human consumption and that marijuana product packaging materials are safe and suitable. All reasonable precautions will be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures will be used to identify sanitation failures or possible marijuana product contamination. Any marijuana product that has become contaminated to the extent that it is adulterated within the requirements of the Code of Federal Regulations will be rejected, or if permissible, treated or processed to eliminate the contamination.

The development of comprehensive quality assurance and quality control measures will be overseen by HOL'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 HOL Quality Management System and related training modules will be built.

The Chief Operating Officer ("COO") will ensure a Quality Control Team ("QCT") is in place at all times, which will be comprised of qualified employees holding other positions within the company to perform all duties related to quality assurance and product safety. 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.

As described in the attached SOPs, HOL will establish a relationship with a Hawai'i DOH-approved independent testing laboratory with marijuana testing protocols and methods. We have had preliminary dialogue with local laboratories, such as Clinical Labs of Hawai'i, that will ensure the highest quality medical marijuana products for patients in the event that we are issued a license (see Exhibit 1). Samples will be transported to the independent testing laboratory and analyzed in accordance with scientifically valid methods. The independent testing laboratory will then provide HOL with a certificate of analysis for each batch which provides results and a statement as to whether the batch meets pre-determined specifications. The Inventory Manager will ensure that no batch may be released for distribution by the QCT prior to receipt and confirmation of a certificate of analysis which demonstrates conformance with specifications. Test results will be recorded and attached to the appropriate batch in the electronic automatic data processing/point-of-sale ("ADP/POS") system, Biotrack. The test results will be 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. Additionally, pursuant to §11-850-85.a HOL 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.

The Inventory Manager shall develop, implement, and maintain detailed written procedures for the receipt, identification, storage, handling, sampling, testing, and approval or rejection of product inputs, 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. 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 and product inputs must be stored under quarantine until they have been checked for conformity to specifications and approved by the Inventory Manager.

HOL's Packaging and Labeling Standard Operating Procedure (See Exhibit 4) fulfills components of the safety, quality, identity, purity and potency expectations that HOL demands from every product batch. HOL requires that packaging of all marijuana and manufactured marijuana products, at a minimum, be: (1) child-resistant and opaque so that the product cannot be seen from outside the packaging; (2) uses only black lettering on a white background with no pictures or graphics; (3) is clearly labeled with the phrase "for medical use only"; (4) is clearly labeled with the phrase "Not for resale or transfer to another person"; (5) includes instructions for use and a "use by date"; (6) contains information about the contents and potency of the product; (7) includes the name of the Production Facility where marijuana in the product was produced, including the batch number and date of packaging; (8) includes a barcode generated by tracking software; (9) in the case of a manufactured marijuana product, a listing of the equivalent physical weight of the marijuana used to manufacture the amount of the product that is within the packaging; and (10) any manufactured product containing marijuana or its principal psychoactive constituent tetrahydrocannabinol shall be packaged so that one dose, serving, or single wrapped item contains no more than ten milligrams of tetrahydrocannabinol; provided that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, nor any containers of oils, shall contain more than a total of one hundred milligrams of tetrahydrocannabinol per pack or container.

HOL will take all reasonable steps to prevent any spoiled, defective, misrepresented, or contaminated products, or products of insufficient quality, from being dispensed to qualified registered patients and to remove

such products from the patient supply chain immediately. Upon the discovery of product contamination, safety concerns, patient adverse reaction, or quality-related issues, HOL will quickly and efficiently carry out recall or withdrawal procedures in accordance with this policy in order to protect the health and wellbeing of patients. The best way to ensure that a recall or withdrawal is effective is to have a Recall and Withdrawal SOP already in place and to execute the plan as quickly as possible. This Plan distinguishes between two levels of product recall: withdrawal and recall. Classification standards and appropriate responses for each type of event are discussed herein. Procedures for handling voluntary withdrawals and mandatory recalls of marijuana products are included herein. Procedures for addressing and recording complaints, including reports of product-related adverse events from patients or caregivers, are also provided. Incident classification terms are defined, with distinct mitigation procedures for each, as the term "recall" can have legal significance and implications for insurance and liability. The withdrawal and recall procedures provided in this Plan are designed to ensure that marijuana products are withdrawn or recalled quickly and efficiently, whether voluntarily or by mandate. The objectives of withdrawal and recall procedures are to stop distribution of the affected product, effectively notify all relevant patients, efficiently remove the affected product from the patient population, dispose of the affected product, conduct a root cause analysis, report the effectiveness and outcome of the recall, and conduct a post-recall meeting for evaluation. In accordance with the incident classification schema and the associated definitions, the term "recall" will only be used when the situation mandates. Examples of incidents to be addressed with recall or withdrawal procedures and guidelines for required mock withdrawal and recall drills are provided in this Plan. Additional provisions include plans for tracking affected products in the event of potential or verifiable contamination, and for the establishment of an internal Recall and Withdrawal Team, which will be responsible for executing and coordinating all aspects of a withdrawal or product recall. In the instance of a product recall, the Hawai'i DOH will be notified immediately. **<END OF NARRATIVE>**

APPENDIX – SUPPLEMENT TO NARRATIVE

TABLE OF CONTENTS

12.2 Exhibit 2: CGMPs SOP

12.2.1 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
§11-850-37.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.

HAR Requirement	Description
§11-850-75.g	The floors, walls, and ceilings of a dispensary facility shall be constructed in such a manner that they may be 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

12.2.2 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.

12.2.3 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")

12.2.4 Current Good Manufacturing Practices

All processing operations conducted by Hale O Laulima will be carried out in compliance with the United States Food and Drug Administration cGMPs as described in Title 21 of the CFR.

12.2.4.1 Personnel Training

All production employees must receive standard Hale O Laulima training as well as training specific to the department and their work functions including food handling. Training shall be provided by the Production Facility Manager and outside providers as necessary according to the requirements determined in the Staffing and Training SOP.

12.2.4.2 Personnel Responsibilities

The Production Facility Manager is responsible for ensuring that any employee who might be a source of microbial contamination due to a health condition to any product constituent including marijuana or any given contact surface used in operations is prohibited from the production area until no longer a potential source of contamination. Such measures include the following:

1. Removing the employee from the schedule until the health condition no longer exists. The Production Facility Manager may require a doctor's return to work authorization as necessary; and
2. Requiring employees to notify the Production Facility Manager if there exists or a reasonable possibility exists as a condition of continued employment.

12.2.4.3 Prevention of Adulteration

Hygienic practices must be employed by every employee in the Production and Retail Dispensary Facilities facility. Every department employee must adhere to the hygiene and sanitation practices found in the Hygiene, Sanitation and Facility Requirements SOP. These hygienic practices include the following:

1. Use of clothing or uniforms that protect against the contamination of any constituents or a product (including marijuana) and any contact surface;

2. Maintaining adequate personal cleanliness;
3. Washing hands thoroughly with soap (and sanitizing if necessary to protect against contamination with microorganisms):
    a. Before any work period;
    b. After any break; and
    c. At any other time when the hands may have become soiled or contaminated during manufacturing processes.
4. No removable jewelry may be worn during work;
5. Gloves are required for handling product constituents at risk for contamination. The gloves must be of an impermeable material;
6. Hair nets, caps, beard covers, or other effective hair restraints must be used when necessary;
7. Product constituents should be stored in clean and safe conditions according to the item's needs away from employee personal effects, cleaning supplies, and other products;
8. Personal food items, chewing gum, drinking beverages, and use of tobacco products in production areas is prohibited;
9. Every employee is required to take any other precaution necessary to protect against the contamination of marijuana products; and
10. Every employee is required to take any precaution necessary to maintain the security of facility, to prevent unauthorized access to controlled access areas, and to maintain strict control of all marijuana in storage and in-process.

12.2.4.1 Prevention of Diversion

The production area must be secured at all times and limited access areas are subject to the policies and procedures defined in the Anti-Diversion SOP.

12.2.4.2 Limited Access Areas

The production area must be secured at all times and limited access areas are subject to the policies and procedures defined in the Access Control SOP.

12.2.4.3 Personnel Safety

The Production Facility Manager is responsible for the implementation of policies and procedures to protect personnel in all operations and provide personnel with adequate safety training to comply with these policies. Such policies must be in compliance with the Worker Safety SOP and be similar to personnel safety policies in similar operations in comparable industries, such as food manufacturers including at a minimum:

1. Employee accident reporting and investigation policies;
2. Fire prevention and response plans;
3. Materials handling and hazard communications policies; and
4. Personal protective equipment policies.

12.2.4.4 Safety Equipment

The Production Facility Manager must ensure all department-specific safety equipment needed is provided and maintained. For example, all personal protective equipment required by the SDS record for solvents and gases must be provided to an employee handling the materials and at least one emergency eye flushing station is readily accessible to all employees handling dangerous materials.

12.2.4.5 Production Area Design, Construction, and Maintenance:

1. The production area must be suitable in size, design, and construction for safe production operations. The Production Facility Manager shall not permit any operation in the department that is unsafe or unsuitable for the facility;
2. Operations must have sufficient space as to promote safe and orderly processes and prevent constituent mix-ups;
3. Production areas must be able to be maintained. Any repairs necessary to maintain sanitary conditions must be caused by the Production Facility Manager as soon as possible; and
4. If a condition exists that prohibits the safe and sanitary production of marijuana products, the Production Facility Manager, in his or her discretion may suspend production operations until resolved.

12.2.4.6 Daily Walk Through Inspections

The Production Facility Manager or designee must visually inspect all production areas daily to identify potential hazards. The inspection shall cover at a minimum an assessment of the condition of:

1. Floors, walls, and ceilings must be clean and in good repair;
2. Fixtures, ducts, and pipes must not contaminate product constituents or contact surfaces by dripping, other leakage, or condensation; and
3. Aisles or working spaces between equipment must be adequately unobstructed and permit all persons to work and protect against contamination of constituents, contact surfaces, and garments.

12.2.4.7 Separate Production Areas

The Production Facility Manager must ensure each production operation has sufficient room and storage to prevent cross-contamination and mix-ups of constituents. Separate areas are required for:

1. Receiving constituents including marijuana by-product, packaging materials, cleaning supplies, etc.;
2. Waste including separate locked storage of marijuana and marijuana product waste;
3. Storage of marijuana by-product, in-process marijuana, and finished marijuana products must be separate from other supplies and secured at all times when not in use. Packaging and labeling operations should be separate from production areas;
4. Any in-house analysis operation must be separate from production and storage areas; and

5. Cleaning and sanitation products must be stored away from all constituents and packaging and labeled in accordance with the Inventory Control and Management SOP as well as the Quality Assurance and Quality Control SOP.

12.2.4.8 Production Environment

All necessary precautions must be taken during the processing, manufacture, and packaging of marijuana products to prevent contamination of product constituents, packaging materials, and marijuana products. These safeguards include, but are not limited to:

1. Cleaning and sanitizing equipment, containers, and other contact surfaces;
2. Controlling airborne contamination;
3. Using sanitary handling procedures;
4. Washing or cleaning constituents that contain soil or other contaminants;
5. Using quality water;
6. Performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated marijuana in marijuana products;
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 decomposition;
8. Storing constituents, in-process materials, and marijuana products appropriately to prevent contamination and adulteration;
9. Preventing cross-contamination and mix-ups between contaminated items and clean items; 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.

12.2.4.9 Repairs and Maintenance

The Production Facility Manager in coordination with the QCT must ensure all production areas are maintained in a manner that prevents the contamination of any product constituents or contact surfaces.

12.2.4.10 Water Supply

The Production Facility Manager must ensure the safety of the water supply used in production operations.

12.2.4.11 Environmental Controls

1. Adequate ventilation equipment must be provided such as filters, fans, exhausts, dust collection, and other air-blowing equipment, that minimize odors, dust, and vapors (including steam and noxious fumes) in areas where they may contaminate product constituents or contact surfaces;

2. Equipment that controls temperature, humidity, and/or microorganisms must be used as necessary to ensure the quality of the marijuana product; and
3. When air moving equipment is used, it must be designed, located, and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate product constituents or contact surfaces.

12.2.4.12 Plumbing

Plumbing, bathrooms, and hand-washing facilities must be compliant and maintained as described in the Hygiene, Sanitation and Facility Requirements SOP. All draining areas must be maintained so that they do not contribute to the contamination of product constituents or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests. Waste treatment and disposal systems must be maintained in good working order so that they do not constitute a source of contamination in areas where product constituents or contact surfaces are exposed.

12.2.4.13 Lighting:

1. Sufficient lighting that allows for employees must be provided in:
    a. All areas where product constituents are examined, processed, or stored;
    b. All areas where contact surfaces are cleaned; and
    c. Hand-washing areas and bathrooms.
2. Safety lighting products must be used when the light bulbs, fixtures, skylights or other glass or glass-like materials are suspended over exposed product constituents.

12.2.4.14 Sanitation Requirements:

1. The Production Facility Manager must ensure all production areas are maintained in compliance with the sanitation requirements found in the Hygiene, Sanitation and Facility Requirements SOP. Additionally, all necessary department-specific requirements must be developed and enforced by the Production Facility Manager in order to ensure safe production areas and unadulterated marijuana products;
2. The Production Facility Manager must maintain written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the production area; such written procedures must be followed, and records of cleaning and sanitation must be kept in the facility maintenance log;
3. All Hale O Laulima employees are required to report unsanitary conditions in any Hale O Laulima facility to their department manager;
4. UV sterilization door strips and dip tanks should be used in critical locations throughout the production facility;
5. Frequent hand-washing is necessary in all production activities and must be enforced by the Production Facility Manager. Cultivation employees that do not comply with hand-washing requirements may be terminated;

6. All production employees are responsible for the sanitation of productions areas. All critical areas must be clean and free of any contamination risks at the end of each shift; and
7. Any mold found in the facility must be addressed by a mold removal expert immediately.

12.2.4.15 Hazardous Materials

1. Cleaning compounds and sanitizing agents must be free from microorganisms of public health significance, approved by the EPA, and be safe and adequate under the conditions of use;
2. Cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials must be identified, stored, and used in a manner that protects against contamination of product constituents or contact surfaces;
3. Hazardous materials, including butane and CO2 tanks, and toxic chemicals may not be used or stored in production areas where product constituents or contact surfaces are manufactured or exposed, unless those materials are necessary as follows:
    a. To maintain clean and sanitary conditions;
    b. For use in laboratory testing procedures, if applicable;
    c. For maintaining or operating the facility or equipment; or
    d. For use in the production operations.

12.2.4.16 Pest Control

The Production Facility Manager is responsible for surveillance of pest activity and must ensure that pest management activities comply with procedures found in the Pest Management SOP.

12.2.4.17 Waste Disposal

All marijuana waste from production operations must be disposed of in accordance with the Marijuana Waste Disposal SOP. All other production waste must be stored and disposed of as to:

1. Minimize the development of odors;
2. Minimize the potential for waste to attract, harbor, or become a breeding place for pests;
3. Protect against contamination of product constituents, marijuana products, contact surfaces, water supplies, and grounds surrounding the facility; and
4. Control hazardous waste to prevent contamination of product constituents, marijuana products, contact surfaces, water supplies, and grounds surrounding the facility.

12.2.4.18 Security Requirements

The Facility Manager must ensure that all production areas are compliant with security requirements found in the Premises Security SOP. All areas that contain stored marijuana or marijuana in process must be surveyed and secure at all times.

12.2.5 cGMP Production Processes and Controls

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of marijuana products will be conducted in accordance with adequate sanitation principles and cGMP production processes and controls. The appropriate quality control operations will be implemented to ensure that marijuana products are suitable for human consumption and that marijuana product packaging materials are safe and suitable. Overall sanitation of the plant will be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions will be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures will be used where necessary to identify sanitation failures or possible marijuana product contamination. Any marijuana product that has become contaminated to the extent that it is adulterated within the requirements of the CFR will be rejected, or if permissible, treated or processed to eliminate the contamination.

12.2.5.1 Buildings and Facilities:

1. Grounds. The grounds for cultivation and processing under the control of the Hale O Laulima will be kept in a condition that will protect against the contamination of marijuana products. The methods for adequate maintenance of grounds include, but are not limited to:
    a. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the company buildings or structures that may constitute an attractant, breeding place, or harborage for pests;
    b. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where marijuana product is exposed;
    c. Adequately draining areas that may contribute contamination to marijuana products by seepage, foot-borne filth, or providing breeding places for pests; and
    d. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where marijuana product is exposed.
2. Construction and design. Hale O Laulima buildings and structures will be suitable in size, construction, and design to facilitate maintenance and sanitary operations for marijuana product-manufacturing purposes. Hale O Laulima facilities will:
    a. Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe marijuana products;
    b. Permit the taking of proper precautions to reduce the potential for contamination of marijuana products, product-contact surfaces, and product-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate marijuana product safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means;

c. Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate marijuana products, product-contact surfaces, and product-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating marijuana products or product-contact surfaces with clothing or personal contact;
d. Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where marijuana product is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed marijuana products in any step of preparation or otherwise protect against marijuana products contamination in case of glass breakage;
e. Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate marijuana products; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating marijuana products, marijuana product-packaging materials, and marijuana product-contact surfaces; and
f. Provide, where necessary, adequate screening or other protection against pests.

12.2.5.2 CGMPs - Personnel

The criteria and definitions in this section will apply in determining whether a marijuana product is adulterated. Within the meaning of Section 402(a)(3) of Title 21 of CFR in that the marijuana product has been manufactured under such conditions that it is unfit for distribution as marijuana products; or within the meaning of Section 402(a)(4) of Title 21 of CFR in that the marijuana product has been prepared, packaged, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Marijuana products covered by specific cGMP regulations are also subject to the requirements of those regulations. Hale O Laulima plant management will take all reasonable measures and precautions to ensure the following:

1. Disease control: Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of marijuana products, marijuana products-contact surfaces, or marijuana products-packaging materials becoming contaminated, will be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel will be required to report such health conditions to their supervisors;
2. Cleanliness: All persons working in direct contact with marijuana products, marijuana product-contact surfaces, and marijuana product packaging materials will conform to

hygienic practices while on duty to the extent necessary to protect against contamination of marijuana products. The methods for maintaining cleanliness include, but are not limited to:

a. Wearing outer garments suitable to the operation in a manner that protects against the contamination of marijuana products, marijuana product contact surfaces, or marijuana product packaging materials;
b. Maintaining adequate personal cleanliness;
c. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated;
d. Removing all unsecured jewelry and other objects that might fall into marijuana products, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which marijuana products are manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material, which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the marijuana products, marijuana products-contact surfaces, or marijuana products-packaging materials;
e. Maintaining gloves, if they are used in marijuana products handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material;
f. Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints;
g. Storing clothing or other personal belongings in areas other than where marijuana products are exposed or where equipment or utensils are washed;
h. Confining the following to areas other than where marijuana products may be exposed or where equipment or utensils are washed: eating, chewing gum, drinking beverages, or using tobacco;
i. Taking any other necessary precautions to protect against contamination of marijuana products, marijuana products-contact surfaces, or marijuana products-packaging materials with microorganisms or foreign substances including, but not limited to:
    i. Perspiration;
    ii. Hair, cosmetics;
    iii. Tobacco;
    iv. Chemicals; and
    v. Medicines applied to the skin.

3. Education and training. Personnel responsible for identifying sanitation failures or marijuana products contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe marijuana products. Marijuana product handlers and supervisors should receive appropriate training in proper marijuana products handling techniques and marijuana product-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices; and

4. Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part will be clearly assigned to competent supervisory personnel.

12.2.5.3 Manufacturing Operations:

1. Equipment and utensils and finished marijuana product containers will be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. As necessary, equipment will be taken apart for thorough cleaning;
2. All marijuana product manufacturing, including packaging and storage, will be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of marijuana products. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of marijuana products;
3. Marijuana products that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, will be held in a manner that prevents the marijuana products from becoming adulterated within the requirements of Title 21 of the CFR. Compliance with this requirement may be accomplished by any effective means, including:
    a. Maintaining refrigerated marijuana products at 45 °F (7.2 °C) or below as appropriate for the particular marijuana products involved; and
    b. Maintaining frozen marijuana products in a frozen state.

4. Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, will be adequate under the conditions of manufacture, handling, and distribution to prevent marijuana products from being adulterated within the requirements of Title 21 of the CFR;
5. Work-in-process will be handled in a manner that protects against contamination;
6. Effective measures will be taken to protect finished marijuana products from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they will not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated marijuana products. Marijuana products transported by conveyor will be protected against contamination as necessary;
7. Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or marijuana products will be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination;
8. Effective measures will be taken to protect against the inclusion of metal or other extraneous material in marijuana products. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means;

9. Marijuana plant material, other raw materials and ingredients that are adulterated within the requirements of Title 21 of the CFR will be disposed of in a manner that protects against the contamination of other marijuana products. If the adulterated marijuana plant material, or other raw materials and ingredients are capable of being reconditioned, it will be reconditioned using a method that has been proven to be effective or it will be reexamined and found not to be adulterated within the meaning of the Act before being incorporated into other marijuana products;
10. Mechanical manufacturing steps such as trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming will be performed so as to protect marijuana products against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of marijuana products from contaminants that may drip, drain, or be drawn into the marijuana product. Protection may be provided by adequate cleaning and sanitizing of all marijuana product-contact surfaces, and by using time and temperature controls at and between each manufacturing step;
11. Filling, assembling, packaging, and other operations will be performed in such a way that the marijuana product is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:
    a. Use of a quality control operation in which the critical control points are identified and controlled during manufacturing;
    b. Adequate cleaning and sanitizing of all marijuana products-contact surfaces and marijuana products containers;
    c. Using materials for marijuana product containers and marijuana product- packaging materials that are safe and suitable, as defined in §130.3(d) of Title 21 of the CFR;
    d. Providing physical protection from contamination, particularly airborne contamination; and
    e. Using sanitary handling procedures.

12. Marijuana products such as, but not limited to, intermediate moisture marijuana products that rely on the control of aw for preventing the growth of undesirable microorganisms will be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
    a. Monitoring the moisture content of marijuana products;
    b. Controlling the soluble solids-water ratio in finished marijuana products; and
    c. Protecting finished marijuana products from moisture pickup, by use of a moisture barrier or by other means, so that the moisture content of the marijuana products does not increase to an unsafe level.

12.3 Exhibit 3: Quality Assurance and Quality Control SOP

12.2.1 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
§11-850-37.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.

HAR Requirement	Description
§11-850-75.g	The floors, walls, and ceilings of a dispensary facility shall be constructed in such a manner that they may be 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

12.2.2 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.

12.2.3 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")

12.2.4 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.

12.2.5 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).

12.2.6 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.

12.2.7 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.

12.2.8 Facility Quality Control

12.2.8.1.1 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).

12.2.8.2 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.

12.2.8.2.1 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.

12.2.8.2.2 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.

12.2.8.2.3 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.

12.2.8.3 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.

12.2.8.3.1 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.

12.2.8.3.2 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..

12.2.8.3.3 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).

12.2.8.3.4 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.

12.2.8.3.5 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.

12.2.8.3.6 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.

12.2.8.3.7 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.

12.2.8.3.8 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.

12.2.8.3.9 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.

12.2.8.4 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.

12.2.8.4.1 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.

12.2.8.4.2 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.

12.2.8.4.3 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.

12.2.8.4.3.1 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).

12.2.8.4.3.2 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.

12.2.9 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.

12.2.10 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

12.2.11 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.

12.2.12 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

12.2.13 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.

12.2.14 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.

12.2.15 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.

12.2.15.1 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.

12.2.15.2 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.

12.4 Exhibit 4: Packaging and Labeling SOP

12.3.1 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
§11-850-74	A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.
§11-850-74.a	A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale. Eff. DEC 14 2015
§11-850-92.a	A dispensary licensee shall use packaging for marijuana and manufactured marijuana products that:
§11-850-92.a.1	Is child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
§11-850-92.a.2	Is opaque so that the product cannot be seen from outside the packaging;
§11-850-92.a.3	Protects the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product; and
§11-850-92.a.4	Contains no more than ten milligrams tetrahydrocannabinol for one dose, service, or single wrapped item; provided that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
§11-850-92.b	Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:
§11-850-92.b.1	Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
§11-850-92.b.1.A	Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;
§11-850-92.b.1.B	The concentration of tetrahydrocannabinol or Δ^9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;
§11-850-92.b.2	The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;
§11-850-92.b.3	the batch number and date of packaging;
§11-850-92.b.4	Includes a computer tracking inventory identification number barcode generated by tracking software;
§11-850-92.b.5	Date of harvest or manufacture and "Use by date";
§11-850-92.b.6	Instructions for use;
§11-850-92.b.7	The phrases "For medical use only" and "Not for resale or transfer to another person";
§11-850-92.b.8	The following warnings:
§11-850-92.b.8.A	"This product may be unlawful outside the State of Hawai'i and is unlawful to possess or use under federal law";
§11-850-92.b.8.B	"This product has intoxicating effects and may be habit forming";
§11-850-92.b.8.C	"Smoking is hazardous to your health";
§11-850-92.b.8.D	"There may be health risks associated with consumption of this product";
§11-850-92.b.8.E	"This product is not recommended for use by women who are pregnant or breast feeding"; and
§11-850-92.b.8.F	"Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and
§11-850-92.b.8.G	"When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
§11-850-92.b.9	A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
§11-850-92.b.10	The name of the laboratory that performed the testing; provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
§11-850-92.c	A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act. Eff DEC 14 2015

12.3.2 Local Compliance

In accordance with applicable packaging and labeling requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-850-74, 11-850-92 and enforced by the Hawai'i DOH, Hale O Laulima will utilize policies and procedures to ensure patients receive medical products that assure the safety, quality, identity, purity and potency expectations of the Hawai'i DOH and end user. All packaging and labeling 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): §11-850-74 and §11-850-92.

12.3.3 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")

12.3.4 Packaging and Labeling Policies and Procedures

It is established that all marijuana will be packaged in plain, opaque, tamper-evident and is child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act and

without depictions of the product, cartoons, or images (including logos). Only 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 are addressed, with particular attention to how all packaging and labeling will be compliant with all Hawai'i DOH laws and regulations. Child-resistant and tamper-evident packaging for each product type is detailed herein, as well as the quantities of marijuana or doses of marijuana products that will be individually packaged.
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 ADP/POS system whenever possible.

Labels will include legible wording and be firmly affixed on each package of marijuana and marijuana product prepared for distribution. An example of an appropriate label is included for reference and a detailed description of information required by the Hawai'i DOH to be contained on all labels is provided. Organic labeling restrictions are addressed.

This plan illustrates our commitment to compliance, safety, protecting children from accessing marijuana products, and implementation of industry best practices in all aspects of Production and Retail Dispensary Facilities operations.

12.3.5 Measurement Standards

All packaging operations must be executed by the Packaging Manager or Inventory Manager and performed utilizing a NTEP Legal for Trade scale. Such scales will be fully integrated with the ADP/POS system, Biotrack, by the Inventory Manager, allowing immediate entry of accurate weights in the system. The Inventory Manager will ensure the following for each commercial weighing and measuring device used in the Production and Retail Dispensary Facilities:

1. The commercial device is licensed pursuant to the Weights and Measures Act;
2. The scale is regularly calibrated;
3. Documentation of the licensure of the commercial device is maintained on the premises at all times; and
4. A copy of the commercial device license can be made available immediately upon request from a Department representative or other relevant authority figure.

12.3.6 Utensils and Separate Work Surface Required

The Packaging Manager and assisting employees will utilize sterile gloves and sanitized utensils for packaging marijuana products. Packaging will take place on a work surface that has been sanitized prior to packaging operations and after any contact with raw marijuana, foods, or other potential contaminants. All packaging operations involving the handling of marijuana or marijuana products will occur in full view of the surveillance video recording system.

12.3.7 Equipment Use Restricted

The use of equipment in packaging operations is limited to a responsible, trained Packaging Manager and employees familiar with any potential hazards of the operation.

12.3.8 Label Alterations and Restrictions

It is Hale O Laulima policy that no one other than the end user (i.e., qualified registered patient) or patient's legal representative may alter, obliterate or destroy any label attached to a marijuana product package to administer the product.

The Packaging Manager and Inventory Manager will assure that a marijuana product label does not contain any of the following information:

1. Any false or misleading statement;
2. Any pictures or graphics

12.3.9 Label Issuance and Compliance

The Packaging Manager in coordination with the Inventory Manager is responsible for compliant labeling in the Production and Retail Dispensary Facilities:

1. The Packaging Manager and the Inventory Manager will maintain written procedures for the issuance of labels;
2. The Packaging Manager or their designee must issue labels to be used in any labeling operations for marijuana products, and maintain strict control over labeling materials used during labeling operations;
3. All printed labels must be obtained from and integrated with the ADP/POS, Biotrack system, allowing assurance of the accuracy of label information and the ability to track the product through transport and distribution;
4. The Inventory Manager must review labels issued for a batch for identity and conformity to the labeling specified in the applicable Production and Retail Dispensary Facilities or control records; and
5. Standard labels described in this plan must be used for labeling all marijuana products.

12.3.9.1 Hale O Laulima Standard Label

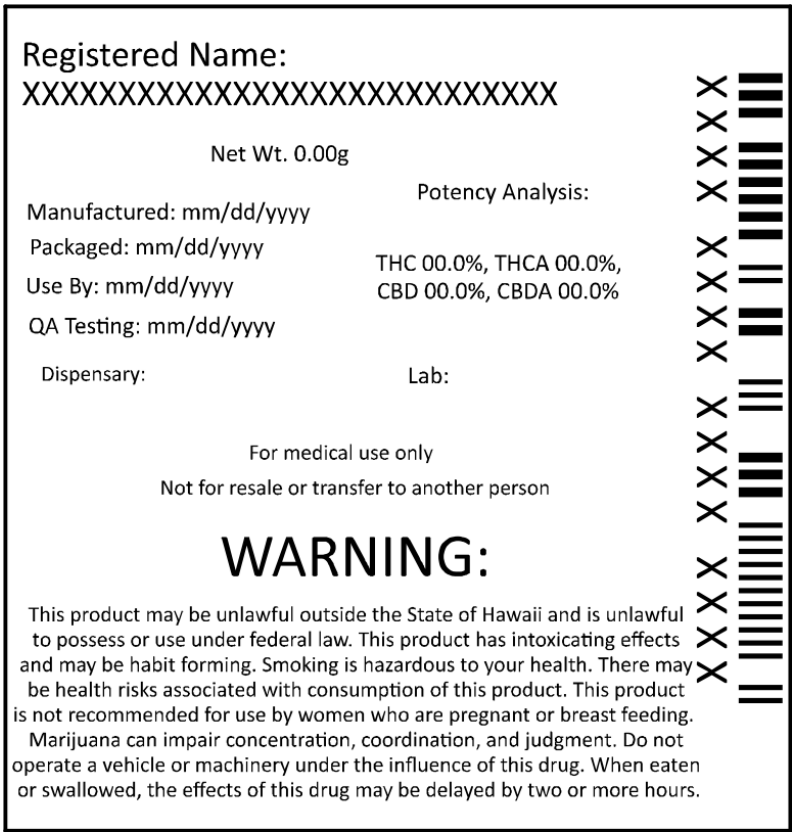
Hale O Laulima will label all product packaging pursuant to HAR §11-850-92. The Production Facility will ensure that all harvested marijuana intended for distribution to the Retail Dispensary is packaged in a sealed, labeled, medical marijuana container. The Production Facility will ensure all packaging of any product containing marijuana shall be child-resistant and light-resistant consistent with current standards, including the Consumer Product Safety Commission standards referenced by the Poison Prevention Act. Hale O Laulima will ensure each marijuana product is labeled in black lettering on a white background with no pictures or

graphics by the Production Facility prior to transport to the Retail Dispensary and each label is securely affixed to the package and states the following in legible English:

1. Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
2. Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;
3. The concentration of tetrahydrocannabinol or delta-9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;
4. The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;
5. The batch number and date of packaging;
6. Includes a computer tracking inventory identification number barcode generated by tracking software;
7. Date of harvest or manufacture and "Use by Date"'
8. Instructions for use;
9. The phrases "For medical use only" and "Not for resale or transfer to another person";
10. The following warnings:
11. "This product may be unlawful outside the State of Hawai'i and is unlawful to possess or use under federal law";
12. "This product has intoxicating effects and may be habit forming";
13. "Smoking is hazardous to your health";
14. "There may be health risks associated with consumption of this product";
15. "This product is not recommended for use by women who are pregnant or breast feeding"; and
16. "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and
17. "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
18. A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
19. The name of the laboratory that performed the testing; provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.

12.3.9.1.1 Hale O Laulima Sample Label:

The Packaging Manager will ensure the label utilized for transfer of marijuana to the Retail Dispensary is in compliance with all applicable regulations and conforms substantially to the following label example:



12.3.9.2 Organic Labeling Requirements

No Hale O Laulima marijuana product may be labeled as "organic" unless it is compliant with National Organic Standards[1]. Because third-party certification is not yet available for marijuana products, no "certified organic" labeling may be used at present. The COO must approve any "organic" labeling used when third-party certification becomes available. Hale O Laulima will pursue Clean Green Certification on all marijuana products and if such a certification is achieved, Hale O Laulima will label products as Clean Green Certified.

12.3.9.3 Hale O Laulima Standard Packaging

Hale O Laulima will require that all finished marijuana products be individually wrapped or packaged at the Production Facility and that packaging of the medical marijuana products conform to marijuana industry best practices and are in compliance with HAR §11-850-92.. Labels as described above will be affixed to the packaging and all packaging will conform to the following:

[1] National Organic Standards: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=3f34f4c22f9aa8e6d9864cc2683cea02&tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl

1. All packaging is child resistant in accordance with Title 16 C.F.R 1700 of the Poison Prevention Packaging Act;
2. Is opaque so that the product cannot be seen from outside the packaging;
3. Protects the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product; and
4. Contains no more than ten (10) milligrams tetrahydrocannabinol for one dose, service, or single wrapped item; provided that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred (100) milligrams of tetrahydrocannabinol per pack or container.
5. Each package shall be labeled using only black lettering on a white background with no pictures or graphics.

12.3.9.3.1 Hale O Laulima Sample Packaging:

The Packaging Manager will ensure the packaging utilized for transfer of marijuana to the Retail Dispensary is in compliance with all applicable regulations and conforms substantially to the following packaging example:

12.3.9.4 Child Resistant, Opaque and Tamper-Evident Packaging

Hale O Laulima will ensure all final marijuana products will be packaged in child resistant, opaque and tamper evident packaging prior to distribution to the Retail Dispensary Facilities. "Child-resistant" means special packaging that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly according to American Society for Testing and Materials (ASTM) classification standard D3475-14[2]. The Production facility will also ensure that all child resistant packaging is closable for any product intended for more than a single use or containing multiple servings, and labeled properly. The Production facility will package all marijuana products using one of the child resistant, opaque, and tamper evident packages. If marijuana product or marijuana product is packaged in another type of container, that package must be further packaged into one of the child resistant, opaque, and tamper evident packages before sale or transfer to a Retail Dispensary Facilities.

12.3.9.5 Use of Gases in Packaging

Presently Hale O Laulima has no plans to utilize gases in packaging; however, the Hawai'i DOH and Hale O Laulima do not currently prohibit the method. The Production facility will adhere to all of the rules produced by the Hawai'i DOH pertaining to the use of gases in packaging, upon release of such rules.

[2] This incorporation by reference does not include any later amendments or editions. The DEPARTMENT maintains copies of the applicable federal regulation and ASTM classification standard that are available to the public. http://www.astm.org/Standards/D3475.htm

12.3.10 THC and CBD Container Content and Restriction

The Packaging Manager and Inventory Manager will ensure that each individually packaged marijuana product, even if comprised of multiple servings, will show the total milligram content of THC and CBD and content percentages for each. Hale O Laulima marijuana products contain not more than ten (10) milligrams tetrahydrocannabinol for one dose, service, or single wrapped item; provided that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred (100) milligrams of tetrahydrocannabinol per pack or container (§11-850-92.a.4).

12.3.11 Packaging and Labeling Materials Issuance and Compliance

The Packaging Manager in coordination with the Inventory Manager will approve all packaging and labeling processes and materials in the Production and Retail Dispensary Facilities. The Packaging Manager is responsible for compliance with all packaging and labeling material requirements. It is Hale O Laulima policy that:

1. Written procedures for the receipt, identification, storage, handling, sampling, examination and testing of all packaging and labeling components must be maintained by the Inventory Manager;
2. Labeling and packaging materials must be approved and released for use by the Inventory Manager. Any packaging or labeling materials that do not meet requirements must be rejected, separated from approved materials, marked as unusable and disposed of by the Inventory Manager in accordance with the appropriate waste disposal SOP;
3. Packaging and labeling materials for each type, strength, dosage and quantity of marijuana or marijuana product will be stored separately to prevent errors in selection; and
4. The Inventory Manager will destroy obsolete and outdated labeling and packaging materials.

12.3.12 Medical Marijuana Bulk Packaging

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 following sections address bulk packaging and labeling requirements as well as appropriate package types.

12.3.12.1 General Requirements

The Production Facility Manager in coordination with the Inventory Manager must accurately identify and label all marijuana products packaged in bulk packages. Packaging of bulk marijuana must be in food- or pharmaceutical-grade containers approved by the Production Facility Manager. No bulk package may contain more than two (2) pounds of marijuana.

12.3.12.2 Bulk Marijuana Tracking

All marijuana 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.

12.3.12.3 Bulk Packaging Requirements:

All marijuana 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.

1. Packaging must be transparent;
2. Packaging must be tamper-evident;
3. Packaging must be inspected by the Inventory Manager and/or the Packaging Manager for any potential contaminants or imperfections; and

12.3.12.4 Bulk Marijuana Labeling Requirements:

All bulk packaged marijuana will be affixed with a label at all times. The label will include the following:

1. Strain name or identifier;
2. Batch identification number;
3. Package weight;
4. Testing results, if available, including pass/fail and CBD and THC content by weight;
5. Employee or manager responsible for packaging;
6. A list of all soil amendments, fertilizers, and other crop inputs;
7. Date of harvest;
8. Date of packaging; and
9. Expiration date.

12.5 Exhibit 5: Extraction Methodology SOP

12.5.1 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
§11-850-37.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.

HAR Requirement	Description
§11-850-75.g	The floors, walls, and ceilings of a dispensary facility shall be constructed in such a manner that they may be 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

12.5.2 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.

12.5.3 Extraction Methods Overview

Hale O Laulima will extract cannabinoids from mature marijuana flower using the three extraction methods and solvents outlined below. Because cannabinoids are not water soluble, cannabinoids must be dissolved in a solvent to allow extraction. Hale O Laulima will only utilize marijuana by-product of acceptable quality in the production of marijuana concentrates and infused products. Marijuana concentrates will be available to Retail Dispensary customers in ready-to-use form as well as infused in further processed products. All marijuana and manufactured marijuana products shall pass laboratory analysis prior to entering the Retail Dispensary supply chain.

12.5.3.1 Extraction Methodology

Three extraction methods will be employed by Hale O Laulima:

1. Ice-water separation:
    a. Cannabinoids can be extracted by using purified water and ice in food-grade agitation equipment to separate resin glands from plant material;

   b. Processed marijuana may undergo additional processing to mitigate low yields from water extraction; and
   c. This water-based, solvent-less process results in residue-free marijuana concentrate.

2. Butane extraction:
   a. Butane solvent in an ASME certified closed loop system and purged via vacuum oven;
   b. Retains high level of compounds and terpenes;
   c. Results in high quality oil from lower grade by-product; and
   d. Allows for some ability to selectively extract targeted compounds allowing targeted products.
3. Supercritical fluid CO2 extraction:
   a. CO2 used as a solvent in an ASME certified closed loop system to extract cannabinoids and terpenes;
   b. Extracts chemical compounds using carbon dioxide in its supercritical state instead of hydrocarbon-based solvents;
   c. CO2 is an excellent solvent because it is nontoxic, nonflammable, and compatible with compounds that are temperature-sensitive. The relatively low temperature of the process and the stability of CO2 permits most cannabinoids to be extracted with little damage or denaturing;
   d. By manipulating the temperature and pressure of the fluid, the extractor can solubilize the chemical compounds of interest and selectively extract them. This provides the ability to selectively extract targeted cannabinoids and terpenes, allowing for targeted products;
   e. Though this method produces extract with little or no residual solvent, the extracted product is purged via vacuum oven to remove any potential residual solvent;
   f. Vapors produced during the purging process are collected, managed and vented to atmosphere; and
   g. After extraction, the CO2 can be recycled for further extraction use.

12.5.3.2 CO2 Extraction

Hale O Laulima will create a variety of marijuana products with various routes of administration using decarboxylated extract as the source marijuana product input. CO2 will be the preferred solvent used for extraction processes due to its benign nature, and the resulting extract, after decarboxylation, will be the marijuana material incorporated into all finished marijuana products. By using the supercritical fluid extraction ("SFE") machine detailed in Hygiene, Sanitation and Facility Requirements SOP, and applying the right amount of pressure, temperature and time, the supercritical CO2 will selectively extract targeted compounds from the marijuana plant and collect the essential cannabinoids and terpenes needed to produce Hale O Laulima's specialized line of marijuana products. The Production facilities will request internal and independent testing of each finished production lot, and confirm the identity,

purity, potency and safety profile of each product created in accordance with the product specifications, as described in the Inventory Control and Management SOP as well as the Quality Assurance and Quality Control SOP. Lots are carefully tracked, labeled, and packaged in accordance with state laws and regulations, Hale O Laulima policies, industry best practices, and any additional requirements set forth by the Department. See the Inventory Control and Management SOP for more information about marijuana product tracking, labeling, and packaging.

The Medical Director and Laboratory Director will consult with the Production Manager about new developments in processes or procedures regarding the CO2 extraction process. The Production Manager will review quality control, safety and emergency procedures, sanitary conditions and cleanliness and environmental controls prior to beginning production procedures at the Production facility. The Production Manager will also ensure that all products are properly labeled at all times, and packaged properly prior to being placed in storage or transported to the Retail Dispensary Facilities.

12.5.3.3 Butane Extraction

Following the SOPs submitted with this application, Hale O Laulima intends to safely produce high quality marijuana concentrate through the method of using butane and a closed-loop extraction system to extract cannabinoids.

Butane is used for a wide variety of purposes ranging from cooking to cleaning and is a premier solvent for plant-based extractions. It is used to extract caffeine, aloe vera, and vanilla. Industries choose butane due to its unique, non-polar selectivity and low-boiling point (which makes it easier to remove from the finished product.) The FDA has listed it among the "food-safe solvents". According to the Food and Drug Administration, the generally accepted consumption rate for butane is approximately 50mg/day, which equates to approximately 5000 ppm or 0.5%. According to the Occupational Safety and Health Administration (OSHA), the permissible exposure limit for butane is 800 ppm over an eight-hour workday. Proper operation of a closed loop extraction system will keep exposure far below both of these permissible limits.

Butane is used by the marijuana industry to extraction the essential cannabinoids and terpenes from the marijuana plant into a clean, effective medicine. The selectivity of butane allows for the maximum retention of these medicinal benefits while leaving behind unwanted carbons found in the plant material. Many edible and topical marijuana product manufacturers have converted to using butane extracted marijuana oil as the active ingredient in their products rather than raw plant material because it easier to accurately measure dosing and limits the marijuana flavor. Additionally, many marijuana users have moved from burning raw plant material and have begun vaporizing extractions exclusively.

12.5.3.4 Ice Water Extraction

Ice water extraction is by far the safest method for separating trichomes, which contain therapeutic cannabinoids and terpenes, from marijuana plant material in order to obtain only the resin. As resin glands possess greater density than water and trichomes become brittle at low temperatures, ice water and agitation are all that is needed to separate the desired resinous material from the plant material.

In this process, marijuana plant material is placed in a mesh bag which is agitated in ice water, which separates trichomes from the plant material. Due to the density and size of the trichomes, they will pass through the holes in the mesh and sink to the bottom of the container. After passing the material through a series of mesh bags, filtering the solid content from the water used throughout the process, and pressing the resulting product to remove excess moisture, the result is pure, solvent-free marijuana resin, or hashish.

12.6 Exhibit 6: GAPs SOP

12.6.1 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.

HAR Requirement	Description
§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 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

12.6.2 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.

12.6.3 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")

12.6.4 Good Agricultural Practices

At the production facility level, Good Agricultural Practices (GAPs) involve multi-faceted efforts at ensuring that cannabis products are safe for human use and consumption. The United States Department of Agriculture (USDA) and the United States Food and Drug Administration (FDA) are responsible for recalling products. However, as agriculturally based products can become contaminated at all levels of the production system, Hale O Laulima will keep its products safe through GAPs.

The Production Facility Manager will develop and institute a GAP program to assist in self-auditing the production facility in order to safeguard the products, the environment, and the people who consume the products. In developing and implementing a GAPs program, the Production Facility Manager will focus on four primary components of production and processing: soil, water, hands, and surfaces. Hale O Laulima will use established agricultural principles and practices for minimizing microbial safety hazards from propagation through distribution of cannabis derived products. By identifying basic principles of microbial safety within the realm of growing, harvesting, processing, storing, and transferring cannabis, Hale O Laulima will recognize and address the GAPs principal elements known to mitigate microbial safety concerns. Members of Hale O Laulima Company with direct experience with USDA T-GAP and Global GAP certification programs will assist in the development of the GAP program for Hale O Laulima. Applicable USDA T-GAP and Global GAP standards, practices, and controls will be adopted.

12.6.5 Core Principles and Understandings

1. Prevention of microbial contamination of cannabis is favored over reliance on corrective actions once contamination has occurred.
2. To minimize microbial safety hazards in cannabis, Hale O Laulima will use good agricultural, handling, and management practices in those areas over which they have control.

3. Fresh cannabis and derivative products can become microbiologically contaminated at any point along the production and distribution chain.
4. Whenever water comes in contact with cannabis or derived products, its source and quality dictates the potential for contamination.
5. Minimize the potential of microbial contamination from water used with cannabis and derived products.
6. Practices using worm castings or other animal waste will be managed or avoided entirely to minimize the potential for microbial contamination of cannabis.
7. Worker hygiene and sanitation practices during cultivation, harvesting, sorting, packing, and transport will play a critical role in minimizing the potential for microbial contamination of fresh plant material.
8. Production Facility Manager will ensure compliance with all applicable local, state, and Federal laws and regulations for agricultural practices.
9. Accountability at all levels of the production facility environment is important to a successful program for ensuring the safety and quality of cannabis in accordance with federal and international GAPs. See the Inventory Management SOP as well as the Quality Assurance and Quality Control SOP for more information. At a minimum, the production facility will have qualified personnel and effective monitoring and recordkeeping to ensure that all elements of the program function correctly and to help track product lots back through to the production facility.

12.7 Exhibit 7: Hygiene Sanitation and Facility Requirements SOP

12.6.1 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
§11-850-75.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 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.

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

12.6.2 Local Compliance

In accordance with the requirements defined by Hawai'i Administrative Rules Chapter(s): 11-850-37, 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 including proper hygiene and facility cleanliness will be in full compliance with the provisions set forth in Hawai'i Administrative Rules Chapter(s): §11-850-37, §11-850-75 and §11-850-81.

12.6.3 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")

12.6.4 General Hygienic Practices

All employees, managers, and contractors will be required to adhere to the following personal cleanliness items:

1. Hale O Laulima uniform must be clean and worn at all times in the Production and Retail Dispensary Facilities;
2. A high degree of personal cleanliness must be maintained during all shifts; and
3. All persons who handle marijuana products, product constituents, utensils, equipment, etc. must:
    a. Wear a hairnet, beard net, or other hair restraint;
    b. Keep fingernails trimmed, clean, and maintained;
    c. Not wear fingernail polish or artificial nails while working in the production area unless wearing gloves;
    d. Not eat or drink in areas used for storage, production, and sanitation; and
    e. Not wear jewelry on arms or hands when producing or handling marijuana products.

12.6.5 Hand-washing Policies

Instructive hand washing signs must be maintained in appropriate areas such as bathrooms, kitchens, and lunch areas, and in multiple languages as needed. Each manager must enforce hand-washing policies before and during procedures that involve direct contact with marijuana, after handling soiled equipment or utensils, after touching skin that has not just been washed, and after all bathroom breaks.

12.6.5.1 Hand Washing

12.6.5.1.1 Production Facility

Production and Processing Employees, managers, and contractors will be required to wash their hands and exposed portions of their arms at designated hand washing facilities at the following times:

1. After touching bare human body parts other than clean hands and clean, exposed portions of arms;
2. After using the toilet room;
3. After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
4. Immediately before engaging in product preparation including working with exposed marijuana and clean equipment and utensils;
5. Immediately before handling marijuana plants, exposed harvested marijuana, and clean equipment and utensils;

6. Before, during, and after cloning procedures, as necessary in order to prevent cross-contamination;
7. During post-harvest processing activities, as often as necessary to remove soil and other potential sources of contamination and prevent cross contamination when changing tasks;
8. After handling and treating pest infested, diseased, or otherwise contaminated plants;
9. During preparation activities, as often as necessary to remove soil and other potential sources of contamination and prevent cross contamination when changing tasks;
10. When switching between working with plants and working with harvested plant material; and
11. When switching between working with raw products and working with finished products; and
12. After engaging in other activities that contaminate the hands.

Hand-washing facilities will be adequate and conveniently located, and be furnished with running water at a suitable temperature for cleansing.

12.6.5.1.2 Retail Dispensary Facilities

Dispensary Employees, managers, and contractors will be required to wash their hands and exposed portions of their arms at designated hand washing facilities at the following times:

1. After touching bare human body parts other than clean hands and clean, exposed portions of arms;
2. After using the toilet room;
3. After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
4. Immediately before handling marijuana products, and cleaning equipment and utensils;
5. After handling or removing solid waste material from the facility; and
6. After engaging in other activities that contaminate the hands.

Hand-washing facilities will be adequate and conveniently located, and be furnished with running water at a suitable temperature for cleansing.

12.6.6 Production Facilities Requirements Generally

In accordance with §11-850-75, the Facility Manager, is responsible for maintaining suitable facilities by ensuring the following:

1. The procedures and policies of each unit are designed to prevent contamination;
2. Biosecurity measures will be implemented at all times;
3. Floors, walls, and ceilings will be constructed in such a manner that they may be adequately kept clean and in good repair. Hale O Laulima intends on sanitizing all cultivation production and processing spaces with hot steam, if available, and all building materials will be adequate to allow for such.

4. All production areas will maintain open egress aisles on all sides of plant groups and will be free of debris and equipment;
5. There will be adequate space and safety lighting in all processing and storage areas, as well as areas where equipment or utensils are cleaned and sanitized;
6. Buildings, fixtures, and other physical facilities will be maintained in a sanitary condition at all times;
7. The facility's water supply will be sufficient for necessary operations and shall be derived from a source that is regulated. Any private water supply will be capable of providing a safe, potable, and adequate supply of water to meet the cultivation center's needs;
8. Plumbing will be of adequate in size and design, and adequately installed and maintained to carry sufficient quantities of water required to locations throughout the facility, with back flow protection required as necessary. Plumbing must properly convey sewage and liquid disposable waste from the facility. There must be no cross-connections between the potable and wastewater lines;
9. There will be adequate physical screening, mechanical systems and policies and procedures implemented for protection against pest entry. Waste disposal shall be carried out in accordance with the procedures set forth in the Waste Disposal SOP and Marijuana Waste Disposal SOP and shall be adequate to assure that waste will not constitute a source of contamination in cultivation, manufacturing, and processing areas or attract pests; and
10. Toxic cleaning compounds, sanitizing employees, solvents, and pesticides will be identified, help, and stored in a manner that protects against contamination.

12.6.6.1 Cultivation Area Design, Construction and Maintenance

The cultivation production area will be suitable in size, design, and construction for efficient and safe cultivation operations. The Production Facility Manager will not permit any operation that is unsafe or unsuitable for the facility.

Operations must have sufficient space as to promote safe and orderly processes and prevent cross-contamination.

All rooms, equipment, and infrastructural components of the cultivation production area will be constructed and installed in a manner that allows for their maintenance and cleansing. The Production Facility Manager will ensure any repairs necessary are made as soon as possible to maintain the sanitary and safe condition of the cultivation production area.
If a condition exists that prohibits the safe and sanitary cultivation of marijuana, the Production Facility Manager, in his or her discretion, may suspend cultivation operations until resolved.

12.6.6.2 Daily Walk Through Inspections

The Production Facility Manager or designee will visually inspect the entirety of the cultivation production area daily to identify potential hazards or suboptimal conditions. During the daily walk-through inspection of the cultivation production area, the Production Facility Manager will, at a minimum, assess whether the following requirements are met:

1. Floors, walls, and ceilings are clean and in good repair;
2. Fixtures, ducts, and pipes do not contaminate product constituents or contact surfaces by dripping, other leakage, or condensation;
3. Aisles or working spaces between equipment are adequately unobstructed and permit all persons to work and protect against contamination of constituents, contact surfaces, and garments; and
4. Equipment is functioning properly, in the specified location, up-to-date with required maintenance schedule and with required items to perform that maintenance, and maintained in a sanitary condition.

12.6.6.3 Clean Room Processing and Manufacturing Environment

In all phases in the extraction and manufacturing processes, marijuana products will be processed in rooms utilizing clean room design features. International Organization for Standardization defines a clean room as a "room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary" (ISO 14644-1) The clean rooms will be designed and maintained in accordance with the standards set forth in ISO 14644. Each production space will be enclosed and environmentally controlled with respect to airborne particulates, temperature, humidity, living organisms, pressure, and airflow. External and internal sources of contamination will be controlled through a variety of methods, including the use of construction materials that meet clean room standards, including antimicrobial surfaces, the required use of sanitary garments, materials, and equipment by Processing Employees, the installation of equipment designed to minimize contaminants, and the implementation of procedures for preventing and limiting contamination. All processing spaces will be slightly pressurized.

All clean rooms will be environmentally controlled through the use of an HVAC system with mechanical air-handling units outfitted with commercial HEPA filters. The HVAC system will supply a sufficient volume of clean air to support the cleanliness rating of the room, prevent stagnant areas in which particles could accumulate, and condition the air to meet temperature, humidity, and filtration specifications. High efficiency particulate arrestance (HEPA) filters will be installed to ensure the removal of small particles. These filters will serve all spaces and will be used to assist in mitigating environmental contaminants by catching airborne particulates, infectious employees, and pests, if present. HEPA filters will be added on the return side of all air-handling units and on all intake points for make-up air. In addition, ultraviolet light emitters will be installed ahead of these HEPA filters in the return and make-up air ducts, which will aid in the destruction of additional microorganisms in the facility and specifically the processing rooms.

Clean rooms will be constructed using smooth, easily cleanable materials and all doors will seal tightly. The number of joints, cracks and crevices in the walls, floors, and ceilings will be reduced during facility build out. These clean rooms will be subject to stringent sanitation requirements, including scheduled floor to ceiling cleansing and decontamination, and will have sanitary features built into their very design. Each person entering the Production and Retail Dispensary Facilities will be required to pass through the decontamination area and change into Hale O Laulima-provided garments in an effort to prevent potential contaminants from entering the clean rooms. Measures for maintaining the clean room processing environment are described throughout this Plan.

12.6.6.4 Processing Area Design, Construction and Maintenance

The processing production area will be suitable in size, design, and construction for safe and efficient processing operations. The Processing Manager will not permit any operation that is unsafe or unsuitable for the facility and its occupants.
Operations must have sufficient space as to promote safe and orderly processes and prevent constituent mix-ups.

All rooms, equipment, and infrastructural components of the processing production area will be constructed and installed in a manner that allows for their efficient maintenance. The Processing Manager will ensure any repairs necessary are made as soon as possible to maintain the sanitary and safe condition of the processing production area.
If a condition exists that prohibits the safe and sanitary processing of marijuana products, the Processing Manager, in his or her discretion, will suspend processing operations until resolved.

12.6.6.4.1 Separate Processing Areas

The Processing Manager will ensure each distinct aspect of the processing operation (e.g., extraction, infusion, packaging, etc.) is conducted in a separate space in the processing production area with sufficient room and storage in each separate space to prevent cross-contamination and mix-ups of constituents. Separate areas are required for:

1. Receiving and storing constituents and supplies, including packaging materials, cleaning supplies, etc;
2. Storage of marijuana by-product, in-process marijuana, and finished marijuana products will be separate from other supplies, secured, and labeled at all times. Marijuana source material and products must be stored in a safe within the Secure Product Storage Room when not in use;
3. Waste storage and mixing, including separate locked storage of marijuana plant waste and processing by-product waste;
4. The processing, packaging, and labeling room will be separate from areas used for extractions and manufacturing/concentration;
5. In-house analysis operations will be separate from storage, packaging, extraction, and concentration spaces; and

6. Cleaning and sanitation products will be stored away from all product constituents in a secure cabinet located in the manufacturing area.

12.6.7 Signage

Hale O Laulima 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. The point of access to the processing production area will bear a sign indicating that the area beyond the door is a limited access area and that only authorized personnel may enter;
5. All rooms will be labeled by name and corresponding access level; and
6. "Employees must wash hands" signs at all hand washing sinks in production area and in toilet and locker area.

12.6.8 Sanitation

12.6.8.1 Sufficient Facilities Required:

1. Floors, walls, and ceilings must be constructed in such a manner that they may be adequately kept clean and in good repair;
2. There must be adequate safety lighting in all processing and storage areas, as well as areas where equipment or utensils are cleaned;
3. Buildings, fixtures, and other physical facilities must be maintained in a sanitary condition;
4. The facility's water supply must be sufficient for necessary operations. Any private water source must be capable of providing a safe, potable, and adequate supply of water to meet the operation's needs; and
5. Plumbing must be of adequate size and design, and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the facility. Plumbing must properly convey sewage and liquid disposable waste from the facility. There must be no cross-connections between the potable and waste water lines.

12.6.8.2 Regular Facility Maintenance Required

The Facility Manager must ensure proper facility maintenance to ensure safe and sanitary conditions. Maintenance practices include:

1. Keeping work areas clean, dry, and free of algae and other clutter and trash. Remove trash from critical areas immediately;

2. All Production and Retail Dispensary Facilities managers must schedule and oversee regular cleaning and maintenance in their departments;
3. Maintain cracks, window and door frames, drain areas, and floor joints with sealant to limit pest movement;
4. Use appropriate traps and baits on a regular basis and replace as needed;
5. Maintain roads to the Production facility so they are free of trash and debris that border, irrigate dirt roads to reduce dust and use slow speeds. Overhead irrigation will decrease dust and disrupt the behavior mite populations;
6. Eradicate any weeds or pest habitats surrounding the facility;
7. The Facility Manager must ensure that trees, bushes, and other foliage outside of the licensed facility do not allow for a person or persons to conceal themselves from sight; and
8. If the facility is bordered by grounds not under Hale O Laulima's control, and if those other grounds are not maintained in the manner described in this section, care must be exercised in the facility by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous materials that may be a source of contamination.

12.6.8.3 Sanitation Requirements:

1. The Production and Retail Dispensary Facilities manager must ensure the facility is maintained in a sanitary condition to ensure the safety of employees and marijuana products. Additionally, all necessary Hawai'i DOH-specific requirements must be developed and enforced by Production and Retail Dispensary Facilities managers;
2. Production and Retail Dispensary Facilities managers must maintain written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the licensed facility; such written procedures must be followed, and records of cleaning and sanitation must be kept in the Facility Maintenance Log;
3. Contractors must be informed of and held to sanitation standards while working on Hale O Laulima premises;
4. All Hale O Laulima employees are required to report unsanitary conditions in any Hale O Laulima facility to their supervisor;
5. UV sterilization door strips and dip tanks should be used in critical locations throughout the Production and Retail Dispensary Facilities facilities;
6. Frequent hand-washing is necessary in all handling activities and must be enforced by the Production and Retail Dispensary Facilities managers. Employees that do not comply with hand-washing requirements may be terminated;
7. All critical areas in Hale O Laulima's facility must be clean and free of any contamination risks at the end of each shift; and
8. Any mold found in the facility must be addressed by a mold removal expert immediately.

12.6.8.4 Equipment Sanitation, Maintenance, and Calibration

12.6.8.4.1 Repairs and Maintenance

The Facility Manager, in coordination with the QCT and the manager of each facility area, will ensure all areas are maintained in a manner that prevents the contamination of any product constituents or contact surfaces. The Facility Manager, in coordination with the COO, is responsible for scheduling and overseeing repairs and maintenance of the Production and Retail Dispensary Facilities and all Hale O Laulima equipment.

12.6.8.4.2 Equipment Sanitation, Maintenance, and Calibration Policies:

1. All equipment will be sanitized, maintained and calibrated in accordance with manufacturer recommendations;
2. Written procedures will be established and implemented for the sanitation, maintenance, and calibration of all systems and equipment. Written procedures will include, without limitation:
    a. Assignment of responsibility for cleaning and maintaining systems and equipment;
    b. A description in sufficient detail of the methods, equipment and materials used in cleaning and maintenance operations and the methods of disassembling and reassembling equipment as necessary to ensure proper cleaning and maintenance;
    c. Protection of clean equipment from contamination before use; and
    d. Periodic inspection of all equipment and systems for proper functioning, accuracy, and condition;
3. All equipment, including measurement devices, will be regularly calibrated and checked to ensure accuracy and proper performance. Third-party calibration services will be utilized as necessary or desired;
4. The Facility Manager will create a sanitation, maintenance and calibration schedule; and
5. All cleaning/sanitation, maintenance and calibration of equipment will be recorded in internal logs.

12.6.8.4.3 Pre- and Post-Procedural Inspections and Checks

Hale O Laulima employees will be required to inspect cleaned and sanitized equipment after cleaning and prior to use in production. An employee executing a production procedure must check the maintenance, sanitation, and calibration logs for the equipment to be used to ensure that the equipment is up-to-date on all required maintenance and calibration and has been cleansed and/or sanitized in accordance with standard operating procedure since the last use.

12.6.8.4.4 Equipment Maintenance

12.6.8.4.4.1 HVAC Maintenance:

1. All equipment filters will be cleaned or replaced monthly;

2. All pipes associated with mechanical and irrigation systems will be inspected for clogs or leaks monthly;
3. An air compressor will be utilized to blow out air-handling unit condensers monthly;
4. Schedules and settings on thermostat and light cycle timers will be reviewed monthly;
5. Temperature control exhaust fans will be monitored daily for abnormal running times, which indicate radical microclimate developments; and
6. Thermostats will be professionally calibrated as directed by the manufacturer.

12.6.8.4.4.2 Odor Control Equipment Maintenance

The Facility Manager will be responsible for ensuring that all odor control equipment is operating properly and serviced in accordance with manufacturer's recommendations. Odor control equipment will be cleaned regularly and all filters will be replaced as often as suggested by the manufacturer. All cleaning and maintenance activities will be recorded in the Equipment Maintenance Log and Equipment Sanitation Log.

12.6.8.4.4.3 Water Equipment Maintenance:

1. The Production Facility Manager is responsible for ensuring the maintenance of hoses, the fertigation system, the irrigation runoff recycling system, and other equipment that may contaminate water or marijuana crops;
2. Back flow prevention devices will be installed on all incoming water sources;
3. The fertigation system installed in the facility will be professionally maintained and routinely calibrated in accordance with the manufacturer's recommendations.
4. The fertigation system will be maintained in good working condition to prevent wasting of water and to avoid high soil moisture levels that may contribute to mold and fungal problems;
5. If reverse osmosis (RO), ultra-violet light systems (UV), active carbon or other water quality systems are utilized, they will be professionally serviced in accordance with manufacturer's recommendations;
6. Filters, and other parts that come in contact with water will be cleaned and replaced as often as needed to prevent contamination;
7. The Facility Manager is responsible for monitoring and inspecting all water equipment to ensure it is in good working order on a regular basis;
8. The Facility Manager will also ensure that any spills are cleaned up immediately, runoff is reduced, and irrigation is adjusted to reflect plant needs; and
9. Sanitation, maintenance, and calibration activities will be recorded in the appropriate internal logs.

12.6.8.4.4.4 Processing Equipment:

1. The Production Facility Manager in coordination with the Inventory Manager will ensure all equipment used for harvesting, trimming, curing, or storage is made of non-toxic and non-corrosive materials;

2. All equipment will be inspected by a designated Production Facility Employee to ensure it is in proper working order prior to each use; repairs must be made as necessary;
3. Equipment will be maintained in a clean condition ensuring that all parts that come in direct contact with the crop during processing are clean and free of potential contaminants;
4. Remnants of any prior processing activity will be removed from equipment prior to each use to prevent cross-contamination;
5. Harvest containers will not be used for storing or holding non-harvest materials, such as tools or chemicals. Containers will be cleaned and sanitized prior to use in each harvest;
6. All necessary personnel will be properly trained in the use of processing equipment, especially mechanized equipment; and
7. Equipment will be operated in a manner that ensures the safety of the operators and avoids or minimizes damage to the harvested material.

12.6.8.4.4.5 Lighting Equipment

Proper light function will be verified by visual inspection during daily crop inspection, and by measuring Photosynthetically Active Radiation (PAR) below each lamp prior to a new crop cycle being placed beneath the lamp. PAR is defined as the micromolar quantity of photons in the 400-700 nanometer wavelength range striking a 1 m2 area in 1 second (mmol/m2/sec), and can be measured using a handheld light meter. A normal PAR operating range each type of light will be established following facility build out. This will be used as a standard to verify proper function of the lamps. A specific protocol for using the light will be based on the light meter manufacturers operating instructions and will be prepared once the device is acquired.
Light readings must be taken weekly by a designated Cultivation Employee and recorded on the Weekly Light Reading Log. The Production Facility Manager will oversee a monthly rotation schedule of reflector cleaning and lamp replacements. Failed lamps and ballasts must be replaced immediately. Cultivation Employees must wear gloves when handling lamps.
Lighting equipment will be sanitized, maintained, and monitored regularly in accordance with standard operating procedure and will be promptly replaced as necessary or as directed by the manufacturer.

12.6.8.4.4.6 Extraction and Production Equipment

All extraction and production equipment will be constructed of materials that are suitable for use in commercial pharmaceutical and food manufacturing environments. The product contact surface of the extraction system(s) and all production equipment will be sanitized before and after each production run; more thorough cleansing and sanitation of equipment will be conducted on a schedule produced by the Production Facility Manager.

All equipment and supplies used in the production of marijuana concentrates and infused products will be maintained and calibrated as directed by the manufacturer. Periodic checks will be conducted internally to ensure proper performance of all automatic, mechanical, and electronic equipment. Failure of a lot to meet specifications may require investigation of the performance of the equipment used in production.

12.6.8.4.4.7 Thermometers

Hale O Laulima employees will perform regular checks of all thermometers to ensure accuracy.

12.6.8.4.4.8 Measurement Equipment

In accordance with SECTION of the RULES, all scales, balances, and other measurement devices will be routinely and professionally calibrated and periodically checked by Hale O Laulima employees to ensure accuracy. All calibration activities will be recorded in the Equipment Calibration Log. Scales must be approved by the Hawai'i - Department of Agriculture - Standards and Technical Services, for use in a legal trade environment.

12.6.8.5 Sanitation Measures

12.6.8.5.1 General Housekeeping

All parts of the Production and Retail Dispensary Facilities premises will be kept neat, clean and free of litter and rubbish. Cleaning operations will be conducted in such a manner as to minimize contamination of marijuana products and product-contact surfaces. Vacuum cleaning, wet cleaning, steam cleaning and other dustless methods will be used for cleaning floors, walls and ceilings, but dust-arresting sweeping compounds and push brooms may be employed for floors. All such cleaning, except emergency floor cleaning, will be done during periods when the least amount of product is exposed, such as between production runs.

Maintenance and cleaning tools such as brooms, mops, vacuum cleaners and similar equipment will be maintained and stored in a manner that does not contaminate marijuana products, product constituents, utensils, tools, or equipment and will be stored in an orderly manner. Soiled cloths and uniform apparel will be kept in suitable containers until removed for laundering.

12.6.8.5.2 Facilities, Fixtures, and Controls

Buildings, fixtures, and other physical features of the Production and Retail Dispensary Facilities will be maintained in a sanitary condition and will be kept in good repair to prevent marijuana source material from becoming adulterated. The cleaning, sanitizing, inspecting, and calibrating of all utensils and equipment will be conducted in a manner that protects against contamination of marijuana, contact surfaces, or packaging materials. In addition, all Production and Retail Dispensary Facilities equipment, systems, and utensils will be designed, constructed, and installed to be adequately cleanable, prevent adulteration, and will be properly placed, installed, used, cleaned, stored, and maintained. Control instruments, such as those for measuring temperatures, pH, and water activity will be calibrated as needed for accuracy and properly maintained. Contact surfaces will be maintained to protect marijuana from being contaminated by any source. Post-harvest Production and Retail Dispensary Facilities surfaces will be made of non-toxic materials and will be corrosion-resistant.

12.6.8.5.3 Cleanliness

All floors and plumbing fixtures in the Production and Retail Dispensary Facilities will be cleaned and sanitized, to the degree possible without contaminating product or contact surfaces, at least once per day and beyond that, as needed. Cleaning tools, approved products, and facilities (e.g., mop sink, hand washing sink, etc.) will be provided and conveniently located to ensure all parts of the Production and Retail Dispensary Facilities equipment, and tools may be easily maintained in a clean and sanitary condition. Hand washing sinks and ware washing sinks will provide hot and cold running water at a sufficient pressure and dispensed through a mixing valve. Hand washing sinks will be conveniently located for use by Production and Retail Dispensary Facilities Employees and managers in ware washing areas and the toilet rooms, and in some spaces in the Production and Retail Dispensary Facilities production area, as needed.

All surfaces of equipment that come in contact with marijuana and are used solely for licensed activities will be thoroughly cleaned and sanitized after each use. Non-product-contact surfaces of equipment will be cleaned as necessary to keep them free of dust, dirt, product constituent particles, and otherwise in a clean and sanitary condition. After cleaning and until use, all equipment and supplies will be stored and handled in a manner that protects from manual contact, splash, dust, dirt, insects and other contaminants. Cleansing and sanitizing may be done manually or mechanically (i.e., dishwasher). Regardless of method, cleansing and sanitizing processes must meet the requirements of §11-850-75.

12.6.8.5.4 Use and Storage of Cleaning, Sanitizing, and Toxic Materials

Cleaning compounds and sanitizing employees used in the Production and Retail Dispensary Facilities to maintain clean and sanitary operations, or for equipment maintenance and operation, will be uncontaminated and will be safe and adequate under the conditions of use, verified by supplier's guarantee or certification, or examination for contamination. The Production and Retail Dispensary Facilities Facility Manager will avoid the acquisition, storage and use of toxic or otherwise hazardous materials in the Production and Retail Dispensary Facilities, and will only do so if operationally necessary and no other feasible option exists. It is Hale O Laulima policy to only use EPA-approved cleaning and sanitizing employees. Toxic cleaning compounds, sanitizing employees, and pesticide chemicals, if any, will be identified, held, and stored in a manner that protects against contamination of marijuana, contact surfaces, constituents, or packaging and labeling materials.

12.6.8.5.5 Equipment and Utensils

All equipment and utensils will be designed, constructed, and installed to be easily cleanable, and will be properly maintained. The design, construction, and use of equipment and utensils will preclude the adulteration of marijuana products with lubricants, metal fragments, contaminated water, or any other contaminants. Production surfaces will be made of non-toxic materials and will be corrosion-resistant. The following requirements will be implemented by

Hale O Laulima regarding the use and maintenance of equipment and utensils in the Production and Retail Dispensary Facilities:

1. All equipment and utensils will be made from safe and durable materials and will be smooth, easy to clean, nonabsorbent, and corrosion resistant;
2. Seams on product-contact surfaces will be smoothly bonded or maintained so as to minimize accumulation of marijuana particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms;
3. Equipment that is in the Production and Retail Dispensary Facilities or marijuana products-handling area and that does not come into contact with marijuana products will be constructed that it can be kept in a clean condition;
4. Holding, conveying, and manufacturing systems, including automated systems (once acquired), will be of a design and construction that enables them to be maintained in an appropriate sanitary condition;
5. Equipment will be installed in a manner that provides aisles and adequate space to ensure Production and Retail Dispensary Facilities personnel can carry out work activities without contaminating marijuana or product-contact surfaces through contact with their clothing or person;
6. Each freezer and cold storage compartment used to store and hold marijuana products will be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and will be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change;
7. Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in marijuana products will be routinely calibrated to ensure accuracy and adequately maintained in accordance with manufacturer's directives, and adequate in number for their designated uses;
8. All scales or other measurement devices will be routinely calibrated and regularly checked to ensure accuracy;
9. All automatic, mechanical, or electronic equipment will be routinely calibrated and periodically checked to ensure proper performance;
10. Compressed air or other gases mechanically introduced into marijuana products or used to clean product-contact surfaces or equipment will be treated in such a way that marijuana products are not contaminated or adulterated and no safety risks are posed to Hale O Laulima facilities or employees;
11. All equipment will be installed to allow adequate space for cleaning. Floor mounted equipment will either have a 6" clearance from the floor for cleaning purposes or will be sealed to the floor. Table or counter mounted equipment will have at least a 4" clearance from the table or counter for ease of cleaning; and
12. All equipment will be installed according to manufacturer's specifications and in accordance with federal standards.

12.6.8.5.6 Product Contact Surfaces

All marijuana product-contact surfaces, including utensils and marijuana product-contact surfaces of equipment, will be cleaned as frequently as necessary to protect against contamination of marijuana products. The Production and Retail Dispensary Facilities Facility Manager will establish a cleaning and sanitation schedule for product contact surfaces as well as equipment and facilities. Generally, product contact surfaces and product contact surfaces of equipment will be cleaned and sanitized after the completion of a procedure and the sanitary condition of a given product contact surface must be confirmed prior to commencement of any procedure involving that surface.

Marijuana product-contact surfaces used for Production and Retail Dispensary Facilities or holding low-moisture marijuana products will be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they will, when necessary, be sanitized and thoroughly dried before subsequent use.

In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into marijuana products, all marijuana product-contact surfaces will be cleaned and sanitized before use and after any interruption during which the marijuana product-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and marijuana product-contact surfaces of the equipment will be cleaned and sanitized as necessary.

Cleaning and sanitizing employees will be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment, without introducing unnecessary hazards or toxins.

12.6.8.5.7 Unsanitary Nuisance Abatement

Hale O Laulima employees will regularly inspect the Production and Retail Dispensary Facilities premises for unsanitary conditions that could constitute a public nuisance and take measures to correct such unsanitary conditions, if discovered.

12.6.8.5.8 Prompt Waste Disposal

It is Hale O Laulima policy to ensure that all waste is stored appropriately and disposed of as promptly as possible to ensure it does not become a nuisance or unsanitary condition. In accordance with this policy, it will be strictly prohibited to keep, deposit on, or scatter over the Production and Retail Dispensary Facilities premises any of the following:

1. Accumulated media, junk, trash or debris;
2. Abandoned, discarded, or unused tools, objects or equipment; and

3. Any compost pile or pile of trash which may spread or harbor disease, emit unpleasant odors or harmful gas, attract vermin or disease-carrying pests, animals or insects.

12.6.8.5.9 Sanitary Facilities

All sanitary facilities in the Production and Retail Dispensary Facilities will be adequate in number, furnished with soap and approved single-service towels or another approved commercial hand-drying device. Common towels will not be provided and the use of common towels will be strictly prohibited by Hale O Laulima policy. All sanitary facilities will be conveniently located and provided with toilet tissue and hand sanitizer. In addition, sanitary facilities will be supplied with a sufficient and appropriate water supply with adequate plumbing to provide proper drainage, including floor drainage, and preclude backflow or other contamination from cleaning, Production and Retail Dispensary Facilities operations, sewage, or flooding. All entries and exits pertaining to sanitary facilities will be designed to protect against airborne contamination in the Production and Retail Dispensary Facilities.

If needed, adequate signage will be used to direct Production and Retail Dispensary Facilities EmployeeS in appropriate hand washing and sanitizing procedures and schedules, including before work commences, after each absence, and when hands become soiled or contaminated. Refuse receptacles will be constructed, maintained, and located in a manner that protects against contamination of marijuana.

12.6.8.5.10 Water Supply

The water supply will be adequate, of safe and sanitary quality, sufficient for Production and Retail Dispensary Facilities operations (including irrigation), and from an approved source. Any water that comes in contact with marijuana plants, additives, or any equipment or surfaces that touch marijuana will be safe and from an approved and regulated source. Hot and cold running water under pressure will be provided in all areas where required for Production and Retail Dispensary Facilities, cleaning, or employee sanitary needs.

12.6.8.5.11 Plumbing

The Production and Retail Dispensary Facilities' plumbing system will be sized, installed, and maintained in accordance with the Hawai'i Plumbing Code.
All plumbing fixtures and plumbing in the facility will be maintained in good repair and free from odor.

The potable water supply will be protected from contamination, including maintaining separate potable and non-potable water lines and installing backflow prevention devices, if necessary. Plumbing will be of adequate size and design and adequately installed and maintained to:

1. Carry sufficient quantities of water to required locations throughout the Production and Retail Dispensary Facilities;

2. Properly convey sewage and liquid disposable waste from the facility;
3. Avoid constituting a source of contamination to marijuana, water supplies, equipment, or utensils or creating an unsanitary condition; and
4. Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for licensed activities.

12.6.8.5.12 Toilet Facilities

Toilet facilities and fixtures will be installed according to the Hawai'i Building Code and the plumbing section of that code. Fixtures will be designed and installed to be easily cleanable and will be cleaned and sanitized at least once per day. Toilets will be maintained in a clean state, in good repair, and free of offensive odors. Toilet seats will be the open front type for sanitary reasons. The Production and Retail Dispensary Facilities will have physical separation between the production area and the toilet rooms in order to ensure that access to toilet rooms is not allowed through areas where marijuana is exposed, or where Production and Retail Dispensary Facilities equipment and supplies are cleaned, handled, used, or stored.

All sanitary facilities in the Production and Retail Dispensary Facilities will be furnished with soap and approved single-service towels or another approved hand-drying device. Common towels will not be provided and the use of common towels will be strictly prohibited per Hale O Laulima policy. All sanitary facilities will be provided with toilet tissue and hand sanitizer. Signs will be posted requiring employees to wash hands with soap after using the toilet.

12.6.8.5.13 Construction Materials and Finishes

All floor surfaces in the Production and Retail Dispensary Facilities will be smooth, non-absorbent, and easy to clean. No rooms in the Production and Retail Dispensary Facilities will be carpeted. Walls and ceilings will be constructed of easily cleanable surfaces. Any room used for marijuana production, equipment and supply cleansing, storage of waste, and employee dressing, as well as the toilet rooms will have ceilings of a low enough height to ensure that the ceiling and walls can be cleaned regularly during room turnover.

12.6.8.5.14 Pest Control

During facility build-out, the Production and Retail Dispensary Facilities will be structured and reinforced to prevent the entrance of pests. All walls, floors, and ceilings will be sealed and all doors will be tight fitting. All air vents will be protected from pest entry with the use of screens and filters. A decontamination room will be constructed, which personnel must pass through when entering the facility, to provide pest and other contaminant control.

Effective measures will be taken to exclude pests from the Production Facility production area and to protect against the contamination of marijuana plants on the premises by pests. Production Facility personnel will be required to change into a uniform upon arrival at the Production Facility and will not be allowed to wear personal items that have the potential to

carry pests or microscopic contaminants. Rodent traps will be placed around the perimeter of the building and rodenticides may be used as a last resort, and must be in full compliance with state laws and regulations. The Production Facility Manager will aim to avoid using insecticides, fungicides, and pesticides through the implementation of good pest prevention strategies and mechanical, cultural, biological, and organic controls, but if all other strategies fail and the use of synthetic chemicals is necessary, such chemicals will be acquired in the smallest amount possible and stored, handled, used, and disposed of in a manner that is safe for the plants, Production Facility personnel, and the environment.

12.6.8.5.15 Ventilation

All rooms in which marijuana is cultivated, stored, processed, or packaged, where utensils are cleaned and sanitized, and the toilet facilities, dressing and locker rooms and waste storage areas will be well ventilated. Odors, fumes and vapors will be effectively managed or neutralized and vented to the outside air. Ventilation devices will be designed and installed to prevent condensate from dripping onto marijuana plants, harvested plant material, additives, and product-contact surfaces. Filters, where used, will be readily removable for cleaning or designed to be cleaned in place. Ventilation systems will comply with applicable fire prevention requirements and will discharge in such a manner as not to create a public nuisance. Intake and exhaust air ducts will be maintained to prevent the entrance of dust, dirt and other contaminating materials.

12.6.8.5.16 Chemicals and Hazardous Materials

Cleaning compounds and sanitizing employees used in cleaning and sanitizing procedures will be free from undesirable microorganisms and will be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification and examination of these substances upon acquisition and prior to use for contamination.

Toxic cleaning compounds, sanitizing employees, and pesticide chemicals, if any, will be identified, held, and stored in a manner that protects against contamination of marijuana, product-contact surfaces, and packaging materials. All relevant regulations promulgated by Federal, State, and local governments for the application, use, or holding of these products will be followed. See the Worker Safety SOP and Emergency Management and Response SOP for more information on hazardous materials and pesticides.