



3. Facility Manager:

- a. Position Summary: Responsibilities include maintaining all dispensary facilities and equipment are in good working condition; exterior and interior facility maintenance and cleanliness; addressing all compliance issues related to the maintenance of the facility; and coordinating with manufacturers and contractors for the maintenance, repair, and installation of all equipment and for any construction activities.

**Retail Positions**

1. Director of Retail Operations:

- a. Position Summary: Responsible for supervision of Dispensary General Managers; participating in senior leadership meetings relative to overall retail and outreach operations; the oversight, development and implementation of Retail Dispensary policies and procedures; initial and ongoing staff education and training programs; coordination between Retail Dispensary locations to ensure consistent product quality and patient experience; development and implementation of Company-wide Retail Dispensary patient education programs.

2. Dispensary General Manager

- a. Position Summary: Responsible for managing the day-to-day operations of one retail dispensary facility in accordance with the State and standards set by Hale O Lahuli; providing support for all Retail Dispensary employees, including schedules, training, policy and procedure updates, industry news, and product information; ordering and receiving of all inventory and products, arranging deliveries, maintaining facility compliance and cleanliness; and reporting of any compliance violations to Company's Chief Compliance Officer.

3. Patient Coordinator:

- a. Position Summary: Responsible for customer orientation, data, paperwork, and management; maintaining accurate records of customers identification and registration documents; managing patient traffic flow, answering phones and respond to patient, caregiver and public inquiries; recording patient orders; and maintaining an organized environment and facility appearance.

4. Dispensary Agent:

- a. Position Summary: Responsible for providing superior customer service and educational guidance to registered patients and caregivers; arranging and packaging patient orders, recording sales in Company's automated data processing / point-of-sale system; handling transactions including cash, check, and credit card payments; and maintaining an organized environment and facility appearance.



## Advisory Board

Advisory Board members are not employees of Hale O Laulima. These members provide expert opinions and provide suggestions for the improvement of Hale O Laulima policies and procedures, based on their respective disciplines. Positions that have been filled on the Advisory Committee are depicted in Hale O Laulima organizational chart. The roles of Advisory Committee members are described in all plans contained within this application, when applicable.

### 5.14.8.3 Training

#### 5.14.8.3.1 Hale O Laulima Training Philosophy

Training is a critical component of Hale O Laulima's operations. The Human Resources Manager in coordination with the Hale O Laulima Facility Managers is responsible for the development and execution of the Staffing and Training SOP. Hale O Laulima is committed to training all employees as necessary and required in order to perform all job duties and functions safely and in compliance with all applicable laws and regulations. It is our policy to ensure that all employees receive professional and appropriate training on items including, but not limited to: compliance with state law, cultivation activities, processing and manufacturing procedures, the therapeutic use of marijuana, retail operations, patient interaction, worker safety, security (including prevention of diversion and theft), emergency management, recalls, and inventory control. Dispensary facility personnel in particular will be required to undergo additional training on the topics of patient education, patient counseling, the Health Insurance Portability and Accountability Act (HIPAA), confidentiality and patient privacy, compliance, and data collection, in accordance with Section of the Rules. No employee or consultant may work on-site prior to receiving orientation training or when any required critical training is two (2) weeks or more past due.

#### 5.14.8.3.2 Training Mandatory for All Employees

The Human Resources Manager will provide or cause to be provided all relevant and adequate training for each individual involved in Hale O Laulima operations. Training will be tailored to the roles and responsibilities of the job function of each employee employed in a dispensary facility. At a minimum, staff will receive eight (8) hours of on-going training annually. No Dispensary Employee or Patient Coordinator may begin work until they receive training on the proper use of security measures and controls for the prevention of diversion, theft or loss of marijuana and marijuana products; confidentiality, privacy, and HIPAA compliance; patient education and counseling; data collection; Hale O Laulima marijuana products, methods of administration, constituents, and benefits and potential risks; and facility emergency response protocols.





#### 5.14.8.3.3 New Employee Orientation and Training

All dispensary personnel will receive employee onboarding and training manuals, the Employee Manual, and attend new employee orientation prior to commencing employment. Orientation is a formal welcoming process that is designed to make the new employee feel comfortable, informed about Hale O Lahuli and prepared for their position. New employee orientation is conducted by a management representative and includes an overview of Hale O Lahuli's history, an explanation of Hale O Lahuli's core values, vision and mission; and Hale O Lahuli's goals and objectives. In addition, the new employee will be:

1. Given an overview of benefits, tax and legal issues;
2. Provided time to complete any necessary paperwork;
3. Given all codes, access cards, keys and procedures needed to navigate within the workplace, as described in the Access Control SOP;
4. Introduced to the support staff and management personnel throughout the facility;
5. Instructed regarding the job description;
6. Informed about Hale O Lahuli evaluation procedures; and
7. Helped with getting started on specific job functions.

##### 5.14.8.3.3.1 New Employee Orientation Training – Retail Dispensary Facilities

All new Retail Dispensary employees are required to receive new employee orientation prior to beginning work in the Retail Dispensary. Each Retail Dispensary Facility Manager provides the new employee orientation for employees assigned to their facility, in coordination with the Human Resources Manager and Chief Medical Officer, if necessary or desired. The new employee orientation includes a summary overview of all training modules. Topics that will be highlighted include:

1. Overview of the applicable laws and regulations;
2. Hale O Lahuli and operations overview;
3. A definition of a qualified patient and the services Hale O Lahuli provides;
4. Standards of conduct and reasons for dismissal;
5. Federal laws impacting the employee and operation;
6. Employee's role in community and customer relations;
7. Marijuana science and Hale O Lahuli's commitment to science based operations;
8. The legal importance of confidentiality and records management;
9. The employee's role in emergency management;
10. Dispensary-specific safety;
11. Dispensary-specific security measures and the employee's access to records and storage;
12. The employee's role in inventory management and diversion prevention; and
13. Hale O Lahuli's focus on quality operations and preventing product contamination.



#### 5.14.8.3.3.2 New Employee Orientation Training – Production Facility

All new employees are required to receive new employee orientation prior to beginning work in any facility. The Director of Cultivation provides the new employee orientation, in coordination with the Human Resources Manager, and other management personnel if necessary or desired. The new employee orientation includes a summary overview of all training modules. Topics that will be highlighted include:

1. Overview of the applicable laws and regulations;
2. Hale O Lahuli company, mission and operations overview;
3. Standards of conduct and reasons for dismissal;
4. Federal laws impacting the employee and operation;
5. Employee's role in Hale O Lahuli's overall operations;
6. marijuana science and Hale O Lahuli's commitment to science-based operations;
7. The methods of cultivation;
8. The methods of fertilization;
9. The methods for recognizing and treating insect infestation and disease in marijuana plants and the procedures for responsible eradication and the safe disposal of plants affected;
10. The nutritional requirements of marijuana plants at various growth stages, including without limitation, proper mixing and application of nutrients, irrigation practices, and signs of nutrient deficiencies and toxicities.
11. The safe handling of equipment, including without limitation, lamps, electrical ballasts, pumps, fans, cutting implements and other equipment for cultivation.
12. The employee's role in emergency management;
13. Cultivation safety;
14. Cultivation security measures and controlled access to records and storage;
15. The employee's role in inventory management and diversion prevention; and
16. Hale O Lahuli's focus on quality operations and preventing product contamination;

#### 5.14.8.3.3.3 New Employee Orientation Training – Processing Facility

All new employees are required to receive new employee orientation prior to beginning work in any facility. The Director of Cultivation provides the new employee orientation, in coordination with the Human Resources Manager, and other management personnel if necessary or desired. The new employee orientation includes a summary overview of all training modules. Topics that will be highlighted include:

1. New employee orientation;
2. Train the trainer;
3. Monthly processing meetings;
4. Compliance, regulation and law;
5. Processing safety;
6. Processing security;
7. Emergency management;
8. Inventory management and diversion prevention;



9. Medical marijuana science;
10. Recordkeeping;
11. Product handling and sanitation;
12. Recall and withdrawal;
13. Extraction methods;
14. Marijuana product production;
15. Current Good Manufacturing Practices;
16. Routes of administration;
17. Quality assurance and testing;

#### 5.14.8.3.4 Manuals

The new employee orientation includes a summary overview of all training modules and a review of the Onboarding and Training Manual as well as the Employee Manual. The Employee Manual provides in-depth information on dispensing policies and procedures and outlines mandatory training. Each employee must receive, read, and acknowledge their understanding of the material covered in the Staffing and Training SOP and Employee Manuals. All Dispensary Employees and Patient Coordinators will be trained by the Retail Dispensary Facility Manager, Chief Medical Officer, and Human Resources Manager and must continually demonstrate a working knowledge of training materials as a condition of employment.

#### 5.14.8.3.5 Responsible Parties

The Human Resources Manager is responsible for coordinating all relevant and adequate training for each individual involved in Hale O Lahuli operations with appropriate personnel. The Human Resources Manager, in coordination with the Retail Dispensary Facility Managers and Chief Medical Officer, will develop appropriate and necessary training modules for dispensary personnel, which will be updated as needed. Input from Facility Managers on training needs will be considered when modifying modules or training schedules. The Human Resources Manager will determine the need for retraining current employees after a module update or modification.

#### 5.14.8.3.6 Authorized Trainers

Each Facility Manager will be trained by the Human Resources Manager, COO and Chief Medical Officer to provide new employee orientation and basic training. Specialized areas of training, such as marijuana product manufacturing training, may be provided by managers of other operational units or third-party experts, if no Hale O Lahuli staff member has the appropriate body of knowledge. The Human Resources Manager will ensure training content and presentations from outside trainers meets the needs and requirements of Hale O Lahuli. The COO, Chief Medical Officer and members of the Board will receive training and advice from contracted consultants as well as external resources, as necessary.



#### 5.14.8.3.7 Module-Based Training

Hale O Lahuli employs a strategy of module-based training. Each module covers a single topic in-depth for general training or for job-specific training and will be tracked/documented for reporting and management purposes. Training will be production or dispensary- and patient-centric and address all items in contained herein, as well as relevant portions of other narratives and plans. Most modules are developed and implemented by the Human Resources Manager in coordination with the Retail Dispensary Facility Manager and Chief Medical Officer. Other Hale O Lahuli managers will be involved in development of specific training modules when their area of expertise is relevant to the topic. Training modules include:

1. New employee orientation;
2. Train the trainer;
3. Monthly facility staff meetings;
4. Compliance, regulation and law;
5. Confidentiality, privacy protection, and HIPAA;
6. Patient, product and public safety;
7. Facility security;
8. Patient education and counseling;
9. Emergency and incident management;
10. Inventory management and diversion prevention;
11. Medical marijuana science;
12. Recordkeeping;
13. Product handling and sanitation;
14. Transportation;
15. Recall and withdrawal; and
16. Data collection.

#### 5.14.8.3.8 Train the Trainer Program

Hale O Lahuli utilizes the “train the trainer” method throughout the organization. The benefits for trainer managers include enhanced skills and knowledge, mastery of materials and knowledge transfer to personnel. Using this method, Hale O Lahuli gains increased organizational knowledge and a staff that continually engages and operates in a training-based environment.

#### 5.14.8.3.9 Monthly Facility Meetings

Each facility is required to hold monthly meetings. The Facility Managers will create an agenda for each meeting addressing operational issues and reinforcing training priorities. Updates to any training module that do not require a re-training as determined by the Human Resources Manager will be addressed at the monthly meetings. Facility managers and assistant managers are encouraged to implement staff-to-staff mini-trainings at monthly meetings.



#### 5.14.8.3.10 Compliance, Regulation and Law Training

In accordance with Section of the Rules, Hale O Lahilima will provide training for employees that addresses compliance. The Quality Control Team, COO and Human Resources Manager develop compliance training. All dispensary personnel will have a thorough understanding of the legal and regulatory requirements of Hale O Lahilima in general and specifically related to their duties in the dispensary facilities. All compliance aspects of the Onboarding and Training Manual will be highlighted in the training. Support staff will receive updated training annually and more often as necessary to maintain a safe and compliant operation.

#### 5.14.8.3.11 Confidentiality, Privacy Protection, and HIPAA Training

In accordance with Section of the Rules, Hale O Lahilima will provide training for employees that addresses the Health Insurance Portability and Accountability Act (HIPAA). Confidentiality and privacy protection will be included in the HIPAA training in order to provide employees with a comprehensive understanding of their responsibilities toward maintaining patient confidentiality and privacy. Confidentiality, privacy protection, and HIPAA training will be developed and implemented by the Chief Medical Officer. Training will cover the HIPAA-compliance items discussed in the Staffing and Training SOP, statutory provisions pertaining to confidentiality and privacy of information in the Compassionate Use Registry, and procedures and best practices for protecting patient confidentiality and privacy in all production and retail activities. All dispensary staff will be trained upon hire and at least once annually thereafter. The Chief Medical Officer will periodically monitor the dispensary facilities and provide follow-up training if any confidentiality, privacy protection, and HIPAA compliance items are determined to be inadequate or any non-compliance is detected.

#### 5.14.8.3.12 Safety Training

Facility-specific safety training is developed and implemented by the Facility Manager in coordination with the Human Resources Manager and COO. Training is focused on employee, visitor, facility, marijuana product and public safety. The training will be work-area-focused and address all safety items in Worker Safety SOP, as well as the Emergency Management and Response SOP, and the Employee Manual which covers OSHA regulations. Training will additionally cover unsafe marijuana product storage conditions and requirements for reporting potentially unsafe marijuana products to a supervisor. All employees will receive an orientation of the safety policy and rules upon initial employment, and are required to bring to the attention of their supervisor any unsafe or non-compliant conditions or practices. Safety training will be provided as often as necessary and annually at a minimum.

#### 5.14.8.3.13 Security Training

Facility-specific security training is developed and implemented by the Facility Manager and Chief Security Officer, in coordination with the Human Resources Manager. Training is focused on employee, visitor, facility, and marijuana product security. All employees will be trained to identify indicators of diversion, including suspicious behavior, parking lot surveillance and other indications of planned diversion. Training will also familiarize employees with facility security



features, including the surveillance system, alarm system, and access control system. The training will address all security items in the Access Control SOP and Anti-Diversion SOP. All Hale O Lahuli personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.

#### 5.14.8.3.14 Patient Education and Counseling Training

Hale O Lahuli will provide training for dispensary personnel addressing patient education and patient counseling. Patient education and counseling training is developed and implemented by the Chief Medical Officer and Facility Manager, in coordination with the Human Resources Manager. Training is focused on providing patients with information and suggestions tailored to their individual needs and drawn from reputable sources. All employees will be trained to provide marijuana education to new patients, to explain all portions of the patient education packet, to counsel patients on marijuana products and administration, to provide and explain educational materials kept on-site, and to suggest approved sources for seeking additional information. All employees will also be trained to interpret analytical test results and communicate the results to patients. Training will emphasize employee professionalism and individualized care, but also cover common patient questions and appropriate responses. All dispensary personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.

#### 5.14.8.3.15 Emergency Management Training

Emergency management training is developed and implemented by the COO in coordination with the Human Resources Manager. The training will be developed and implemented by the Chief Security Officer, Facility Manager, and COO. Training is focused on protecting human assets, inventory assets and physical assets in the event of an emergency. Third-party trainers may be utilized as necessary. The training will be facility-location-specific. All Hale O Lahuli personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.

#### 5.14.8.3.16 Inventory Management and Diversion Prevention

Inventory management and diversion prevention training is developed and implemented by the Chief Security Officer and Inventory Manager, in coordination with the Facility Manager. Training is focused on accuracy in inventory counts and preventing and identifying diversion. All employees will be trained to report any suspected theft or loss to their immediate supervisor, who will pass the information along to the COO for investigation and reporting to the Hawai'i DOH and appropriate law enforcement authorities immediately. The training will be facility-specific and address all items in the Inventory Control and Management SOP, as well as portions of the Anti-Diversion SOP. All Hale O Lahuli personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.





#### 5.14.8.3.17 Marijuana Science Training

Marijuana science training will be conducted by the Chief Medical Officer in coordination with the Facility Manager. Americans for Safe Access and Marijuana Training Institute are approved sources of training materials, but the Chief Medical Officer may select additional materials. All dispensary personnel will be trained upon hire, at least once annually thereafter, and more often as necessary. Training will address, at a minimum:

1. The endocannabinoid system;
2. CBD and its effect on qualifying conditions;
3. Clinical trial information;
4. Efficacy and dosing;
5. Strains and genetics;
6. Delivery methods;
7. Types of products;
8. Condition management; and
9. Side effects.

#### 5.14.8.3.18 Recordkeeping Training

Recordkeeping training is developed and implemented by the COO in coordination with the Human Resources Manager and Facility Manager. Training is focused on regulatory and operational recordkeeping requirements. Training will be facility-specific and clearly identify each employee's role and responsibilities in regards to recordkeeping activities as described in the Quality Assurance and Quality Control SOP. All Hale O Lahilima personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.

#### 5.14.8.3.19 Product Handling and Sanitation Training

Product handling and sanitation training is developed and implemented by the Inventory Manager and Director of Processing in coordination with the Facility Managers. The Director of Processing and QCT will approve the training regimen, which will be focused on quality control and product safety. Training will be dispensary-specific and clearly identify the employee's role and responsibilities in preventing contamination and product degradation. All dispensary personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.

#### 5.14.8.3.20 Quality Assurance and Quality Control Training

Quality assurance (QA) and quality control (QC) training is developed and implemented by the Quality Control Team, and Director of Cultivation in coordination with the Human Resources Manager. The training will cover the difference between quality assurance and quality control, potential contaminants and adulterants and their typical sources, restricted pesticides and pesticide tolerance limits, required inspections, and quality assurance testing. QA/QC training will be provided at least once annually, and more often if necessary or desired.



#### 5.14.8.3.21 Recall and Withdrawal Training

Recall and withdrawal training is developed and implemented by the Facility Manager(s), Inventory Manager and Human Resources Manager. Other Hale O Laulima personnel with recall experience will participate in the development of this training module. Training will cover all aspects of the Recall and Withdrawal SOP, including complaint documentation, recall and withdrawal definitions and classifications, required notifications and records, and recall and withdrawal procedures. All Hale O Laulima personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.

#### 5.14.8.3.22 Marijuana Cultivation Methods Training

The marijuana cultivation methods training module is developed and implemented by the Director of Cultivation in coordination with the Human Resources Manager. This training module covers the early harvest method, phases of the cultivation cycle, cultivation procedures in each phase, cultivation media and containers, marijuana strains, techniques for maximizing yield, and sustainable practices. The training module will also cover approved and prohibited crop applications and GAPs. All cultivation personnel will be trained upon acquisition and at least once annually thereafter. Cultivation personnel must be re-trained each time cultivation methods and procedures are modified.

#### 5.14.8.3.23 Propagation and Cloning Training

The propagation and cloning training module is developed and implemented by the Director of Cultivation in coordination with the Human Resources Manager. Propagation and cloning training will cover how to properly identify propagation material by genus, species, variety, and chemotype, the various available propagation methods, methods used in the Production facility, cloning procedures, identifying desirable cutting characteristics, inventory tracking and labeling of clones, propagation room optimal environmental conditions, transplanting, and the process and timing for transferring clones to the vegetative room. All cultivation personnel will be trained upon acquisition and at least once annually thereafter, with more frequent trainings if desired by the Director of Cultivation or in response to procedural changes.

#### 5.14.8.3.24 Plant Care Training

The plant care training module is developed and implemented by the Director of Cultivation in coordination with the Human Resources Manager. The aim is to introduce employees to daily, weekly, and monthly plant care tasks for plants in each phase of cultivation. Plant care training will include environmental condition monitoring, light adjustments, plant monitoring, training, pruning, trellising, plant spacing and canopy rotation, and required plant care records. The plant care training module will cover all items on the daily, weekly, and monthly checklists for each cultivation room. All cultivation personnel will be trained upon acquisition and at least once annually thereafter, with more frequent trainings if desired by the Director of Cultivation or in response to procedural changes.



#### 5.14.8.3.25 Cultivation Environment Training

The cultivation environment training module is developed and implemented by the Director of Cultivation in coordination with the Human Resources Manager, and is aimed at educating Production Employees about the cultivation environment. Production Employees will be introduced to clean room cultivation and optimal cultivation conditions for each cultivation phase. Employees will learn how to maintain the clean room environment and optimal environmental conditions. Cultivation environment training will cover standards for clean rooms and all environmental systems and conditions, including but not limited to, adjusting and monitoring light intensity, air movement and ventilation, temperature, relative humidity, and carbon dioxide levels. All cultivation personnel will be trained upon acquisition and at least once annually thereafter, with more frequent trainings if desired by the Director of Cultivation or in response to procedural changes.

#### 5.14.8.3.26 Nutrients and Fertilization Training

The nutrients and fertilization training module is developed and implemented by the Director of Cultivation in coordination with the COO and Human Resources Manager. Nutrients and fertilization training will cover key nutrients and appropriate levels of each, transpiration and diffusion, signs of nutrient deficiency and toxicity, nutrient recipes, nutrient mixing, optimal nutrient solution temperature, pH, and EC, water quality standards, nutrients in cultivation media, fertilization schedules, and other nutrient and fertilization topics that will help Production Employees promote optimum plant growth. All cultivation personnel will be trained upon acquisition and at least once annually thereafter, with more frequent trainings if desired by the Director of Cultivation or in response to procedural changes.

#### 5.14.8.3.27 Pest and Disease Management Training

The pest and disease management training module is developed and implemented by the Director of Cultivation in coordination with the COO and Human Resources Manager. The training will cover all information provided about pests and disease in the Pest Management and Control SOP. Plant and disease management training will cover common marijuana diseases and typical symptoms, common marijuana pests and typical indicators, regionally prevalent pests, measures for monitoring pest populations, approved pest and disease eradication methods, and Integrated Pest Management principles and practices. Production Employees will be informed that it is Hale O Lahuli policy to avoid the use of synthetic chemicals except as a last resort; mechanical, cultural, biological and organic pest and disease controls will be emphasized. Plant and disease management training is aimed at introducing practices for prevention and early identification of pest activity and disease, and the appropriate strategies for addressing any pest or disease issues that occur. All cultivation personnel will be trained upon acquisition and at least once annually thereafter, with more frequent trainings if desired by the Director of Cultivation or in response to procedural changes.



#### 5.14.8.3.28 Room Care Training

The room care training module is developed and implemented by the Director of Cultivation in coordination with the COO and Human Resources Manager. Room care training will cover various requirements for maintaining all rooms used for the cultivation of marijuana plants, including but not limited to, sanitation and hygiene protocols and schedules for each room, standard room turnover and disinfection procedures, and daily, weekly, and monthly room upkeep tasks. The training will cover all items on the room care checklists and all room care procedures and will be designed to ensure that all cultivation rooms are kept clean and sanitary without disturbing or contaminating the plants. All cultivation personnel will be trained upon acquisition and at least once annually thereafter, with more frequent trainings if desired by the Director of Cultivation or in response to procedural changes.

#### 5.14.8.3.29 Harvest and Post-Harvest Processing Training

The harvest and post-harvest processing training module is developed and implemented by the Director of Cultivation in coordination with the Human Resources Manager, Inventory Manager, and Quality Control Team. The training module will cover harvest timing and procedures, harvest records, post-harvest processing procedures, post-harvest processing inventory management and recordkeeping, drying and curing procedures and conditions, proper storage conditions for dried marijuana, GHPs, and marijuana waste disposal procedures. Sanitation requirements for each post-harvest production space and work surfaces, and hygiene requirements for cultivation personnel engaged in harvest and post-harvest activities will be identified. All cultivation personnel will be trained upon acquisition and at least once annually thereafter, with more frequent trainings if desired by the Director of Cultivation or in response to procedural changes.

#### 5.14.8.3.30 Transportation Training

Transportation training is developed and implemented by the Transportation Manager in coordination with the Inventory Manager and Chief Security Officer. Training is focused on familiarizing dispensary staff with transportation procedures carried out by the Transportation Employee(s) and their roles in the transportation process. Facility staff will be trained on receiving delivery orders, placing employee delivery orders in the ADP/POS system, verification requirements for delivery orders, and procedures for receiving incoming shipments from the production / processing facility. Training includes preventative measures to avoid diversion, emergency response protocols and corrective measures, such as reporting and tracking, used to address theft or any breach in security. The training will address all items in the Anti-Diversion SOP, and Organizational Security SOP, including security features of the shipping containers. All dispensary personnel will be trained upon hire, at least once annually thereafter, and more often as necessary.

#### 5.14.8.3.31 Data Collection Training

In accordance with Section of the Rules, Hale O Laulima will provide training for employees addressing data collection. Data collection training is developed and implemented by the Chief



Medical Officer and Human Resources Manager in coordination with the Facility Managers. This training module will cover the purposes and content of the bio-assessment sheets used for in-house research. The training also covers educating patients about the importance and uses of bio-assessment sheets, measures for maintaining patient confidentiality and privacy in data collection, entering and maintaining data, appropriate uses for data collected, and secure data storage. Data collection training will also cover policies and procedures for collecting patient data for internal patient records, and how patient records are protected in accordance with HIPAA standards. All dispensary personnel will be trained upon hire, at least once annually thereafter, and more often as necessary

#### 5.14.8.4 Training Evaluation

The Hale O Laulima training program is essential to achieving quality, efficient and compliant operations. The Human Resources Manager shall evaluate the training program annually. Based on the results of the evaluation, the Facility Managers shall implement necessary changes and determine the need for re-training of staff. Major training program changes must be approved by the PRESIDENT/CEO.

##### 5.14.8.4.1 Staff Feedback

The Human Resources Manager shall solicit and record feedback on the quality and efficacy of a training module from employees that received the training. Feedback may be solicited utilizing the following methods:

1. Post-training group discussions;
2. Individual interviews; and
3. Anonymous surveys.

##### 5.14.8.4.2 Stakeholder Feedback

The Human Resources Manager in coordination with the Facility Managers will solicit and record feedback from patients and caregivers, vendors, consultants, community members, law enforcement and other interested parties about the competence of the company and our employees. Feedback solicited from stakeholders should address the following:

1. The quality of interactions with employees;
2. Any changes in company policies or procedures directly affecting the stakeholder;
3. The effectiveness of the company overall; and
4. Any changes in the way the company is perceived by the stakeholder.

##### 5.14.8.4.3 Observation and Performance Review

The Human Resources Manager, in coordination with the Facility Managers, shall evaluate the effectiveness of training through observation of employee performance. These evaluations should consider:



1. Adoption of policies, procedures, concepts and attitudes presented in the training for new employees;
2. Level of improvement, drive or lack thereof toward improvement, in the performance of veteran employees;
3. Adoption of the training topics in practice and how well they are working;
4. Managers and trainer observations of employee attitudes, methods or competency; and
5. The level of discussion between employees and managers regarding training topics presented on an ongoing basis.

#### 5.14.8.4.4 Observation and Performance Review

1. Managers are required to communicate all necessary information on employee performance to the Human Resources Manager as often as necessary;
2. Managers are encouraged to provide verbal feedback to employees regularly; and
3. Managers are required to complete formal performance reviews at least annually at the end of any probationary period.

#### 5.14.8.5 Transition

##### 5.14.8.5.1 Intracompany Transfers

In the event an employee requests or is required to transition to another position, the Production Manager will assume or re-assign the departing employee's responsibilities. The Production Manager is responsible for ensuring any pending work is transferred to a remaining employee to ensure timely transition and completion of the work. If appropriate, the Production Manager will ensure the receiving employee receives any additional training required to support the new responsibilities. At a minimum, job shadowing is performed for at least one week before an employee transitions off the position to assure that key tasks and responsibilities will be properly fulfilled or executed.

##### 5.14.8.5.2 Replacement of Employees, Managers, and Consultants

Vacancies are addressed through the normal acquisition process. Employees may also be replaced by redirecting resources from within or outside of the unit or other employees may absorb their workload if it will not impact the quality of the marijuana or the efficiency of cultivation operations.

Key personnel, such as the Production Manager, Inventory Manager, and Chief Security Officer, will be asked to remain in their position until a suitable replacement can be found. This provision will be included as a clause in the employment contracts for key management personnel to ensure all critical human resources are consistently maintained by Hale O Lahilima. The Human Resources Manager will discuss the proposed length of employment with any key manager upon acquisition to allow planning for manager replacement, if employment length is known.





Hale O Laulima will be active in the local community and Hawai'i marijuana industry, and will require the Human Resources Manager to maintain a file with resumes for potential replacements for key personnel.

Key personnel will be asked to allow the replacement to shadow for a week or more, to train their replacement over the course of several days to a week (depending on level of experience) and observe the replacement for at least one day to ensure the replacement is prepared to fulfill all duties and responsibilities associated with the position.

The COO and the Board must approve any proposed replacement for key personnel. The Chief Medical Officer will be replaced in accordance with the measures set forth herein.

Most consultant relationships will be established under a contract that defines the length of contractual obligation and identifies procedures and criteria for termination and replacement. This type of contract will be preferred, as it will allow the Human Resources Manager to plan for consultant replacement, if needed. Resumes for proposed replacements will be submitted for the Board's approval.

Replacement staff must meet the original minimum qualifications for the position. If possible, the replacement should be trained by the original staff member and begin work prior to his or her departure to ensure appropriate transition of responsibilities and knowledge.

#### 5.14.8.6 Termination

##### 5.14.8.6.1 Termination Policy

It is company policy to ensure that employee terminations are handled in a professional manner with minimal disruption to ongoing work functions.

##### 5.14.8.6.2 Adherence to Law and Regulation Required

It is Hale O Laulima policy to terminate any employee if they are found to have violated any provision of law or regulation and to report any such violation to the Hawai'i DOH and law enforcement authorities as appropriate and in accordance with company termination policies.

##### 5.14.8.6.3 Authority to Terminate Employment

Unit managers require approval from the Human Resources Manager prior to any termination except when an employee has been found stealing, diverting product, knowingly distributing product to an unauthorized person or any other criminal activities.

##### 5.14.8.6.4 Grounds for Termination of Association

Any manager, owner, or director who fails a level-2 background screening or any employee who fails an internal background screening will be terminated immediately. The COO will inform the



Hawai'i DOH immediately if a person ceases to work, manage or otherwise be associated with the operation due to failure of a level-2 background check.

#### 5.14.8.6.5 Violation of Law or Policy Prohibited

No Hale O Lahilima employee may engage in or permit conduct at any Hale O Lahilima facility that is in violation of company policy, state law, local ordinance or Hawai'i DOH regulation, including but not limited to:

1. Making a false statement on an application or in any accompanying statement that the Hawai'i DOH may require;
2. Knowingly making a false statement on an internal or submitted report;
3. Consuming or allowing use of alcohol or any controlled substance at the facility or on the property;
4. Causing or permitting the facility to be operated in an unsafe manner, which will be reported to the Hawai'i DOH by the COO as necessary;
5. Unlawful sale or diversion of marijuana or marijuana products, which will be reported to law enforcement and the Hawai'i DOH immediately;
6. Providing direct financial compensation to an employee of any independent laboratory providing testing services; or
7. Speaking to the media without permission from a manager.

#### 5.14.8.6.6 Cause for Immediate Termination

Hale O Lahilima may terminate employment or other association immediately with any employee who:

1. Has been convicted in a court of law of one or more violations of the applicable laws and regulations or the regulations issued by the Hawai'i DOH;
2. Has knowingly engaged, permitted or condoned inside or outside of the establishment the illegal sale or negotiations for sale or the use, of any controlled substance identified in the Controlled Substances Act;
3. Has been convicted of a felony or any drug-related offense;
4. Engages or assists in the diversion of marijuana or marijuana products, which will be reported to law enforcement officials and the Hawai'i DOH by the COO or Chief Security Officer; or
5. Has permitted any Hale O Lahilima facility to operate in an unsafe manner, which will be reported to the Hawai'i DOH by the COO as necessary.

#### 5.14.8.6.7 Other Reasons for Termination

Any failure to comply with any provision of company policies and procedures, law, ordinance or regulations that does not result in Hawai'i DOH sanctions may still result in immediate termination and disassociation from Hale O Lahilima. The Human Resources Manager will refer any major infraction to the Board and Quality Control Team for review and determination. The



Human Resources Manager and the Board have the authority to suspend access to Hale O Lahima facilities by any individual in question while the Board makes a timely decision. Should the infraction involve one or more members of the Board, they may not be permitted to vote until the other Board members approve a resolution.

#### 5.14.8.6.8 Documentation Required

The Human Resources Manager and Facility Manager must ensure proper documentation of the termination in the employee file.

#### 5.14.8.6.9 Voluntary Termination

Voluntary termination of employment occurs when an employee informs his or her supervisor of employee's resignation or termination is deemed to have occurred when an employee is absent from work for two consecutive workdays and fails to contact his or her supervisor (job abandonment).

#### 5.14.8.6.10 Involuntary Termination:

1. An involuntary termination of employment, including layoffs and stand-downs over 30 days is a management-initiated dismissal;
2. Termination may be for any legal reason, including but not limited to, misconduct, tardiness, absenteeism, unsatisfactory performance, inability to perform, etc. In some cases progressive discipline may be used, prior to termination, to correct a performance problem. However, certain types of employee misconduct are so severe that one incident of misconduct will result in immediate dismissal without prior use of progressive discipline; and
3. Prior to an involuntary termination, consideration will be given to an employee's service and past contributions to the company. The possibility of transfer or demotion will be explored in all cases except those that involve gross misconduct.

#### 5.14.8.6.11 Termination Procedures:

1. Upon receipt of an employee's resignation, the Facility Manager must notify the Facility Manager and Human Resources Manager with pertinent information including the employee's reason for leaving, last day of work and other details;
2. The Facility Manager shall determine an employee's last day of work based on the type of termination and the sensitivity of their position;
3. The Human Resources Manager shall manage and document the termination process including:
  - a. Returning all company property (i.e., keys, Hawai'i DOH identification, ID cards, parking passes, etc.);
  - b. Review of benefits status; and
  - c. Completion of an Exit Interview Questionnaire. The exit interview provides employees the opportunity to freely express views about working at the company and will be held in strict confidence.



4. The Human Resources Manager will compile data from exit interviews to determine if feedback to an employee's supervisor or changes to operations, policies or procedures are needed;
5. A termination summary will need to be completed by the Facility Manager; and
6. Employees or managers who possess the credentials to enter restricted or controlled areas of any Hale O Laulima facility are required to check out and debrief with the COO no later than their last day of employment.

5.14.8.6.12 Deceased Employees:

1. A termination due to the death of an employee will be made effective as of the date of death; and
2. Upon receiving notification of the death of an employee, the Human Resources Manager must notify the appropriate benefits providers immediately.

5.14.8.6.13 Final Pay

1. An employee who resigns or is discharged will be paid through the last day of work, plus any unused PTO, less outstanding loans, advances or other agreements the employee may have with the company. Final pay due, upon the death of an employee, will be paid to the deceased employee's estate; and
2. It is the responsibility of the employee's manager to ensure that the Human Resources Manager receives the terminating employee's time record in sufficient time to process the final paycheck.

5.14.8.6.14 Unemployment Compensation

Hale O Laulima is able to monitor and control the cost of unemployment insurance by being responsive to regulatory authorities. Typically, the Human Resources Manager must submit employer information to the appropriate state office within seven days of request. Failure to respond in a timely manner often results in unemployment compensation awards to former employees who otherwise may not qualify.

































































































































































































































































































































































As a true member of the community **Hale O Laulima** ("HOL") understands the importance of trust. One of the greatest responsibilities of HOL is to ensure the protection of individually identifiable information gathered as part of the sale and distribution of marijuana products to its community members. HOL is committed to maintaining detailed patient records and gathering data on patient reactions to marijuana products, while protecting patient confidentiality and remaining compliant with HIPAA at all times.

Our company has assembled a strong data security team with decades of collective experience protecting patient medical information. Our group includes quite a few people with careers in healthcare and the medical fields. I myself am the former CEO and President of St. Francis Healthcare Foundation, our Medical Advisory Board includes **Dr. Laurie Tom** and 4 other physicians, 1 registered nurse and 2 pharmacists, we have **Bob Morgan**, the former General Counsel of the Illinois Department of Public Health, and finally a former Validation Engineer from the pharmaceutical industry.

### **1. Patient medical condition and health status**

Hale O Laulima is responsible for maintaining confidential records on qualified patients and dispensing activities including visitations, monitoring inventory, preventing unlawful activity, and maintaining compliance with laws and regulations pertaining to recordkeeping – we take this responsibility seriously. Also, utilizing the Biotrack ADP/POS system, we will collect and access individually identifiable health information for purposes of quality control, repeat customer preferences, and interface with a patient's healthcare practitioners.

While some license applicants may have aspirational goals surrounding patient data protection, we have a proven record of security of such records servicing over 25,000 medical



marijuana patients in 3 states over a total of 7 years. Our patient records have never been compromised as a direct result of our robust Quality Management System that includes honed standard operating procedures (“SOPs,”) (see Exhibit 1). Our SOPs are subject to continuous improvement with ongoing mandatory employee training to create an atmosphere of confidence for patients trusting us with their most vital information. Our Compliance Manager will coordinate all data protection systems and firewalls, employee training programs, breach protocols, and ongoing audits of the information security programs.

Although HOL is not subject to the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), because limited Retail Dispensary employees will have access to the electronic patient registration, and therefore to individually identifiable health information, HOL will comply with HIPAA security standards for the protection of electronic health information (45 C.F.R. Part 164 Subpart C) and provisions for the privacy of individually identifiable health information (45 C.F.R. Part 164 Subpart E). Any real or suspected breach of patient information – whether through inadvertent sharing, malicious theft, or any other incident – will be immediately addressed by the HOL’s Chief Compliance Officer and Medical Director. Subject to the particular circumstances, HOL will launch an internal investigation to confirm the extent of any breach, report such a breach to the Department of Health or law enforcement as appropriate, initiate a non-conformance record and follow corrective and preventive action (“CAPA”) guidelines. Any actual breach of a patient’s health information will result in a notice to all affected patients of 1) the steps taken by the Company to retrieve the data and correct any system failings, 2) information regarding identity theft protection services offered by HOL, and 3) contact information for all relevant state and federal authorities.



## 2. Purchases of marijuana or manufactured marijuana products

As the backbone of our Company's information technology, the marijuana industry's premier tracking system, Bio-Track, will be utilized by Hale O Laulima with seed-to-sale functionality. Serving as the contracted vendor designing the Department of Health's ("DOH") tracking system, HOL will seamlessly integrate its real-time purchase logs with DOH's web-based software.

HOL will utilize SOPs designed to track the product from the throughout the growing process until the sale and transfer to a registered patient or caregiver (Exhibit 2).

Tracking all sales will ensure compliance with limits on patient purchases, allow better counsel patients on dosage and strains, and maintain precise inventory and supplies. Collecting information on a specific patient's purchases requires additional security measures by HOL. Both technology and training safeguards will mitigate the risk of a confidentiality breach. Bio-Track's systems are linked to SSAE 16-certified servers, rely on SSL-encrypted system authentication, and use integrated peripherals (barcode scanning) within the system to eliminate human error.

The human element of data entry will be targeted by HOL through repetitive interactive trainings, unannounced compliance audits, and strict competency testing (see Exhibit 3). Any employee at the Retail Dispensary, whether or not they have access to patient data, will be exhaustively trained on the laws protecting patient confidentiality, how to identify a potential data breach, and the indiscriminate discipline that will be taken against any employee who fails to comply with these standards – up to, and including, discharge and filing of criminal charges (see Exhibit 4). **<END OF NARRATIVE>**



## **APPENDIX – SUPPLEMENT TO NARRATIVE**

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## 8.0 Exhibits:

### 8.1 Exhibit 1: Confidentiality

#### 8.1.1 Purpose

The creation and development of this procedure has been completed to ensure compliance with administrative rules as defined by the Hawaii 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
§11-850-34.a	A dispensary licensee shall establish and maintain written policies and procedures governing the qualifications, recruitment, hiring, and training of operators, employees, or subcontractors of production centers and retail dispensary locations.
§11-850-34.b	No person under the age of twenty-one shall be employed by a dispensary facility.
§11-850-34.c	Operators, employees, and subcontractors shall wear an identification badge issued by the dispensary with the photograph and name of the wearer in a visible location at all times when on the premises of a dispensary facility.
§11-850-34.d	A dispensary licensee shall provide training upon hire and annually to each employee. The training shall include, but not be limited to the following:
§11-850-34.d.1	Health, safety, and sanitation standards in accordance with this chapter;
§11-850-34.d.2	Security pursuant to this chapter;
§11-850-34.d.3	Prohibitions and enforcement pursuant to this chapter;
§11-850-34.d.4	Confidentiality pursuant to this chapter; and
§11-850-34.d.5	All other provisions of this chapter and chapter 329D, HRS, that apply to that person's scope of employment.
§11-850-34.d.6	The dispensary licensee shall provide the names of all employees to the department. Eff. DEC 14 2015
§11-850-40.a	A dispensary licensee shall safeguard and keep confidential from public disclosure any personally identifying information or the medical condition of a qualifying patient.
§11-850-40.b	A dispensary licensee shall prohibit photography or video recording inside a dispensary facility by anyone other than the dispensary licensee, the department, law enforcement personnel, or persons approved in writing by the department. Eff DEC 14 2015

#### 8.1.2 Local Compliance

In accordance with applicable confidentiality requirements as defined by Hawaii Administrative Rules Chapter(s): 11-850-34, 11-850-40 and enforced by the Hawaii DOH, Hale O Lahilima will utilize policies and procedures to ensure patients receive medical products that assure the safety, quality, identity, purity and potency expectations of the Hawaii DOH and end user. All patient related interactions and records implemented in Hale O Lahilima's Production and Retail Dispensary Facilities will be kept confidential and will be in full compliance with the provisions set forth in Hawaii Administrative Rules Chapter(s): §11-850-34 and §11-850-40.

#### 8.1.3 Definitions and Abbreviations:

Air-Conditioning ("A/C")

American National Standards Institute ("ANSI")

American Society for Testing and Materials ("ASTM")

Automated Data Processing/Point-of-Sale System ("ADP/POS")





Batch Production Record ("BPR")  
BBC Research & Consulting ("BBC")  
Board of Directors ("the Board")  
Cannabidiol ("CBD")  
Cannabidiolic Acid ("CBDA")  
Cannabigerol ("CBG")  
Chief Executive Officer ("CEO")  
Chief Operations Officer ("COO")  
Code of Federal Regulations ("CFR")  
Community Right to Know Act ("EPCRA")  
Compassionate Use Registry ("the Registry")  
Conditionally Exempt Small Quantity Generator ("CESQG")  
Continuing Medical Education (CME)  
Critical Process Parameter ("CPP")  
Current Good Manufacturing Practices ("cGMP")  
Denver Relief Consulting ("DRC")  
Department of Health ("DOH")  
Electro-Conductivity ("EC")  
Environmental Health Agency ("EHA")  
Equal Employment Opportunity Commission ("EEOC")  
Equipment Testing Laboratory ("ETL")  
Executive Management Team ("EMT")  
Executive Vice President ("EVP")  
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")  
Global Positioning System ("GPS")  
Good Agricultural Practices ("GAP")  
Good Handling Practices ("GHP")  
Hale O Lahuli ("HOL")  
Hawaii Administrative Rules ("HAR")  
Hawaii 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 ("SQIPP")  
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")

#### 8.1.4 Confidentiality and HIPAA Compliance

##### 8.1.4.1 Overview

Hale O Laulima is committed to maintaining detailed patient records and gathering data on patient reactions to marijuana products, while protecting patient confidentiality and remaining compliant with HIPAA at all times. The Retail Dispensary Facilities must maintain records on qualified patients and dispensing actions for the purpose of tracking and monitoring inventory, to prevent and discourage unlawful activity, and to maintain compliance with laws and regulations pertaining to recordkeeping by the Retail Dispensary. However, because the Retail Dispensary must handle and access individually identifiable health information to maintain compliance and dispense medicine to patients in need, it is critical that policies and procedures are in place to protect the privacy of individually identifiable health information and adhere to national standards for the security of electronic protected health information. Furthermore, it is of utmost importance that all employees are trained to appropriately handle and protect confidential information.



#### 8.1.4.2 Patient Confidentiality

Information held by Hale O Lahuli concerning patients, legal representatives, recommending physicians, and employees is confidential and will not be disclosed by any employee without the written consent of the individual to whom the information applies or as required by court order or the Hawaii DOH. Any release of information by the Retail Dispensary Employee will be reported to the Administrative Controller immediately.

Hale O Lahuli has developed policies and procedures regarding patient records, which are HIPAA-compliant and will be implemented by all employees of the Retail Dispensary. In order to assure that all identifying information about a qualified patient or legal representative is kept in compliance with the privacy and security rules of HIPAA (45 CFR 164), all Retail Dispensary Employees will receive mandatory training on the confidentiality of records, security measures for electronic health information, and privacy protections. The Retail Dispensary Facilities Manager, in coordination with the Human Resources Manager, will develop and implement this training protocol. The training will include a description of information required from patients and legal representatives, an explanation of information that should not be collected from patients, procedures from handling and storing patient information, and notice that any disclosure of any patient or legal representative information without written consent is a terminable offense. Exceptions include court orders, which will be handled by appropriate management personnel, and access required by the Hawaii DOH to carry out official duties. Such training, Hale O Lahuli's confidentiality policies, and the HIPAA-compliant ADP/POS system, Biotrack, which securely stores confidential information and limits employee access to such information will assure that all confidential information is collected, stored, and accessed in a manner that protects qualified patients and patient legal representatives.

#### 8.1.4.3 Importance of Registry Protections

Maintaining the confidentiality and exempt status of patient and physician information contained in the Registry is critical for a number of reasons. Medical treatment is a private matter; the choice made by a physician and patient to use marijuana for treatment of a certain condition or symptoms is not an exception to this rule. If registry information is not kept confidential and exempt from public records, inappropriate parties could become aware of the patient's personal choice to use marijuana as well as the patient's diseases or medical conditions. Such information could potentially be used to embarrass, discriminate against, and harass the patient and physician. With the patient's best interest in mind, it is critical that all Hale O Lahuli employees protect patient and physician confidentiality in accordance with the provisions set forth in the Hawaii DOH-approved patient confidentiality course, if applicable, as well as all applicable state laws and HIPAA provisions.

#### 8.1.4.4 HIPAA Compliance

Hale O Lahuli does not qualify as a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and therefore is not required to adhere to the requirements of the Administrative Simplification regulations. Hale O Lahuli is not a covered entity because



Hale O Lahuli will not conduct any of the covered transactions detailed in 45 Code of Federal Regulations (C.F.R.) Part 162. However, because certain Hale O Lahuli employees will have access to the electronic Registry, and therefore to individually identifiable health information, Hale O Lahuli will comply with HIPAA security standards for the protection of electronic health information (45 C.F.R. Part 164 Subpart C) and provisions for the privacy of individually identifiable health information (45 C.F.R. Part 164 Subpart E).

#### 8.1.4.5 General Security Standards for the Protection of Electronic Health Information

Hale O Lahuli will:

1. Ensure the confidentiality, integrity, and availability of all electronic protected health information created, received, maintained, or transmitted by Hale O Lahuli;
2. Protect against any reasonably anticipated threats or hazards to the security or integrity of electronic protected health information;
3. Protect against any reasonably anticipated uses or disclosures of electronic protected health information that are not permitted or required under 45 C.F.R. Part 164 Subpart E;
4. Ensure that all employees of Hale O Lahuli comply with the security standards for the protection of electronic health information; and
5. Periodically review and modify security measures implemented to protect electronic health information to ensure that reasonable and appropriate security measures are provided for the protection of electronic protected health information.

#### 8.1.4.6 Specific Security Measures for the Protection of Electronic Health Information

In order to comply with HIPAA security standards, Hale O Lahuli will:

1. Implement policies and procedures to prevent, detect, contain, and correct security violations;
2. Analyze potential risks and vulnerabilities to the confidentiality of electronic protected health information accessed by authorized Hale O Lahuli employees through the Registry;
3. Apply appropriate sanctions against employees who fail to comply with the security policies and procedures;
4. Implement procedures to regularly review records of access to the Registry and any other electronic protected health information. This may include the maintenance of a list of employees with access to the Registry and periodic review of their registry access;
5. Implement policies and procedures to ensure that employees authorized to access protected health information through the registry have appropriate access, and to prevent employees who are not authorized to access the registry from obtaining access to any electronic health information. The Retail Dispensary Facilities Manager will be responsible for determining if providing an employee with authorization to seek registry access is



appropriate and providing authorization to certain employees to request registry access from the Hawaii DOH;

6. Implement procedures for terminating access to the registry and any protected health information held or received by Hale O Laulima;
7. Implement security measures, such as measures for protection against malicious software, the provision and monitoring of individual employee log-ins and password management measures, and train all employees on their responsibilities related to these measures;
8. Identify and respond to suspected or known security incidents;
9. Establish and implement procedures to maintain copies of patient information and order fulfillment records, and to restore this information if any data is lost;
10. Implement policies and procedures, including a security plan and access control measures, to limit physical access to the registry, the electronic "ADP/POS" system, Biotrack, and the facilities in which these electronic information systems are housed;
11. Implement policies and procedures for the final disposition of protected patient information;
12. Implement technical policies and procedures for electronic information systems that contain protected patient information to allow access only to those employees that have been granted access rights by the Retail Dispensary Facilities Manager. This will include assignment of unique user identifiers for the purpose of identifying and tracking users, automatic logoffs, and mechanisms for encrypting and decrypting protected information;
13. Implement policies and procedures to protect electronic protected health information from improper alteration or destruction;
14. Implement technical security measures to guard against unauthorized access to electronic health information that is being transmitted over an electronic communications network; and
15. Train each employee employed in the Retail Dispensary Facilities on HIPAA security standards and their responsibilities related to compliance with these standards. Employees will be trained upon hire, at least once annually thereafter, and each time Hale O Laulima's measures for adherence to these standards are modified.

#### 8.1.4.7 Privacy of Individually Identifiable Health Information

For the purposes of this policy, if health information does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual, that information is not considered individually identifiable health information. All employees of Hale O Laulima's Retail Dispensary Facilities must adhere to the following requirements as a condition of employment:

1. All employees of the Hale O Laulima must adhere to Hale O Laulima's provisions for the protection of all individually identifiable health information held or transmitted by Hale O Laulima in any form or media, whether electronic, paper, or oral. Protected information includes a patient's qualifying medical condition;
2. A patient's individually identifiable health information may not be disclosed to anyone other than the patient, unless required by law, required by regulation, or if the patient specifically authorizes disclosure (in writing);



3. The minimum possible number of employees will be authorized to access individually identifiable health information, and uses and disclosures of identifiable health information will be kept to a minimum. Employees who are not authorized to do so may not attempt to access individually identifiable health information of patients under any circumstances and employees who are authorized to use or disclose such information may not use or disclose more private identifiable health information than is necessary for the task at hand;
4. Employees who are not specifically authorized by the Retail Dispensary Facilities Manager to access individually identifiable health information may only have access to de-identified information, such as patient records that include only a unique patient identifier instead of the patient's name;
5. All de-identified health information must meet the standard and implementation specifications for de-identification under 45 C.F.R. 164.514(a) and (b);
6. All employees of the Retail Dispensary Facilities must adhere to the permitted and required uses and disclosures of protected health information, which will be established by Hale O Lahima once more information about the features of the Registry is available;
7. Employees with knowledge of any coding system used by Hale O Lahima to de-identify health information may not, under any circumstances, be disclosed to or discussed with other employees of Hale O Lahima, as their level of clearance may be unknown, contractors, or any person external to Hale O Lahima. If an employee of the Retail Dispensary Facilities is unsure whether an individual should be privy to the de-identification systems utilized by Hale O Lahima, that employee should seek immediate clarification from his or her supervisor or the Security Manager;
8. All employees of the Retail Dispensary Facilities must undergo training in regards to Hale O Lahima policies and procedures for maintaining the privacy of individually identifiable health information. Training will be completed upon hire and at least once annually, with training updates when privacy protection measures are modified;
9. Hale O Lahima may, for internal purposes only, gather and maintain data from patients regarding reactions to marijuana products. Any employee authorized to handle, input, and/or store such data must ensure that all patient identifiers are redacted or de-identified prior to entering that data in any electronic system. Data gathered may not include patient names, addresses, phone numbers, email addresses, social security numbers, medical record numbers, license numbers, vehicle identifiers, photographic images, recommending physician names, or any other information that could potentially identify the patient. Such data may only be maintained in Hale O Lahima's electronic cloud-based storage system as a limited data set, as defined in 45 C.F.R. 164.514. The Medical Director will be authorized to use de-identified data for research purposes and to share such data with recommending physicians without violating patient confidentiality or privacy;
10. Patient Coordinators who handle individually identifiable health information must shred documents containing such information before discarding them; and

All employees of the Retail Dispensary Facilities with access to individually identifiable health information will be required to secure such information with lock and key, if in paper format, or with a passcode, if in electronic format. It is strictly prohibited to share keys or passcodes with other individuals, including other employees of the Retail Dispensary Facilities.



Title: State of Hawai'i Department of Public Health, Medical Marijuana Dispensary License  
Application Merit Criteria Question 08

Date: January 29, 2016





## 8.2 Exhibit 2: Inventory Control and Management SOP

### 8.2.1 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 (SQulPP) that patients deserve.

HAR Requirement	Description
§11-850-36.f	For transport between or among dispensary facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a dispensary facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras.
§11-850-41.a	A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:
§11-850-41.a.1	Inventory tracking including transport of marijuana and manufactured marijuana products;
§11-850-41.a.2	Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
§11-850-41.a.3	Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
§11-850-41.a.4	Logs of entry and exit for dispensary facilities; and
§11-850-41.a.5	Employee records.
§11-850-41.b	A dispensary licensee shall retain for a minimum of one year all security recordings. Eff.
§11-850-42.a	A dispensary licensee may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four ounces of marijuana during a period of fifteen consecutive days, and shall not exceed eight ounces of marijuana during a period of thirty consecutive days.
§11-850-42.b	Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter. Eff. DEC 14 2015
§11-850-43.a	A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.
§11-850-51.a.1	A video surveillance system professionally installed that allows for twenty-four hour continuous video monitoring and recording of all dispensary facilities as follows:
§11-850-51.a.1.C	The surveillance system storage device and the cameras must be internet protocol (IP) compatible;
§11-850-51.a.1.D	The video surveillance system shall have minimum camera resolution to allow for the clear and certain identification of any person and activities in any area of a dispensary facility where marijuana and manufactured marijuana products are produced, moved, or stored; all points of sale areas, any room used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; any room or area storing a surveillance system storage device; and all exits and entrances to a dispensary facility from both indoor and outdoor locations;
§11-850-51.a.1.E	The surveillance system video recording storage device shall be secured in a lockbox, cabinet, or closet, or secured in another manner that limits access to protect the system from tampering or theft; and
§11-850-61.a	A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to ADP/POS, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-85.j	A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming





HAR Requirement	Description
	batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c). Eff. DEC 14 2015
§11-850-92.b.4	Includes a computer tracking inventory identification number barcode generated by tracking software;

#### 8.2.1.1 Local Compliance

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

#### 8.2.2 Definitions and Abbreviations:

Air-Conditioning ("A/C")  
American National Standards Institute ("ANSI")  
American Society for Testing and Materials ("ASTM")  
Automated Data Processing/Point-of-Sale System ("ADP/POS")  
Batch Production Record ("BPR")  
BBC Research & Consulting ("BBC")  
Board of Directors ("the Board")  
Cannabidiol ("CBD")  
Cannabidiolic Acid ("CBDA")  
Cannabigerol ("CBG")  
Chief Executive Officer ("CEO")  
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 Lahuli ("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 ("SQIPP")  
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")

### 8.2.3 Inventory Control Policies

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

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

### 8.2.4 Responsibility for Inventory Control and Management

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

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



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

#### 8.2.5 Inventory Limits

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

#### 8.2.6 Real-Time Inventory Reporting Required

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

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

#### 8.2.7 Surveillance Coverage of Inventory Activities

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



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

#### 8.2.8 Production Facility Inventory Control Procedure

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

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



- f. If disposed, additional records must be kept in the Waste Disposal Log, as set forth in the Marijuana Waste Disposal SOP.
6. At least once every 30 days, the Inventory Manager will conduct an inventory audit in the Production facility:
  - a. The Inventory Manager will compare physical inventory counts conducted by the Director of Cultivation with electronic inventory records in Biotrack;
  - b. Using this method, the Inventory Manager will promptly detect diversion, theft, or loss and take immediate action to reconcile inventory discrepancies, if any;
  - c. The Inventory Manager will conduct the audit and produce an inventory audit report for the COO at least once every 30 days;
  - d. If any inventory discrepancy is identified during the audit, Hale O Laulima will conduct an investigation, identify the source of the discrepancy, and take corrective action; and
  - e. Discrepancy investigation and resolution will be recorded, and records maintained for a minimum of six (6) years. The Hawai'i DOH will be notified of any discrepancy and all corrective actions taken with five (5) business days.
7. The Inventory Manager will receive a receipt for any sample of marijuana or record that is removed from the Production facility by an authorized person, such as a Hawai'i DOH representative. Samples of marijuana collected by the QA / Laboratory Director for the purpose of conducting quality assurance testing in the Production Facility's on-site laboratory will be held to the same standards. All sample and record receipts will be recorded in Biotrack and will be kept for a minimum of six (6) years. See the Sampling and Testing SOP for more information about laboratory sampling and testing.

#### 8.2.9 Retail Dispensary Facilities Inventory Control Procedure

1. The Inventory Manager must ensure that the inventory management system (i.e., the ADP/POS system, Biotrack) is maintained and provides adequate documentation of all marijuana product movements from acquisition to sale;
2. The Inventory Manager must ensure that the ADP/POS system requires verification of patient registration, order contents, and order fulfillment status before a Dispensary Employee may dispense any marijuana product, in accordance with HAR 11-850-42.a, 11-850-42.b and 11-850-61;
3. The Inventory Manager must ensure that the ADP/POS system either interfaces with the Compassionate Use Registry ("the Registry") or requires a Retail Dispensary Employee to enter a dispensing action into the Registry immediately upon dispensing a marijuana product to a qualified registered patient or patient's legal representative, in accordance with HAR 11-850-42.a, 11-850-42.b and 11-850-61;
4. The Inventory Manager must ensure that the ADP/POS system maintains patient profiles and records, and protects patient privacy and confidentiality in accordance with HIPAA standards





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

5. The Inventory Manager will conduct an initial comprehensive inventory of all marijuana products at each Hale O Lahuli facility, which will be recorded in the ADP/POS system. If no marijuana products are on the Retail Dispensary Facilities premises when business commences, the initial inventory for each Retail Dispensary Facilities will be recorded as zero.;
6. The Inventory Manager in coordination with the Retail Dispensary Managers must maintain procedures which reconcile marijuana products acquired with marijuana products disposed, in storage, on display in the sales area, in transport, and dispensed on-site in real-time. Significant variances in a Hale O Lahuli facility must be documented, investigated by the Facility Manager for that unit and/or Inventory Manager, and reported to the Board. This will enable each Hale O Lahuli facility to promptly detect diversion, theft, or loss;
7. The Inventory Manager will ensure that each Hale O Lahuli Facility Manager conducts all required cycle counts and electronic inventory management activities. Quarterly comprehensive inventory counts will be conducted under the Inventory Manager's supervision and reconciled to the perpetual inventory records in the ADP/POS system. Significant variances or discrepancies will be documented, investigated by the COO, and reported to the Hawai'i DOH if criminal activity is suspected;
8. The Inventory Manager will keep records of all marijuana products sold or otherwise disposed at each Hale O Lahuli facility. These records will include, at a minimum:
  - a. Name and form of the marijuana product dispensed;
  - b. Batch number;
  - c. Amount of the marijuana product dispensed;
  - d. Sales price;
  - e. Date of sale;
  - f. Name and identification number of the qualified registered patient or patient's legal representative to which the marijuana product was dispensed; and
  - g. If disposed, the name, form, batch number, quantity, date, manner of disposal and reason for disposal for any marijuana products destroyed.
9. At least once every 30 days, the Inventory Manager will conduct an inventory audit in each Hale O Lahuli facility:
  - a. The Inventory Manager will compare physical inventory counts conducted by the Facility Manager with electronic inventory records in Biotrack;
  - b. Using this method, the Inventory Manager will promptly detect diversion, theft, or loss and take immediate action to reconcile inventory discrepancies, if any;
  - c. The Inventory Manager will conduct the audit and produce an inventory audit report for the COO at least once every 30 days;



- d. If any inventory discrepancy is identified during the audit, Hale O Laulima will conduct an investigation, identify the source of the discrepancy, and take corrective action; and
  - e. Discrepancy investigation and resolution will be recorded, and records maintained for a minimum of six (6) years. The DEPARTMENT will be notified of any discrepancy and all corrective actions taken with five (5) business days.
10. The Inventory Manager will receive a receipt for any sample of marijuana product or record that is removed from a Retail Dispensary Facilities by a Hawai'i DOH representative. No other persons may remove samples of marijuana products from any Hale O Laulima premises.

#### 8.2.10 General Inventory Recordkeeping

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

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

#### 8.2.11 Dispensing Errors and Near Misses

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





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

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

#### 8.2.12 Reconciliation, Resolution, and Reporting

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

#### 8.2.13 Product Storage

All inventory stored in Hale O Laulima facilities will be secured in a limited access area and tracked consistently in accordance with this inventory control and management SOP. Pursuant to §11-850-71 and §11-850-72, Hale O Laulima in coordination with the Inventory Manager will



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

#### 8.2.13.1 General Storage Requirements

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

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

#### 8.2.13.2 Secure Product Storage

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

1. All marijuana and marijuana-infused products within a Hale O Lahilima facility will be stored in a vault located within a limited access area;
2. All marijuana that is still in process will be stored in a secure location within a Hale O Lahilima facility, to which access is limited to a minimum number of authorized personnel;
3. All vaults, security equipment, and secure areas used for the production and storage of marijuana will be securely locked and protected from entry, other than during the time required to move or replace marijuana, pursuant to §11-850-51;
4. All marijuana and infused products must be returned to a secure, locked area at the end of any process (i.e. trimming, manufacturing, etc.) or and at the end of the day (i.e. Retail Dispensary Facilities products on display);



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

#### 8.2.13.3 Environmental Control Required

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

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

#### 8.2.13.4 Removal From Storage

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

1. Only to prepare for final packaging prior to transport
2. Only to transport the marijuana or marijuana product;
3. Only to dispense the marijuana or marijuana product;
4. Only immediately before the marijuana is dispensed; and

Only by a registered employee of Hale O Laulima.



### 8.3 Exhibit 3: Quality Assurance and Quality Control SOP

#### 8.2.14 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 (SQulPP) 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

#### 8.2.15 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.

#### 8.2.16 Definitions and Abbreviations:

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American Society for Testing and Materials ("ASTM")  
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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")  
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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 ("SQIPP")  
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")

#### 8.2.17 Quality Assurance and Quality Control

Hale O Lahuli 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 Lahuli'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 Lahuli Quality Management System and related training modules will be built.

#### 8.2.18 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).

#### 8.2.19 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.

#### 8.2.20 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.

#### 8.2.21 Facility Quality Control

##### 8.2.21.1.1 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).

#### 8.2.21.2 Retail Dispensary Sanitation and Quality Control Practices

It is Hale O Lahuli 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.

##### 8.2.21.2.1 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.



#### 8.2.21.2.2 Testing Required for Intake

All marijuana products distributed by Hale O Lahuli 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.

#### 8.2.21.2.3 Vendor Compliance Required

It is the policy of Hale O Lahuli 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.

#### 8.2.21.3 Production Facility Sanitation and Quality Control Practices

It is Hale O Lahuli 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 Director of Cultivation 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.

#### 8.2.21.3.1 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.

#### 8.2.21.3.2 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 Director of Cultivation must ensure that pest management activities comply with procedures found herein and in the Product Process Control SOP, including an Integrated Pest Management program..

#### 8.2.21.3.3 Quality Control Measures in Production / Cultivation Operations

The Director of Cultivation 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 Director of Cultivation 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).



#### 8.2.21.3.4 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.

#### 8.2.21.3.5 Quality Control Measures in Post-Harvest Processing Operations

1. The Director of Cultivation 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 Director of Cultivation 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 Director of Cultivation.
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 Director of Cultivation approval and in accordance with the Marijuana Waste Disposal SOP.



#### 8.2.21.3.6 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.

#### 8.2.21.3.7 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.

#### 8.2.21.3.8 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.

#### 8.2.21.3.9 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.

#### 8.2.21.4 Processing Area Sanitation and Quality Control Procedures

It is Hale O Lahima 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 Director of Cultivation 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.

##### 8.2.21.4.1 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.

#### 8.2.21.4.2 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.

#### 8.2.21.4.3 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.

##### 8.2.21.4.3.1 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).

#### 8.2.21.4.3.2 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.

#### 8.2.22 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.

#### 8.2.23 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

#### 8.2.24 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.



### 8.2.25 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

### 8.2.26 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.

### 8.2.27 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.

### 8.2.28 Proper Storage Required

The Inventory Manager and the Director of Cultivation, 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.

#### 8.2.28.1 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.

#### 8.2.28.2 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.



## 8.4 Exhibit 4: Anti-Diversion SOP

### 8.4.1 Purpose

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

HAR Requirement	Description
§11-850-32.a	Not less than thirty days prior to producing or manufacturing any marijuana or manufactured marijuana products at a licensed production center, a dispensary licensee shall provide the department with the address, tax map key number, and a copy of the premises title or lease, as applicable, of the proposed location of that production center and allow the department to inspect the premises to determine the dispensary's ability to comply with the requirements of this chapter and chapter 329D, HRS.
§11-850-32.b	Until the department approves its facility, the dispensary shall not possess marijuana or begin producing or manufacturing marijuana or manufactured marijuana products.
§11-850-32.c	Production centers shall:
§11-850-32.c.1	Remain secured pursuant to this chapter at all times;
§11-850-32.c.2	Be in an enclosed indoor facility;
§11-850-32.c.3	Be accessible to authorized individuals only as identified in this chapter;
§11-850-32.c.4	Maintain a twenty-four hour security system pursuant to this chapter and chapter 329D, HRS; and
§11-850-32.c.5	Display a copy of the dispensary license at all times. Eff. DEC 14 2015
§11-850-33.a	Not less than sixty days prior to opening a licensed retail dispensing location for business, a dispensary licensee shall provide the department with the address, tax map key number, and a copy of the premises title or lease, as applicable, of the proposed location of that retail dispensing location and allow the department to inspect the premises to determine the dispensary's ability to comply with the requirements of this chapter and chapter 329D, HRS.
§11-850-33.b	Until the department approves its facility, the dispensary shall not possess or dispense marijuana or manufactured marijuana products.
§11-850-33.c	Retail dispensing locations shall:
§11-850-33.c.1	Remain locked at all times;
§11-850-33.c.2	Be open for dispensing only between 8:00 a.m. and 8:00 p.m. Hawai'i-Aleutian Standard Time, Monday through Saturday;
§11-850-33.c.3	Be closed on Sundays and official state and federal holidays;
§11-850-33.c.4	Be in an enclosed indoor facility;
§11-850-33.c.5	Be accessible to authorized individuals only as identified in this chapter;
§11-850-33.c.6	Maintain a twenty-four hour security system pursuant to this chapter
§11-850-33.c.7	Require a qualifying patient or primary caregiver to present a valid government-issued photo identification and a valid medical use of marijuana registration card issued by the department pursuant to chapter 329, HRS, and use the sign-in system in accordance with section 11-850-51, before entering the premises;
§11-850-33.c.8	Display a copy of the dispensary license and any other required permits or licenses at all times, including pursuant to 11-50; and
§11-850-33.d	Store all marijuana or manufactured marijuana products behind a counter or other barrier to ensure that a qualifying patient or primary caregiver does not have direct access to the product prior to sale.
§11-850-33.d.1	Retail dispensing locations shall not:
§11-850-33.d.2	Provide free samples of marijuana or manufactured marijuana products;
§11-850-33.d.3	Dispense marijuana or manufactured marijuana products as premade or manufactured cigarettes or in any form prepared specifically for smoking or inhaling; or
§11-850-34.a	Make available for sale or as gifts or premiums any supplies or paraphernalia that provide for the use of medical marijuana in smokeable or inhalable form. Eff. DEC 14 2015
§11-850-34.b	A dispensary licensee shall establish and maintain written policies and procedures governing the qualifications, recruitment, hiring, and training of operators, employees, or subcontractors of production centers and retail dispensary locations.
§11-850-34.b	No person under the age of twenty-one shall be employed by a dispensary facility.



Title: State of Hawai'i Department of Public Health, Medical Marijuana Dispensary License  
Application Merit Criteria Question 08

Date: January 29, 2016

HAR Requirement	Description
§11-850-34.c	Operators, employees, and subcontractors shall wear an identification badge issued by the dispensary with the photograph and name of the wearer in a visible location at all times when on the premises of a dispensary facility.
§11-850-34.d	A dispensary licensee shall provide training upon hire and annually to each employee. The training shall include, but not be limited to the following:
§11-850-34.d.1	Health, safety, and sanitation standards in accordance with this chapter;
§11-850-34.d.2	Security pursuant to this chapter;
§11-850-34.d.3	Prohibitions and enforcement pursuant to this chapter;
§11-850-34.d.4	Confidentiality pursuant to this chapter; and
§11-850-34.d.5	All other provisions of this chapter and chapter 329D, HRS, that apply to that person's scope of employment.
§11-850-34.d.6	The dispensary licensee shall provide the names of all employees to the department. Eff. DEC 14 2015
§11-850-36.a	A dispensary may transport marijuana and manufactured marijuana products between its facilities, and between its facilities and a laboratory for testing.
§11-850-36.b	Only employees designated by the dispensary licensee, who are trained and knowledgeable on the transportation protocols required by this chapter, shall transport marijuana and manufactured marijuana products. Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.
§11-850-36.c	Each time marijuana and manufactured marijuana products are transported, the dispensary licensee shall prepare a manifest on a form prescribed by the department that lists the elements required by the department's tracking system.
§11-850-36.d	A dispensary licensee shall only transport marijuana or manufactured marijuana products that are listed on the manifest.
§11-850-36.e	A dispensary licensee shall transport marijuana or manufactured marijuana products in secured containers. The dispensary licensee shall include a copy of the manifest in the interior and on the exterior of the container.
§11-850-36.f	For transport between or among dispensary facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a dispensary facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras.
§11-850-36.g	Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety.
§11-850-36.h	Upon receipt of marijuana and manufactured marijuana products the dispensary licensee or the laboratory shall immediately report to the department any discrepancies between what is received and what is on the manifest.
§11-850-36.i	The designated employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest.
§11-850-36.j	The dispensary licensee shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion.
§11-850-36.k	A dispensary licensee shall not transport marijuana or manufactured marijuana products:
§11-850-36.k.1	Off site to qualifying patients or to primary caregivers;
§11-850-36.k.2	To another county or another island within the same county; or
§11-850-36.k.3	To, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government. Eff DEC 14 2015
§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
§11-850-41.a	A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:
§11-850-41.a.1	Inventory tracking including transport of marijuana and manufactured marijuana products;
§11-850-41.a.2	Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
§11-850-41.a.3	Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
§11-850-41.a.4	Logs of entry and exit for dispensary facilities; and
§11-850-41.a.5	Employee records.
§11-850-41.b	A dispensary licensee shall retain for a minimum of one year all security recordings. Eff. DEC 14 2015
§11-850-51.a	All dispensary facilities shall have the following security features:
§11-850-51.a.1	A video surveillance system professionally installed that allows for twenty-four-hour continuous video monitoring and recording of all dispensary facilities as follows:





HAR Requirement	Description
§11-850-51.a.1.A	All video equipment used in a dispensary facility shall have back up capability;
§11-850-51.a.1.B	All recorded images must clearly and accurately display the time and date;
§11-850-51.a.1.C	The surveillance system storage device and the cameras must be internet protocol (IP) compatible;
§11-850-51.a.1.D	The video surveillance system shall have minimum camera resolution to allow for the clear and certain identification of any person and activities in any area of a dispensary facility where marijuana and manufactured marijuana products are produced, moved, or stored; all points of sale areas, any room used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; any room or area storing a surveillance system storage device; and all exits and entrances to a dispensary facility from both indoor and outdoor locations;
§11-850-51.a.1.E	The surveillance system video recording storage device shall be secured in a lockbox, cabinet, or closet, or secured in another manner that limits access to protect the system from tampering or theft; and
§11-850-51.a.1.F	The dispensary licensee shall make video recordings available to the department upon request;
§11-850-51.a.2	An alarm system to detect unauthorized entry and allow notification of law enforcement in an emergency. The alarm system shall be:
§11-850-51.a.2.A	Electronic with a backup power source for a minimum of four hours;
§11-850-51.a.2.B	Connected to a security response organization or to law enforcement;
§11-850-51.a.2.C	Activated twenty-four hours a day every day; and
§11-850-51.a.2.D	Professionally installed;
§11-850-51.a.3	A locked entry point to screen individuals for authorized entry to the facility. Only the following may be authorized to enter dispensary facilities:
§11-850-51.a.3.A	Persons included on a current department-approved list provided to the department by the licensee of those persons who are allowed into that dispensary's facilities for a specific purpose for that dispensary in accordance with section 329D-15 and 329D-16, HRS; and
§11-850-51.a.3.B	Other approved individuals with government issued photo identification including:
§11-850-51.a.3.B.i	Qualifying patients;
§11-850-51.a.3.B.ii	Primary caregiver;
§11-850-51.a.3.B.iii	A government employee or official acting in the person's official capacity;
§11-850-51.a.3.B.iv	Dispensary employees; provided that qualifying patients and primary caregivers may only be authorized to enter retail dispensing locations;
§11-850-51.a.4	All entrances, exits, windows and other points of entry shall be equipped with commercial-grade, non-residential locks or other functioning mechanical or electrical security devices; and
§11-850-51.a.5	A sign-in system to record the names of persons listed in paragraph (3) entering the dispensary facility and the date and time of entry to and exit from the dispensary facility.
§11-850-51.b	In the event of a breach or failure of its security system, a dispensary licensee shall immediately suspend operations and secure the affected dispensary facility until the security system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations. Eff. DEC 14 2015
§11-850-52	In addition to other security features as set forth in this chapter and chapter 329D, HRS, all production centers shall have the following security features:
§11-850-52.1	Secure fencing that surrounds the premises sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any marijuana in any form;
§11-850-52.2	All marijuana and manufactured marijuana products shall be secured in a locked room, vault, or locked container securely affixed to a wall or floor. Eff. DEC 14 2015
§11-850-53	In addition to the other security features as set forth in this chapter and chapter 329D, HRS, all retail dispensing locations shall have the following security features:
§11-850-53.1	A protocol for admitting qualifying patients or primary caregivers with valid government issued photo identification and medical marijuana registration cards issued pursuant to chapter 329, HRS, prior to allowing them access to the secured room for sales;
§11-850-53.2	A separate secured room for sales which shall include secured and locked display cases for marijuana and manufactured marijuana products;
§11-850-53.3	A maximum occupancy limit ratio in the secured sales room of two customers to every one retail dispensing location employee;
§11-850-53.4	All marijuana and manufactured marijuana products shall be secured in a locked room, vault, or locked container securely affixed to a wall or floor; and
§11-850-53.5	Exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities. Eff. DEC 14 2015
§11-850-61.a	A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.



HAR Requirement	Description
§11-850-61.b	A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 329D-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.
§11-850-61.c	A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.
§11-850-61.d	In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations. Eff. DEC 14 2015

#### 8.4.1.1 Local Compliance

In accordance with applicable security, transportation and tracking related requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-850-32 through 11-850-34, 11-850-36, 11-850-37, 11-850-41, 11-850-51, 11-850-52, 11-850-53, 11-850-61 and enforced by the Hawai'i Department of Health (DOH), Hale O Laulima will implement anti-diversion policies and procedures that will encompass all areas and stages of manufacturing and distribution. All controlled access, security, transportation, tracking 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): §11-850-32 through §11-850-34, §11-850-36, §11-850-37, §11-850-41, §11-850-51, §11-850-52, §11-850-53 and §11-850-61.

#### 8.4.2 Definitions and Abbreviations:

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





Department of Health ("DOH")  
Electro-Conductivity ("EC")  
Environmental Health Agency ("EHA")  
Equal Employment Opportunity Commission ("EEOC")  
Equipment Testing Laboratory ("ETL")  
Executive Management Team ("EMT")  
Executive Vice President ("EVP")  
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")  
Global Positioning System ("GPS")  
Good Agricultural Practices ("GAP")  
Good Handling Practices ("GHP")  
Hale O Lahuli ("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 ("SQIPP")  
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")  
Standard Operating Procedure ("SOP")  
Superfund Amendments Reauthorization Act ("SARA")  
Tetrahydrocannabinol ("THC")













































**Hale O Laulima ("HOL")** has assembled a team of professionals with an unmatched level of experience to comply with certified laboratory testing related to agricultural food products, marijuana and manufactured marijuana products, including (1) Director of Processing **Jennifer Bash**, who is currently a Senior Analytical Forensic Toxicology Specialist with the Analytical Forensic Testing Laboratory at the University of Illinois at Chicago College of Pharmacy and recently assisted the Illinois Department of Agriculture with the development of sampling and testing standards for the Illinois Medical Cannabis Pilot Program; (2) General Counsel **Bob Morgan**, who was the primary architect of the Illinois Medical Cannabis Pilot Program - one of the most regulated and highly-regarded medical marijuana programs in the country, including oversight of the initial development of sampling and testing standards in the state; (3) partners and executive team members within **Cresco Labs** and **Denver Relief Consulting ("DRC")** who collectively own and operate or have assisted in the management of over 25 regulated medical marijuana cultivation and processing production facilities in North America that are subject to testing by a certified testing laboratory; (4) Agriculture & Horticulture Advisory Board Member **Forrest Sawlaw**, who opened and managed the country's largest indoor recirculating aquaculture farm with Archer Daniels Midland, managed a 12.5 acre tomato greenhouse, and constructed and managed the country's largest indoor lettuce production facility; and (5) **Michael Nottoli** who has 10 years of medical device and pharmaceutical manufacturing experience, including participation in over 75 successful automated system qualifications that have gone on to produce a wide range of medical devices (including Class III) and pharmaceutical products. Collectively this team is well versed on certified laboratory testing compliance from the experienced perspective of a regulatory authority, a DEA-Licensed Laboratory operator, an equipment and process quality control manager, operators in traditional food and pharmaceutical manufacturing, and operators in regulated marijuana and manufactured marijuana product production. Throughout the development and management of each of these operations and using the experiences of our team of tenured professionals, our Sampling and Testing Plan (see Exhibit 4) has evolved into



what is now our Quality Management System (“QMS”), often regarded as the industry model for best practices, policies and procedures and compliance related to certified laboratory testing on medical marijuana products. (see Exhibit 3) Denver Relief was recently part of a round of surprise inspections by the Colorado Department of Agriculture and Denver Department of Environmental Health, which concluded that Denver Relief was the only operator (out of 38) in Denver not to have any infractions related to the storage and use of pesticides of concern to human health (see Exhibit 2).

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 (“SQulPP”) that the pharmaceutical industry requires and that patients deserve. In accordance with the requirements developed by the Hawai'i Department of Health (“DOH”), we have developed a QMS that assures each step in our cultivation, manufacturing and distribution processes is carefully performed and controlled, as well as to ensure patient, product and public safety.

We will establish a relationship with a DOH-approved independent testing laboratory with established marijuana testing protocols and methods – we have already had discussions with Clinical Laboratories of Hawaii to collaborate on developing testing protocols and procedures (see Exhibit 1). The samples will be transported to the independent testing laboratory and analyzed in accordance with scientifically valid methods. The analytical tests conducted will be appropriate for determining whether the batch meets specifications for the marijuana product. The independent testing laboratory will then provide us with a certificate of analysis for each batch. A batch will not be released for distribution prior to receipt and confirmation of a certificate of analysis. All certificates of analysis will be stored and maintained for a minimum of six (6) years. We will maintain a similar sample in a secure tamper-evident manner from the same batch for subsequent verification testing as directed by the DOH.



It is the responsibility of the Production Facility managers in coordination with the Inventory Manager and Chief Compliance Officer (“CCO”) to ensure compliance with all DOH testing rules, including but not limited to utilization of DOH-registered laboratories; required testing, which includes the chemical compounds and contaminants listed in HAR §11-850-85; testing of every finished batch; contamination response plans; and scientifically valid sampling and analytical methods. The Inventory Manager and CCO are responsible for ensuring no finished marijuana products are released for distribution until batch test results have been received that establish that the batch meets our imposed standards for purity, potency, identity, and safety. Upon completion of a batch, the entire batch will be immediately quarantined until sampling, testing, and verification of conformance to specifications is complete and documented. Any batch found to be non-conforming must be rejected and disposed or destroyed in accordance with the Marijuana Waste Disposal SOP (See Exhibit 5).

The Director of Processing, Jennifer Bash, will be responsible for conducting all internal product testing and overseeing independent product testing. Ms. Bash will be responsible for the maintenance of analytical equipment and implementation of laboratory procedures and best practices to ensure that product test results are reliable measures of the quality, safety, and composition of the marijuana products produced by the company, as well as all quality assurance and quality control activities. Ms. Bash will be responsible for redundant and intermediate testing to supplement testing activities that are required by an independent testing laboratory per §11-850-85, which will be accomplished in HOL’s in-house testing laboratory at each Production Facility. This may include, but is not limited to, chromatographic analysis of in-process marijuana plants, development and verification of product specifications, and analytical testing for the purposes of research and development, formulation, process and procedural validation. Internal test results will be used for internal improvement of methods and practices, as well as for further educating the managers and employees in each production area.

**<END OF NARRATIVE>**



## **APPENDIX -- SUPPLEMENT TO NARRATIVE**

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## 9.2 Exhibit 2: 2015 Denver Pesticide Inspections

1/28/2016

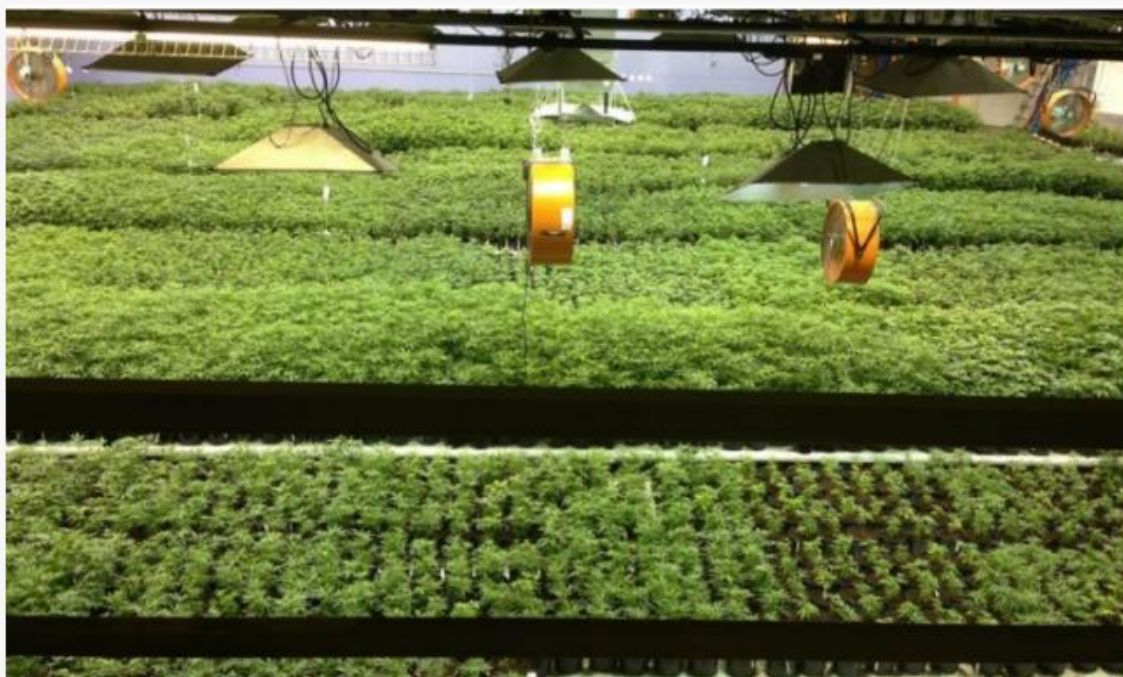
Denver Investigated 10 Pot Grows for Use of Banned Pesticides, Holds Plants | Westword

**Westword**

# DENVER INVESTIGATED 10 POT GROWS FOR USE OF BANNED PESTICIDES, HOLDS PLANTS

BY THOMAS MITCHELL

MONDAY, MAY 18, 2015 | 9 MONTHS AGO



<http://www.westword.com/news/denver-investigated-10-pot-grows-for-use-of-banned-pesticides-holds-plants-6654706>

1/6



1/28/2016

Denver Investigated 10 Pot Grows for Use of Banned Pesticides, Holds Plants | Westword



Large-scale marijuana grows allow for more product but carry a heavier risk of spreading pests.

Colorado.gov

This spring, ten commercial cannabis grows have been investigated by the City of Denver for allegedly using potentially harmful chemicals on plants, and many of those grows are directly connected to popular dispensaries.

In documents obtained by the Cannabis Consumers Coalition via the Colorado Open Records Act (the documents are below), the Denver Department of Environmental Health reports on recent investigations of nine marijuana cultivation facilities for reportedly using chemical pesticides such as Avid, Mallet and Eagle 20 – a petroleum-based fungicide. According to Denver Citywide Communications Advisor Daniel Rowland, all nine of the grows complied with the city during its investigations, but Denver still has many of the plants on hold. Putting marijuana plants on hold allows the business to continue growing them, but the plants cannot be sold until cleared by the city.

The nine grows mentioned in the documents aren't the only cultivation operations under scrutiny. As reported by 9News, a Denver growing operation for LivWell – a chain of dispensaries with nine locations in the state – had approximately 60 plants put on hold in April after health officials deemed LivWell's use of Eagle 20 could be unsafe for consumption.

"Testing of our finished product by an independent, state-licensed lab approved by the City of Denver showed that our products are safe – as we have always maintained," John Lord said in a statement. "We have reached an agreement with the City resulting in a release of the hold order on the tested products and all similar products. More importantly, over the last two weeks, we have been working hand-in-hand with the Denver Department of Environmental Health to design and implement what we hope will be an industry standard testing regime to ensure safe cannabis products. We are proud to be able to meaningfully contribute to the standards that will ensure public health and safety moving forward."

Asked about that LivWell statement, Rowland says that some of its products did receive a release from the city's hold.

Used to fight powdery mildew on plants, Eagle 20 has become a subject of debate among cannabis growers because of its unknown long-term effects. A 2012 study by Dow AgroSciences showed that Eagle 20 contained numerous chemicals that caused cancer in lab animals, but whose effect on humans has not been documented. The lack of conclusive science regarding pesticide and cannabis has created a gray area for regulated pot cultivation.

Because marijuana is illegal on a federal level, few pesticides have been created specifically for it, and states in which cannabis has been legalized have to do their own research on what's harmful and what isn't. Neither the Environmental Protection Agency nor the U.S. Department of Agriculture lists pesticides that may be used by marijuana grows; nor do they list prohibited pesticides. While the Colorado Department of Agriculture does not have a list of pesticides banned for cannabis cultivation, there is a CDA-approved list of marijuana pesticides that regulated growing operations in the state are supposed to follow. The approved list, last updated April 30, does not contain Eagle 20, Avid or Mallet.

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The Environmental Health inspection team will get a referral, typically from the Fire Department while they're inspecting grows, and if they see some chemicals or red flags, they act on it," Rowland says of Denver inspectors. "Sometimes it's the employees of the grows themselves."

Rowland compares inspections of the grows to inspections of Denver restaurants. "What we do is purely on consumer health and safety," he explains. "Environmental Health is checking not just if the chemicals are approved or not, but also how they're used. There could be an approved pesticide on the list being used, but if the label says use for once a month and the grow is using it once a day, then there's a problem."

Organic Greens, one of the grows with plants on hold for use of Eagle 20, sought to lift the hold in court, claiming city officials had no right to quarantine its products and arguing that the amount of the chemical fungicide used on its plants was safe. On May 15, a Denver judge denied Organic Greens's request for a preliminary injunction to stop the Denver Department of Environmental Health's pesticide enforcement and lift the hold.

Here is the status of eight other growing facilities investigated by the city, according to Rowland.

Altitude East Treatments: Plants remain on hold. This grow was found using Avid, Eagle and Mallet; it supplies plants for Altitude dispensary locations on Evans Avenue and Federal Boulevard. Those dispensaries did not respond to *Westword* requests for comment.

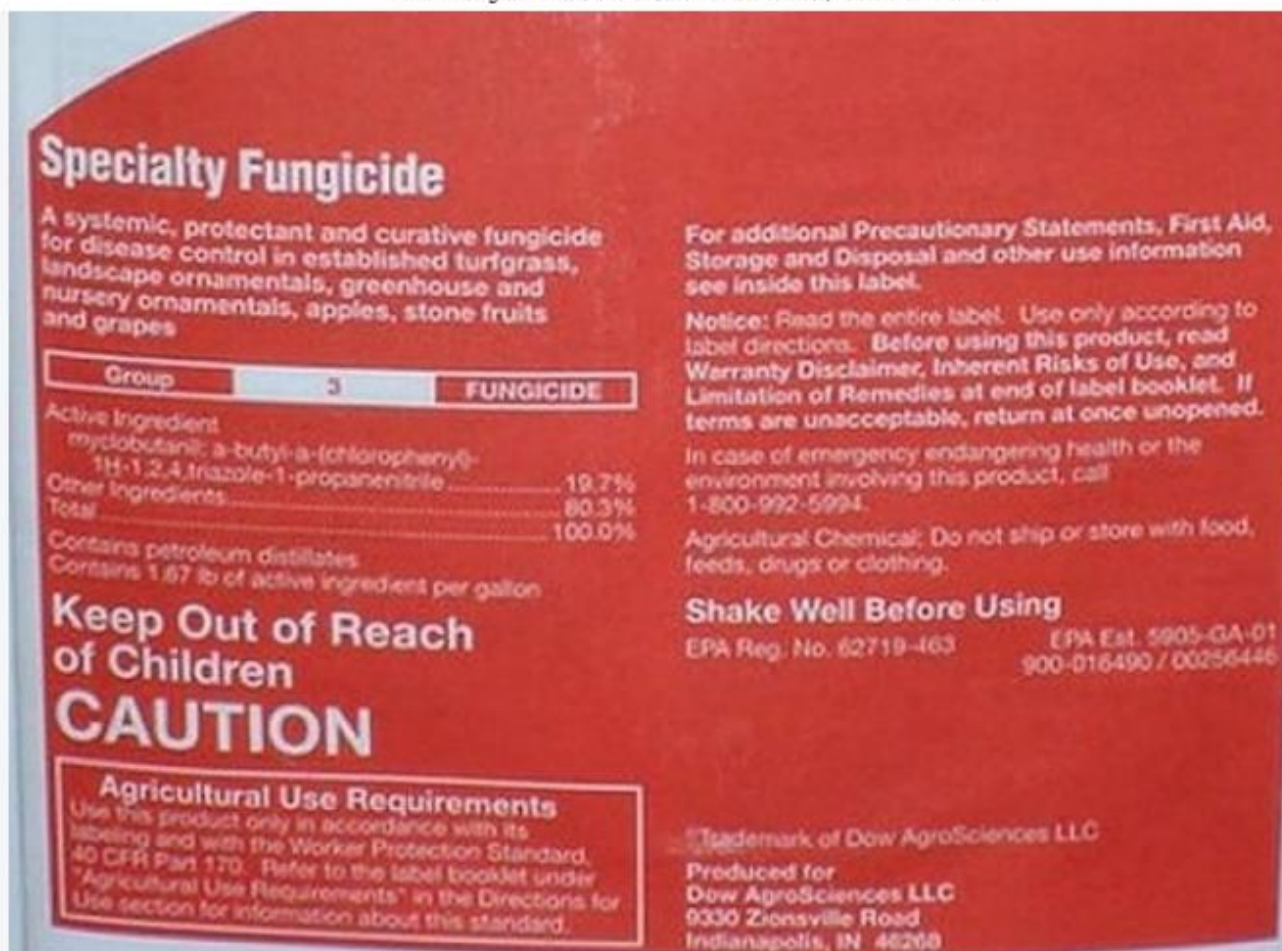
Evolutionary Holdings: Plants remain on hold. The grow, which sells its products through Denver dispensary Element420, was found using Eagle 20 and "other pesticides" at its grow site. "We are waiting to hear from the regulatory authorities and will hold off on commenting until we know more," Evolutionary Holdings said in a statement.



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Myclobutanil, the active ingredient in Eagle20, has an acute toxicity rating of "slightly hazardous" by the World Health Organization.

Green Cross Colorado: Plants remain on hold. This grow produces plants for edibles; it's been quarantined for Eagle 20 Mallet. Green Cross Colorado owner Daniel Griffin says it would be inappropriate to comment on the city's active investigation.

The Green Solution: The company, which has nine dispensaries in Colorado, had plants put on hold because at one of its grows, the city found "Eagle 20 and other pesticides that may cause potential contamination and a potential health risk."





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according to the documents. Plants remain quarantined, but some of its dried product received a limited, conditional release as a result of testing by the Colorado Department of Agriculture. The released product is for smoking only, and customers must be informed at the point of sale that it is not suitable for human consumption in any other manner.

In an official statement, the company said it takes customer safety very seriously. "We have been working closely with city and state governmental officials to find a resolution to their concerns over pesticide use on cannabis product and have cooperated fully and openly in these efforts," the statement reads. "The pesticides we use on our cannabis products are approved for use on food similar to cannabis, such as hops, grapes, berries, and corn. We use the recommended and proper amounts of all substances, as determined by our team of plant-science experts and as established by product labeling. Pesticides in general are appropriately and safely used in cultivation to eliminate potentially harmful pests and disease from plants, including cannabis, which might otherwise harm consumers."

**Mindful:** Plants remain on hold. The grow's plants were quarantined after city officials found they were treated with Eagle 20. Company spokesman Erik Williams says Mindful has cooperated fully with Denver and the matter has been resolved.

**MMJ America:** Grow destroyed plants after city officials confirmed they were sprayed with Avid. According to company CEO Jake Salazar, an employee had treated 100 clones with the banned insecticide, was fired for it and then alerted the city in retaliation. "The state came in and tested every room in our facility, and we tested negative for Eagle 20 and any other banned pesticide," he says. The quarantine has been lifted.

**Organic Greens:** Plants remain on hold. The grow, which sells its plants through downtown dispensary Natural Remedies, had plants quarantined for treating them with Eagle 20 and failing to update pesticide logs. The company did not respond to requests for comment.

**RINO Supply:** Voluntarily destroyed approximately 1,548 plants after the city investigated a grow facility for pesticide use. "It was my personal decision, in an abundance of caution for my patients, that I decided to destroy the plants and start fresh in that facility," says RINO president Jared Penman. "It didn't make sense to do anything else." The hold has been lifted.

**Sweet Leaf:** The company, which has three locations in Denver and one in Aurora, had plants put on hold after city officials found evidence of Eagle 20 at one of its facilities. "We're waiting to see the test results on it," says a Sweet Leaf spokesman. "We wouldn't put anything in our stores that wasn't safe."

Larisa Bolivar, the director of the Cannabis Consumers Coalition who filed the request for information on the city's investigations of the grows, says she understands the challenges that large-scale growing operations go through in regards to pests and fungi, but points out that those challenges are no excuse to cut corners.

"This is dangerous to public safety, and we need better testing policies that put consumer safety first," she said in a press release. "Retail cannabis is supposed to be tested for harmful pesticides, and there already exists a list of acceptable pesticides. This is at best gross negligence on behalf of the offending businesses that shows more concern for money than for safety."

<http://www.westword.com/news/denver-investigated-10-pot-grows-for-use-of-banned-pesticides-holds-plants-6654706>



Title: State of Hawai'i Department of Public Health, Medical Marijuana Dispensary License  
Application Merit Criteria Question 09

Date: January 29, 2016

1/28/2016

Denver Investigated 10 Pot Grows for Use of Banned Pesticides, Holds Plants | Westword

Mandatory testing for all marijuana intended for retail sale in Colorado was supposed to begin this past October, but in state-approved marijuana testing labs prevented that from happening. During the recent legislative session, a state panel recommended a \$300,000 allocation for the Colorado Department of Agriculture for chemical testing of commercial cannabis, but that proposal was not approved by the legislature.

Here are the documents obtained by the Cannabis Consumers Coalition:

*Have a tip? Send it to [thomas.mitchell@westword.com](mailto:thomas.mitchell@westword.com)*

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<http://www.westword.com/news/denver-investigated-10-pot-grows-for-use-of-banned-pesticides-holds-plants-6654706>



## Facilities with Documented Use of Pesticides

Name	Address	Fumigation/Pesticide	Date/Names of who visited	Status	Notes
<b>River Rock</b>	4921 & 4935 York St	Sulphur/ Eagle-20/Avid/Pyganic/Azamax / Actinovate	<b>Michael/Kim 3/19</b>	<b>No enforcement</b>	Facility had no SOP's for pesticide use. Missing 1 month in pesticide log. Facility stated never used E20. Observed only approved pesticides being used.
<b>Herbal Alternative</b>	2568 S Broadway St	Eagle20 /Avid			
<b>Citi Med Row – BallPark Hollistic</b>	4228 York St Suite 101-105	Eagle20 /Avid	<b>Michael/Kim 3/19</b>	<b>Pending</b>	Fire explained that the owner is Charles Denver Parks and can be contacted at 303-534-7283  No one at facility when site initially visited.
<b>Rocky Mountain High</b>	4237 Josephine St 102-103/ 4228 York St Suite 106-107	Sulphur/Eagle20 /Avid/ Akari/Floamite/Mallet/Grandvo/ Conserve/Abamectin/Pyrethrins	<b>Antonio/Danica 3/12-3/14</b>  <b>Emily/Rich 3/17</b>	<b>No enforcement</b>	Facility had no documentation of spraying pesticides of concern. No pesticides of concern onsite. Facility explained they had removed when ownership changed and that none of their plants have recently been treated.
<b>Starbuds</b>	4228 York St Suite 101	N/A	<b>Emily/Rich 3/17</b>	<b>No enforcement</b>	Facility had no SDS, SOP's, door placards or spray logs. Indicated no pesticides of concern used ever or onsite.





## Facilities with Documented Use of Pesticides

<b>Native Roots Apothecary</b>	680 Lipan St 101-102	Several pesticides in use	<b>Abby/Emily 3/10</b>	<b>No enforcement</b>	Facility had Beethoven TR onsite but had nothing on logs as to application. Facility removed.
<b>Kind Love</b>	4155 Grape St.	Sulphur/Pesticides			
<b>The Green Solution</b>	4394 Grape St	Avid, Mallet, E20, etc.	<b>Emily/Kara 3/18</b>	<b>Order Issued on 3/18</b>	Facility has logs indicating pesticide application within the last day or two. Numerous pesticides stored onsite. SDS, placards and SOP's all provided. <b>2015-FS-INS-2222</b>
<b>Current Occupant</b>	400 S. Lipan St Suite 2-6	Several pesticides in use			
<b>Evolved Healing/Evolutionary Holdings</b>	5231 Monroe St Suite 200	Sulphur/Pesticides	<b>Emily/Maggie 3/10</b> <b>Emily/Abby 3/16</b>	<b>Order Issued on 3/12</b>	Hold on plants that have been sprayed with E20 : <b>2015-FS-INS-2127</b>
<b>Lodo Wellness Center</b>	1617 Wazee St	Pesticides in use	<b>Rich/Emily 3/17</b>	<b>Pending</b>	No logs, or REI outside of doors. The facility had SDS sheet. <b>Facility visit required.</b>
<b>Sweet Leaf</b>	110-124 Yuma St	Pesticides and Insecticides in use	<b>Rich/Antonio/Alison 3/10</b> <b>Emily/Rich 3/17</b>	<b>Order Issued on 3/17</b>	Hold on plants that have been sprayed with E20: <b>2015-FS-INS-2175</b>
<b>Kind Love</b>	4890 Joliet St	Pesticides and insecticides in use	<b>Alison/Michael 3/11</b>	<b>Pending</b>	
<b>Organic Greens</b>	4675 Kingston St	Sulphur/Pesticides/insecticides	<b>Alison/Michael 3/18</b>	<b>Order issued on 3/18</b>	Hold on all plants due to no pesticide



## Facilities with Documented Use of Pesticides

					logs and acknowledgment of using Eagle 20 within the last 90 days. 2015-FS-INS-2206
JBC LLC.	4700 Kingston St	Pesticides and insecticides in use	Michael/Kim 3/19	No enforcement	Facility had no SOP's, or door sign's for pesticide use. Pesticide log was only started in March. Observed an un-opened container of GC-Mite broad. Directed facility to remove un-approved pesticide.
Satica	860 N Navajo St	Pesticides and insecticides in use			
Green Medicals	870 N Navajo St	Pesticides and insecticides in use			
Current Occupant	2424 E 43 <sup>rd</sup> Ave	Eagle 20/Mallet/Avid	Maggie/Emily 3/18	Pending	Facility stated they had E20 onsite, no logs, SDS, or SOP's available. Date of application for E20 was not remembered during visit.
MMJ America	1617 W 12 <sup>th</sup>	Sulphur/burners and pesticides	Emily/Antonio/E&L 3/20	Order issued on 3/19	Facility identified plants having been sprayed with Avid. Facility did not have REI placards, current pesticide logs. SOP available. 2015-FS-INS-2281
MMJ America	1319 N Elati St.	(?) – Referral from fire			This is a retail center, no cultivation occurring per grow manager for 12 <sup>th</sup> St. and Dartmouth



Date: January 29, 2016

## Facilities with Documented Use of Pesticides

					location.
<b>Current Occupant (MMJ America?)</b>	5025 & 5035 E 39 <sup>th</sup> Ave	(?) – Referral from fire			
<b>MMJ America (?)</b>	1885 W Dartmouth Ave 6-8	(?) – Referral from fire			
<b>Current Occupant (?)</b>	1205 W Evans St	(?) – Referral from fire			
<b>Frosted Leaf</b>	50 Lipan St.	Eagle 20 onsite	<b>Rich/Grace/EXL 3/27</b>	<b>Pending</b>	Facility has Eagle 20/Mallet/Floramite and other chemicals on hand in facility, but was instructed to stop using them by DFD. The MSDS sheets are in place, and logs indicate last use of Eagle 20 was in January, which flower form January has already been sold through dispensary per compliance manager. Compliance manager states they are looking to dispose of E20/Mallet/Floramite through a hazmat waste company.
<b>Rino Supply</b>	2200 S. Lipan	Mallet observed by DFD	<b>Danica/Emily 3/19</b>	<b>Order issued on 3/19</b>	Facility had documented the application of E20 on plants in the facility within the last month. Facility explained that they use Mallet on their plants. It was also explained that all the plants in the facility had been treated at one point. <b>2015-FS-INS-2252</b>
<b>Herbal Alternatives</b>	2568 Broadway St.	Logs state they use E20 and Avid			



## Facilities with Documented Use of Pesticides

<b>LivWell</b>		Explained to Fire that they are actively using E20			
<b>Pink House Blooms</b>	4925 38 <sup>th</sup> Ave.	Logs claim they have Avid, Mallet, etc.			
<b>Strainwise</b>	777 Canosa Ct	E20 stored on site			
<b>Altitude/AMA/Mile High</b>	2252 Kalamath St Units A-D	Sprayed Mallet on 3/19 DFD could not conduct inspection. (Mis-communicated to DFD, never used the Mallet product, removed from facility on 3/19).	<b>Rich/David Schlote with DFD, and Paul Strete with DPD/E&amp;L 3/20</b>	No enforcement	3 each facilities with 3 separate licenses, all 3 (Units A-C) are run by same management team. Unit D is currently vacant. All 3 units have MSDS sheets on hand and are developing logs, placards for doors, and SOP's. (Facility is using AzaMax).
<b>Denver Relief</b>	5051 E 41 <sup>st</sup>	Routine inspection required	<b>Emily/Pueblo County 3/23</b>	No enforcement	Facility has SOP's, REI placards and SDS. The facility is not using pesticides of any concern.
<b>Medicine Man</b>	4750 Nome St.	Eagle 20 and other pesticides	<b>Emily/Abby/EXL-DPD 3/25</b>	No enforcement	Facility only had logs for two months 01/2014 and 02/2014 available during visit. SDS sheets provided. Facility had a list of pesticides used in the SOP's however, the owner stated that they don't use those pesticides at that facility. No record of keeping REI placards. Facility claimed that they do not



## Facilities with Documented Use of Pesticides

					document the "organic" pesticides being used in logs.
<b>Altitude East</b>	4550 Jackson St.	Eagle 20 and other pesticides, no Eagle 20 or Avid seen on site, but use indicated on white board.	<b>Rich/Jerry/EXL 3/26</b>  <b>Emily/Jerry/EXL 3/31 – Issued order</b>	<b>Order Issued</b>	Facility logs indicated that they used Mallet, Eagle 20 and Avid since January 2015. Operators indicated that there may have been possible pesticide application. Facility was able to identify the plants and rooms by RFID numbers. Facility has marked out information on the logs since the original inspection. Facility had created SDS, REI placards, etc by second visit.
<b>Mindful (TR Scientific)</b>	3880 Holly St.	Eagle 20 and other pesticides	<b>Emily/Dave Schlote DFD 4/9/2015</b>	<b>Order Issued</b>	Facility identified using Eagle20 and which plants that had been treated. The RFID numbers of all plants currently in the room that had been sprayed were provided. Facility did not have logs past January of 2015. Placards were posted on the identified room. Facility did not have Eagle 20 in the SDS sheet they had



## Facilities with Documented Use of Pesticides

<b>Green Cross Colorado</b>	660 Bryant St	Label on retail packaging states that they use Mallet and Eagle 20 in their grow process	<b>Emily/Jerry/EXL 4/2</b>	<b>Order Issued</b>	created. Facility had no logs, SOP's or SDS available. Facility explained that they were using E20 and Mallet prior to Feb.1, 2015. Operator verified that plats may still be in the building. Facility manufactures CannaPunch with same plant material. Facility provided RFID numbers for plants/byproducts in house.
<b>Current Occupant</b>	1441 W 46 <sup>th</sup> Ave Unit 6	Sulphur onsite, no pesticide inventory list submitted.			
<b>Current Occupant (Same owner as facility above)</b>	11080 E 47 <sup>th</sup> Ave	See comment above			