure storage location immediately after being rendered unusable;
    a. Check the Automated Data Processing / Point-of-Sale System (ADP/POS) and relevant internal logs to determine the recordkeeping requirements for plant maintenance, harvest and trimming procedures;
    b. Put an empty plant waste container on the scale and tare the scale. Remove the empty container from the scale;
    c. Individually weigh each plant waste container holding plant waste from a single harvest batch. Write down the weight of each on a sheet of paper. Repeat until all containers with plant waste from a single batch have been weighed and recorded;
    d. Using your calculator, add up all of the weights (remember: one harvest batch at a time!);
    e. During a harvest, complete the relevant sections of the Harvest Log (i.e. record cumulative waste weight as the "By-Product Weight" for the batch);
    f. Dump all pre-weighed and recorded plant waste into one or more trash bags. Tie up trash bags and set aside;
    g. Transport trash bags containing plant waste to the grinder;
    h. Grind all plant waste until very fine. Return ground waste to trash bag(s);
    i. Place trash bags with ground plant waste in a 44-gallon trashcan;
    j. Using a trashcan dolly, wheel each trashcan containing ground plant waste to the exterior waste receptacle. Transport fabric pots containing used media and other post-consumer waste out to the exterior waste receptacle;
    k. Open plant waste trash bags and dump contents into the exterior waste receptacle;
    l. Dump post-consumer waste and used media on top of the ground up plant material. Continue adding non-Marijuana waste until you are sure the mixture contains more than 50% non-Marijuana waste by weight;
    m. Using your poly-scoop shovel, mix the Marijuana waste and non-Marijuana waste. The Marijuana waste must be rendered unusable and unrecognizable;
    n. Lock or otherwise secure the exterior waste receptacle;
    o. Fill out all relevant sections of the Waste Disposal Log;
    p. Report plant waste in the ADP/POS system. Be sure to attach the plant waste to the harvest batch.
    q. Sanitize and clean all used supplies and work surfaces;

r. Ensure that all required records have been entered into the ADP/POS system and that all portions of relevant internal logs have been completed;
s. Coordinate pick up with the approved disposal Hale O Laulima; and
t. Complete sections relevant to pick up in the Waste Disposal Log after pick up.

4. After being rendered unusable, mixed Marijuana waste will be securely stored until it is transported to a permitted waste-to-energy plant where the plant waste will be combusted for renewable energy generation, if available; Hale O Laulima will dispose of Marijuana waste in the manner set forth herein until the Hawai'i DOH specifies an approved method of Marijuana waste disposal. Hale O Laulima will appropriately revise all related procedures and comply with the Hawai'i DOH approved method immediately after it is identified;
5. The secure area used for the storage and mixing of Marijuana waste will be securely locked and protected from unauthorized entry, other than during the time required to move or render Marijuana unusable, or prepare mixed waste for transport to the specified disposal facility;
6. If, for any reason, Hale O Laulima's Dispensary License approval is revoked or not renewed, Hale O Laulima will not cultivate Marijuana on or after the date that its authorization expires, and not until the Dispensary License approval is renewed and in good standing. All Marijuana possessed by Hale O Laulima will be destroyed within 48 hours of the expiration or revocation of approval;
7. Marijuana waste will be stored and disposed of in a manner that minimizes the development of odors that could present a public nuisance;
8. Marijuana waste will be stored and disposed of in a manner that minimizes the potential for such waste to attract, harbor, or become a breeding place for pests;
9. Marijuana waste will be stored and disposed of in a manner that protects against contamination of Marijuana, contact surfaces, production and Retail Dispensary Facilities areas, water supplies, and grounds surrounding the facilities;
10. Marijuana waste will be stored and disposed of in a manner that prevents diversion, theft, or loss of Marijuana plant material and Marijuana products;
11. Marijuana waste will be stored and disposed of in a manner that ensures traceability through internal documentation and real-time electronic tracking in the ADP/POS;
12. All Marijuana waste on the premises of the Production and Retail Dispensary Facilities will be stored in a secured and locked container within an area covered by continuous video surveillance; and
13. All Marijuana waste and waste disposal activities will be recorded in Hale O Laulima's ADP/POS and in Hale O Laulima's internal Waste Disposal Log. These records will be maintained in an electronic format for a six (6) year period and will be made available for inspection upon request by the Hawai'i DOH, and, when necessary for investigative purposes by law enforcement agencies.

Several members of the **Hale O Laulima ("HOL")** team have been involved with heavily regulated industries that have strict requirements as to signage, packaging, labeling and chain of custody of products, including those related to (a) forensic samples; (b) pharmaceutical products; (c) agricultural food products; and (d) marijuana products, including (1) Director of Processing **Jennifer Bash**, a Senior Analytical Forensic Toxicology Specialist with the Analytical Forensic Testing Laboratory at the University of Illinois at Chicago College of Pharmacy, has spent the past 10 years working in forensics as a toxicologist analyzing biological samples for compounds of interest; (2) General Counsel **Bob Morgan**, who oversaw the initial development of standards related to signage, packaging, labeling and chain of custody of marijuana products for the Illinois Medical Cannabis Program; (3) Medical Advisory Board Member **Neal Akamine** a pharmacist with over 30 years' experience in pharmaceutical retail management, including most recently as Retail Pharmacy Manager for Pharmacare Hawai'i where he oversaw eight locations, including all staff and operations; (4) Medical Advisory Board Member **Jason Castro**, a Hawai'i licensed pharmacist of ten years; (5) partners and executive team members within **Cresco Labs** and **Denver Relief Consulting** who collectively own and operate or have assisted in the management of over 35 regulated medical marijuana cultivation, processing and retail facilities in North America that are subject to stringent signage, packaging, labeling and chain of custody rules and regulations; (6) Agriculture & Horticulture Advisory Board Member **Forrest Sawlaw**, who opened and managed the country's largest indoor recirculating aquaculture farm with Archer Daniels Midland, managed a 12.5 acre tomato greenhouse, and constructed and managed the country's largest indoor lettuce production facility; and (7) **Michael Nottoli** who has 10 years of medical device and pharmaceutical manufacturing experience, including experience with validating and operating packaging and labeling machines.

Packaging and Labeling. HOL will package all final marijuana products in plain, opaque, tamper-evident and child resistant packaging in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act and without depictions of the product, cartoons, or images (see Exhibit 1). Only certified food- or pharmaceutical-grade packaging

materials will be utilized. This plan details measures that will ensure that products are free of contaminants and are in compliance with state requirements. Types of containers, labels, and information included on labels will be compliant with all DOH laws and regulations. All packaging operations will take place on sanitized work surfaces, supervised by a manager, and performed utilizing a properly registered NTEP Legal for Trade scale. Approved scales will be integrated into the automated data processing / point-of-sale ("ADP/POS") system. Labels will include legible wording and be firmly affixed on each package of marijuana product. (see Exhibit 2) Our Packaging and Labeling SOP, along with an example of an appropriate label reference and a detailed description of information required by the DOH to be contained on all labels is provided (see Exhibits 2 and 6).

Marijuana will be packaged in bulk at the Production facility while awaiting test results or transfer to final packaging to be transported to the Retail Dispensary Facilities. The Production Facility General Manager in coordination with the Inventory Manager must accurately identify and label all marijuana products packaged in bulk packages. No bulk package may contain more than two (2) pounds of marijuana and all products packaged in bulk will be affixed with a bar code that allows scanning and tracking in the ADP/POS system, Biotrack. The bar code will be connected to marijuana product(s) and harvest records associated with the batch inside the bulk package which will include the following: strain name or identifier; batch identification number; package weight; testing results, if available, including pass/fail and cannabinoid content by weight; employee or manager responsible for packaging; a list of all soil amendments, fertilizers, and other crop inputs; date of harvest; date of packaging; and expiration date.

Signage. External signage for the Retail Dispensary Facilities will only display the registered company name and address in order to assist patients in locating Hale O Laulima retail facilities. Separate production facilities will not display the company name associated with the retail dispensary facilities. Hours of operation, a phone number and website shall also be displayed at the Retail Dispensary Facilities for additional information for patients about HOL. All external signage will be maintained in compliance with applicable State and city laws and regulations. HOL will

conspicuously display appropriate signage as follows: (1) any permits or notices, including those pertaining to employment, required by applicable federal, state or local laws; (2) hazard warning signs, the hazard rating diamond sign and 'no smoking' signs on the entrances to the extraction room, oven room, manufacturing room, chemical storage area, and the exterior door of the building; (3) any permits or notices required by law will be posted near areas in which solvents are utilized and stored; (4) all points of change to a stricter access level will bear a sign indicating only authorized personnel may enter; (5) all rooms will be labeled by name and access level; and (6) "Employees must wash hands" signs at all hand washing sinks.

Chain of Custody. The Inventory Control and Management SOP of HOL (see Exhibit 5) outlines operational procedures for inventory management and chain of custody control. The Production and Retail Dispensary Facilities General Manager(s) and Inventory Manager will work collaboratively to assure that inventory is tracked from seed to sale, counted and recorded at required intervals, and that any discrepancies are documented, investigated and reported to the appropriate authorities. This seed to sale tracking includes (1) all marijuana plants in any phase of production such as mother plants, clones, vegetative plants, and flowering plants; (2) marijuana products in process; (3) finished marijuana and marijuana products; (4) all marijuana products awaiting disposal; (5) acquisitions; (6) harvests; (7) sales; (8) shipments or transfers; and (9) disposals of unusable marijuana products.

The ADP/POS, herein referred to as, "Biotrack", and its inventory management module will be accurate and capable of producing reports on all marijuana products in production, finished, stored and distributed. Discrepancies identified during inventory that are not due to documented causes will be reported to the Facility General Manager and Inventory Manager and the causes will be investigated. Any suspected cases of diversion, theft, loss and any criminal action involving an employee will be reported to the Hawai'i DOH and associated Law Enforcements. The Facility General Manager will also report any verifiable incident of theft or loss of marijuana to the Hawai'i DOH and the Hawai'i State Police, as required. **<END OF NARRATIVE>**

APPENDIX – SUPPLEMENT TO NARRATIVE

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Members of our **Hale O Laulima ("HOL")** team have significant experience in the secure handling and disposal of marijuana plants, marijuana byproduct, marijuana finished product and manufactured marijuana products (marijuana products). Our members include (1) General Counsel **Bob Morgan**, who was the primary architect of the Illinois Medical Cannabis Pilot Program - one of the most regulated and highly-regarded medical marijuana programs in the country, including oversight of rules development related to marijuana waste destruction and disposal; and (2) partners and executive team members within **Cresco Labs** and **Denver Relief Consulting** who collectively own and operate or have assisted in the management of over 35 regulated medical marijuana cultivation, processing and retail facilities in North America that are subject to state-mandated waste destruction and disposal requirements. Throughout the development and management of each of these operations and using the experiences of our team's tenured professionals, our Marijuana Waste Disposal Plan (see Exhibit 3) has evolved into what is now our Quality Management System (QMS), often regarded as the industry model for best practices, policies and procedures and compliance related to the safe destruction and disposal of marijuana.

In accordance with applicable Marijuana waste storage and disposal requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-850 and enforced by the Hawai'i Department of Health (DOH), we will strictly prohibit any activity that may deviate from the administrative rules. All Marijuana waste disposal procedures and policies implemented in our Production and Retail Dispensary facilities will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-58.1, §11-62, §11-260 and §11-850. All waste, including waste composed of or containing marijuana products, will be stored, secured, locked and managed in accordance with state laws and regulations as detailed in HAR §11-850. "Marijuana waste" means any part of the plant that is not usable or marijuana products that cannot be processed as provided in HAR §11-850.

All disposed waste will be recorded in the Waste Disposal Log with details pertaining to the date of disposal, type and quantity of waste disposed of and the manner of disposal. Additional waste disposal provisions include detailed plans for excess product disposal, liquid and solid waste disposal based on guidelines from the DOH, composting practices, and the disposal of expired, contaminated, or otherwise unusable marijuana products. The Production and Retail Dispensary Facilities General Managers will also report any verifiable incident of unauthorized destruction of marijuana products to the DOH and law enforcement.

We will not produce or maintain quantities of marijuana products in excess of what is needed for normal, efficient operation and to meet the needs of the qualifying patients who obtain their medicine from our retail dispensary facilities. Prior to any disposal, marijuana product waste will be securely stored in a locked compartment that is located in an area under video surveillance and kept quarantined from all usable marijuana products in order to prevent contamination. All marijuana product waste will be ground until very fine and mixed with at least an equal amount of Bokashi or other organic material for the purposes of rendering the marijuana product waste unusable and accelerating the composting process. After being rendered unusable, mixed marijuana product waste will be securely stored until a compost waste hauler transports it to a permitted facility for composting, if allowed by DOH. It is the intention of the company to work with a compost hauler company that will work with local farmers to provide this weight in composted material at a steep discount or free of charge. HOL has confirmed composting services with Hawaiian Earth Products. (see Exhibit 2)

Though compostable material is a form of waste, it is ultimately less environmentally harmful than non-compostable material. Hale O Laulima will minimize grow media waste by utilizing local composting services to collect and process organic material. Hale O Laulima will use new organic media as the primary cultivation medium and will coordinate with local composting companies to collect used media that would otherwise be diverted to a landfill. All composting activities will be carried out in accordance with the rules set forth in HAR §11-

58.1. Ultimately, we will dispose of marijuana product waste in the manner set forth herein until the DOH specifies an approved method of marijuana product waste disposal. HOL will appropriately revise all related procedures and comply with the DOH-approved method immediately after it is identified.

The secure area used for the storage and mixing of marijuana product waste will be securely locked and protected from unauthorized entry, other than during the time required to move or render marijuana products unusable, or prepare mixed waste for transport to the specified disposal facility. Marijuana product waste will be stored and disposed of in a manner that (1) minimizes the development of odors that could present a public nuisance; (2) minimizes the potential for such waste to attract, harbor, or become a breeding place for pests; (3) protects against contamination of usable marijuana products, contact surfaces, Production and Retail Dispensary Facilities areas, water supplies, and grounds surrounding the facilities; (4) prevents diversion, theft, or loss of marijuana products; and (5) ensures traceability through internal documentation and real-time electronic tracking in the automated data processing / point-of-sale system (ADP/POS system). All marijuana product waste and waste disposal activities will be recorded in our ADP/POS and in HOL's internal Waste Disposal Log. These records will be maintained in an electronic format for a six (6) year period and will be made available for inspection upon request by the DOH, and, when necessary for investigative purposes by law enforcement agencies.

Our group will utilize policies and procedures to enhance the ability to minimize waste of all types, including marijuana plant waste. Waste generated at the production and retail dispensing facility will be stored on the premises until disposal and disposed of solely in locations and in a manner designated by DOH and Mililani Township in Honolulu County as appropriate for that type of waste. HOL aims to eliminate marijuana product waste wherever possible. When waste cannot be eliminated, efforts will be made to minimize waste output, reduce environmental harm, and compost materials. Efforts to minimize marijuana product waste include (1) regular coordination between the Production Facility General Managers, Retail Dispensary Facility General

Managers and the Inventory Manager to determine the appropriate level of production anticipating qualifying patient needs in order to minimize waste due to excess marijuana production; (2) maintenance of an integrated environmental and pest management plan to effectively protect crops from pest and environmental related damage and detect contamination early, thereby minimizing marijuana waste due to contamination; (3) incorporation of segregated Production and Retail Dispensary Facilities areas and a designated quarantine room in Production Facility design to physically limit the spread of pests and reduce waste due to marijuana product contamination; and (4) proper storage and product handling, detailed in the Product Handling and Storage SOP, which will minimize marijuana product contamination and adulteration.

Conservative 12-month waste projections are derived from our industry partners Cresco Labs and Denver Relief Consulting, which incorporate similar waste mitigation strategies. It is anticipated that the proposed Production Facilities will produce approximately 20,250 pounds of fan and stem weight (10 lbs. of waste per flowering light per year) of waste annually. These amounts were determined by examining existing data from operations in Colorado, Illinois and Nevada. Our group will strive to produce an appropriate quantity of marijuana products to meet the projected needs of qualifying patients. The Chief Operating Officer, in coordination with the Director of Cultivation, will determine the number of marijuana plants to cultivate based on the known patient base and estimated HOL market share, with consideration for ramp-up in the patient population over time. The explicit goal of such projections is to avoid excess production, which poses an additional security risk and results in financial loss and degraded product if it is stored for too long. Though HOL aims to avoid overproduction, any marijuana product that is not needed for normal, efficient operation in order to serve the projected needs of the registered qualifying patients will be disposed of in accordance with the procedures set forth below. The Cultivation General Manager will determine and document the need for excess inventory disposal in coordination with the Inventory Manager.

The Human Resources Manager will provide or cause to be provided all relevant and adequate waste destruction and disposal training for each individual involved in Hale O Laulima operations. Training will be tailored to the roles and responsibilities of the job function of each employee employed in a dispensary facility. At a minimum, staff will receive eight (8) hours of on-going training annually regarding all responsibilities, including waste disposal and destruction. No employee may begin work until they receive training on proper waste destruction and disposal marijuana products.

For HOL Marijuana Waste Disposal SOPs, please refer to Exhibits 3-5. **<END OF NARRATIVE>**

APPENDIX – SUPPLEMENT TO NARRATIVE

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11.3 Exhibit 3: Non-Marijuana Waste Disposal SOP

11.1.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawai'i Department of Health and to promote patient, product and public safety. As rule changes occur and best practices evolve, the content of this document will be reviewed and updated where appropriate. Each step in our manufacturing and distribution processes is carefully performed and controlled so that the resulting medical marijuana products possess the safety, quality, identity, purity, and potency (SQuIPP) that patients deserve.

HAR Requirement	Description
§11-58.1	"Solid Waste Management Control". 01/13/94. Note: Effective March 13, 1999, Section 54 of HAR 11-58.1 is replaced by HAR Chapter 11-279, "Standards for the Management of Used Oil"
§11-62	"Wastewater Systems" 12/09/04
§11-260	"Hazardous Waste Management". 09/22/1999
§11-850-43.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.
§11-850-43.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.
§11-850-43.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. Eff. DEC 14 2015
§11-850-61.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 ADP/POS, 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.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-75.f	A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.
§11-850-75.i	The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.
§11-850-85.f.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; and shall make all the records available to the department upon request.

11.1.2 Local Compliance

In accordance with applicable non-marijuana waste storage and disposal requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-58.1, 11-62, 11-260 and enforced by the Hawai'i DOH, Hale O Laulima will strictly prohibit the placement, dumping, or disposal of trash, garbage, litter, or any other kind of waste on the property of another legal entity or any public place in the county, including streets, sidewalks, and parks. Waste generated at the production and retail dispensing facility will be securely stored on the premises until disposal and disposed

of solely in locations and in a manner designated by Mililani Township in Honolulu County as appropriate for that type of waste. All waste disposal procedures and policies implemented in Hale O Laulima's Production and Retail Dispensary Facilities will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-58.1, §11-62, §11-260 and §11-850.

11.1.3 Definitions and Abbreviations:

Air-Conditioning ("A/C")
American National Standards Institute ("ANSI")
American Society for Testing and Materials ("ASTM")
Automated Data Processing/Point-of-Sale System ("ADP/POS")
Batch Production Record ("BPR")
BBC Research & Consulting ("BBC")
Board of Directors ("the Board")
Cannabidiol ("CBD")
Cannabidiolic Acid ("CBDA")
Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
Chief Operations Officer ("COO")
Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)
Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")
Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")

Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)
Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")
Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")
National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")
Quality Control Team ("QCT")
Quality Control Unit ("QCU")
Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")
Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

11.1.4 Non-Marijuana Waste Storage and Disposal Policies

11.1.4.1 Liquid Waste

It is Hale O Laulima policy that liquid waste resulting from Production and Retail Dispensary Facilities operations may not enter the municipal sewer system. In order to prevent this, all liquid waste will be disposed of in an on-site septic system that is compliant with the requirements of the Hawai'i EHA and all applicable local and state laws and regulations. In accordance with applicable Hawai'i EHA and US EPA regulations, Hale O Laulima will ensure that no wastes are discharged from Hale O Laulima facilities to any waters of the state without first

being given the degree of treatment necessary, at a permitted facility, to protect the beneficial uses of such water.

11.1.4.2 Sewage and Wastewater

The bathrooms and area drains in the Production Facilities in Mililani Township will be connected to an approved on-site septic system. All liquid waste potentially containing marijuana solids or residues, nutrients, chemicals, or any other potential pollutant will be disposed of in the on-site septic system. The on-site septic system will be maintained in compliance with §11-62 and the system tanks will be pumped by a permitted septic disposal service if needed. Hale O Laulima does not anticipate needing to have the tanks pumped because bacteria will break down the liquid waste before it is discharged to the drain field on-site. However, a permitted septic disposal service will be used if a clog or other issue arises that impacts the system's operation. The system will meet all applicable standards set forth in §11-62. The Production facilities' septic and graywater systems will be periodically checked to assure that sewage, wastewater, and other liquid waste are adequately transported from the facility to the on-site septic system via waste water lines that pose no threat of crossing with potable water lines. Disposal of liquid chemical waste will be executed in full compliance with federal, state and local laws and regulations as well as in accordance with instructions on the product's label and any safety data sheet (SDS), if applicable.

11.1.4.2.1 Wastewater Minimization

The Production and Retail Dispensary Facilities Manager will implement policies to eliminate water waste and to recycle water, including the reclamation of water from air-conditioning (A/C) condenser units and dehumidifiers, whenever possible. Refer to the Waste Minimization SOP for additional detail.

11.1.4.3 Solid Waste

As used in this SOP, solid waste definitions are set forth by HAR §11-58.1. "Solid waste" or "waste" means:

> *garbage, refuse, and other discarded materials, including solid, liquid, semi-solid, or contained gaseous materials resulting from industrial, commercial, mining, and agricultural operations, sludge from waste treatment plants and water supply treatment plants, and residues from air pollution control facilities and community activities, but does not include solid or dissolved materials in domestic sewage or other substances in water sources such as silt, dissolved or suspended solids in industrial waste water effluents, dissolved materials in irrigation return flows, or other common water pollutants, or source, special nuclear, or by-product material as defined by the federal Atomic Energy Act of 1954, as amended (68 Stat. 923).*

Hale O Laulima will comply with all guidelines and requirements of the Hawai'i DOH solid waste management program. Recyclable materials are considered a subtype of solid waste, which are stored and disposed of separately from other solid wastes. Hale O Laulima will obtain commercial solid waste and recyclable materials collection service from Mililani Township's solid waste management franchise. The selected collection service will regularly collect and transfer all solid waste generated at the Production or Retail Dispensary Facilities to one of the approved facilities in Honolulu County for proper disposal. Hale O Laulima plans not to use pesticides in cultivation operations, but reserves the right to use approved products as a last resort. If locally available, Hale O Laulima will take empty, triple-rinsed containers that held non-hazardous pesticides to a pesticide container recycling center.

11.1.4.3.1 Solid Waste Management

1. All solid wastes, including recyclables, will be stored in a manner so that they do not constitute a fire, health, or safety hazard or provide a food or harbor for vermin;
2. All solid waste containing food wastes will be securely stored in covered or closed containers which are nonabsorbent, leak-proof, durable, easily cleanable, and designed for safe handling;
3. Waste containers used for storing solid waste or recyclables will meet the American National Standards Institute (ANSI) standards for waste containers;
4. Solid waste will be placed into recycling bins or trash bags within trashcans inside the Production and Retail Dispensary Facilities;
5. At the end of each day, one or more Production or Retail Employees will tie up the trash bags, carry the recycling containers and trash bags to the external secure containers, and place the bags and recyclables into their appropriate container for pick up;
6. External waste containers will be installed in a manner that prevents spillage or leakage during on-site collection; and
7. Hale O Laulima will ensure that solid wastes are collected at least once per week.

11.1.4.4 Hazardous Waste

In accordance with HAR §11-260, hazardous waste will be transported and disposed of pursuant to the rules and regulations of the Hawai'i DOH and the EPA. A waste can be classified as a hazardous waste in 3 ways:

1. §11-261-3 provides the definition of hazardous waste in the state of Hawai'i.
2. If it is listed in 40 Code of Federal Regulations (CFR) 261 Subpart D[1] as hazardous by the EPA;
3. If it is characterized in 40 CFR 261 Subpart C[2] as hazardous by exhibiting one of the four hazardous characteristics:
    a. Ignitability;
        i. Has a flash point of less than 140°F or could catch fire under certain circumstances;

[1]http://www.ecfr.gov/cgi-bin/text-idx?SID=acc3fec2e729642231b9817bdf8afcf7&mc=true&node=sp40.26.261.d&rgn=div6

ii. Examples: solvents, mineral spirits, paint waste;
iii. Ignitable hazardous wastes are assigned the EPA hazardous waste code of D001.

b. Corrosivity:
   i. Is aqueous and has a pH that is very low (2 or less) or very high (12.5 or higher), or can corrode metal;
   ii. Examples: acids or alkali cleaning baths, battery acid;
   iii. Corrosive hazardous wastes are assigned the EPA hazardous waste code of D002.

c. Reactivity:
   i. Unstable, reacts violently, explodes, or produces toxic vapors under certain conditions;
   ii. Examples: cyanide waste, sulfide waste, peroxides;
   iii. Reactive hazardous wastes are assigned EPA hazardous waste code of D003.

d. Toxicity:
   i. Has specific toxic contaminants present in high enough concentrations to be harmful to humans or the environment;
   ii. Toxic contaminants and their toxicity threshold levels are included in the federal hazardous waste regulations;
   iii. Examples: wastes that contain heavy metals or certain chemicals (e.g., benzene, pesticides);

Toxic hazardous wastes are assigned the EPA hazardous waste codes of D004 through D043, depending on the contaminant present.

11.1.4.4.1 On-Site Management of Hazardous Waste

1. Hale O Laulima will actively try to avoid using hazardous materials by selecting non-hazardous options whenever possible, and will put measures in place to avoid generating hazardous waste altogether.
2. Hale O Laulima employees who will manage hazardous waste may refer to the EPA's Handbook for Hazardous Waste Containers for guidance.
3. Hazardous waste will be characterized using information from Safety Data Sheets, markings, and labels before it is placed in a waste container. Employees will identify hazardous characteristics and determine if the waste is reactive, incompatible with other wastes, or has properties that require special methods and equipment for proper management.
4. Incompatible wastes will be stored in separate containers and separate storage areas.
5. All hazardous waste will be secured in containers appropriate for the type of hazard, compatible with the contents, and appropriate for the amount of waste.
6. Containers will be kept in good condition (e.g. free of dents, free of corrosion, no leaking, no bulging, etc.).
7. If a container begins to leak or show damage, the waste will be carefully transferred to another container. The employee transferring the waste must wear personal protective equipment (PPE) relevant to the hazardous characteristics of the waste inside.

8. Lids to hazardous waste containers will remain closed and secure when not actively adding waste to or removing waste from the container.
9. Hazardous waste container labels will contain the words "Hazardous Waste", a description of the contents, and EPA waste codes.
10. Hazardous waste containers will be stored in a climate-controlled area so that containers remain cool and dry.
11. Hale O Laulima will store hazardous waste in appropriate containers on-site for no more than 90 days before collection and transport for proper disposal.
12. Container storage areas will be inspected weekly. At a minimum, the inspection will cover leaks or staining from containers, general container condition, labeling, and management practices.

When hazardous materials must be used or handled in the facility, they will be used and handled in accordance with instructions on the SDS for that product and while using the appropriate PPE, then returned to the hazardous materials storage area promptly after use.

11.1.4.5 Determining Generator Status

Hale O Laulima will follow the guidelines presented in 40 CFR 261.5 for determining Hale O Laulima's hazardous waste generator status. Hale O Laulima anticipates achieving a conditionally exempt small quantity generator (CESQG) status each month if any hazardous waste is generated at all. A generator is a CESQG in a calendar month if the entity generates no more than 100 kilograms (220 pounds) of hazardous waste in that month.

Hale O Laulima does not intend on being a hazardous waste generator by implementing good Production and Retail management practices. If hazardous waste is generated, generator status at each facility will be determined on a monthly basis by the Quality Control Team. Hale O Laulima will monitor hazardous waste quantities and take steps to minimize the amount of hazardous waste generated in order to ensure that Hale O Laulima can either avoid hazardous waste generation altogether or maintain CESQG status. Pursuant to HAR §11-260 -, the Quality Control Team will notify the Hawai'i DOH of all changes in generator status using the EPA Form 8700-12, "Notification of Regulated Waste Activities".

Provided Hale O Laulima complies with the hazardous waste disposal requirements set forth, as a CESQG, Hale O Laulima's hazardous wastes, if any, will not be subject to regulation under 40 CFR Parts 262-268, Parts 270 and 124, and the notification requirements of Hawai'i DOH §11-260.

11.1.4.6 Universal Waste

Hale O Laulima will comply with Federal rules (40 CFR Part 273[3]) for the identification and management of universal waste. Four potential hazardous wastes may be managed as universal waste:

[3] http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=1ce91cc9988cc26b5bf9c888b27cab58&n=pt40.27.273&r=PART&ty=HTML

1. Lamps;
2. Batteries;
3. Mercury-containing devices; and
4. Recalled, cancelled, suspended, or unusable pesticides.

Hale O Laulima will follow federal, state, and local guidelines for the identification, management, and disposal of universal waste. The universal waste requirements for lamps are relevant for production and retail operations. For present purposes, lamp is defined as the bulb or tube portion of an electric lighting device. Examples of common universal waste electric lamps include, but are not limited to, fluorescent, high intensity discharge, neon, mercury vapor, high-pressure sodium, and metal halide lamps.

Hale O Laulima plans not to use pesticides in cultivation operations, but reserves the right to do so as a last resort if mechanical, cultural, biological, and organic controls are unable to control a pest or disease problem, or as needed for cultivation room sanitation and decontamination purposes after a widespread pest or disease outbreak. If pesticides must be acquired, good management practices will be in place to ensure that non-hazardous pesticides are selected if at all possible, and that the smallest amount of the pesticide needed to address the issue is acquired. With the application of these management practices, Hale O Laulima does not anticipate generating universal waste in the form of recalled, cancelled, suspended, or unusable pesticides. If the Hawai'i DOH establishes a list of approved pesticides for use in marijuana cultivation, Hale O Laulima will immediately incorporate the list into cultivation standard operating procedures and training materials, and will strictly prohibit the acquisition and use of any pesticide not included on the list. The Production Facility Manager, in coordination with the Quality Control Team, will be responsible for adapting practices, procedures, and documents to comply with any future pesticide standards or restrictions, and will ensure all Cultivation Employees are informed and trained accordingly.

Hale O Laulima anticipates being classified as a Small Quantity Handler of Universal Waste, as defined in 40 CFR Part 273.9, which means Hale O Laulima will not accumulate 5,000 kilograms or more of universal waste at any time and is therefore exempt from many universal waste management regulatory provisions.

11.1.4.7 Separate Disposal Services Required for Special Waste Types

It is Hale O Laulima policy that hazardous waste and universal waste will not be mixed with or disposed with other solid waste, and will be managed separately.

11.1.4.8 Non-Marijuana Waste Disposal Service Providers

Hale O Laulima will comply with Honolulu County Department of Environmental Services preferred methods of waste disposal and will only use locally authorized waste disposal providers.

11.4 Exhibit 4: Marijuana Waste Disposal SOP

11.2.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawai'i Department of Health and to promote patient, product and public safety. As rule changes occur and best practices evolve, the content of this document will be reviewed and updated where appropriate. Each step in our manufacturing and distribution processes is carefully performed and controlled so that the resulting medical marijuana products possess the safety, quality, identity, purity, and potency (SQuIPP) that patients deserve.

HAR Requirement	Description
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§11-62	"Wastewater Systems" 12/09/04
§11-260	"Hazardous Waste Management". 09/22/1999
§11-850-43.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.
§11-850-43.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.
§11-850-43.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. Eff. DEC 14 2015
§11-850-61.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 ADP/POS, 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.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-75.f	A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.
§11-850-75.i	The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.
§11-850-85.f.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; and shall make all the records available to the department upon request.

11.2.1.1 Local Compliance

In accordance with applicable Marijuana waste storage and disposal requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-850 and enforced by the Hawai'i DOH, Hale O Laulima will strictly prohibit ANY activity that may deviate from the administrative rules. All Marijuana waste disposal procedures and policies implemented in Hale O Laulima's Production and Retail Dispensary Facilities will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-58.1, §11-62, §11-260 and §11-850.

11.2.2 Definitions and Abbreviations:

Air-Conditioning ("A/C")
American National Standards Institute ("ANSI")
American Society for Testing and Materials ("ASTM")
Automated Data Processing/Point-of-Sale System ("ADP/POS")
Batch Production Record ("BPR")
BBC Research & Consulting ("BBC")
Board of Directors ("the Board")
Cannabidiol ("CBD")
Cannabidiolic Acid ("CBDA")
Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
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Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)
Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")
Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")
Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)
Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")

Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")
National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")
Quality Control Team ("QCT")
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Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")
Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

11.2.3 Marijuana Waste Storage and Disposal Policies

11.2.3.1 Important Points

All waste, including waste composed of or containing finished Marijuana and Marijuana products, will be stored, secured, locked and managed in accordance with state laws and regulations as detailed in HAR §11-850. "Marijuana waste" means any part of the plant that is not usable Marijuana, or Marijuana that cannot be processed as provided in HAR §11-850.

All disposed waste will be recorded in the Waste Disposal Log with details pertaining to the date of disposal, type and quantity of waste disposed of and the manner of disposal. Additional waste disposal provisions include detailed plans for excess product disposal, liquid and solid waste disposal based on guidelines from the Hawai'i DOH, composting practices, and the disposal of expired, contaminated, or otherwise unusable Marijuana products. The Production and Retail Dispensary Facilities General Managers will also report any verifiable incident of unauthorized destruction of Marijuana to the Hawai'i DOH and law enforcement.

11.2.3.2 Marijuana Waste Storage and Disposal Procedure

1. Hale O Laulima will not produce or maintain quantities of Marijuana in excess of what is needed for normal, efficient operation and to meet the needs of the qualified registered patients who obtain their medicine from Hale O Laulima's dispensary facilities;
2. Prior to disposal, Marijuana waste will be securely stored in a locked compartment that is located in an area under video surveillance and kept quarantined from all usable Marijuana products, Marijuana source material, or Marijuana plants in order to prevent contamination;
3. Prior to disposal, Marijuana waste will be rendered unusable via the methods set forth below. All Marijuana waste will be returned to the secure storage location immediately after being rendered unusable;
    a. Check the Automated Data Processing / Point-of-Sale System (ADP/POS) and relevant internal logs to determine the recordkeeping requirements for plant maintenance, harvest and trimming procedures;
    b. Put an empty plant waste container on the scale and tare the scale. Remove the empty container from the scale;
    c. Individually weigh each plant waste container holding plant waste from a single harvest batch. Write down the weight of each on a sheet of paper. Repeat until all containers with plant waste from a single batch have been weighed and recorded;
    d. Using your calculator, add up all of the weights (remember: one harvest batch at a time!);
    e. During a harvest, complete the relevant sections of the Harvest Log (i.e. record cumulative waste weight as the "By-Product Weight" for the batch);
    f. Dump all pre-weighed and recorded plant waste into one or more trash bags. Tie up trash bags and set aside;
    g. Transport trash bags containing plant waste to the grinder;
    h. Grind all plant waste until very fine. Return ground waste to trash bag(s);
    i. Place trash bags with ground plant waste in a 44-gallon trashcan;
    j. Using a trashcan dolly, wheel each trashcan containing ground plant waste to the exterior waste receptacle. Transport fabric pots containing used media and other post-consumer waste out to the exterior waste receptacle;
    k. Open plant waste trash bags and dump contents into the exterior waste receptacle;
    l. Dump post-consumer waste and used media on top of the ground up plant material. Continue adding non-Marijuana waste until you are sure the mixture contains more than 50% non-Marijuana waste by weight;
    m. Using your poly-scoop shovel, mix the Marijuana waste and non-Marijuana waste. The Marijuana waste must be rendered unusable and unrecognizable;
    n. Lock or otherwise secure the exterior waste receptacle;
    o. Fill out all relevant sections of the Waste Disposal Log;
    p. Report plant waste in the ADP/POS system. Be sure to attach the plant waste to the harvest batch.
    q. Sanitize and clean all used supplies and work surfaces;

r. Ensure that all required records have been entered into the ADP/POS system and that all portions of relevant internal logs have been completed;
s. Coordinate pick up with the approved disposal Hale O Laulima; and
t. Complete sections relevant to pick up in the Waste Disposal Log after pick up.

4. After being rendered unusable, mixed Marijuana waste will be securely stored until it is transported to a permitted waste-to-energy plant where the plant waste will be combusted for renewable energy generation, if available; Hale O Laulima will dispose of Marijuana waste in the manner set forth herein until the Hawai'i DOH specifies an approved method of Marijuana waste disposal. Hale O Laulima will appropriately revise all related procedures and comply with the Hawai'i DOH approved method immediately after it is identified;
5. The secure area used for the storage and mixing of Marijuana waste will be securely locked and protected from unauthorized entry, other than during the time required to move or render Marijuana unusable, or prepare mixed waste for transport to the specified disposal facility;
6. If, for any reason, Hale O Laulima's Dispensary License approval is revoked or not renewed, Hale O Laulima will not cultivate Marijuana on or after the date that its authorization expires, and not until the Dispensary License approval is renewed and in good standing. All Marijuana possessed by Hale O Laulima will be destroyed within 48 hours of the expiration or revocation of approval;
7. Marijuana waste will be stored and disposed of in a manner that minimizes the development of odors that could present a public nuisance;
8. Marijuana waste will be stored and disposed of in a manner that minimizes the potential for such waste to attract, harbor, or become a breeding place for pests;
9. Marijuana waste will be stored and disposed of in a manner that protects against contamination of Marijuana, contact surfaces, production and Retail Dispensary Facilities areas, water supplies, and grounds surrounding the facilities;
10. Marijuana waste will be stored and disposed of in a manner that prevents diversion, theft, or loss of Marijuana plant material and Marijuana products;
11. Marijuana waste will be stored and disposed of in a manner that ensures traceability through internal documentation and real-time electronic tracking in the ADP/POS;
12. All Marijuana waste on the premises of the Production and Retail Dispensary Facilities will be stored in a secured and locked container within an area covered by continuous video surveillance; and
13. All Marijuana waste and waste disposal activities will be recorded in Hale O Laulima's ADP/POS and in Hale O Laulima's internal Waste Disposal Log. These records will be maintained in an electronic format for a six (6) year period and will be made available for inspection upon request by the Hawai'i DOH, and, when necessary for investigative purposes by law enforcement agencies.

11.5 Exhibit 5: Waste Minimization SOP

11.3.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawai'i Department of Health and to promote patient, product and public safety. As rule changes occur and best practices evolve, the content of this document will be reviewed and updated where appropriate. Each step in our manufacturing and distribution processes is carefully performed and controlled so that the resulting medical marijuana products possess the safety, quality, identity, purity, and potency (SQuIPP) that patients deserve.

HAR Requirement	Description
§11-58.1	"Solid Waste Management Control". 01/13/94. Note: Effective March 13, 1999, Section 54 of HAR 11-58.1 is replaced by HAR Chapter 11-279, "Standards for the Management of Used Oil"
§11-62	"Wastewater Systems" 12/09/04
§11-260	"Hazardous Waste Management". 09/22/1999
§11-850-43.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.
§11-850-43.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.
§11-850-43.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. Eff. DEC 14 2015
§11-850-61.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 ADP/POS, 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.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-75.f	A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.
§11-850-75.i	The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.
§11-850-85.f.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; and shall make all the records available to the department upon request.

11.3.1.1 Local Compliance

In accordance with applicable waste storage and disposal requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-58.1, 11-62, 11-260, 11-850 and enforced by the Hawai'i DOH, Hale O Laulima will utilize policies and procedures to enhance the ability to minimize waste of all types. Waste generated at the production and retail dispensing facility will be stored on the premises until disposal and disposed of solely in locations and in a manner designated by Mililani Township in Honolulu County as appropriate for that type of waste. All

waste disposal procedures and policies implemented in Hale O Laulima's Production and Retail Dispensary Facilities will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-58.1, §11-62, §11-260 and §11-850.

11.3.2 Definitions and Abbreviations:

Air-Conditioning ("A/C")
American National Standards Institute ("ANSI")
American Society for Testing and Materials ("ASTM")
Automated Data Processing/Point-of-Sale System ("ADP/POS")
Batch Production Record ("BPR")
BBC Research & Consulting ("BBC")
Board of Directors ("the Board")
Cannabidiol ("CBD")
Cannabidiolic Acid ("CBDA")
Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
Chief Operations Officer ("COO")
Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)
Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")
Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")
Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)

Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")
Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")
National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")
Quality Control Team ("QCT")
Quality Control Unit ("QCU")
Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")
Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

11.3.3 Waste Projections and Minimization Strategies

Hale O Laulima aims to eliminate waste wherever possible. When waste cannot be eliminated, efforts will be made to minimize waste output, reduce environmental harm, and reuse materials. Conservative 12-month waste projections are derived from industry consultants who operate a similar Medical Marijuana Production and Retail Dispensary operation, which incorporate similar waste mitigation strategies to those described below.

It is anticipated that the proposed Medical Marijuana Dispensary license which will be initially composed of (1) production facility and (2) retail dispensary locations will produce approximately 5,530 pounds of fan and stem weight (5 lbs. of waste per flowering light per

year) of waste annually. These amounts were determined by examining existing data from operations in Illinois and Colorado.

11.3.3.1 Waste Waster

Zero toxic wastewater is expected during a 12-month period at both the Production and Retail Dispensary Facilities. The Production and Retail Dispensary Facilities will produce quantities of sewage waste consistent with a facility with a similar size staff. Hale O Laulima will not produce toxic wastewater or runoff during the cultivation of marijuana. All cultivation production water runoff will be recycled and reapplied into the irrigation cycle. This goal will be achieved through the successful collection of all runoff water generated during Production Facility operations and the processing of this runoff water through proper filtration and reconditioning procedures that will ensure impeccable water quality and nutrient levels prior to reapplication. To help ensure all runoff water is kept clean of contaminants prior to recycling and reapplication, Hale O Laulima will use organic supplementary resources whenever possible. Organic supplementary resources will aid in efforts to eliminate exposure to harmful pesticides, synthetic additives, and the creation of toxic wastewater.

There will be no sewage waste leaving the Production and Retail Dispensary Facilities through the plumbing system beyond that which would be typical of any facility with a similar number of employees present. The adequacy of the plumbing system will assure that no sewage or other liquid waste will contaminate areas surrounding the Production and Retail Dispensary Facilities or the potable water line. Backflow prevention devices will be installed on all incoming water sources at the Production Facilities to protect against contamination.

The Production Facility Manager and the Retail Dispensary Facilities General Manager will also ensure that any spills are cleaned up immediately, runoff is reduced, and irrigation (where utilized) is adjusted to reflect plant needs in an effort to reduce water consumption, and ultimately, water waste. These water preservation efforts extend to ensure the safety of the environment, employees and patients. If an event requiring the treatment of wastewater or runoff occurs, Hale O Laulima will dispose of wastewater according to procedures outlined by the local municipal wastewater treatment plant.

11.3.3.2 Grow Media Waste

Though compostable material is a form of waste, it is ultimately less environmentally harmful than non-compostable material. Hale O Laulima will minimize grow media waste by utilizing local composting services to collect and process organic material. Hale O Laulima will use new organic media as the primary cultivation medium and will coordinate with local composting companies to collect used media that would otherwise be diverted to a landfill. All composting activities will be carried out in accordance with the rules set forth in HAR §11-58.1.

11.3.3.3 Green / Marijuana Waste

Minimal marijuana waste will be generated by the Production Facility, and will typically be limited to expired marijuana products, unusable marijuana plant material, and any marijuana determined to be unfit for human consumption. All marijuana waste will be rendered unusable and disposed of in accordance with the policies and procedure in the Marijuana Waste Disposal SOP set forth in previous sections. Efforts to minimize marijuana waste include:

1. Regular coordination between the Production Facility Manager, Retail Dispensary Facilities General Manager and the Administrative Controller to determine the appropriate level of production anticipating customer needs in order to minimize waste due to excess marijuana production;
2. Maintenance of an integrated environmental and pest management plan to effectively protect crops from pest and environmental related damage and detect contamination early, thereby minimizing marijuana waste due to contamination;
3. Incorporation of segregated Production and Retail Dispensary Facilities areas and a designated quarantine room in Production Facility design to physically limit the spread of pests and reduce waste due to marijuana product contamination; and
4. Proper storage and product handling, detailed in the Inventory Control and Management SOP which will minimize marijuana product contamination and adulteration.

11.3.3.4 Hazardous and Chemical Waste

Hale O Laulima aims to minimize or eliminate the use of hazardous substances and toxic chemicals wherever possible. Using the following strategies, Hale O Laulima will minimize waste due to usage of hazardous substances and toxic chemicals, and will always dispose of such waste in accordance with State, Federal, and local law as well as all relevant environmental regulations. Hale O Laulima will minimize hazardous and chemical waste by:

1. Using integrated pest management (IPM) strategies, which minimize harmful pesticide usage, thereby minimizing hazardous chemical usage;
2. Segregating Production Facility areas and quarantine rooms, which physically limit the spread of pests and diseases, thereby creating a controlled environment in which less toxic plant treatments will succeed in early-stage issues and preventing the need for use of toxic synthetics commonly applied during the mitigation of larger issues occurring in an open-plan Production Facility layout;
3. Developing, implementing, and training Production Facility employees to adhere to stringent policies regarding the proper storage of pesticides and hazardous materials; and
4. Incorporating antimicrobial building materials in designated sanitation areas, which will reduce the need for chemical cleaning employees and prevent groundwater contamination.

11.3.3.5 Solid and Recyclable Waste

Hale O Laulima will continuously strive to produce zero waste at the Production and Retail Dispensary Facilities. Paper waste is expected to be minimal. The facilities are expected to

produce average levels of plastic, glass, and aluminum waste and all such materials will be recycled.

11.3.3.6 Recycling

Hale O Laulima will provide recycling bins for assorted plastics, glass, aluminum, and paper products at all facility locations. Hale O Laulima will engage with Honolulu County waste management authorities to schedule recycling services and regular pick-ups. Hale O Laulima will also ensure the implementation of proper resource disposal techniques for the removal of all regulated materials including lamps, nutrient waste, and applicable electronics.

11.3.3.7 Reusable Materials

Hale O Laulima will incorporate reusable materials for all available cultivation supplies, such as vessels used for containing plants, nutrients, and water. Hale O Laulima will also incorporate reusable tools made from recycled materials for cultivation, such as plant-reinforcement posts, watering and spraying devices, reflective materials and storage containers. These supplies will be reused after a chemical-free (hot steam) sterilization process and will reduce the resource consumption and needs of Hale O Laulima.

11.3.3.8 Paperless Communication

Hale O Laulima will use email and other direct dialogue services as the primary channel of communication between management, employees, customers, and vendors, in an effort to reduce paper waste generated from internal communications. Hale O Laulima will utilize secure cloud-based tracking systems to store electronic forms of all compliance documents, allowing for mobile access and the reduction of waste paper.

11.6 Exhibit 6: Inventory Control and Management SOP

11.4.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawai'i Department of Health and to promote patient, product and public safety. As rule changes occur and best practices evolve, the content of this document will be reviewed and updated where appropriate. Each step in our manufacturing and distribution processes is carefully performed and controlled so that the resulting medical marijuana products possess the safety, quality, identity, purity, and potency (SQuIPP) that patients deserve.

HAR Requirement	Description
§11-850-36.f	For transport between or among dispensary facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a dispensary facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras.
§11-850-41.a	A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:
§11-850-41.a.1	Inventory tracking including transport of marijuana and manufactured marijuana products;
§11-850-41.a.2	Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
§11-850-41.a.3	Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
§11-850-41.a.4	Logs of entry and exit for dispensary facilities; and
§11-850-41.a.5	Employee records.
§11-850-41.b	A dispensary licensee shall retain for a minimum of one year all security recordings. Eff.
§11-850-42.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.
§11-850-42.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. Eff. DEC 14 2015
§11-850-43.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.
§11-850-51.a.1	A video surveillance system professionally installed that allows for twenty-four hour continuous video monitoring and recording of all dispensary facilities as follows:
§11-850-51.a.1.C	The surveillance system storage device and the cameras must be internet protocol (IP) compatible;
§11-850-51.a.1.D	The video surveillance system shall have minimum camera resolution to allow for the clear and certain identification of any person and activities in any area of a dispensary facility where marijuana and manufactured marijuana products are produced, moved, or stored; all points of sale areas, any room used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; any room or area storing a surveillance system storage device; and al exits and entrances to a dispensary facility from both indoor and outdoor locations;
§11-850-51.a.1.E	The surveillance system video recording storage device shall be secured in a lockbox, cabinet, or closet, or secured in another manner that limits access to protect the system from tampering or theft; and
§11-850-61.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 ADP/POS, 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.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-85.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

HAR Requirement	Description
	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). Eff. DEC 14 2015
§11-850-92.b.4	Includes a computer tracking inventory identification number barcode generated by tracking software;

11.4.1.1 Local Compliance

In accordance with applicable inventory related rules as defined by Hawai'i Administrative Rules Chapter(s): 11-850-41 through 11-850-43, 11-850-51, 11-850-61, 11-850-71, 11-850-72, 11-850-85, 11-850-92 and enforced by the Hawai'i DOH, Hale O Laulima will utilize policies and procedures to enable record keeping activities that meet or exceed the minimal requirements. All inventory and record keeping policies implemented in Hale O Laulima's Production and Retail Dispensary Facilities will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-850.

11.4.2 Definitions and Abbreviations:

Air-Conditioning ("A/C")
American National Standards Institute ("ANSI")
American Society for Testing and Materials ("ASTM")
Automated Data Processing/Point-of-Sale System ("ADP/POS")
Batch Production Record ("BPR")
BBC Research & Consulting ("BBC")
Board of Directors ("the Board")
Cannabidiol ("CBD")
Cannabidiolic Acid ("CBDA")
Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
Chief Operations Officer ("COO")
Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)
Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")

Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")
Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)
Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")
Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")
National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")
Quality Control Team ("QCT")
Quality Control Unit ("QCU")
Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")
Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")

Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

11.4.3 Inventory Control Policies

The Inventory Control and Management Standard Operating Procedure (SOP) of Hale O Laulima outlines operational procedures for inventory management in compliance with HAR §11-850. The Inventory Manager is assigned responsibility for oversight of all inventory management activities and for implementing and enforcing the contained policies and procedures. It is established that the Production Facility Manager in coordination with the Retail Dispensary Facilities General Manager will ensure the cumulative inventory of seeds, plants and usable marijuana reflects the projected needs of qualifying patients. The Production and Retail Dispensary Facilities General Manager(s) and Inventory Manager will work collaboratively to assure that inventory is tracked from seed to sale, counted and recorded at required intervals, and that any discrepancies are documented, investigated and reported to the appropriate authorities.

The ADP/POS, herein referred to as, "Biotrack", and its inventory management module will be accurate and capable of producing, upon request, reports on all marijuana and marijuana products in production, finished and stored. Cycle counts are required and will be recorded in the Inventory Log. An outline of required shift, daily, weekly, monthly, semi-annual, and annual inventory counts in Hale O Laulima's licensed premises is included. All inventory policies and procedures relevant to the acquisition, receipt and transport of marijuana are comprehensively addressed. Discrepancies identified during inventory that are not due to documented causes will be reported to the Facility Manager as well as the Inventory Manager and the causes will be investigated. Any suspected cases of diversion, theft, loss and any criminal action involving Hale O Laulima or an employee will be reported to the Hawai'i DOH and associated Law Enforcement, in accordance with State regulations. The Facility Manager will also report any verifiable incident of theft or loss of marijuana to the Hawai'i DOH and the Hawai'i State Police, as required.

11.4.4 Responsibility for Inventory Control and Management

The Inventory Manager is responsible for oversight of all inventory control and management. The Inventory Manager's responsibilities include, but are not limited to: real-time inventory tracking, inventory counts and audits, reconciliation of inventory discrepancies, preparing shipments and transfers, packaging and labeling final marijuana products, inventory recordkeeping, and reporting. The Inventory Manager is also responsible for developing and implementing inventory training for all employees, and will have the authority to delegate specific inventory control, management, or recordkeeping tasks to qualified managers or employees.

The Inventory Manager will designate the Facility Manager to have oversight of the inventory control system for the facility. The Facility Manager and Inventory Manager share responsibility for ensuring accurate recording and accountability of inventory at all Production and Retail

Dispensary Facilities, as well as accurate recording of all inventory movements in Hale O Laulima's facilities.

11.4.5 Inventory Limits

The Inventory Manager must ensure the cumulative inventory of clones, marijuana plants, source material, and marijuana products reflect the projected needs of qualified registered patients. Production volumes should be sufficient to meet, but not substantially exceed, registered patient needs. Beginning inventories will be established based on projected patient demand. Hale O Laulima has contracted with BBC Research to estimate patient demand statewide. BBC Research was selected by the state of Colorado to estimate demand in Colorado's marijuana marketplace and had the contract renewed for a second year. On the basis of their impressive credentials, Hale O Laulima is confident that BBC Research's demand estimate for Honolulu County is reasonably accurate, and will use their patient demand projections to establish beginning inventory limits. Once the medical marijuana program is operational and data is available, the Inventory Manager will use any available local and state-wide patient registration and dispensing data to adjust inventory limits to anticipate future inventory needs. Adam Orens, Director at BBC Research serves as Market Data Advisor for Hale O Laulima and will review market demand models ongoing during operations.

11.4.6 Real-Time Inventory Reporting Required

The Production and Retail Dispensary Facilities Manager(s) in coordination with the Inventory Manager is responsible for the accurate real-time reporting of marijuana inventory. The selected ADP/POS, Biotrack, will be used for real-time inventory management and tracking marijuana throughout all facilities' operations. The system utilized involves reporting daily beginning and ending inventory including:

1. Marijuana plants in any phase of production such as mother plants, clones, vegetative plants, and flowering plants;
2. Marijuana products in process;
3. Finished marijuana and marijuana products;
4. All damaged, defective, expired or contaminated marijuana and marijuana products awaiting disposal;
5. Acquisitions;
6. Harvests;
7. Sales;
8. Shipments or transfers; and
9. Disposals of unusable marijuana.

11.4.7 Surveillance Coverage of Inventory Activities

The entirety of the Production and Retail Dispensary Facilities will be covered by surveillance video cameras. All facility activities, including inventory management and control activities, will be recorded by surveillance cameras and the footage will be stored in a secure location. Hale O

Laulima will retain for a minimum of one year all security recordings. Surveillance footage can be watched in real-time, on the display monitor in the security room, or stored footage can be accessed for review by select managers, including the Security Manager. The room containing surveillance equipment will be restricted to the Security Manager, COO, and other personnel authorized by the Security Manager. Constant, comprehensive surveillance camera coverage provides an additional protection against diversion or theft and allows verification and surveillance of all inventory activities.

11.4.8 Production Facility Inventory Control Procedure

The Production Facility Manager is responsible for assuring that all of the following inventories, procedures, and documents are completed or created, with the Inventory Manager retaining reports on premises for a minimum of six (6) years:

1. The Inventory Manager must ensure that the inventory management system (i.e., the ADP/POS, Biotrack) is maintained and provides adequate documentation of the chain of custody throughout the cultivation process. The physical location of plants will be recorded at all times to allow Hale O Laulima to promptly identify diversion, theft, or loss;
2. The Inventory Manager will conduct an initial comprehensive inventory of all marijuana at the Production facility, which will be recorded in the ADP/POS. The integrated ADP/POS, Biotrack provides for input of an initial comprehensive inventory. If no marijuana is on the cultivation premises when business commences, the initial inventory will be recorded as zero;
3. The Inventory Manager, in coordination with the Harvest Lead, must maintain procedures that reconcile the wet weight of harvested marijuana plants to the weight of post-harvest processing waste, trimmed wet weight, and cured weight of marijuana source material. Significant variances must be documented, investigated by the Production Facility Manager and/or Inventory Manager, and reported to the Quality Control Team (CCO);
4. The Inventory Manager will ensure that the Production Facility Manager conducts all required cultivation cycle counts and electronic inventory management activities. Quarterly comprehensive inventory counts will be conducted under the Inventory Manager's supervision and reconciled to the perpetual inventory records in the ADP/POS. Significant variances or discrepancies will be documented, investigated by the COO, and reported to the CCO and the Hawai'i DOH, if criminal activity is suspected;
5. The Inventory Manager will keep records of all marijuana source material transferred from the Production facility to the Retail Dispensary Facilities, and all marijuana waste disposed of. These records will include, at a minimum:
    a. Strain;
    b. Batch number;
    c. Weight (in grams);
    d. Test results;
    e. A link to the transportation manifest, including identifying information about the destination facility, date of transport, employee responsible for transport or transfer, and other relevant information; and

f. If disposed, additional records must be kept in the Waste Disposal Log, as set forth in the Marijuana Waste Disposal SOP.

6. At least once every 30 days, the Inventory Manager will conduct an inventory audit in the Production facility:
   a. The Inventory Manager will compare physical inventory counts conducted by the Production Facility Manager with electronic inventory records in Biotrack;
   b. Using this method, the Inventory Manager will promptly detect diversion, theft, or loss and take immediate action to reconcile inventory discrepancies, if any;
   c. The Inventory Manager will conduct the audit and produce an inventory audit report for the COO at least once every 30 days;
   d. If any inventory discrepancy is identified during the audit, Hale O Laulima will conduct an investigation, identify the source of the discrepancy, and take corrective action; and
   e. Discrepancy investigation and resolution will be recorded, and records maintained for a minimum of six (6) years. The Hawai'i DOH will be notified of any discrepancy and all corrective actions taken with five (5) business days.

7. The Inventory Manager will receive a receipt for any sample of marijuana or record that is removed from the Production facility by an authorized person, such as a Hawai'i DOH representative. Samples of marijuana collected by the QA / Laboratory Director for the purpose of conducting quality assurance testing in the Production Facility's on-site laboratory will be held to the same standards. All sample and record receipts will be recorded in Biotrack and will be kept for a minimum of six (6) years. See the Sampling and Testing SOP for more information about laboratory sampling and testing.

11.4.9 Retail Dispensary Facilities Inventory Control Procedure

1. The Inventory Manager must ensure that the inventory management system (i.e., the ADP/POS system, Biotrack) is maintained and provides adequate documentation of all marijuana product movements from acquisition to sale;

2. The Inventory Manager must ensure that the ADP/POS system requires verification of patient registration, order contents, and order fulfillment status before a Dispensary Employee may dispense any marijuana product, in accordance with HAR 11-850-42.a, 11-850-42.b and 11-850-61;

3. The Inventory Manager must ensure that the ADP/POS system either interfaces with the Compassionate Use Registry ("the Registry") or requires a Retail Dispensary Employee to enter a dispensing action into the Registry immediately upon dispensing a marijuana product to a qualified registered patient or patient's legal representative, in accordance with HAR 11-850-42.a, 11-850-42.b and 11-850-61;

4. The Inventory Manager must ensure that the ADP/POS system maintains patient profiles and records, and protects patient privacy and confidentiality in accordance with HIPAA

standards and HAR 11-850-40, and restricts access to confidential patient information through the issuance of user permissions;

5. The Inventory Manager will conduct an initial comprehensive inventory of all marijuana products at each Hale O Laulima facility, which will be recorded in the ADP/POS system. If no marijuana products are on the Retail Dispensary Facilities premises when business commences, the initial inventory for each Retail Dispensary Facilities will be recorded as zero.;

6. The Inventory Manager in coordination with the Retail Dispensary Managers must maintain procedures which reconcile marijuana products acquired with marijuana products disposed, in storage, on display in the sales area, in transport, and dispensed on-site in real-time. Significant variances in a Hale O Laulima facility must be documented, investigated by the Facility Manager for that unit and/or Inventory Manager, and reported to the Board. This will enable each Hale O Laulima facility to promptly detect diversion, theft, or loss;

7. The Inventory Manager will ensure that each Hale O Laulima Facility Manager conducts all required cycle counts and electronic inventory management activities. Quarterly comprehensive inventory counts will be conducted under the Inventory Manager's supervision and reconciled to the perpetual inventory records in the ADP/POS system. Significant variances or discrepancies will be documented, investigated by the COO, and reported to the Hawai'i DOH if criminal activity is suspected;

8. The Inventory Manager will keep records of all marijuana products sold or otherwise disposed at each Hale O Laulima facility. These records will include, at a minimum:
    a. Name and form of the marijuana product dispensed;
    b. Batch number;
    c. Amount of the marijuana product dispensed;
    d. Sales price;
    e. Date of sale;
    f. Name and identification number of the qualified registered patient or patient's legal representative to which the marijuana product was dispensed; and
    g. If disposed, the name, form, batch number, quantity, date, manner of disposal and reason for disposal for any marijuana products destroyed.
9. At least once every 30 days, the Inventory Manager will conduct an inventory audit in each Hale O Laulima facility:
    a. The Inventory Manager will compare physical inventory counts conducted by the Facility Manager with electronic inventory records in Biotrack;
    b. Using this method, the Inventory Manager will promptly detect diversion, theft, or loss and take immediate action to reconcile inventory discrepancies, if any;
    c. The Inventory Manager will conduct the audit and produce an inventory audit report for the COO at least once every 30 days;

d. If any inventory discrepancy is identified during the audit, Hale O Laulima will conduct an investigation, identify the source of the discrepancy, and take corrective action; and
e. Discrepancy investigation and resolution will be recorded, and records maintained for a minimum of six (6) years. The DEPARTMENT will be notified of any discrepancy and all corrective actions taken with five (5) business days.

10. The Inventory Manager will receive a receipt for any sample of marijuana product or record that is removed from a Retail Dispensary Facilities by a Hawai'i DOH representative. No other persons may remove samples of marijuana products from any Hale O Laulima premises.

11.4.10 General Inventory Recordkeeping

Policies and procedures for recordkeeping are addressed throughout this Inventory Control and Management plan, in compliance with Hawai'i DOH 11-850 rules. The Inventory Manager, in coordination with Hale O Laulima Facility Managers, will oversee the documentation of all inventory procedures conducted in the Production and Retail Dispensary Facilities and ensure that all inventory records are maintained. Inventory will be comprehensively tracked and recorded in the ADP/POS system, Biotrack, and standard or custom reports can be produced upon demand. The ADP/POS system will also maintain employee records, transportation records, records of recall or withdrawal activities, analytical test results, and any other type of record pertaining to Hale O Laulima operations or products. Hale O Laulima will utilize a secure cloud-based document management system for the electronic storage of all required records, including but not limited to: business records, compliance-related records, and security records. All inventory documentation required will be retained for at least six (6) years and records will be made available to the Hawai'i DOH upon request. Each Hale O Laulima Facility Manager will maintain an internal Inventory Log to record:

1. The date of an inventory process;
2. A summary of the inventory findings;
3. Any discrepancies found;
4. Discrepancy resolution, if any; and
5. The name, identification number, and title of the employee or manager who conducted the inventory process.

11.4.11 Dispensing Errors and Near Misses

All Retail Dispensary Employees are responsible for identifying and recording dispensing errors and near misses. All dispensing errors and near misses will be recorded on an internal Dispensing Errors and Near Miss Log which will be stored in the secure cloud-based document management system. The Retail Dispensary Facilities Manager responsible for the location must be notified immediately to determine necessary corrective actions and must review near misses monthly at a minimum to identify means for preventing near misses and dispensing errors. The Retail Dispensary Manager must enact necessary actions as soon as possible, which

may include updates or modifications to applicable policies and procedures, training or re-training of Retail Dispensary personnel, and/or electronic records systems updates. The Retail Dispensary Manager must determine if the dispensing error requires correction and shall contact any affected patients as soon as possible. If a dispensing error resulted in dispensing of a marijuana product to an individual other than a qualified registered patient or a qualified patient's legal representative, the Retail Dispensary Manager will immediately notify the Hawai'i DOH and take appropriate corrective action, in accordance with HAR 11-850-101. Recordable dispensing errors and near misses include, but are not limited to:

1. Wrong product;
2. Expired product;
3. Wrong label on product;
4. Missing product from sale;
5. Wrong patient name/identification number;
6. Unauthorized person;
7. Wrong quantity;
8. Wrong potency; and
9. Wrong route of administration.

11.4.12 Reconciliation, Resolution, and Reporting

Physical inventory counts and real-time, electronic inventory in the ADP/POS system, Biotrack will be compared, and all discrepancies will be investigated. Cross-checking of periodic physical inventory counts with perpetual inventory records in the system will allow the identification, documentation, investigation and immediate reporting of significant variances that cannot be accounted for. Any inventory discrepancies discovered by any employee will be reported to the Inventory Manager and COO upon discovery. If the Inventory Manager identifies a significant variance between physical inventory counts and inventory accounted for in the system that is not due to documented causes, it will be reported to the Quality Control Team. The COO in coordination with the Inventory Manager will conduct an investigation, using the ADP/POS system, will determine where the loss has occurred, and pursue and document corrective action. The COO will report all inventory discrepancies and corrective actions to the Hawai'i DOH and law enforcement authorities as necessary. If any reduction in the amount of marijuana products in inventory is due to suspected criminal activity by an employee, the COO will report the employee to the Hawai'i DOH and to the appropriate law enforcement agencies. Documentation of all inventory variances, reconciliation, resolution, and reporting will be stored in the system and retained in physical form through printing of PDF documents, and will be readily available to present the Hawai'i DOH or law enforcement upon request or in the event of an unannounced Hawai'i DOH inspection or audit.

11.4.13 Product Storage

All inventory stored in Hale O Laulima facilities will be secured in a limited access area and tracked consistently in accordance with this inventory control and management SOP. Pursuant

to §11-850-71 and §11-850-72, Hale O Laulima in coordination with the Inventory Manager will develop, implement, and maintain handling and storage measures that prevent spoilage, molding, and other damage to marijuana product(s) while preparing it for distribution. Storage activities will be properly recorded and comply with the procedures detailed herein. All marijuana products found to be in non-conformance will be properly disposed of per the Marijuana Waste Disposal SOP. Security procedures surrounding the storage areas are robust and were developed with anti-diversion features and processes in mind. Refer to the Anti-Diversion SOP for additional detail regarding storage area security.

11.4.13.1 General Storage Requirements

The Facility Manager, in coordination with the Inventory Manager and Quality Control Team, is responsible for ensuring compliance of all storage areas:

1. All marijuana and marijuana products must be stored in an enclosed and locked facility where no toxic or flammable materials are kept;
2. Adequate lighting, ventilation, temperature, humidity, space, and equipment must be provided in all marijuana and marijuana product storage areas with oversight by the quality control unit;
3. Separate areas for storage of marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until such products are destroyed must be provided in each department;
4. All storage areas must be maintained in a clean and orderly condition;
5. All storage areas must be kept free from infestation by insects, rodents, birds, and pests of any kind; and
6. All storage areas must be maintained in accordance with applicable laws and regulations as well as Hale O Laulima's secure storage provisions.

11.4.13.2 Secure Product Storage

In accordance with Hale O Laulima policy, industry best practice, and §11-850-71 and §11-850-72, all finished marijuana and marijuana-infused products, and marijuana in the process of production, distribution, transfer, or analysis will be stored in such a manner as to prevent diversion, theft or loss. Product storage security measures are covered in detail herein:

1. All marijuana and marijuana-infused products within a Hale O Laulima facility will be stored in a vault located within a limited access area;
2. All marijuana that is still in process will be stored in a secure location within a Hale O Laulima facility, to which access is limited to a minimum number of authorized personnel;
3. All vaults, security equipment, and secure areas used for the production and storage of marijuana will be securely locked and protected from entry, other than during the time required to move or replace marijuana, pursuant to §11-850-51;

4. All marijuana and infused products must be returned to a secure, locked area at the end of any process (i.e. trimming, manufacturing, etc.) or and at the end of the day (i.e. Retail Dispensary Facilities products on display);
5. If a facility process cannot be completed by the end of a working day, the facility area or tanks, vessels, bins or bulk containers containing marijuana will be securely locked inside an area that affords appropriate security and is covered by video surveillance, in accordance with §11-850-51. All marijuana and marijuana products must be stored separately with suitable identification the labels and other labeling materials for each type of marijuana or marijuana product, and the different strength, dosage form or quantity of contents; and
6. Access to marijuana products must be restricted by the Inventory Manager and the Facility Manager. Only necessary personnel must receive access rights to areas housing security equipment, marijuana, marijuana products or cash.

11.4.13.3 Environmental Control Required

The Facility Manager in coordination with the Inventory Manager must ensure that storage areas holding marijuana and marijuana products are maintained to be dry, well ventilated, and have sufficient insulation or other temperature-control features to avoid extreme temperature fluctuations:

1. Hale O Laulima shall incorporate a humidifier or de-humidifier if needed to ensure product quality; and
2. Storage areas must utilize and maintain carbon filtration or other means of odor control as necessary.

11.4.13.4 Removal From Storage

Marijuana and marijuana products may only be removed from secure storage by an employee authorized by the Production Facility Manager or Retail Dispensary Facilities Manager:

1. Only to prepare for final packaging prior to transport
2. Only to transport the marijuana or marijuana product;
3. Only to dispense the marijuana or marijuana product;
4. Only immediately before the marijuana is dispensed; and
5. Only by a registered employee of Hale O Laulima.

The ability to ensure product safety for all patients and the local community is of the utmost concern that is present in all **Hale O Laulima ("HOL")** operations and activities. A critical approach to product safety is embedded into the robust Quality Management System that HOL strictly adheres to. These efforts will be led by Director of Processing **Jennifer Bash**, currently a Senior Analytical Forensic Toxicology Specialist with the Analytical Forensic Testing Laboratory at the University of Illinois at Chicago College of Pharmacy. Ms. Bash will direct the creation and ongoing operation of and in-house testing laboratory, which will be utilized in addition to testing mandated by the Hawai'i Department of Health to establish and continually validate production methods and processes. Additionally, with nearly 10 years of medical device and pharmaceutical manufacturing experience, Product Safety Advisor **Michael Nottoli** has participated in over 75 successful automated system qualifications that have gone on to produce a wide range of medical devices (including Class III) and pharmaceutical products, ensuring the integrity of equipment and processes throughout all aspects of FDA-regulated pharmaceutical operations. His system-level pharmaceutical manufacturing history includes CQV of aseptic compounding / filling rooms, depyrogenation tunnels, in-process vision / leak detection / inductive proximity and photo eye inspection systems, and secondary packaging machines. His knowledge base includes utilities, environmental, equipment and process commissioning, qualification and validation activities. HOL partners **Cresco Labs** and **Denver Relief Consulting** have already developed and executed these processes within a Quality Assurance and Quality Control Standard Operating Procedure ("SOP") (see Exhibits 2-17), which have exceeded strict testing limits for safety, quality, identity, purity and potency in Colorado and Illinois.

All operations, processes and controls in the receiving, inspecting, transporting, cultivation, extraction, segregating, preparing, manufacturing, packaging, and storing of marijuana products will be conducted in accordance with adequate sanitation principles and current Good Manufacturing Practice ("cGMP") standards. The appropriate quality control operations will be implemented to ensure that marijuana products are suitable for