12.8 Exhibit 8: Sampling and Testing SOP

12.7.1 Purpose

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

HAR Requirement	Description
§11-850-81	A dispensary licensee shall not dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter. Eff. DEC 14 2015
§11-850-85.a	A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-evident manner a similar sample from the same batch, for verification testing as directed by the department.
§11-850-85.b	A certified laboratory shall test and analyze samples according to standard operating procedures prepared by the laboratory based on validated methods published in peer reviewed scientific or regulatory literature, subject to approval by the department.
§11-850-85.c	A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things for which it is certified. The certificate of analysis shall include the results with the supporting data for the following:
§11-850-85.c.1	The chemical profile of the batch for the following compounds:
§11-850-85.c.1.A	Δ^9 (delta 9) - tetrahydrocannabinol (THC)
§11-850-85.c.1.B	Tetrahydrocannabinol Acid (THCA)
§11-850-85.c.1.C	Cannabidiol (CBD)
§11-850-85.c.1.D	Cannabidiolic Acid (CBDA)
§11-850-85.c.1.E	Cannabigerol (CBN)
§11-850-85.c.1.F	Cannabinol (CBN)
§11-850-85.c.2	The presence of the following contaminants, which shall not exceed the following levels:
§11-850-85.c.2.A	Heavy metals:
§11-850-85.c.2.A.i	Arsenic 10.0 ppm
§11-850-85.c.2.A.ii	Lead 6.0 ppm
§11-850-85.c.2.A.iii	Cadmium 4.0 ppm
§11-850-85.c.2.B	Mercury 2.0 ppm
§11-850-85.c.2.C	Solvents:
§11-850-85.c.2.C.i	Butanes 800 ppm
§11-850-85.c.2.C.ii	Heptanes 500 ppm
§11-850-85.c.2.C.iii	Benzene** 1 ppm
§11-850-85.c.2.C.iv	Toluene** 1 ppm
§11-850-85.c.2.C.v	Hexane** 10 ppm
§11-850-85.c.2.C.vi	Total Xylenes (m, o, p-xylene) 1 ppm **Contaminants in solvents
§11-850-85.c.2.D	Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;
§11-850-85.c.2.E	Moisture content of plant material <15%
§11-850-85.c.2.F	Microbiological impurities, including but not limited to:
§11-850-85.c.2.F.i	Total Viable Aerobic Bacteria:
§11-850-85.c.2.F.i.a	Unprocessed and Processed Materials: 10^5 Colony Forming Unit (CFU)/g
§11-850-85.c.2.F.i.b	CO2 and Solvent Based Extracts: 10^4 CFU/g
§11-850-85.c.2.F.ii	Total Yeast and Mold:
§11-850-85.c.2.F.ii.a	Unprocessed and Processed Materials: 10^4 CFU/g
§11-850-85.c.2.F.ii.b	CO2 and Solvent Based Extracts: 10^3 CFU/g

HAR Requirement	Description
§11-850-85.c.2.F.iii	Total Coliforms:
§11-850-85.c.2.F.iii.a	Unprocessed and Processed Materials: 10^3 CFU/g
§11-850-85.c.2.F.iii.b	CO2 and Solvent Based Extracts: 10^2 CFU/g
§11-850-85.c.2.F.iv	Bile-tolerant Gram Negative Bacteria:
§11-850-85.c.2.F.iv.a	Unprocessed and Processed Materials: 10^3 CFU/g
§11-850-85.c.2.F.iv.b	CO2 and Solvent Based Extracts: 10^2 CFU/g
§11-850-85.c.2.F.v	E. coli (pathogenic strains) and Salmonella spp.: Not detected in 1 g
§11-850-85.c.2.F.vi	Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger:<1 CFU/g;
§11-850-85.c.2.F.vii	Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and
§11-850-85.c.3	Additional testing requested at the discretion of the department.
§11-850-85.d	The certified laboratory may retest or reanalyze the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense.
§11-850-85.e	The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of marijuana or manufactured marijuana products that remain after testing and analysis are completed.
§11-850-85.f	A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana products, including but not limited to:
§11-850-85.f.1	The time and date the sample was obtained;
§11-850-85.f.2	A description of the sample, including the amount;
§11-850-85.f.3	What tests were conducted on each sample;
§11-850-85.f.4	the results of the tests including the certificate of analysis; and
§11-850-85.f.5	Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount; and shall make all the records available to the department upon request.
§11-850-85.g	A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection ©, and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.
§11-850-85.h	A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.
§11-850-85.i	The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection ©, and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.
§11-850-85.j	A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection © as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c). Eff. DEC 14 2015

12.7.2 Local Compliance

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

12.7.3 Definitions and Abbreviations:

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

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

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

12.7.4 Mandatory Sampling and Testing by Independent Laboratory

12.7.4.1 Mandatory Testing Overview

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

manner from the same batch for subsequent verification testing as directed by the Hawai'i DOH.

12.7.4.2 Compliance with Hawai'i DOH Testing Rules

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

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

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

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

12.7.4.3 Authorized Laboratories

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

12.7.4.4 Quality Assurance Responsibilities

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

12.7.4.5 Frequency of Testing

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

12.7.5 Product Sampling and Quarantine

12.7.5.1 Sampling Requirements:

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

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

12.7.5.2 Batch Sampling Procedure Post-Harvest:

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

10. Once the test results are received by all relevant persons and entered in the ADP/POS system:
    a. If the sample meets specifications, the Quality Control Team and Inventory Manager will release the entire batch for distribution and physically move the batch to regular storage; and
    b. If the sample fails to meet specifications, the Inventory Manager will execute the procedure for failed batches, which includes secure segregated storage until disposal in accordance with standard operating procedure.

12.7.5.3 Batch Sampling Procedure Post-Processing:

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

b. If the sample fails to meet specifications, the Inventory Manager will execute the procedure for failed batches, which includes secure segregated storage until disposal in accordance with standard operating procedure.

12.7.5.4 Mandatory Quarantine of Product

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

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

12.7.5.5 Sterile and Statistically Valid Techniques Required

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

12.7.5.6 Special Considerations for Sampling Raw Marijuana

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

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

12.7.5.7 Sample Handling

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

12.7.5.8 Sample Transportation

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

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

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

12.7.6 Failure to Meet Specifications / Non-Conformance

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

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

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

12.7.7 Results May Not Be Falsified

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

12.7.8 Sample Return or Disposal

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

12.7.9 Additional Testing May Be Required

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

12.7.10 In-House Analysis Program

12.7.10.1 Laboratory Director

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

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

12.7.10.2 Laboratory Director Responsibilities

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

12.9 Exhibit 9: Recall and Withdrawal SOP

12.9.1 Purpose

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

HAR Requirement	Description
§11-850-36.f	For transport between or among dispensary facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked, in full view of security surveillance cameras. For transport from a dispensary facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras.
§11-850-37.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.
§11-850-41.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.
§11-850-43.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

HAR Requirement	Description
	manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.
§11-850-51.a.1	A video surveillance system professionally installed that allows for twenty-four hour continuous video monitoring and recording of all dispensary facilities as follows:
§11-850-51.a.1.C	The surveillance system storage device and the cameras must be internet protocol (IP) compatible;
§11-850-51.a.1.D	The video surveillance system shall have minimum camera resolution to allow for the clear and certain identification of any person and activities in any area of a dispensary facility where marijuana and manufactured marijuana products are produced, moved, or stored; all points of sale areas, any room used to pack or unpack a secured container used to transport marijuana or manufactured marijuana products; any room or area storing a surveillance system storage device; and al exits and entrances to a dispensary facility from both indoor and outdoor locations;
§11-850-51.a.1.E	The surveillance system video recording storage device shall be secured in a lockbox, cabinet, or closet, or secured in another manner that limits access to protect the system from tampering or theft; and
§11-850-61.a	A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to ADP/POS, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-75.a	A dispensary licensee shall ensure that all marijuana and manufactured marijuana products it dispenses are safe for use or consumption by qualifying patients.
§11-850-75.b	A dispensary licensee shall comply with State and county health, safety, and sanitation regulations and may be subject to inspection to confirm that no health or safety concerns are present which may contaminate the products.
§11-850-75.c	Any person who has or appears to have an illness, or open lesion including boils, sores, or infected wounds, or any other source of contamination, shall be excluded from any contact with a dispensary's marijuana or manufactured marijuana products until the condition is corrected.
§11-850-75.d	A dispensary shall have hand washing facilities that are adequate and convenient, furnished with running water, and provide effective hand cleaning and sanitizing preparations.
§11-850-75.e	All persons working in direct contact with marijuana and manufactured marijuana products shall conform to hygienic practices while on duty, including but not limited to:
§11-850-75.e.1	Maintaining adequate personal cleanliness; and
§11-850-75.e.2	Washing hands thoroughly in an adequate hand washing area before starting work and at any other time when the hands may have become soiled or contaminated.
§11-850-75.f	A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.
§11-850-75.g	The floors, walls, and ceilings of a dispensary facility shall be constructed in such a manner that they may be adequately cleaned and kept clean and in good repair.
§11-850-75.h	The dispensary licensee shall ensure that there is adequate lighting in all areas where marijuana or manufactured marijuana products are stored or sold, and where equipment or utensils are cleaned.
§11-850-75.i	The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.
§11-850-75.j	The dispensary licensee shall not allow animals in dispensary facilities, except for service animals in accordance with section 347-2.5, HRS.
§11-850-75.k	The dispensary licensee shall maintain buildings, fixtures and other facilities in a sanitary condition.
§11-850-75.l	The dispensary licensee shall use and maintain any toxic cleaning compounds, sanitizing employees, and pest control measure such as bait traps, in a manner that protects against contamination of marijuana or manufactured marijuana products and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance.
§11-850-75.m	A dispensary licensee shall not alter marijuana or manufactured marijuana products to change their appearance, flavor, or smell in a way that would appeal to minors.
§11-850-81	A dispensary licensee shall not dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter. Eff. DEC 14 2015
§11-850-85.j	A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this

HAR Requirement	Description
	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;

12.9.2 Local Compliance

In accordance with the requirements defined by Hawai'i Administrative Rules Chapter(s): 11-850-36 through 11-850-38, 11-850-41, 11-850-43, 11-850-51, 11-850-61, 11-850-71, 11-850-72, 11-850-75, 11-850-81, 11-850-85, 11-850-92 and enforced by the Hawai'i DOH, Hale O Laulima has developed a Recall and Withdrawal policy and procedure to manage any product non-conformance found at any time in the supply chain or at the request of the Hawai'i DOH. Recall and Withdrawal procedures assure 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): §11-850-36 through §11-850-38, §11-850-41, §11-850-43, §11-850-51, §11-850-61, §11-850-71, §11-850-72, §11-850-75, §11-850-81, §11-850-85 and §11-850-92.

12.9.3 Definitions and Abbreviations:

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

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

Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

12.9.4 Recall and Withdrawal

12.9.4.1 Introduction

Patient health and safety is a top priority for Hale O Laulima. Hale O Laulima is committed to consistently providing high-quality, safe, medicinally effective marijuana products to the qualified registered patients of Hawai'i. To this end, Hale O Laulima will do everything in its power to prevent any spoiled, defective, misrepresented, or contaminated products, or products of insufficient quality, from being dispensed to qualified registered patients and to remove such products from the patient supply chain immediately. Upon the discovery of product contamination, safety concerns, patient adverse reaction, or quality-related issues, Hale O Laulima will quickly and efficiently carry out recall or withdrawal procedures in accordance with this policy in order to protect the health and wellbeing of patients. The best way to ensure that a recall or withdrawal is effective is to have a Recall and Withdrawal SOP already in place and to execute the plan as quickly as possible.

In compliance with §11-850 of the HAR ("the Hawai'i Administrative Rules") pertaining to the implementation of the Hawai'i Medical Use of Marijuana Act ("the ACT"), the Hale O Laulima Recall and Withdrawal Plan details the activities for the recall of any marijuana products that have a reasonable probability of causing adverse health consequences based on a testing result, adverse patient reaction, or other reason.

12.9.4.2 Overview

This Plan distinguishes between two levels of product recall: withdrawal and recall. Classification standards and appropriate responses for each type of event are discussed herein. Procedures for handling voluntary withdrawals and mandatory recalls of marijuana products are included herein. Procedures for addressing and recording complaints, including reports of product-related adverse events from patients or caregivers, are also provided. Incident classification terms are defined, with distinct mitigation procedures for each, as the term "recall" can have legal significance and implications for insurance and liability. The withdrawal and recall procedures provided in this Plan are designed to ensure that marijuana products are withdrawn or recalled quickly and efficiently, whether voluntarily or by mandate. The objectives of withdrawal and recall procedures are to stop distribution of the affected product, effectively notify all relevant patients, efficiently remove the affected product from the patient population, dispose of the affected product, conduct a root cause analysis, report the effectiveness and outcome of the recall, and conduct a post-recall meeting for evaluation.
In accordance with the incident classification schema and the associated definitions, the term "recall" will only be used when the situation mandates. Examples of incidents to be addressed

with recall or withdrawal procedures and guidelines for required mock withdrawal and recall drills are provided in this Plan.

Additional provisions include plans for tracking affected products in the event of potential or verifiable contamination, and for the establishment of an internal Recall and Withdrawal Team, which will be responsible for executing and coordinating all aspects of a withdrawal or product recall. In the instance of a product recall, the Hawai'i DOH will be notified immediately.

12.9.4.3 Recall and Withdrawal Disambiguation

There are two distinct levels of action that involve the removal of marijuana product from market: recall and withdrawal. A recall is generally undertaken when there is verifiable evidence that a marijuana product is defective or has health and safety hazards that reasonably could or already have caused serious adverse effects. A withdrawal is typically conducted when there is a quality-related issue with marijuana products that are not likely to pose health risks, or as a precautionary measure prior to an official recall when health or safety risks are suspected but not yet verifiable. The classification of a recall typically involves the presence of bacteria, a substance that may cause a potential allergic reaction, or some other contaminant that could cause adverse reactions in patients, whether such reaction is serious or temporary. The term "recall" should only be used when mandated by verifiable evidence (i.e., analytical test results) that the affected product poses significant health and safety risks to the patient population. Any determination to implement recall procedures must be supported by test results or other scientific documentation or expert opinion.

12.9.4.4 Responsibility

The COO, Quality Control Team and Inventory Manager will be primarily responsible for the determination of the need for a marijuana product recall or withdrawal and oversight of the execution of recall and withdrawal procedures. If the COO, Quality Control Team and Inventory Manager are unsure of the need for recall or withdrawal or appropriate event classification, the Medical Director and/or Laboratory Director may be asked to participate in determination. The Medical Director and Board of Directors ("the Board") will be informed of all event determinations and may participate in procedural oversight, if necessary, appropriate for the incident, or desired. As the Laboratory Director and Inventory Manager have recall experience, they will be called upon to oversee aspects of recall and withdrawal procedures and provide suggestions for improvement, as needed or desired.

12.9.4.4.1 Recall and Withdrawal Team

The COO will select and maintain a Recall and Withdrawal Team, composed of Hale O Laulima employees, managers, and members of the Board, which will be responsible for executing withdrawal and recall procedures. The team will be responsible for coordinating all aspects of a withdrawal or product recall:

1. A Recall and Withdrawal Coordinator, to be appointed by the COO and members of a Recall and Withdrawal Team, will be selected from each operational unit;

2. Together the team will assist the Recall and Withdrawal Coordinator in the event of a recall or withdrawal event in accordance with the procedures in this Plan;
3. All team members must ensure that all procedures are carried out effectively and efficiently;
4. The COO, Quality Control Team, and Inventory Manager will ensure the team receives appropriate training utilizing mock withdrawal and recall procedures semi-annually so that they understand their responsibilities and are prepared to execute; and
5. The COO must maintain a Recall and Withdrawal Team list and provide quarterly updates to ensure all names, contact phone numbers and responsibilities of team members and alternates are updated.

12.9.4.5 Federal Compliance

As marijuana and marijuana products are not FDA-regulated products, Hale O Laulima is not bound by law or rule to comply with United States Food and Drug Administration (FDA) recall requirements. However, Hale O Laulima has elected to implement FDA recall standards and procedures as a guideline for self-imposed recall and withdrawal policies and practices.

12.9.4.6 Recall and Withdrawal Procedures

The following procedures will be implemented once a product complaint, report of a patient adverse reaction, or evidence suggesting quality- or safety-related issues is received.

12.9.4.6.1 Investigate Complaint:

Investigate complaint or report of serious adverse event as outlined above. This process generally involves the following steps:

1. Gather information from the patient, supplier, or regulator about the nature of the product complaint or concern;
2. Assemble the personnel or experts needed to conduct a product complaint investigation;
3. Conduct a thorough investigation into the problem with the affected product;
4. Determine the nature and potential causes of the problem;
    a. If a serious adverse event report is involved, this includes requesting sampling and testing of the retention sample of the product in question;
5. Determine any other product(s) that may potentially be affected;
6. Determine, from the information provided herein, whether the situation meets criteria for:
    a. Product Recall;
    b. Product Withdrawal; or
    c. No Corrective Action (i.e., an isolated incident with the affected product).

12.9.4.6.2 Assess and Classify Event

Conduct an assessment to determine the procedures to implement. Items to consider include:

6. Whether or not adverse reactions or serious health issues have already occurred from use of the product;
7. Hazard to various segments of the population (e.g., immune-compromised patients undergoing chemotherapy) who are expected to be exposed to the product being considered;
8. Degree of seriousness of the health hazard to which the population at risk would be exposed;
9. Likelihood of occurrence of hazard;
10. If it is determined that recall procedures are appropriate, assign the recall event to one of the following classes, in accordance with FDA guidelines and the level of hazard involved:
    a. Class I: A situation in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences;
    b. Class II: A situation in which use of or exposure to a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote; and
    c. Class III: A situation in which use of or exposure to a product is not likely to cause any adverse health reaction, but may pose safety risks (e.g. non-hazardous labeling violation substantiated by test results).
11. Seek the Board's approval for event classification. If the Board approves a recall, a press release must be issued to the Hawai'i DOH immediately.

12.9.4.6.3 Track Affected Product(s)

Determine type of product(s) affected:

1. Finished product = All marijuana products that have been packaged and partially or completely distributed, including products for sale in Retail Dispensary facilities;
2. Work in progress = All marijuana products that have not been distributed and their constituents, including, but not limited to, marijuana plants, marijuana and marijuana products in storage, and in-process marijuana products;
3. Ingredient = All ingredients, including crop inputs and marijuana product constituents, used in processing operations;
4. Packaging material = All packaging material or containers used for work in progress or finished products;
5. If affected product is finished product:
    a. Assemble personnel needed to conduct tracking of a finished product;
    b. Identify affected and any other potentially affected product(s), product identifiers(s) and production date(s);
    c. Determine the quantity of affected product(s) produced;
    d. Determine from the automatic data processing/point-of-sale, Biotrack system the last day of shipment/dispensing (and the recipient) for the affected product(s);

   e. Determine from the ADP/POS system all patients and legal representatives who purchased the affected product(s) during this period (i.e. period = day of packaging to last day of shipment); and
   f. Determine from the ADP/POS system the remaining quantity of the affected product(s) in Retail Dispensary inventory.
6. If affected product is work in progress:
   a. Assemble the personnel needed to conduct tracking of a work-in-progress product;
   b. Identify the affected and any other potentially affected product(s), product identifiers(s) and production date(s) from the production records; and
   c. Determine from the ADP/POS system and production records the quantity of the affected product(s) produced.
   d. Locate the affected product(s) from the production and storage areas.
7. If affected product is an ingredient:
   a. Assemble the personnel needed to conduct tracking of an ingredient;
   b. Identify the affected and any other potentially affected ingredient(s) and lot number(s)/production code(s)/best before date(s)/receiving date(s);
   c. Determine the quantity and receiving date of the affected ingredient(s) received;
   d. Based on the lot number/receiving date, determine from the production records the period of use for the ingredient;
   e. Determine from the production records all finished product(s) produced with the affected ingredient(s);
   f. Determine from the production records the quantity of the affected product(s) produced during this period;
   g. Determine from the production records and inventory records the day the affected product(s) entered Hale O Laulima inventory (i.e. packaging date);
   h. Determine from the ADP/POS system the last day of shipment (and the recipient) for the affected product(s);
   i. Determine from the ADP/POS system all the patients and legal representatives who purchased the affected product(s) during this period (i.e. period = day of packaging to last day of shipment); and
   j. Determine from the inventory management portion of the ADP/POS system the remaining quantity of the affected product(s) in Hale O Laulima inventory.
8. If affected product is packaging material:
   a. Identify affected and any other potentially affected packaging material(s) and lot number(s)/quality control code/receiving date(s);
   b. Determine the quantity and receiving date of the affected packaging material(s) received;
   c. Based on the type and size of packaging material, determine all the finished product(s) associated with the affected packaging material(s);
   d. Determine from the production records the period of use for the affected packaging material(s);

e. Given the affected period and product, determine from the ADP/POS system the quantity of the affected product(s) associated with the affected packaging material(s) in this period;
f. Determine from the production records and ADP/POS system the day the affected product(s) entered into Hale O Laulima inventory (i.e. packaging date);
g. Determine from the ADP/POS system the last day of shipment (and the recipient) for the affected product(s);
h. Determine from the ADP/POS system all the patients and patients' legal representatives who purchased the affected product(s) during this period (i.e. period = day of packaging to last day of shipment);
i. Determine from the ADP/POS system the remaining quantity of the affected product(s) in our inventory; and
j. Locate any remaining affected packaging material(s) from the storage shelves and cabinets.

12.9.4.6.4 Execute Withdrawal or Product Recall:

1. Assemble the Recall and Withdrawal Team, ensuring adequate resources are available for the severity of the issue;
2. Gather all information collected in the tracking process;
3. Detain and segregate all products to be recalled or withdrawn which are in Hale O Laulima's control. Adhere a DO NOT DISTRIBUTE sign, place in quarantine, and complete any relevant internal logs/forms;
4. Depending on event type, send a Notification of Recall or Notification of Withdrawal to the affected patients and legal representatives;
5. Ensure the following information is accurately recorded:
    a. Name and Product Identifier of the withdrawn/recalled product(s);
    b. Production date(s);
    c. Reason for withdrawal/recall;
    d. Quantity of withdrawn/recalled product(s) distributed;
    e. Quantity of withdrawn/recalled product(s) in inventory (for internal use only); and
    f. Site(s) of distribution (i.e., Production and Retail Dispensary Facilities) and patients affected (for internal use only).
6. Coordinate and monitor the recovery of all affected product(s); all products in the homes of patients should be picked up by Transportation Employees in accordance with the procedures for patient delivery described in the Shipping and Receiving SOP and Inventory Control and Management SOP or returned by the patient or patient's legal representative to the Retail Dispensary location;
7. Using the ADP/POS system, conduct a reconciliation of the total quantity of recalled product and affected product in inventory against the total quantity produced;
8. Contact the independent testing laboratory to request sampling and testing of recalled or withdrawn product(s), as appropriate;

9. Test results and corrective actions must be recorded internally and discussed with the Hawai'i DOH, if applicable; and
10. The COO must prepare an internal Withdrawal and Recall Report, which will be saved in the secure cloud-based records system for a minimum of six (6) years.

12.9.4.6.5 Storage of Recalled Material

All recalled material will be segregated from unaffected products. The Inventory Manager will place "QUARANTINE- DO NOT DISTRIBUTE" tags on all recalled material, including recalled products returned by patients, caregivers, or other licensees. The Inventory Manager will mark all recalled products as quarantined and recalled in the ADP/POS system. Records must be kept in the Product Into Quarantine Log and the ADP/POS system, Biotrack where applicable. Recalled products will remain in quarantine storage until disposal of the recalled material is authorized by the Commission.

12.9.4.6.6 Disposal of Recalled Material

Within 24 hours of Commission authorization, Hale O Laulima will dispose of the recalled medical marijuana in accordance with waste disposal procedures set forth in Marijuana Waste Disposal SOP. The recalled material will be ground and incorporated with non-marijuana compostable waste until the mixture is no more than 49% marijuana waste by volume and will be securely stored until transport to the waste disposal location. These measures will ensure that the recalled material cannot be salvaged and/or used, whether by an employee of Hale O Laulima or by an unaffiliated person.

12.9.4.6.7 Follow-Up Measures

After the above procedures have been carried out and the affected product(s) have been properly disposed of, the COO will conduct a root cause analysis and report the effectiveness and outcome of the recall or withdrawal. The COO will also conduct a meeting with the Recall and Withdrawal Team, the QCT, the Medical Director, the Board, and all other involved parties for evaluation and suggestions for improvement.

12.9.5 Complaints

12.9.5.1 Complaint Classification

The Retail Dispensary Manager must record all complaints in an internal Complaint Log and categorize all complaints as a product complaint or other complaint. Product complaints include, but are not limited to, dispensing errors, patient adverse reactions, and quality-related product complaints. Complaints classified as "other" may include, but are not limited to, neighborhood-related issues, general service-related issues, grievances with particular Hale O Laulima Facility employees, or other issues related to Hale O Laulima operations but not marijuana products themselves.

Complaints connected with reports of adverse patient reactions to a product must still be categorized as product-related complaints, but also require recordkeeping in the Adverse Events Log and compliance with additional measures tailored specifically to adverse effect response.

12.9.5.2 Dispensing Errors and Near Misses

All Retail Dispensary Facilities Employees are responsible for identifying and recording dispensing errors and near misses. Proper procedures for recording and responding to dispensing errors and near misses are detailed in the Inventory Control and Management SOP.

12.9.5.3 Complaint Handling

All employees employed in Hale O Laulima facilities are responsible for documenting any complaint received from another employee, a representative of the Hawai'i DOH, another regulatory body, a qualified registered patient, a patient's legal representative, or any other party in the Complaint Log. A Retail Dispensary Facilities or Patient Coordinator may receive a complaint in person, by phone or email. The employee receiving the complaint must notify the Manager for their facility of employment immediately. All employees will be trained by their Facility Manager to handle complaints and unhappy patients; such training may include, but will not be limited to, verbal de-escalation techniques and investigative questioning.

Any complaint that appears to be connected with a serious adverse event must be recorded in the Adverse Event Log. Adverse Events require different kinds of questioning, follow-up, and recordkeeping which are outlined herein.

12.9.5.4 Product Complaint Response Policy

It is Hale O Laulima policy to make a good faith effort to resolve any complaint, whether legitimate or frivolous whenever possible. The Retail Dispensary Manager must respond to any product-related complaint within twenty-four hours to gather information about the nature of the complaint, the affected parties or products, and determine appropriate steps for resolution. If The Retail Dispensary Manager cannot fully resolve the issue, the Chief Operations Officer ("COO") must be notified, and shall determine the appropriate course of action. If the product complaint involves a bad patient reaction, the Medical Director shall be notified and will take responsibility for following up with the affected patient.

12.9.5.4.1 Product Complaint Investigation Procedure

Once notification of a product complaint has been received, it is the responsibility of the Inventory Manager, in coordination with the COO and/or Medical Director, if applicable, to begin accurate and detailed documentation and product tracking. The Inventory Manager must:

1. Gather information from complainant about the nature of the dispensing error or marijuana product complaint;
2. Assemble the personnel or experts needed to conduct a product complaint investigation including the Quality Control Team ("QCT");
3. Conduct a thorough investigation into the complaint;
4. Determine the nature and potential causes of the problem;
5. Determine any other marijuana product(s) that may potentially be affected;
6. Enter all information into the Complaint Log; and
7. Determine the appropriate action, based on the general classifications provided below, follow the appropriate procedures for that classification, and document all actions taken:
    a. Product Recall: Patient safety or health risk due to physical, chemical, biological or immunological cause(s). This includes, but is not limited to, verified or suspected product contamination or test result showing the product does not meet the statutory definition of marijuana. Proceed to Recall and Withdrawal Procedures;
    b. Product Withdrawal: Appropriate for a quality-related issue with affected product(s) that does not pose an immediate health or safety risk to patients. Proceed to Recall and Withdrawal Procedures; and
    c. No Corrective Actions: An isolated incident with the affected product(s), such as an isolated dispensing error or minor labeling error, such as misspelled patient or product name.

12.9.5.4.2 Adverse Event Reporting Methods

Inspired by FDA recommendations for controlled substance manufacturers, Hale O Laulima will provide a toll-free number which patients and caregivers may use to report adverse events. The toll-free number will be established through an online toll free service provider and management system. The system will automatically route calls to the Hale O Laulima facility phone line during normal business hours and will route to the Medical Director after hours. If the call is not answered, the caller will be prompted to leave a message providing contact information and a description of the adverse event or side effects. The number will be provided on point-of-sale labels and will be accompanied by the following statements:

12.9.5.4.3 Adverse Event Reporting Methods

Any Hale O Laulima employee who receives a report of a serious adverse event must, to the best of his or her ability, obtain and record the following information in the Adverse Event Log:

1. Name of the person who is reported to have experienced the adverse event;
2. Qualifying patient registry number of the person who is reported to have experienced the adverse event, if known to the reporter;
3. Phone number and email address of the person who is reported to have experienced the adverse event;
4. Whether the patient's certifying physician has been contacted;

5. The name and phone number of the person reporting the adverse event, if the reporting party is not the person who experienced the adverse event;
6. The identity, route of administration, and dosage of the specific marijuana, marijuana-infused product, or marijuana concentrate used, if known;
7. The identity of any device(s) used to administer the product used, if known; and
8. A detailed description of the adverse event.

12.9.5.4.4 Adverse Event Investigation

When a report of an adverse event is received:

1. The Medical Director, Inventory Manager and Retail Dispensary Manager must be immediately notified;
2. The Medical Director and Retail Dispensary Manager will review the information recorded by the employee who received the report;
3. The Medical Director will contact the affected person to confirm the report details and obtain additional information needed for determination, which may include:
    a. Other medications and supplements taken;
    b. The person's medical issues;
    c. Risk factors, such as age, severity of illness, reduced function of any body systems;
    d. Time and route of administration and time at which adverse event was experienced; and
    e. Allergies.
4. The Medical Director and Retail Dispensary Manager will assess whether the reported outcome was any of the following, which indicate a serious adverse event:
    a. Death;
    b. Life-threatening:
        i. Meaning person was at substantial risk of dying at the time of the adverse event, or if use or continued use of the product in question might have resulted in death.
    c. Hospitalization:
        i. Meaning if person was admitted to the hospital or the event prolonged hospitalization; and
        ii. If the person visited the emergency room but was not admitted to the hospital, evaluate whether other serious outcomes were experienced.
    d. Disability or permanent damage:
        i. Meaning the adverse event resulted in a significant, persistent or permanent change, impairment, damage, or disruption in the patient's body function, structure, physical activities, and/or quality of life.
    e. Congenital anomaly/birth defect:
        i. Meaning exposure to the product prior to conception or during pregnancy is suspected to have resulted in an adverse outcome in the child.

f. Required intervention to prevent permanent impairment or damage:
    i. Meaning medical or surgical intervention was necessary to avoid permanent impairment of body function or prevent permanent damage to a body structure.
g. Any other serious or important medical event:
    i. Meaning the event does not fit the other serious outcomes, but may jeopardize the patient and may require medical or surgical intervention/treatment to prevent one of the other outcomes; and
    ii. Examples: Severe breathing problems requiring emergency room treatment, seizures/convulsions that do not result in hospitalization, etc.

5. The Medical Director will use the World Health Organization - Uppsala Monitoring Center ("WHO-UMC") causality assessment system, to estimate whether it is likely that there is a causal relationship between the adverse event and the medical marijuana; and
6. On the basis of the WHO-UMC assessment, the presence or absence of serious outcomes, and other key findings, the Medical Director will determine whether the incident meets the criteria for a serious adverse event and that the medical marijuana is possibly, likely, or certain to be a causal factor in the adverse event:
    a. If a causal link is possible or certain, but no serious outcomes were experienced, the incident will be considered a substantive product-related complaint and must be responded to accordingly;
    b. If a causal link is possible or certain and one or more serious outcomes were experienced, the incident will be considered a serious adverse event and must be responded to accordingly; and
    c. If a causal link is unlikely and no serious outcomes were experienced, Hale O Laulima must investigate to determine if a voluntary withdrawal would be appropriate.

12.9.5.5 Failure to Meet Specifications

Pursuant to §11-850-85.j, if analytical testing of the retention sample reveals that the batch or lot fails to meet specification, Hale O Laulima will:

1. Order a recall of all products derived from or included in the batch or lot;
2. Notify all patients, caregivers, and licensees who may have obtained the affected products; and
3. Offer and pay reimbursement for any returned products.

12.9.5.5.1 Examples of a Test Result Requiring Recall or Withdrawal

The examples in the following list, which is by no means exhaustive, would constitute an incident requiring a recall or withdrawal:

1. Marijuana product found to have any amount of pesticide residue from an illegal/restricted chemical;
2. Marijuana product found to have an amount of pesticide residue that exceeds the U.S. Environmental Protection Agency's tolerances for pesticide chemical residues in food provided in 40 Code of Federal Regulations (CFR) 180;
3. Marijuana product found to exceed the contaminant limits set forth in the Sampling and Testing SOP;
4. Known, assumed or suspected marijuana product contamination by chemical, physical or microbiological hazards;
5. Incorrect labeling which may constitute a breach in product safety, quality, or legality standards;
6. Notification from a supplier that products supplied were found to pose risks for any of the above reasons;
7. Known or suspected malicious contamination;
8. Internal quality assurance re-testing of improperly stored packaged marijuana products reveals contamination or adulteration;
9. DOH-requested testing of packaged marijuana products or input materials reveals contamination, adulteration, misrepresentation, or non-compliance with statutory definition of marijuana; and
10. Severe patient adverse reaction to marijuana product, once investigated and reasonably suspected or determined to be due to marijuana product quality- or safety-related issues, and therefore not likely to be an isolated incident.

12.9.5.6 Training

12.9.5.6.1 Training Required

All Hale O Laulima employees will be trained to receive, organize, record, and respond to all complaints and reports of adverse events upon acquisition and at least once annually thereafter. The training will include, at a minimum: pertinent definitions, tips for distinguishing between different classes of complaints and identifying a serious adverse event, guidelines for collecting necessary information, reporting requirements, and procedural compliance.

You may use the following toll-free number to report serious adverse reactions or unpleasant side effects: 1-800-XXX-XXXX
Call your doctor for medical advice about side effects.
Seek emergency medical treatment if adverse reaction is severe.

12.9.5.6.2 Training and Mock Withdrawal and Recall Drills Required

The COO, Quality Control Team, Inventory Manager, and Human Resources Manager will develop and implement all necessary withdrawal and recall training for all employees, including mock recall events. Mock recalls are used to determine whether the withdrawal and recall procedure is capable of identifying and quickly controlling a batch of potentially affected

product and reconciling the quantities produced, quantities in inventory, and quantities distributed. A mock recall or withdrawal will identify potential problems and allow employees to become familiar with recall procedures. If problems are identified in the procedures, the COO must correct them and the employees must be retrained on all new procedures. The mock recall training events will be required at least semi-annually. The Laboratory Director and Inventory Manager have experience with recalls and will play central roles in the development and oversight of withdrawal and recall training as well as mock recalls and withdrawals.

12.9.5.6.3 Drill Procedures

The Facility Manager, in coordination with the COO and Recall and Withdrawal Team must carry out mock recall or withdrawal procedures in Hale O Laulima facilities at least semi-annually by randomly selecting at least two finished marijuana products or other accessory products:

1. The mock procedures should follow all regular procedures; however, no product should be retrieved from patients or patients' legal representatives or removed from inventory or storage;
2. All information obtained during a mock withdrawal or recall drill must be documented internally;
3. All parties involved in a mock withdrawal must be notified immediately that it is a mock procedure;
4. The mock recall file should include the name, address and telephone number of clients for the batch tested, production records and the processing, inventory, and distribution history of each lot involved;
5. All recommended corrective actions and deficiencies must be documented in a mock withdrawal and recall report to be submitted to the Board; and

The Facility Manager must correct any deficiencies, and if necessary, procedures should be modified to improve withdrawal and recall performance and efficiency. If procedures are modified, all Hale O Laulima employees must be re-trained on new procedures.

12.10 Exhibit 10: Dispensary Operations SOP

12.9.1 Purpose

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

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

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

12.9.1.1 Local Compliance

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

12.9.2 Definitions and Abbreviations:

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

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

12.9.3 Overview

Hale O Laulima's policies and procedures and operating plans detailed throughout Hale O Laulima's Qaulity Management System provides all plans included in this application illustrate Hale O Laulima's commitment to professionalism, medical marijuana education, compliance, consistency of operations, and above all, a high-quality patient experience. The strategies, policies, and procedures described herein and those integrated into all plans submitted with this application are designed to facilitate smooth Retail Dispensary Facility operations that are managed by qualified managers and by a comprehensive, custom ADP/POS system, Biotrack, designed to manage all aspects of Retail Dispensary Facility operations. Hale O Laulima will update dispensing and patient management practices whenever necessary and will coordinate with industry advisors who have developed best practices through years of experience managing dispensaries in other medical marijuana states. It is Hale O Laulima's goal to assure that all aspects of Retail Dispensary Facility operations are managed in accordance with industry best practices, assure full compliance with all Hawai'i regulations, and exceed DOH expectations, providing a model for effective Retail Dispensary Facility business management in Hawai'i.

12.9.4 Approved and Tested Products Only

Only marijuana products that meet the quality and safety standards set forth in Hale O Laulima standards described in the Quality Assurance and Quality Control SOP will be sold in the Retail Dispensary Facility. All batches and lots of product must have been analyzed by an independent testing laboratory and accompanied by a certificate of analysis in order to be accepted into Retail Dispensary Facility inventory and offered for sale to qualifying patients. The Retail Dispensary Facility will provide only high-quality, medically toned products tailored to the needs of qualifying registered patients.

12.9.5 Implementation of Best Practices

In coordination with industry experts, Hale O Laulima has developed best practices for managing of all aspects of business in a Retail Dispensary Facility, which are incorporated in all sections of the Retail Dispensary Facility application. These best practices comply with and exceed the requirements set forth by the DOH and address topics including patient management, inventory control, and operational efficiencies. Aside from the items addressed elsewhere in the application, best practices for day-to-day Retail Dispensary Facility management include maintaining a defined hierarchy that promotes effective communication, setting and communicating realistic goals through written operating policies and procedures, maintaining an open management style, creating and implementing training modules and schedules, and engaging in regular performance monitoring.

12.9.6 Management Style

The hierarchical structure of the Retail Dispensary Facility is clearly defined in the organizational chart provided in the Staffing and Training SOP, which will be available to all Employees upon

orientation and clearly defines lines of communication and authority within the organization. The written operating policies and procedures were designed in coordination with industry expert advisors and will continuously be updated to reflect industry best practice and regulatory changes. Managers are required to read and refer to written operating policies and procedures; all Retail Dispensary Facility Employees will be trained in accordance with Hale O Laulima's comprehensive operations manual and will have access to a hard copy of the manual at all times while onsite.

Managers will be required to maintain an open management style, which includes communicating openness to feedback and concerns at all times, keeping staff communications confidential, maintaining a confidential comments box on the Retail Dispensary Facility premises, and never punishing staff who raise concerns about Retail Dispensary Facility operations. Management personnel will also assure effective management of the Retail Dispensary Facility by requiring training of all staff upon hire, monthly, and as necessary to address compliance issues or with the development of best practices. Finally, managers will effectively manage Retail Dispensary Facility Employees and operations by engaging in regular performance monitoring, as described herein and in the Staffing and Training SOP.

12.9.7 Patient Supply and Demand

The mission of Hale O Laulima is to provide consistent, safe, and medicinally effective marijuana and marijuana products to registered patients and their caregivers. The Production and Processing Manager, in coordination with the Inventory Manager, will receive a demand report from the Retail Dispensary Facility Manager and modify the next quarter's production levels to meet or exceed the demand. In addition to demand, the Production and Processing Manager will consult with the Retail Dispensary Facility Manager and Medical Director to determine appropriate strains to cultivate and products to produce to meet patient needs.

12.9.8 Registry and Order Verification

A Patient Coordinator and Retail Dispensary Facility Employee will each fulfill a portion of the pre-dispensing verification requirements set forth in Inventory Control and Management SOP. For each patient or patient's caregiver, a Patient Coordinator will verify the following information, at a minimum, before the individual is able to enter limited access areas in which marijuana products are displayed and dispensed:

1. The identity of the patient or patient's caregiver; and
2. The validity and active status of the patient or designated caregiver's registration in the Compassionate Use Registry.

12.9.9 Dispensing Records

In accordance with the requirements contained in the Inventory Control and Management SOP along with the Quality Assurance and Quality Control SOP, immediately after dispensing marijuana product to a patient or patient's caregiver, the Retail Dispensary Facility Employee

will enter the dispensing action into the registry. Records of all dispensing and sales transactions will also be entered into the ADP/POS system, Biotrack, in real time and maintained in the secure cloud-based storage system.

12.9.10 Electronic Business Records

Hale O Laulima will maintain electronic business records consistent with industry standards including, but not limited to, the Hale O Laulima's bylaws, consents, assets and liabilities, monetary transactions, bank statements, audits, journals, ledgers and supporting documents, agreements, checks, invoices and vouchers, and other financial accounts reasonably related to the operations of the Retail Dispensary Facility. All records will be maintained for six (6) years.

12.9.11 Automated Data Processing and Point of Sale System

Hale O Laulima's Retail Dispensary Facility will manage inventory, sales transactions, and related business through an ADP/POS system, Biotrack, described in the Inventory Control and Management SOP. The system is designed to comply with all recordkeeping, product tracking, and sales requirements set forth by Hale O Laulima, allows seed-to-sale inventory control, provides a custom point-of-sale interface that will be integrated with the Hawai'i registry (if the DOH provides the necessary framework for integration), and will be HIPAA-compliant. It provides all means necessary for traceability of products for the purpose of recall; tracks disposal of products that are outdated, damaged, deteriorated, misbranded, or adulterated; ensures first-in-first-out inventory control; provides business reporting consistent with industry standards; and tracks qualified patient records, including purchases and denials of sale, while maintaining patient confidentiality. The system is designed to conform to the privacy and security rules of HIPAA (45 CFR 164).

Biotrack allows the Retail Dispensary Facility Employee and/or Patient Coordinator to qualify a patient or designated caregiver by verifying his or her identity, registration status and written certification in the registry, verify that the patient has a caregiver authorized by the DOH and the identity of that caregiver, and record the date, time, amount, and form of marijuana product purchased. Amounts allowable for each patient will be configured into the system through coordination with physician orders available in the secure registry. The Retail Dispensary Facility will not operate if the ADP/POS system, Biotrack, or the registry is inoperative or inaccessible.

12.9.12 Audits and Inspections

Hale O Laulima will be prepared for any inspection held by the DOH or other regulating authority, allowing access to any Hale O Laulima facility and affiliated vehicles and/or the Hale O Laulima product(s) in order to determine that the Hale O Laulima is operating pursuant with all applicable laws and regulations. The Hale O Laulima will perform regular compliance audits and internal inspections in order to check all records, Employee activities, and operations of the Retail Dispensary Facility to ensure that Hale O Laulima is operating pursuant to all applicable

laws and regulations and provide the results of such compliance audits and internal inspections to the Board of Directors.

12.9.13 Tracking and Monitoring Sales

Once patient and order are verified in the registry and payment is accepted and registered in the ADP/POS system, the Retail Dispensary Facility Employee will notify the Retail Dispensary Facility Manager on duty to remove products from the limited access storage area, if applicable, who will then use his or her Hale O Laulima-issued access control card to enter the storage room, retrieve the purchased items from the safe in which they are stored, and then bring the item(s) back into the sales area for transfer to the registered patient or caregiver who made the purchase. Depending on whether the product has been pre-packaged or is stored in bulk form (flower only), the Employee may need to weigh and package the product in accordance with standard operating procedure.

The bar code on purchased items will be scanned when removed from storage and processed for sale, and the inventory control system will automatically move these items from Retail Dispensary Facility inventory in storage to purchased inventory. All aspects of this process will be recorded by the surveillance system, all access to limited access areas will be recorded in the access control system, all inventory will be tracked from storage to retail sales area to registered patient or caregiver, and all sales records will be securely maintained in the ADP/POS system, Biotrack, and/or secure cloud-based records storage system for a minimum of six (6) years. Point of sale transactions will be linked both to patient profiles and lot or batch records in the system, allowing for comprehensive tracing of product from origin of the genetic material through every step of the production process to final transfer to a qualifying patient or caregiver.

12.9.14 Secure Storage for Products and Cash

Hale O Laulima will utilize a vault with dimensions sufficient for storage of marijuana and placement of an additional interior safe for secure storage of cash awaiting pickup and deposit. Hale O Laulima will also develop and enforce strict cash handling and storage policies, set forth in the standard operating procedures, to ensure the safety of all Employees, patrons, operations, and material assets at all times. The Retail Dispensary Facility Manager will execute money exchanges throughout the daily operations of the Retail Dispensary Facility and will adjust the money exchange schedule according to the levels of cash being accepted at each register on a daily basis. The money drop schedule must be randomized to ensure that no patterns are created. No cash register may have more than $1,000 in cash at any one time. The Retail Dispensary Facility Manager is responsible for the daily monitoring of cash register levels and removing cash as necessary to be stored in the safe within the vault.

12.11 Exhibit 11: Inventory Control and Management SOP

12.10.1 Purpose

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

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

HAR Requirement	Description
§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 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;

12.10.1.1 Local Compliance

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

12.10.2 Definitions and Abbreviations:

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

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

United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

12.10.3 Inventory Control Policies

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

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

12.10.4 Responsibility for Inventory Control and Management

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

The Inventory Manager will designate the Facility Manager to have oversight of the inventory control system for the facility. The Facility Manager and Inventory Manager share responsibility for ensuring accurate recording and accountability of inventory at all Production and Retail Dispensary Facilities, as well as accurate recording of all inventory movements in Hale O Laulima's facilities.

12.10.5 Inventory Limits

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

12.10.6 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:

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

12.10.7 Surveillance Coverage of Inventory Activities

The entirety of the Production and Retail Dispensary Facilities will be covered by surveillance video cameras. All facility activities, including inventory management and control activities, will be recorded by surveillance cameras and the footage will be stored in a secure location. Hale O Laulima will retain for a minimum of one year all security recordings. Surveillance footage can be watched in real-time, on the display monitor in the security room, or stored footage can be accessed for review by select managers, including the Security Manager. The room containing surveillance equipment will be restricted to the Security Manager, COO, and other personnel authorized by the Security Manager. Constant, comprehensive surveillance camera coverage provides an additional protection against diversion or theft and allows verification and surveillance of all inventory activities.

12.10.8 Production Facility Inventory Control Procedure

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

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

   c. Weight (in grams);
   d. Test results;
   e. A link to the transportation manifest, including identifying information about the destination facility, date of transport, employee responsible for transport or transfer, and other relevant information; and
   f. If disposed, additional records must be kept in the Waste Disposal Log, as set forth in the Marijuana Waste Disposal SOP.

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

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

12.10.9 Retail Dispensary Facilities Inventory Control Procedure

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

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

3. The Inventory Manager must ensure that the ADP/POS system either interfaces with the Compassionate Use Registry ("the Registry") or requires a Retail Dispensary Employee to

enter a dispensing action into the Registry immediately upon dispensing a marijuana product to a qualified registered patient or patient's legal representative, in accordance with HAR 11-850-42.a, 11-850-42.b and 11-850-61;

4. The Inventory Manager must ensure that the ADP/POS system maintains patient profiles and records, and protects patient privacy and confidentiality in accordance with HIPAA standards and HAR 11-850-40, and restricts access to confidential patient information through the issuance of user permissions;

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

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

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

8. The Inventory Manager will keep records of all marijuana products sold or otherwise disposed at each Hale O Laulima facility. These records will include, at a minimum:
    a. Name and form of the marijuana product dispensed;
    b. Batch number;
    c. Amount of the marijuana product dispensed;
    d. Sales price;
    e. Date of sale;
    f. Name and identification number of the qualified registered patient or patient's legal representative to which the marijuana product was dispensed; and
    g. If disposed, the name, form, batch number, quantity, date, manner of disposal and reason for disposal for any marijuana products destroyed.

9. At least once every 30 days, the Inventory Manager will conduct an inventory audit in each Hale O Laulima facility:

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

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

12.10.10 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.

12.10.11 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.

12.10.12 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.

12.10.13 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.

12.10.13.1 General Storage Requirements

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

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

12.10.13.2 Secure Product Storage

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

1. All marijuana and marijuana-infused products within a Hale O Laulima facility will be stored in a vault located within a limited access area;
2. All marijuana that is still in process will be stored in a secure location within a Hale O Laulima facility, to which access is limited to a minimum number of authorized personnel;
3. All vaults, security equipment, and secure areas used for the production and storage of marijuana will be securely locked and protected from entry, other than during the time required to move or replace marijuana, pursuant to §11-850-51;
4. All marijuana and infused products must be returned to a secure, locked area at the end of any process (i.e. trimming, manufacturing, etc.) or and at the end of the day (i.e. Retail Dispensary Facilities products on display);
5. If a facility process cannot be completed by the end of a working day, the facility area or tanks, vessels, bins or bulk containers containing marijuana will be securely locked inside an area that affords appropriate security and is covered by video surveillance, in accordance with §11-850-51. All marijuana and marijuana products must be stored separately with suitable identification the labels and other labeling materials for each type of marijuana or marijuana product, and the different strength, dosage form or quantity of contents; and
6. Access to marijuana products must be restricted by the Inventory Manager and the Facility Manager. Only necessary personnel must receive access rights to areas housing security equipment, marijuana, marijuana products or cash.

12.10.13.3 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.

12.10.13.4 Removal From Storage

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

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

Only by a registered employee of Hale O Laulima.

12.12 Exhibit 12: Shipping and Receiving SOP

12.11.1 Purpose

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

HAR Requirement	Description
§11-850-36.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
§11-850-74	A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.
§11-850-74.a	A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale. Eff. DEC 14 2015
§11-850-92.a	A dispensary licensee shall use packaging for marijuana and manufactured marijuana products that:
§11-850-92.a.1	Is child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;
§11-850-92.a.2	Is opaque so that the product cannot be seen from outside the packaging;
§11-850-92.a.3	Protects the product from contamination and does not impart any toxic or harmful substance to the marijuana or manufactured marijuana product; and
§11-850-92.a.4	Contains no more than ten milligrams tetrahydrocannabinol for one dose, service, or single wrapped item; provided that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
§11-850-92.b	Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:

HAR Requirement	Description
§11-850-92.b.1	Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
§11-850-92.b.1.A	Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;
§11-850-92.b.1.B	The concentration of tetrahydrocannabinol or Δ^9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;
§11-850-92.b.2	The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;
§11-850-92.b.3	the batch number and date of packaging;
§11-850-92.b.4	Includes a computer tracking inventory identification number barcode generated by tracking software;
§11-850-92.b.5	Date of harvest or manufacture and "Use by date";
§11-850-92.b.6	Instructions for use;
§11-850-92.b.7	The phrases "For medical use only" and "Not for resale or transfer to another person";
§11-850-92.b.8	The following warnings:
§11-850-92.b.8.A	"This product may be unlawful outside the State of Hawai'i and is unlawful to possess or use under federal law";
§11-850-92.b.8.B	"This product has intoxicating effects and may be habit forming";
§11-850-92.b.8.C	"Smoking is hazardous to your health";
§11-850-92.b.8.D	"There may be health risks associated with consumption of this product";
§11-850-92.b.8.E	"This product is not recommended for use by women who are pregnant or breast feeding"; and
§11-850-92.b.8.F	"Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and
§11-850-92.b.8.G	"When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
§11-850-92.b.9	A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
§11-850-92.b.10	The name of the laboratory that performed the testing; provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
§11-850-92.c	A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act. Eff DEC 14 2015

12.11.2 Local Compliance

In accordance with applicable packaging and labeling requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-850-36, 11-850-74, 11-850-92 and enforced by the Hawai'i DOH, Hale O Laulima will utilize policies and procedures to ensure patients receive medical products that assure the safety, quality, identity, purity and potency expectations of the Hawai'i DOH and end user. All shipping and receiving 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): §11-850-36, §11-850-74 and §11-850-92.

12.11.3 Definitions and Abbreviations:

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

Cannabigerol ("CBG")
Chief Executive Officer ("CEO")
Chief Operations Officer ("COO")
Code of Federal Regulations ("CFR")
Community Right to Know Act ("EPCRA")
Compassionate Use Registry ("the Registry")
Conditionally Exempt Small Quantity Generator ("CESQG")
Continuing Medical Education (CME)
Critical Process Parameter ("CPP")
Current Good Manufacturing Practices ("cGMP")
Denver Relief Consulting ("DRC")
Department of Health ("DOH")
Electro-Conductivity ("EC")
Environmental Health Agency ("EHA")
Equal Employment Opportunity Commission ("EEOC")
Equipment Testing Laboratory ("ETL")
Executive Management Team ("EMT")
Executive Vice President ("EVP")
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")
Global Positioning System ("GPS")
Good Agricultural Practices ("GAP")
Good Handling Practices ("GHP")
Hale O Laulima ("HOL")
Hawai'i Administrative Rules ("HAR")
Hawai'i Medical Use of Marijuana Act ("the ACT")
Hazard Communication Standard ("HCS")
Health Insurance Portability Accountability Act ("HIPAA")
Health Savings Account ("HSA")
High Efficiency Particulate Arrestance (HEPA)
Immediately Dangerous to Life or Health ("IDLH")
Integrated Pest Management ("IPM")
International Fire Code ("IFC")
International Organization for Standardization ("ISO")
Master Batch Record ("MBR")
Masters in Business Administration ("MBA")
National Institute for Occupational Safety and Health ("NIOSH")
National Type Evaluation Program ("NTEP")
Occupational Safety and Health Administration ("OSHA")
Oxidation Reduction Potential ("ORP")
Personal Protective Equipment ("PPE")
Photosynthetically Active Radiation ("PAR")
Quality Assurance ("QA")
Quality Control ("QC")

Quality Control Team ("QCT")
Quality Control Unit ("QCU")
Quality Management System ("QMS")
Reverse Osmosis ("RO")
Safety Committee ("the Committee")
Safety Data Sheets ("SDS")
Safety, Quality, Identity, Purity, and Potency ("SQuIPP")
Self-Contained Breathing Apparatus Type Respirators ("SCBA's")
Standard Operating Procedure ("SOP")
Superfund Amendments Reauthorization Act ("SARA")
Tetrahydrocannabinol ("THC")
Tetrahydrocannabinol Acid ("THCA")
Total Dissolved Solids ("TDS")
Ultra-Violet ("UV")
United States Environmental Protection Agency ("EPA")
United States Food and Drug Administration ("FDA")
Worker Protection Standard ("WPS")
World Health Organization - Uppsala Monitoring Center ("WHO-UMC")

12.11.4 Shipping and Receiving Overview

The Shipping and Receiving SOP describes policies and procedures for the preparation, delivery and recordkeeping of shipping marijuana products in compliance with all laws in the State of Hawai'i and the rules issued by the Hawai'i DOH. The Shipping and Receiving SOP provides supporting inventory management procedures in addition to the Inventory Management and Control SOP to ensure proper delivery of marijuana products to the permitted Retail Dispensary Facilities or Laboratory, including the tracking, recordkeeping, and reporting measures taken to ensure that all products that depart the Production facilities arrive at the appropriate Retail Dispensary Facility or Laboratory. The measures detailed include internal controls, reconciliations of shipping records with receiving records, protocols for reporting discrepancies to the Hawai'i DOH, and procedures for reconciling and taking corrective action in cases where discrepancies are identified.

12.11.5 Shipping and Receiving Policies

12.11.5.1 Authorized Transportation Activities

The Transportation Manager will authorize and oversee all transportation activities and deliveries. Authorized transportation activities are limited to:

1. Receiving products containing medical marijuana from Production Facilities;
2. Shipping products containing medical marijuana to Retail Dispensaries;
3. Shipping marijuana waste to waste disposal facilities; and
4. Shipping product samples to registered independent testing labs.

12.13 Exhibit 13: Marijuana Waste Disposal SOP

12.12.1 Purpose

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

HAR Requirement	Description
§11-58.1	"Solid Waste Management Control". 01/13/94. Note: Effective March 13, 1999, Section 54 of HAR 11-58.1 is replaced by HAR Chapter 11-279, "Standards for the Management of Used Oil"
§11-62	"Wastewater Systems" 12/09/04
§11-260	"Hazardous Waste Management". 09/22/1999
§11-850-43.a	A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.
§11-850-43.b	A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.
§11-850-43.c	A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired marijuana and manufactured marijuana products. Eff. DEC 14 2015
§11-850-61.a	A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to ADP/POS, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.
§11-850-71.b.4	Safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.
§11-850-72.b.5	Safe and appropriate storage and disposal or destruction of manufactured marijuana products at all stages of production and sale.
§11-850-75.f	A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.
§11-850-75.i	The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.
§11-850-85.f.5	Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount; and shall make all the records available to the department upon request.

12.12.1.1 Local Compliance

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

12.12.2 Definitions and Abbreviations:

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

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

12.12.3 Marijuana Waste Storage and Disposal Policies

12.12.3.1 Important Points

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

All disposed waste will be recorded in the Waste Disposal Log with details pertaining to the date of disposal, type and quantity of waste disposed of and the manner of disposal. Additional waste disposal provisions include detailed plans for excess product disposal, liquid and solid waste disposal based on guidelines from the Hawai'i DOH, composting practices, and the disposal of expired, contaminated, or otherwise unusable Marijuana products. The Production

and Retail Dispensary Facilities General Managers will also report any verifiable incident of unauthorized destruction of Marijuana to the Hawai'i DOH and law enforcement.

12.12.3.2 Marijuana Waste Storage and Disposal Procedure

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

p. Report plant waste in the ADP/POS system. Be sure to attach the plant waste to the harvest batch.
q. Sanitize and clean all used supplies and work surfaces;
r. Ensure that all required records have been entered into the ADP/POS system and that all portions of relevant internal logs have been completed;
s. Coordinate pick up with the approved disposal Hale O Laulima; and
t. Complete sections relevant to pick up in the Waste Disposal Log after pick up.

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

12.14 Exhibit 14: Patient Management SOP

12.14.1 Purpose

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

HAR Requirement	Description
§11-850-34.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

12.14.2 Local Compliance

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

12.14.3 Overview

Hale O Laulima is committed to offering qualified patients in Hawai'i with a welcoming, safe environment in which they may access high quality cannabis products and reliable educational materials. All new patients will be offered a Patient Education Packet, which will contain information about patient registration and orders in the Registry, cannabis as medicine,

methods of consumption, cannabinoids and product offerings, dosing, laboratory testing, and patient financial assistance programs, as well as a summary of applicable laws and regulations.

12.14.3.1 New Patient Registration

The Dispensary Facility Manager will ensure that all Patient Coordinators are properly trained to register new patients in the automatic data processing/point-of-sale ("ADP/POS") system, Biotrack. The Retail Dispensary Facility Manager will also ensure that herself or himself and each Patient Coordinator and Retail Dispensary Agent who must utilize the Registry is authorized to access the Registry and has successfully completed a DOH-approved course in their responsibilities related to patient confidentiality. Pursuant to §11-850-34 and §11-850-40, the Patient Coordinator will be responsible for verifying that the patient has an active registration and a current and valid physician's order when registering a new patient and upon each subsequent visit to the Retail Dispensary facility. The Retail Dispensary Facility Manager will be responsible for ensuring that upon new patient intake, any relevant Registry and contact information for the patient, and caregiver (if applicable) is entered into Biotrack and the documentation is properly attached to the patient file and securely stored in Hale O Laulima's HIPAA-compliant cloud-based storage system. When a qualified patient or patient caregiver arrives at Hale O Laulima for the first time, the person fulfilling Patient Coordinator duties will create and complete the new patient record, including an executed patient agreement.

12.14.3.2 Patient Record Information

All Retail Dispensary personnel are responsible for keeping the patient record up-to-date. Only agents authorized to make entries in Biotrack and to access the Registry may grant access to any patient or patient caregiver to the Retail Dispensary facility. The agent who grants access to the Retail Dispensary must ask the patient or patient caregiver at each visit if any changes need to be made to the patient record. The patient record will contain at a minimum:

10. The name of the patient;
11. The Registry number of the patient, or similar Registry information (to be determined once Registry is established);
12. The expiration date of the registration;
13. The date of birth of the patient;
14. The name of the designated caregiver of the patient, if applicable;
15. Documentation of any patient education and support materials provided to the patient or the designated caregiver of the patient, including, without limitation, a description of the materials and the date on which the materials were provided; and
16. Information on all orders dispensed and orders denied.

12.14.3.3 Patient Record Management

The Retail Dispensary Manager must ensure the ADP/POS system, Biotrack, complies with all laws, regulations, and Hale O Laulima policies and procedures.

1. The Retail Dispensary Facility Manager must ensure Biotrack is secure at all times and that each agent authorized to use the system has received all necessary training and has been issued unique user login credentials;
2. The Biotrack system will record all entries made, the date, and the electronic signature and unique identification number of the agent utilizing the system;
3. The patient record will maintain an audit trail and back-up system so that no initial entry can be made illegible and the record is protected from loss, damage, or authorized use.;
4. The ADP/POS system, Biotrack, features and Hale O Laulima procedures requiring verification of patient registration and order contents and will not allow an agent to dispense an amount of cannabis product in excess of the amount specified in the physician's order, to fulfill an order that has already been filled, or allow dispensing to a patient with an expired or invalid registration or their caregiver, if applicable;
5. The patient record will be made available to the DOH upon request;
6. The Retail Dispensary Facility Manager will ensure patient records are maintained for a minimum period of six (6) years after the last sales transaction recorded in the patient record;
7. Any agent dispensing cannabis product will enter dispensing actions into the Registry immediately upon dispensing the product to the qualified registered patient or patient's caregiver.
8. All agents of Hale O Laulima will be trained at least once annually on the appropriate use of the HIPAA compliant computer network, recordkeeping compliance, protection of patient confidentiality, and provisions of HIPAA. The Medical Director will develop and provide this training and periodically monitor agents for the purpose of identifying and correcting non-compliance.

12.14.3.4 Release Required for Information

If a patient would like a Patient Coordinator to discuss their treatment with anyone other than their caregiver, including their physician, they must execute an Information Release Authorization Form. The Patient Coordinator must properly document such release and maintain an original copy of the release in the patient's record. However, patient information may be released to the DOH without authorization from the patient.

12.14.3.5 Patient Management Training

Hale O Laulima will develop and implement a training program covering all aspects of patient management. All agents employed in the Retail Dispensary facility will be responsible for completing this training upon acquisition and at least once annually. Documentation of completion of this training will be maintained in the agent's file.

12.15 Exhibit 15: Access Control SOP

12.15.1 Purpose

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

HAR Requirement	Description
§11-850-32.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.3	Be accessible to authorized individuals only as identified in this chapter;
§11-850-33.c.5	Maintain a twenty-four hour security system pursuant to this chapter
§11-850-33.c.6	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.7	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.c.8	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	Retail dispensing locations shall not:
§11-850-33.d.1	Provide free samples of marijuana or manufactured marijuana products;
§11-850-33.d.2	Dispense marijuana or manufactured marijuana products as premade or manufactured cigarettes or in any form prepared specifically for smoking or inhaling; or
§11-850-33.d.3	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.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.

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
§11-850-37.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
§11-850-51.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:
§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 al exits and entrances to a dispensary facility from both indoor and outdoor locations;
§11-850-51.a.1.E	The surveillance system video recording storage device shall be secured in a lockbox, cabinet, or closet, or secured in another manner that limits access to protect the system from tampering or theft; and
§11-850-51.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

HAR Requirement	Description
	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

12.15.2 Local Compliance

In accordance with applicable security related requirements as defined by Hawai'i Administrative Rules Chapter(s): 11-850-32 through 11-850-34, 11-850-37, 11-850-51, 11-850-52, 11-850-53 and enforced by the Hawai'i Department of Health (DOH), Hale O Laulima will strictly prohibit access to any of the following areas: production, processing, sales and storage areas at all Hale O Laulima facilities to only authorized individuals. All controlled access 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, §11-850-37 and §11-850-51 through §11-850-53. Additionally, Hale O Laulima establishes that no person shall intentionally or knowingly enter or remain upon the premises of a medical marijuana retail dispensing or medical marijuana production center unless the person is:

1. An individual licensee, onsite security guards, or registered employee of the production center;
2. A government employee or official acting in the person's official capacity; and
3. Previously 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, including but not limited to construction, maintenance, repairs, legal counsel, or investors; provided that they meet the additional requirements defined in the HRS:

12.15.3 Definitions and Abbreviations:

Air-Conditioning ("A/C")

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

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

12.15.4 Access Control Policies and Practices

A central component of security is restricting access to the facilities and all internal areas of Hale O Laulima's facilities containing marijuana or manufactured marijuana products in any form. All Hale O Laulima personnel will be responsible for complying with company policies related to facility access, and for preventing unauthorized persons from entering limited access areas.

Company-wide policies and practices for controlling Production and Retail Dispensary Facility access are listed below:

1. Hale O Laulima will only cultivate, process, store, dispense and perform any other activity involving marijuana in DOH-approved facilities which will be enclosed, locked, and will protect all operations from external view as to prevent diversion, theft, loss, or community disturbance;
2. No person(s), except Hale O Laulima personnel, local law enforcement, DOH representatives, and other relevant authorities, when necessary to perform their

governmental duties, will be allowed on the premises of any Hale O Laulima facility, with only a few exceptions:

a. Qualified registered patients and patient legal representatives with an unfilled marijuana product order may access certain areas of any Retail Dispensary facility ONLY upon presenting their medical certification as well as two forms of identification checked against the validated list of qualified patients/caregivers and stored in the company's automatic data processing/point of sale (ADP/POS) system. Patients and caregivers will be escorted while in limited access areas, including the sales area, at all times by Retail Dispensary personnel;
b. Representatives of Hale O Laulima's selected independent testing laboratory can enter Hale O Laulima facilities, including Production, to identify and collect marijuana samples for laboratory testing;
c. Emergency personnel, who will enter Hale O Laulima facilities when necessary to perform their duties;
d. Approved contractors who may enter to complete a defined task or may be given access on a temporary basis; and
e. Authorized visitors, including vendors, service providers, approved third-party trainers, and other similar persons, who have arranged to come to the facility ahead of time and received approval from the DOH and the Chief Operating Officer.

3. Employees will not allow any other person on site without first gaining approval from the company President/CEO or approved manager; only managers may grant facility access. Any person refusing to leave the premises should be considered an incident in violation of Hale O Laulima policy and trespassing. In any incident involving trespassing or invasion, the manager must contact local law enforcement and the Security Manager as soon as possible;
4. All Hale O Laulima employees will visibly display their DOH issued identification card at all times while on any facility premises;
5. Any employee who misplaces, loses, or has their key fob access control and identification card stolen will immediately notify their supervisor and the Director of Security, who will provide a temporary replacement while a new card is ordered and shipped. Upon notification, the Director of Security will immediately deactivate the missing key fob and retain records of all activations and deactivations. Multi-offenses (lost or misplaced key fobs) may result in disciplinary action, up to and including termination;
6. In accordance with Hale O Laulima's Visitation Protocol, all visitors must identify themselves, provide information to sign in and out of the facility in an internal log, visibly display a visitor identification badge at all times, and be escorted by Hale O Laulima personnel at all times. Visitors will be required to comply with all applicable laws, regulations, and company policies and procedures at all times as a condition of facility access. Visitor access will be rare and limited to only those that are absolutely necessary to conduct business;
7. Only authorized Hale O Laulima employees or other authorized persons escorted by a Hale O Laulima employee will access limited access areas (i.e., areas that may contain marijuana, manufactured marijuana products, or sensitive information, equipment, or supplies);

8. The Director of Security will be responsible for assigning and recording access privileges. Access to limited access areas, and thereby to all marijuana and manufactured marijuana products, will be restricted to the minimum number of specifically authorized Hale O Laulima personnel necessary for efficient operations;
9. All doors without electronic access control equipment will be re-coded or re-keyed annually and following any termination of a Hale O Laulima employee, if the employee poses a security threat; and
10. Architectural security features and engineering security systems will be maintained and utilized at all times to deter, prevent, and promptly detect unauthorized access to any Hale O Laulima facility or sensitive interior space.

12.15.5 Limited Access Areas

Limited access areas include all internal spaces of Hale O Laulima's Production and Retail Dispensary Facilities in which marijuana or manufactured marijuana products in any state are cultivated, processed, dispensed, handled, packaged, or otherwise present, and where product constituents, production equipment and supplies are stored. The majority of each Production and Retail Dispensary Facility is considered a limited access area; only select administrative spaces and Retail Dispensary waiting rooms are not limited to authorized personnel or approved visitors escorted by authorized personnel. The access control system described below limits access into all secure areas in each facility, and additionally limits employee access to restricted access spaces, as dictated by the Director of Security.
Hale O Laulima will provide posted signs at all entryways of limited access areas that will be a minimum of 12" x 12" and that states "Do Not Enter – Limited Access Area - Access Limited to Authorized Personnel Only" in lettering no smaller than one inch in height. These Executive Managers will be issued a visual pass with the words "LIMITED ACCESS" in bright red against a white background affixed to a neck chain for quick and easy recognition of access level

12.15.6 Restricted Access Areas

Within the limited access area, access will be further restricted to the secure product storage room(s), record storage room(s) and the security room(s) containing surveillance monitoring and storage equipment and other security equipment; these will be considered restricted access areas. Restricted access areas will be limited to the absolute minimum number of managers, officers, and directors necessary. Hale O Laulima will post signs at all entryways of restricted access areas that will be a minimum of 12" x 12" and that states "Do Not Enter – Restricted Access Area - Access Restricted to Authorized Personnel Only" in lettering no smaller than one inch in height. Employees and onsite guards will be issued a visual pass with the words "RESTRICTED ACCESS LEVEL 2" in green against a white background affixed to a neck chain for quick and easy recognition of access level.

12.15.7 Access Privileges

Access privileges will be awarded through the access control system described below. Hale O Laulima employees will only be awarded access privileges to the facilities and areas within their facility of employment that are relevant to their work tasks. The Director of Security will consider the level of security risk and the degree of necessity for access when awarding employee access privileges. The Director of Security is responsible for assigning and recording access rights, while the access control system will also record entries to the facility and all restricted and limited access areas.

12.15.7.1 Inter-Facility Access (Production)

Access control will be especially important in the Production Facilities, which will house Hale O Laulima's Medical Marijuana Production and Processing operations. As these operations are distinct and will be staffed by distinct groups of people, facility boundaries will be established and maintained for security reasons, but certain persons must be able to cross facility boundaries to fulfill their duties. The access control system will be the key mechanism used in the vertically-integrated building to establish facility boundaries and selectively award and deny inter-facility access on an individual basis to promote operational efficiency while also maintaining product and facility security. All non-essential personnel will be issued a visual pass in black against a white background affixed to a neck chain for quick and easy recognition of access level.

12.15.8 Access to Protected Information

Access to protected information will be restricted to authorized managers, as determined by the Director of Security and Chief Operating Officer. Examples of protected information include:

1. Access control and surveillance equipment locations and records;
2. Network data and credentials;
3. Floor plans of critical areas;
4. Password and code records; and
5. Employee records.

12.15.9 Temporary Access

Only Hale O Laulima's executive and general management personnel may grant temporary access to an authorized visitor such as laboratory staff, emergency personnel, DOH representatives and documented contractors pursuant to 329D-15 and 329D-16 of the HRS. All visitors must adhere to the Visitation Protocol.

12.15.10 Authorized Parties

Hale O Laulima will immediately grant access of entry to all areas of the Production and Retail Dispensary Facility to members of the DOH, law enforcement, and other valid Federal, State or local government officials in compliance with 329D-15 and 329D-16 of the HRS. DOH

representatives and law enforcement officials must adhere to the Visitation Protocol. Upon request, Hale O Laulima will immediately provide current copies of the Production or Retail Dispensary Facility floor plans to the authorized requesting parties.

12.15.10.1 General Visitor Policies

12.15.10.1.1 Visitor Restrictions

Only Hale O Laulima personnel, DOH representatives, law enforcement officials, other officials acting in the course of their duties, outside vendors, contractors, and authorized visitors may access Hale O Laulima facilities. Individuals who have valid reasons to visit the Hale O Laulima facilities but are not employed by Hale O Laulima are defined as visitors.

12.15.10.1.2 No Unannounced Visitors

Aside from DOH representatives and other designated officials operating within the limits of their positions, Hale O Laulima facilities will not accept unannounced visitors. Any unauthorized person will be denied access to the facility and law enforcement will be contacted as necessary to remove unauthorized individuals from the premises.

12.15.10.1.3 Visitor Badge

The employee logging in a visitor must obtain a copy of current and valid identification (driver's license, official badge, etc.) for each visitor and attach it to the Visitor Log. A visitor identification badge must be issued to a visitor and clearly displayed by the visitor prior to entering any limited access area. The visitor badge must be returned to Hale O Laulima upon exit. The employee issuing the badge is responsible for ensuring the badge is returned. If a visitor badge is not returned, the employee must notify the facility manager immediately and the facility manager must record the badge number as missing including the information of the visitor the badge was issued to.

12.15.10.1.4 Lost Visitor Badge

Visitors must be notified by any employee issuing the visitor badge that if the visitor loses their provided badge, they must immediately notify an employee.

12.15.10.1.5 Visitors Must Be Accompanied

All visitors must be accompanied by a manager or their designated employee at all times in limited access areas.

12.15.10.1.6 Visitor Procedures

All employees are required to comply with the following procedures when a visitor arrives at the facility:

1. When a visitor arrives, employees will ask a visitor's name, reason for visit and point of contact at Hale O Laulima. If it becomes clear that the visit was unannounced or

unauthorized, the employee ask the visitor to leave the premises and contact law enforcement if the individual refuses to leave;

2. Obtain management approval for visitor access. If approved, the manager will select an employee to escort the visitor or will choose to escort the visitor personally;
3. Ask the visitor to provide a valid photo ID and scan it. DOH officials and law enforcement officers must be asked to show an official identification card. Scanned IDs will be entered into recordkeeping system, as instructed during training;
4. Verify that the ID matches the person, that the ID is not expired, and verify the authenticity of the visitor's ID card in accordance with training;
5. Hand the visitor a laminated visitor badge and ask visitor to wear the badge around neck in a manner that ensures that the badge is visible above the waist at all times (i.e. cannot be in shirt pocket or under shirt). Explain that the badge is property of the company and it must be returned before leaving;
6. Ask the visitor to fill out the Visitor Log. The visitor must fill in Date, Visitor Badge #, Visitor Name, Visitor Signature, Reason for Visit, and Time In;
7. Fill in Escort Initials and ID Checked on Visitor Log;
8. The Hale O Laulima employee serving as the visitor's escort must accompany the visitor at all times; and
9. Ensure that the visitor records the time out on the Visitor Log and returns the visitor badge before leaving the facility.

12.15.11 Access Issuance

To maintain a secure facility, the following policies and procedures will be implemented:

1. Access will be given only to areas where need can be demonstrated. Facility keys, alarm codes and electronic access control key fobs will only be issued by the Human Resources Manager and Director of Security, depending on the employee's level of authorization. Issuance will be recorded by the issuing individual in internal logs and systems, and these records will be maintained indefinitely;
2. Alarm codes may not be transferred or shared. Key fobs and facility keys will not be loaned, transferred, or shared and may not be left unattended. All key fobs issued on a "permanent" basis should be retained in the possession of the employee to whom issued. Key fobs and facility keys will not be transferred directly from one employee to another;
3. Any employee losing a key fob, alarm code or facility key will report the loss to the Director of Security. The Director of Security will deactivate any lost key fob immediately and make a determination as to whether the system has been compromised and whether re-coring or re-coding is required; and
4. Only in an emergency will a manager issue a key, alarm code or key fob. When a key is issued under these circumstances, the Director of Security will notify the Human Resources Manager as soon as possible.
5. Key fobs will be ordered from a third-party vendor; not produced on site.