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provide this information to State users in a single, easily accessible report by licensees and overall summary at the state level.			
The ability to generate a receipt, in real time, at the point of sale and maintain the copy of the receipt and the sale transaction for at least six years.			
The ability for the registered organization to capture and report a reason for not dispensing to a patient.			
Point of Sale Sub-Section			
The ability to integrate with external data sources, in real time, to verify the validity of the patient's Registry ID Card.			
The ability to automatically enforce state and patient sales limits across all licensed dispensaries regardless of which licensed dispensary the MMJ or manufactured MMJ products were purchased.			
The ability to track product returns to the dispensing facility or registered organization, including reason for return and fate of returned product.			
The ability to generate a unique serial number for each dispensing transaction.			
Include a certification and testing program to ensure that licensees can correctly use the web service interface to submit data to the system.			
Any additional information from Offeror to describe how the proposal meets the requirements of this section ("Functional Requirements"). A separate document, clearly labeled and appended to this Exhibit may be used.			

Security Requirements

Mandatory Qualification	Met/Not Met	Available Y/N?	Est. Cost
Must have a user-based security model that allows licensees to only view data collected for that individual licensee.			
Must also allow department staff or designees to view data for all Marijuana Licensees based on specified search criteria.			
Any additional information from Offeror to describe how the proposal meets the			

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Steep Hill List of Tested Compounds and Contaminants

1) Arsenic
2) Lead
3) Cadmium
4) Mercury
5) Delta-9 Tetrahydrocannabinol
6) Tetrahydrocannabinolic Acid
7) Cannabinol
8) Cannabidiol
9) Cannabidiolic Acid
10) Cannabigerol
11) Butanes and relevant isomers
12) Heptanes and relevant isomers
13) Benzene
14) Toluene
15) Xylenes
16) Hexane
17) Foreign non-plant material
18) Moisture
19) All pesticides regulated by the EPA
20) Mycotoxins including Aflatoxins and Ochratoxin.
21) Total aerobic bacterial count
22) Total yeast and fungal count
23) Bile tolerant gram negative bacterial and coliforms
24) E. Coli
25) Salmonella
26) Aspergillus fumigatus
27) Aspergillus flavus
28) Aspergillus niger
29) Any other analyte deemed by the state or LNP to be a threat to public health or product quality.

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1/12/2015

Reference: BioTrackTHC Support Document and Letter of Intent
Lau Niu Poko

Dear James,

BioTrackTHC provides effective cutting -edge technology solutions for the emerging legal marijuana industry. Solutions that not only prevent product theft, but assist business owners in running their cultivation, processing, packaging, and retail operations more profitably and more legally compliant. Furthermore, this is all done without leaving sensitive business and consumer data vulnerable in the cloud. Specifically, BioTrackTHC is the industry's only true seed--to--sale software system with enterprise resource planning, complete inventory tracking, point--of--sale, marketing, financial reporting and regulatory compliance features. Subsequently, because it is a server -based system with advanced security features, customers can rest assured that no one,- not even the BioTrackTHC team,- can access their business or consumer information without their permission.

This document confirms BioTrackTHC's intentions to enter into a formal agreement with Lau Niu Poko to provide software solutions guaranteed to meet published Hawaii Department of Health reporting, regulation, and compliance guidelines for cannabis production facilities in the event that an authorized license is obtained.

Thank you for your consideration of BioTrackTHC. We are eager to assist you in your efforts to acquire a license and look forward to entering into a software solution agreement with you upon receipt of that license.

Best Regards,

Moe Afaneh
Chief Operating Officer

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Hawaii HB 321

(A) Secure inventory tracking and control;
(B) Protecting confidential customer information;
(1) Ability to comply with the requirements in this chapter and chapters 329 and 3290, HRS, for inventory tracking, security, and sales limits for qualifying patients;
(1) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;
(2) Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 3290-7 and 3290-8, HRS;
(3) Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;
(4) A plan for secure disposal or destruction of marijuana and manufactured marijuana products;

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

(a) A dispensary licensee shall not transfer any marijuana or manufactured marijuana products to any other dispensary.

(b) A dispensary licensee shall not accept any marijuana or manufactured marijuana products from any other dispensary.

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NO pre-rolls, no samples, no paraphernalia

§11-850-35 Employee records

(a) A dispensary licensee shall have available at each dispensary facility a time clock or other adequate method to record the month, day, year, and time that each employee arrives at and leaves the facility.

(b) Time record entries shall be made at the time an employee reports for duty and again when the employee goes off duty and at any time the employee leaves and returns to the premises for any reason.

(c) A dispensary licensee shall maintain all employee records, including the specific employee training provided and hours worked.

The Time Clock function within BioTrackTHC records the date and time that every employee clocks into and out of the system. A manager can be granted the permission within the system to modify the clock in/out times for an employee in the event of an error or someone forgetting to clock out.

[redacted]

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[redacted]

BioTrackTHC provides functionality for Cultivators, Processors and Dispensary Licensees to create transfer manifest documents. Transfer manifests will be stored and tracked by the System. Input data may include, but is not limited to, the following fields: ship from name, license number and route description. For each item include destination address, destination name, license number, address, product description, product ID and lot number, quantity and units of measure. Transfer manifests will be used as shipping documents for transfers between locations within an organization or sales between Licensees.

(b) A dispensary licensee shall give the department access to all parts of the dispensary property, equipment, records, documents, and any other substance, material, or information relevant to ensure the dispensary licensee's compliance with this chapter, upon request.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-38 Reports.

(a) A dispensary licensee shall submit quarterly reports on January 15, April 15, July 15, and October 15.

If the due date for submitting a quarterly report falls on a Saturday, Sunday, or State holiday, the report will be on time if it is submitted on the next day that is not a Saturday, Sunday, or State holiday. Reports shall be submitted on a form and in a manner prescribed by the department.

(b) Reports shall include but not be limited to:

1. Records of entry and exit for all individuals who entered a dispensary facility;

[redacted]

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2. Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
3. Amounts by category of marijuana and manufactured marijuana products sold;
4. A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
5. A summary financial statement;
6. Laboratory results of all tests conducted;
7. Description of any breach or halt in its security system and tracking system; and
8. Any other information requested by the department.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-39 Audits

(a) A dispensary licensee shall obtain an independent financial audit annually, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.
(b) The report shall be completed and submitted to the department no later than sixty days prior to the end of the license expiration date, or at another time as the department may direct.
(c) When a license is revoked, suspended, surrendered, or expires, a dispensary licensee shall file a final report thirty days following revocation, suspension, surrender, or expiration.

In the course of doing business, a user can perform inventory audits to confirm or adjust what's showing in your inventory and what the user actually has on hand. After clicking on the Inventory Audit Icon a list will populate showing all of the items for inventory in the current inventory room. If the user wishes to run a "Blind Audit" this will prevent the employee from seeing the original weights or any differences. The Inventory Shrinkage report allows you to total loss across various products for a given time period with a threshold to ignore adjustments outside of a certain increment (mistakes).

§11-850-41 Record retention.

(a) A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:

(1) Inventory tracking including transport of marijuana and manufactured marijuana products;

(2) Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
(3) Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
(4) Logs of entry and exit for dispensary facilities; and
(5) Employee records.

(b) A dispensary licensee shall retain for a minimum of one year all security recordings.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity. All inventory records, patient records, recall reports, sales/transaction records, product disposal records, and all scanned documents can be accessed at any time (real time), either in-system or through the report creation tool. Though system actions can be adjusted or voided, at no time is any data ever fully deleted as BioTrackTHC™ maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

§11-850-42 Allowed quantities for dispensing.

(a) A dispensary licensee may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four ounces of marijuana during a period of fifteen consecutive days, and shall not exceed eight ounces of marijuana during a period of thirty consecutive days .

(b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter.

Within "Sales Limits" a user can regulate the permissible quantities allotted to a patient or caregiver.

§11-850-43 Disposal or destruction.

(a) A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the

cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.

(b) A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.

(c) A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired marijuana and manufactured marijuana products.

During or after a Harvest or Cure, a user would create a batch for the "green waste" which would include broad leaf trim, and stems that weren't going to be converted into a concentrated format. All waste would be weighed, given it's own 16-digit barcode, which is permanently stored in the system prior to it being destroyed. When a BioTrackTHC user sends a sample for Quality Assurance testing and the sample does not meet minimum standards, a user may; 1) Place the product into quarantine for destruction, or, 2) Convert the product into a different format. If the user converts the non-conforming sample and originating lot, the new converted product must be retested.

§11-850-61 Tracking requirements

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable . The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

PRODUCTS AND PRODUCT STANDARDS

§11-850-71 Marijuana.

(a) A dispensary licensee may dispense marijuana only in the form of dried matured processed flowers of female cannabis plants.

§11-850-72 Manufactured marijuana products.

(a) A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

§11-850-74 Equivalent weights for manufactured marijuana products.

(a) A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.

(b) A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale.

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BioTrackTHC is a complete inventory control system that also creates a searchable, secure, tamper-evident record of each and every action performed within the system. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

LABORATORY CERTIFICATION, TESTING, AND STANDARDS

§11-850-81 Laboratory testing required.

A dispensary licensee shall not dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter.

§11-850-85 Laboratory standards and testing

(a) A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-proof manner a similar sample from the same batch, for verification testing as directed by the department.

(a) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things for which it is certified. The certificate of analysis shall include the results with supporting data for the following:

(1) The chemical profile of the batch for the following compounds:
- (A) 9 (delta 9) - Tetrahydrocannabinol (THC)
- (B) Tetrahydrocannabinol Acid (THCA)
- (C) Cannabidiol (CBD)
- (D) Cannabidiolic Acid (CBDA)
- (E) Cannabigerol (CBG)
- (F) Cannabinol (CBN)

(2) The presence of the following contaminants, which shall not exceed the following levels:
- (A) Heavy metals:
  - (i) Arsenic 10.0 ppm
  - (ii) Lead 6.0 ppm
  - (iii) Cadmium 4.0 ppm (iv) Mercury 2.0 ppm

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(B) Pesticides regulated by the U.S. Environmental Protection Agency: 1.0 ppm

(C) Solvents:

(i) Butanes 800 ppm

(ii) Heptanes 500 ppm (iii) Benzene** 1 ppm

(iv) Toluene** 1 ppm (v) Hexane** 10 ppm

(vi) Total Xylenes

(m,o,p-xylene) 1 ppm

** Contaminants in solvents

(D) Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;

(E) Moisture content of plant material <15%

(F) Microbiological impurities, including but not limited to:

1. Total Viable Aerobic Bacteria:
   a. Unprocessed and Processed Materials: 105 Colony Forming Unit (CFU)/g
   b. C02 and Solvent Based Extracts: 104 CFU/g
2. Total Yeast and Mold:

(a) Unprocessed and Processed Materials: 104 CFU/g

(b) C02 and Solvent Based Extracts: 103 CFU/g

(iii) Total Coliforms:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(iv) Bile-tolerant Gram Negative Bacteria:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(v) *E. coli* (pathogenic strains) and *Salmonella spp.:* Not detected in 1 g

(vi) *Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger :* <1 CFU/g;

(vii) Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and

(3) Additional testing requested at the discretion of the department.

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The above information can all be generated within BioTrackTHC and reflected on the label for each product.

(d) The certified laboratory may retest or reanalyze ,the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense.

(e) The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of marijuana or manufactured marijuana products that remain after testing and analysis are completed.

(f) A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana products, including but not limited to:

1. The time and date the sample was obtained;
2. A description of the sample, including the amount;
3. What tests were conducted on each sample;
4. The results of the tests including the certificate of analysis; and
5. Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount;
6. and shall make all the records available to the department upon request.

(g) A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection (c), and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.

(h) A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.

(i) The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.

(j) A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon

receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c).

BioTrackTHC automatically syncs testing data upon receipt from a certified testing location. Testing will ensure the product is free of contaminants with consistent THC and/or CBD levels. Furthermore, every plant interaction is recorded, including but certainly not limited to what additives are used and when, allowing cultivators to replicate results or make applicable changes to increase plant quality and consistency. BioTrackTHC syncs testing data to the applicable plant batch or barcode for easy display and retrieval. To simplify the process that information can be directly ported onto the associated product labels.

All aspects of the marijuana plants, byproduct wastes, weights, ID numbers and associated data is stored in the system indefinitely. Destruction event information and explanations are also documented and stored within the BioTrackTHC system. This data cannot be modified or deleted by the cultivation center employees or even by BioTrackTHC.

BioTrackTHC records manual inventory adjustments through a detailed notes section. The reason for disposal and, if applicable, disposal company are recorded and archived to the 16 digit barcode associated with the disposed cannabis. As with all transactions in the BioTrackTHC system, the employee responsible for the transaction is required to enter a PIN number or biometric fingerprint recording the date, time, and reason for the transaction.

§11-850-92 Packaging and labeling for retail sale.

(b) Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:

(1) Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:

(A) Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;

(B) The concentration of tetrahydrocannabinol or 9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;

(2) The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;

(3) The batch number and date of packaging;

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(4) Includes a computer tracking inventory identification number barcode generated by tracking software;
(5) Date of harvest or manufacture and "Use by date";
(6) Instructions for use;
(7) The phrases "For medical use only" and "Not for resale or transfer to another person";
(8) The following warnings:
(A) "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";
(B) "This product has intoxicating effects and may be habit forming";
(C) "Smoking is hazardous to your health";
(D) "There may be health risks associated with consumption of this product";
(E) "This product is not reconunended for use by women who are pregnant or breast feeding";
(F) "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
(6) A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
(9) The name of the laboratory that performed the testing;
provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
(c) A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.

BioTrackTHC™'s label creation tool enables licensed producers to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale.

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Hawaii Medical Marijuana Dispensary License Application Support Document

The format of the application asks for one's education, knowledge and experience with the sections outlined below, among others. The information contained within this document is to be used to assist an applicant with answering the questions that fall within the scope of the capabilities of BioTrackTHC; i.e. inventory tracking, sales limits, labeling, etc.

No guarantees or warranties, either expressed or implied, are associated with this document.

I) Secure inventory tracking and control

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

(4) Ability to comply with the security requirements of Chapter 11-850 and Section 329D-7, HRS;

(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;

This is the responsibility of the licensee.

(7) Ability to comply with the requirements in Chapter 11-850 and Sections 329 and 329D, HRS, for inventory tracking, security, and dispensing limits for qualifying patients;

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SUBCHAPTER 5
TRACKING REQUIREMENTS

§11-850-61 Tracking requirements.

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

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

The BioTrackTHC System issues a globally unique, non-repeating 16-digit identification number to each plant. At every stage in the product lifecycle where something needs to be differentiated, the System issues a new "child" identifier (e.g., separating flower from stems during the harvest process, separating edible batches that are going to different dispensaries, the creation of new clones or seeds from a mother plant, etc…). The System issues the identifier to prevent accidental or intentional identifier duplication by the user, and the 16-digit identifier ensure scalability and longevity—the System could generate 1,000,000 identification numbers per second and it would not run out of unique identifiers for over 317 years.

Every identifier is associated with a quantity that is measured in either discrete units or a weight depending on the item's classification; for example, plants, seeds, and infused edibles are measured in discrete units, whereas, bulk flower and stems are measured in continuous weight. This creates an unbroken audit chain. Select any identification number and both the State and the registered organization can backwards-trace the medical cannabis product's lineage all the way

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back to the plant from which it came, and also forwards-trace every gram to where it is still in inventory, where it has been dispensed, to whom it was dispensed, and where it was destroyed.

As an example, if 100 grams were harvested from plant 98765: in this case, 2 grams were consumed by the testing laboratory, 8 grams were dispensed to patient Smith, 15 grams were dispensed to patient Jones, 55 grams are still in inventory, and 20 grams have been destroyed.

Laboratory testing is built-in and tied directly into the inventory typing system. This allows for very complex or very simple rules on what needs to be tested, what the testing requirements are, the pass/fail limits, etc. This testing paradigm provides a model for ensuring that only properly tested product may be sold to a patient. The system's integrated features can be setup to prevent the sale or transfer of product that has not passed state mandated laboratory tests, if necessary.

(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

Within "Sales Limits" a BioTrackTHC user can regulate the permissible quantities allotted to a patient or caregiver. The system stores patient purchases and cross-references with any Department defined limits. As the system will be recording every transaction, this data can be

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parsed, filtered and reported against at any time. The system can also issue stop purchase alerts if a patient attempts to exceed said defined limits and disallow the completion of such a sale.

In the event that a patient has exceeded their purchasing limit; the retail dispensing location will be notified within the Tracking System that the patient has exceeded their sales limit; in response, the System will issue a stop purchase alert. The System does not allow for a retail dispensing location to transact with a patient that has exceeded their pre-defined sales limit.

(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

BioTrackTHC is the winner apparent to the state contract for Hawaii's computer software tracking system for the medical marijuana dispensary system based on and in compliance with Chapter 329D HRS. BioTrackTHC's commercial software provides seamless data exchange integration between a licensee and the state's marijuana tracking system. There will be integration via the application program interface (API) between the registered organization's BioTrackTHC enterprise system and the state interface utilized by the Hawaii DOH. This will

allow data to be sent in real time, not only from the registered organization to the state, but it will allow the registered organization to retrieve transferred data by Hawaii DOH.

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

In the event of a loss of internet access, BioTrackTHC has the ability to operate in Offline mode. While operating in Offline mode a facility may continue to process sales with an on-site server, even if the internet connectivity goes down. When service is restored, all changes made in Offline mode will be updated and synced within the system.

(8) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

BioTrackTHC provides record retention of patient data including purchases and medical information that is voluntarily offered by the patient. Confidentiality of a patient's medical information is the responsibility of the licensee and their staff.

(10) Ability to comply with requirements for packaging, labeling, and chain of custody of products

Labels for medical marijuana and medical marijuana products will be labeled using only black lettering on a white background with no pictures or graphics[i] and will include:

a) Net weight in ounces and equivalent physical weight of the marijuana used to produce the product.
b) The concentration of tetrahydrocannabinol or tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol; as well as the name of the laboratory that performed the testing
c) The dispensary licensee's license number and the name of the production center
d) The batch number and date of packaging
e) A computer tracking inventory identification number barcode generated by tracking software.
f) Date of harvest or manufacture and Use By Date
g) Instructions for use
h) The phrases: "For medical use only"; "Not for resale or transfer to another person"; "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law", "This product has intoxicating effects and may be habit forming"; "Smoking is hazardous to your health"; "There may be health risks associated

with consumption of this product"; "This product is not recommended for use by women who are pregnant or breast feeding"; "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"; and a disclosure of the type of extraction method including any solvents, gases, or other chemicals used (if applicable)

BioTrackTHC's label creation tool enables licensees to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

The following list contains the fields already integrated into BioTrackTHC. Should the State desire additional fields, BioTrackTHC will create and implement those fields per request.

- Custom Text Fields
- Images
- Lines
- Additives
- Barcode
- Batch #
- Custom Batch #
- Customer MMJ #
- Customer Name
- Date
- Date and time
- Employee Name
- Employee License #
- Grow License #
- Harvest Date
- Inventory Grade
- License #
- MITS ID
- Package Date
- Package Weight
- Plant Birthdate
- Product Expiration
- Product Ingredients
- Product Name

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- Strain
- Strain Type
- Testing Date
- Testing Lab
- Usable Weight
- Weight
- Test Results
  - All Available
  - CBC
  - CBD
  - CBD-A
  - CBG
  - CBN
  - D8-THC
  - D9-THC
  - D9-THC-A
  - H2O
  - Heavy Metals
  - Mold
  - Mildew
  - Total THC
  - Total Cannabinoids

(11) A plan for secure disposal of marijuana and manufactured marijuana products;

The BioTrackTHC MMJ Tracking System tracks and reports on all disposal of marijuana and marijuana products within a licensed facility. The System allows for the adjustment of inventory quantities as the result of both non-sales operational activities (such as disposal, wastage, moisture loss, mistakes, and inventory audits) and external factors (such as theft and seizure by law enforcement). Data related to disposal information may include, but is not limited to: the amount disposed, reasons for disposal, day/time, identity of the employee(s) conducting the disposal, and manner of disposal in addition to all product-related data such as inventory classification, etc.

(12) Ability to ensure product safety, in accordance with Chapter 11-850 and Sections 329D-8, 329D-10, 329D-11, HRS.

After a testing laboratory has entered sample test results into the System, the licensee retrieves the testing laboratory results and the System applies those results to the original lot from which

the sample came. Only if the inventory item has a status of "Passed QA" can it be placed on a manifest. A registered organization user cannot, under any circumstance, place an item on transportation manifest if that item requires testing and does not have a "Passed QA" status (e.g. not yet tested or failed testing).

Response to Criterion 10

"Packaging, Labeling, Signage, and Chain of Custody"

Launiupoko Farm

From Julie Okada, Individual Applicant, and Launiupoko Farm, LLC, Entity Applicant with the technical assistance of James Anthony Technical Assistance Consulting (JATAC), consultant.

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ATTACHMENTS:

10-A: Endnotes
10-B: Compliance Checklist
10-C: BioTrackTHC Supporting Documents
10-D: Patient Focused Certification Information

Criterion 10 Language

Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products; Response shall be no longer than three (3) pages.

We at Launiupoko Farm with our dedicated team of expert consultants from James Anthony Technical Assistance Consulting ("JATAC," and both collectively, "we") have the ability to meet and exceed the requirements for signage, packaging, labeling, and chain of custody of products, as demonstrated in this Response. Endnotes throughout the text show compliance with relevant cited HAR and HRS (Hawaiʻi Administrative Rules and Hawaiʻi Revised Statute) sections, and are listed separately as **Attachment 10-A** and in Compliance Checklist form as **Attachment 10-B**.

We will use packaging which meets all established requirements

The primary goal of our packaging plan is to ensure the safety of our patients and the Maui community. In order to achieve this goal we will work closely with our team of expert consultants from James Anthony Technical Assistance Consulting (JATAC) to meet and exceed the requirements. We will test all packaging material. A sample of two individual units for every 100 pieces of packaging will be selected by the Production Manager, or their designee, when we get the packaging and each quarterly inventory review.[1] These will be randomly selected from different locations within the 100 pieces. Each sample will be tested to ensure that it qualifies as child-resistant packaging per 16 C.F.R. §1700,[2] is opaque,[3] will protect the contents from contamination, and not impart any toxic or deleterious substance.[4]

If the packaging meets all regulatory and additional internal requirements, it will be recorded in BioTrackTHC. The packaging components will then be identified with a distinctive code for each lot in each shipment received and will be stored by package type and size. Packaging materials will be stored in sealed containers that are only accessed when they are about to be used. All handling of packaging and components will be done by an employee either wearing new gloves or with freshly scrubbed bare hands.

No product will contain more than 10 milligrams of tetrahydrocannabinol (THC) for one dose, serving, or single wrapped item.[5] No package will contain more than 100 milligrams of THC per pack or container.[6]

We will use BioTrackTHC to create compliant labels and inserts

Our inventory control system, BioTrackTHC, will automatically generate labels that will fully comply with State of Hawai'i requirements (see **Attachment 10-C**: BioTrackTHC Supporting Documents). Its label creation tool enables us to create custom container labels. BioTrackTHC will automatically print the container specific label during packaging or upon completion of the sale. Labels for medical marijuana and manufactured marijuana products (MMPs) will use black lettering on a white background with no pictures or graphics[7] and will include: a) net weight in ounces and equivalent physical weight of the marijuana used to produce the product;[8] b) the concentration of THC or Δ9-THC, total THC and activated THC-A, and cannabidiol;[9] c) the name of the laboratory that performed the testing;[10] d) the dispensary licensee's license number and the name of the production center;[11] e) the batch number and date of packaging;[12] f) a computer tracking inventory identification number barcode generated by BioTrackTHC;[13] g) date of harvest or manufacture[14] and Use By Date;[15] h) instructions for use;[16] and i) the phrases: "For medical use only"; "Not for resale or transfer to another person."[17] No marijuana or MMPs will be labeled as organic unless it meets standards and is permitted through the Organic Food Product Act.[18]

The following information will appear on a package insert:[19] a) the warnings: "This product may be unlawful outside of the State of Hawai'i and is unlawful to possess or use under federal law", "This product has intoxicating effects and may be habit forming"; "Smoking is hazardous to your health"; "There may be health risks associated with consumption of this product"; "This product is not recommended for use by women who are pregnant or breast

feeding"; "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";[20] and b) a disclosure of the type of extraction method including any solvents, gases, or other chemicals used (if applicable).[21]

We will comply with all signage and display requirements

To show both patients and law enforcement that we are a lawfully licensed dispensary, we will display our dispensary license at all times in all locations.[22] We will also display all relevant technical licenses or permits related to manufacturing at our production center.[23]We will not post signs visible from outside, except one sign smaller than one thousand six hundred square inches with our name only.[24] We will not display marijuana or MMPs anywhere in public view.[25]

We will carefully track and document the chain of custody of all marijuana and MMPs, and provide diversion prevention training to all employees

We will prevent any diversion. BioTrackTHC enables us to collect, store, and retrieve all data and activity at any time, in real time. This includes inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents. Inventory will be tracked at every link in the chain of custody, whether still within our control, in transport, or sold to a qualifying patient or caregiver. BioTrackTHC allows both us and the state to backwards track and forwards track any marijuana or MMPs.

All of our employees will go through Patient Focused Certification training, which includes compliance and best practices instruction by the Cannabis Training Institute (see **Attachment 10-D**: Patient Focused Certification Information).

1. HAR §11-850-38(A)
2. HAR §11-850-92(A)(1)
3. HAR §11-850-92(A)(2)
4. HAR §11-850-92(A)(3)
5. HAR §11-850-92(A)(4)
6. HAR §11-850-92(A)(4)
7. HAR §11-850-92(B) (1)
8. HAR §11-850-92(B)(1)
9. HAR §11-850-92(B)(1)
10. HAR §11-850 -92(B)(10)
11. HAR §11-850-92(B)(2)
12. HAR §11-850-92(B)(3)
13. HAR §11-850-92(B)(4)
14. HAR §11-850-92(B)(5)
15. HAR §11-850-92(B)(5)
16. HAR §11-850-92(B)(6
17. HAR §11-850-92(B)(7)
18. HAR §11-850-92(C)
19. HAR §11-850-92(B)
20. HAR §11-850-92(B)(8)
21. HAR §11-850-92(B)(9)
22. HAR §11-850-21(d); HAR §11-850-32(c)(5)
23. HAR §11-850-73(c)
24. HAR §11-850-91
25. HAR §11-850-93(b)

HAR COMPLIANCE CHECKLIST

CRITERION 10 "Packing, Labeling, Signage, and Chain of Custody"

Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;

Response shall be no longer than three (3) pages.

Relevant HAR sections	Endnote Number
HAR §11-850-21(d)	22
HAR §11-850-32(c)(5)	22
HAR §11-850-38(a)	1
HAR §11-850-73(c)	23
HAR §11-850-91	24
HAR §11-850-92(a)(1)	2
HAR §11-850-92(a)(2)	3
HAR §11-850-92(a)(3)	4
HAR §11-850-92(a)(4)	5, 6
HAR §11-850-92(b)	19
HAR §11-850-92(b)(1)	7,8,9
HAR §11-850-92(b)(2)	11
HAR §11-850-92(b)(3)	12
HAR §11-850-92(b)(4)	13
HAR §11-850-92(b)(5)	14,15
HAR §11-850-92(b)(6)	16
HAR §11-850-92(b)(7)	17
HAR §11-850-92(b)(8)	20
HAR §11-850-92(b)(9)	21

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1/12/2015

Reference: BioTrackTHC Support Document and Letter of Intent
Lau Niu Poko

Dear James,

BioTrackTHC provides effective cutting -edge technology solutions for the emerging legal marijuana industry. Solutions that not only prevent product theft, but assist business owners in running their cultivation, processing, packaging, and retail operations more profitably and more legally compliant. Furthermore, this is all done without leaving sensitive business and consumer data vulnerable in the cloud. Specifically, BioTrackTHC is the industry's only true seed--to--sale software system with enterprise resource planning, complete inventory tracking, point--of--sale, marketing, financial reporting and regulatory compliance features. Subsequently, because it is a server -based system with advanced security features, customers can rest assured that no one,- not even the BioTrackTHC team,- can access their business or consumer information without their permission.

This document confirms BioTrackTHC's intentions to enter into a formal agreement with Lau Niu Poko to provide software solutions guaranteed to meet published Hawaii Department of Health reporting, regulation, and compliance guidelines for cannabis production facilities in the event that an authorized license is obtained.

Thank you for your consideration of BioTrackTHC. We are eager to assist you in your efforts to acquire a license and look forward to entering into a software solution agreement with you upon receipt of that license.

Best Regards,

[redacted]

Moe Afaneh
Chief Operating Officer

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Hawaii HB 321

(A) Secure inventory tracking and control;
(B) Protecting confidential customer information;
(1) Ability to comply with the requirements in this chapter and chapters 329 and 3290, HRS, for inventory tracking, security, and sales limits for qualifying patients;
(1) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;
(2) Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 3290-7 and 3290-8, HRS;
(3) Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;
(4) A plan for secure disposal or destruction of marijuana and manufactured marijuana products;

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

(a) A dispensary licensee shall not transfer any marijuana or manufactured marijuana products to any other dispensary.

(b) A dispensary licensee shall not accept any marijuana or manufactured marijuana products from any other dispensary.

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NO pre-rolls, no samples, no paraphernalia

§11-850-35 Employee records

(a) A dispensary licensee shall have available at each dispensary facility a time clock or other adequate method to record the month, day, year, and time that each employee arrives at and leaves the facility.

(b) Time record entries shall be made at the time an employee reports for duty and again when the employee goes off duty and at any time the employee leaves and returns to the premises for any reason.

(c) A dispensary licensee shall maintain all employee records, including the specific employee training provided and hours worked.

The Time Clock function within BioTrackTHC records the date and time that every employee clocks into and out of the system. A manager can be granted the permission within the system to modify the clock in/out times for an employee in the event of an error or someone forgetting to clock out.

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[redacted]

BioTrackTHC provides functionality for Cultivators, Processors and Dispensary Licensees to create transfer manifest documents. Transfer manifests will be stored and tracked by the System. Input data may include, but is not limited to, the following fields: ship from name, license number and route description. For each item include destination address, destination name, license number, address, product description, product ID and lot number, quantity and units of measure. Transfer manifests will be used as shipping documents for transfers between locations within an organization or sales between Licensees.

(b) A dispensary licensee shall give the department access to all parts of the dispensary property, equipment, records, documents, and any other substance, material, or information relevant to ensure the dispensary licensee's compliance with this chapter, upon request.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-38 Reports.

(a) A dispensary licensee shall submit quarterly reports on January 15, April 15, July 15, and October 15.

If the due date for submitting a quarterly report falls on a Saturday, Sunday, or State holiday, the report will be on time if it is submitted on the next day that is not a Saturday, Sunday, or State holiday. Reports shall be submitted on a form and in a manner prescribed by the department.

(b) Reports shall include but not be limited to:

1. Records of entry and exit for all individuals who entered a dispensary facility;

[redacted]

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2. Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
3. Amounts by category of marijuana and manufactured marijuana products sold;
4. A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
5. A summary financial statement;
6. Laboratory results of all tests conducted;
7. Description of any breach or halt in its security system and tracking system; and
8. Any other information requested by the department.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-39 Audits

(a) A dispensary licensee shall obtain an independent financial audit annually, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.
(b) The report shall be completed and submitted to the department no later than sixty days prior to the end of the license expiration date, or at another time as the department may direct.
(c) When a license is revoked, suspended, surrendered, or expires, a dispensary licensee shall file a final report thirty days following revocation, suspension, surrender, or expiration.

In the course of doing business, a user can perform inventory audits to confirm or adjust what's showing in your inventory and what the user actually has on hand. After clicking on the Inventory Audit Icon a list will populate showing all of the items for inventory in the current inventory room. If the user wishes to run a "Blind Audit" this will prevent the employee from seeing the original weights or any differences. The Inventory Shrinkage report allows you to total loss across various products for a given time period with a threshold to ignore adjustments outside of a certain increment (mistakes).

§11-850-41 Record retention.

(a) A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:

(1) Inventory tracking including transport of marijuana and manufactured marijuana products;

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(2) Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
(3) Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
(4) Logs of entry and exit for dispensary facilities; and
(5) Employee records.

(b) A dispensary licensee shall retain for a minimum of one year all security recordings.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity. All inventory records, patient records, recall reports, sales/transaction records, product disposal records, and all scanned documents can be accessed at any time (real time), either in-system or through the report creation tool. Though system actions can be adjusted or voided, at no time is any data ever fully deleted as BioTrackTHC™ maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

§11-850-42 Allowed quantities for dispensing.

(a) A dispensary licensee may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four ounces of marijuana during a period of fifteen consecutive days, and shall not exceed eight ounces of marijuana during a period of thirty consecutive days .

(b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter.

Within "Sales Limits" a user can regulate the permissible quantities allotted to a patient or caregiver.

§11-850-43 Disposal or destruction.

(a) A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the

cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.

(b) A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.

(c) A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired marijuana and manufactured marijuana products.

During or after a Harvest or Cure, a user would create a batch for the "green waste" which would include broad leaf trim, and stems that weren't going to be converted into a concentrated format. All waste would be weighed, given it's own 16-digit barcode, which is permanently stored in the system prior to it being destroyed. When a BioTrackTHC user sends a sample for Quality Assurance testing and the sample does not meet minimum standards, a user may; 1) Place the product into quarantine for destruction, or, 2) Convert the product into a different format. If the user converts the non-conforming sample and originating lot, the new converted product must be retested.

§11-850-61 Tracking requirements

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

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(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable . The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

PRODUCTS AND PRODUCT STANDARDS

§11-850-71 Marijuana.

(a) A dispensary licensee may dispense marijuana only in the form of dried matured processed flowers of female cannabis plants.

§11-850-72 Manufactured marijuana products.

(a) A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

§11-850-74 Equivalent weights for manufactured marijuana products.

(a) A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.

(b) A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale.

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BioTrackTHC is a complete inventory control system that also creates a searchable, secure, tamper-evident record of each and every action performed within the system. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

LABORATORY CERTIFICATION, TESTING, AND STANDARDS

§11-850-81 Laboratory testing required.

A dispensary licensee shall not dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter.

§11-850-85 Laboratory standards and testing

(a) A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-proof manner a similar sample from the same batch, for verification testing as directed by the department.

(a) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things for which it is certified. The certificate of analysis shall include the results with supporting data for the following:

(1) The chemical profile of the batch for the following compounds:
- (A) 9 (delta 9) - Tetrahydrocannabinol (THC)
- (B) Tetrahydrocannabinol Acid (THCA)
- (C) Cannabidiol (CBD)
- (D) Cannabidiolic Acid (CBDA)
- (E) Cannabigerol (CBG)
- (F) Cannabinol (CBN)

(2) The presence of the following contaminants, which shall not exceed the following levels:
- (A) Heavy metals:
  - (i) Arsenic 10.0 ppm
  - (ii) Lead 6.0 ppm
  - (iii) Cadmium 4.0 ppm (iv) Mercury 2.0 ppm

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(B) Pesticides regulated by the U.S. Environmental Protection Agency: 1.0 ppm

(C) Solvents:

(i) Butanes 800 ppm

(ii) Heptanes 500 ppm (iii) Benzene** 1 ppm

(iv) Toluene** 1 ppm (v) Hexane** 10 ppm

(vi) Total Xylenes

(m,o,p-xylene) 1 ppm

** Contaminants in solvents

(D) Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;

(E) Moisture content of plant material <15%

(F) Microbiological impurities, including but not limited to:

1. Total Viable Aerobic Bacteria:
   a. Unprocessed and Processed Materials: 105 Colony Forming Unit (CFU)/g
   b. C02 and Solvent Based Extracts: 104 CFU/g

2. Total Yeast and Mold:

(a) Unprocessed and Processed Materials: 104 CFU/g

(b) C02 and Solvent Based Extracts: 103 CFU/g

(iii) Total Coliforms:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(iv) Bile-tolerant Gram Negative Bacteria:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(v) *E. coli* (pathogenic strains) and *Salmonella spp.:* Not detected in 1 g

(vi) *Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger :* <1 CFU/g;

(vii) Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and

(3) Additional testing requested at the discretion of the department.

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The above information can all be generated within BioTrackTHC and reflected on the label for each product.

(d) The certified laboratory may retest or reanalyze ,the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense.

(e) The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of marijuana or manufactured marijuana products that remain after testing and analysis are completed.

(f) A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana products, including but not limited to:

1. The time and date the sample was obtained;
2. A description of the sample, including the amount;
3. What tests were conducted on each sample;
4. The results of the tests including the certificate of analysis; and
5. Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount;
6. and shall make all the records available to the department upon request.

(g) A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection (c), and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.

(h) A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.

(i) The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.

(j) A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon

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receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c).

BioTrackTHC automatically syncs testing data upon receipt from a certified testing location. Testing will ensure the product is free of contaminants with consistent THC and/or CBD levels. Furthermore, every plant interaction is recorded, including but certainly not limited to what additives are used and when, allowing cultivators to replicate results or make applicable changes to increase plant quality and consistency. BioTrackTHC syncs testing data to the applicable plant batch or barcode for easy display and retrieval. To simplify the process that information can be directly ported onto the associated product labels.

All aspects of the marijuana plants, byproduct wastes, weights, ID numbers and associated data is stored in the system indefinitely. Destruction event information and explanations are also documented and stored within the BioTrackTHC system. This data cannot be modified or deleted by the cultivation center employees or even by BioTrackTHC.

BioTrackTHC records manual inventory adjustments through a detailed notes section. The reason for disposal and, if applicable, disposal company are recorded and archived to the 16 digit barcode associated with the disposed cannabis. As with all transactions in the BioTrackTHC system, the employee responsible for the transaction is required to enter a PIN number or biometric fingerprint recording the date, time, and reason for the transaction.

§11-850-92 Packaging and labeling for retail sale.

(b) Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:

(1) Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:

(A) Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;

(B) The concentration of tetrahydrocannabinol or 9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;

(2) The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;

(3) The batch number and date of packaging;

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(4) Includes a computer tracking inventory identification number barcode generated by tracking software;
(5) Date of harvest or manufacture and "Use by date";
(6) Instructions for use;
(7) The phrases "For medical use only" and "Not for resale or transfer to another person";
(8) The following warnings:
(A) "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";
(B) "This product has intoxicating effects and may be habit forming";
(C) "Smoking is hazardous to your health";
(D) "There may be health risks associated with consumption of this product";
(E) "This product is not reconunended for use by women who are pregnant or breast feeding";
(F) "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
(6) A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
(9) The name of the laboratory that performed the testing;
provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
(c) A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.

BioTrackTHC™'s label creation tool enables licensed producers to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale.

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Hawaii Medical Marijuana Dispensary License Application Support Document

The format of the application asks for one's education, knowledge and experience with the sections outlined below, among others. The information contained within this document is to be used to assist an applicant with answering the questions that fall within the scope of the capabilities of BioTrackTHC; i.e. inventory tracking, sales limits, labeling, etc.

No guarantees or warranties, either expressed or implied, are associated with this document.

I) Secure inventory tracking and control

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

(4) Ability to comply with the security requirements of Chapter 11-850 and Section 329D-7, HRS;

(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;

This is the responsibility of the licensee.

(7) Ability to comply with the requirements in Chapter 11-850 and Sections 329 and 329D, HRS, for inventory tracking, security, and dispensing limits for qualifying patients;

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SUBCHAPTER 5
TRACKING REQUIREMENTS

§11-850-61 Tracking requirements.

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

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

The BioTrackTHC System issues a globally unique, non-repeating 16-digit identification number to each plant. At every stage in the product lifecycle where something needs to be differentiated, the System issues a new "child" identifier (e.g., separating flower from stems during the harvest process, separating edible batches that are going to different dispensaries, the creation of new clones or seeds from a mother plant, etc…). The System issues the identifier to prevent accidental or intentional identifier duplication by the user, and the 16-digit identifier ensure scalability and longevity—the System could generate 1,000,000 identification numbers per second and it would not run out of unique identifiers for over 317 years.

Every identifier is associated with a quantity that is measured in either discrete units or a weight depending on the item's classification; for example, plants, seeds, and infused edibles are measured in discrete units, whereas, bulk flower and stems are measured in continuous weight. This creates an unbroken audit chain. Select any identification number and both the State and the registered organization can backwards-trace the medical cannabis product's lineage all the way

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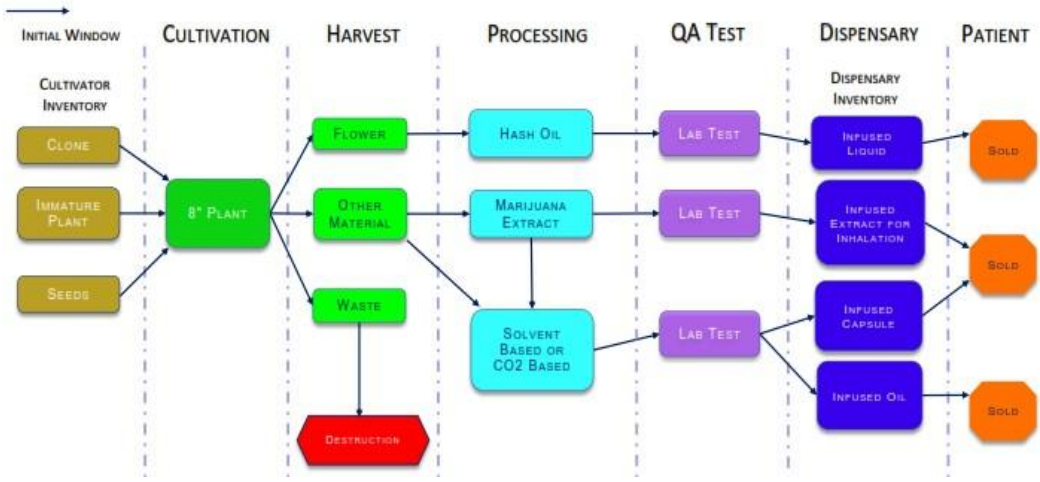
back to the plant from which it came, and also forwards-trace every gram to where it is still in inventory, where it has been dispensed, to whom it was dispensed, and where it was destroyed.

As an example, if 100 grams were harvested from plant 98765: in this case, 2 grams were consumed by the testing laboratory, 8 grams were dispensed to patient Smith, 15 grams were dispensed to patient Jones, 55 grams are still in inventory, and 20 grams have been destroyed.

Laboratory testing is built-in and tied directly into the inventory typing system. This allows for very complex or very simple rules on what needs to be tested, what the testing requirements are, the pass/fail limits, etc. This testing paradigm provides a model for ensuring that only properly tested product may be sold to a patient. The system's integrated features can be setup to prevent the sale or transfer of product that has not passed state mandated laboratory tests, if necessary.

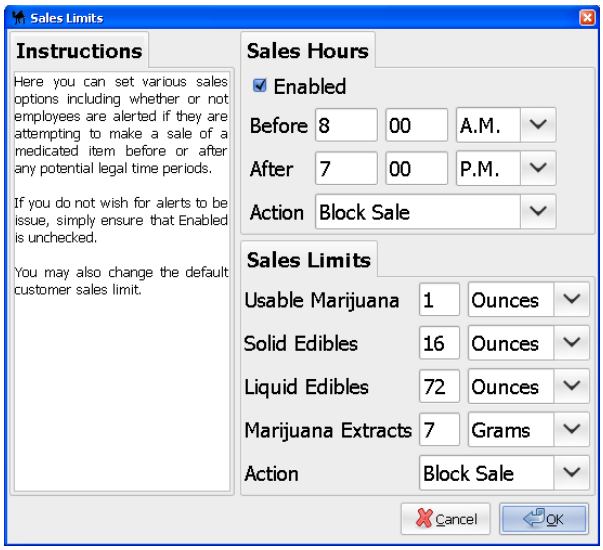


(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

Within "Sales Limits" a BioTrackTHC user can regulate the permissible quantities allotted to a patient or caregiver. The system stores patient purchases and cross-references with any Department defined limits. As the system will be recording every transaction, this data can be

parsed, filtered and reported against at any time. The system can also issue stop purchase alerts if a patient attempts to exceed said defined limits and disallow the completion of such a sale.

In the event that a patient has exceeded their purchasing limit; the retail dispensing location will be notified within the Tracking System that the patient has exceeded their sales limit; in response, the System will issue a stop purchase alert. The System does not allow for a retail dispensing location to transact with a patient that has exceeded their pre-defined sales limit.



(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

BioTrackTHC is the winner apparent to the state contract for Hawaii's computer software tracking system for the medical marijuana dispensary system based on and in compliance with Chapter 329D HRS. BioTrackTHC's commercial software provides seamless data exchange integration between a licensee and the state's marijuana tracking system. There will be integration via the application program interface (API) between the registered organization's BioTrackTHC enterprise system and the state interface utilized by the Hawaii DOH. This will

allow data to be sent in real time, not only from the registered organization to the state, but it will allow the registered organization to retrieve transferred data by Hawaii DOH.

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

In the event of a loss of internet access, BioTrackTHC has the ability to operate in Offline mode. While operating in Offline mode a facility may continue to process sales with an on-site server, even if the internet connectivity goes down. When service is restored, all changes made in Offline mode will be updated and synced within the system.

(8) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

BioTrackTHC provides record retention of patient data including purchases and medical information that is voluntarily offered by the patient. Confidentiality of a patient's medical information is the responsibility of the licensee and their staff.

(10) Ability to comply with requirements for packaging, labeling, and chain of custody of products

Labels for medical marijuana and medical marijuana products will be labeled using only black lettering on a white background with no pictures or graphics[i] and will include:

a) Net weight in ounces and equivalent physical weight of the marijuana used to produce the product.
b) The concentration of tetrahydrocannabinol or tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol; as well as the name of the laboratory that performed the testing
c) The dispensary licensee's license number and the name of the production center
d) The batch number and date of packaging
e) A computer tracking inventory identification number barcode generated by tracking software.
f) Date of harvest or manufacture and Use By Date
g) Instructions for use
h) The phrases: "For medical use only"; "Not for resale or transfer to another person"; "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law", "This product has intoxicating effects and may be habit forming"; "Smoking is hazardous to your health"; "There may be health risks associated

with consumption of this product"; "This product is not recommended for use by women who are pregnant or breast feeding"; "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"; and a disclosure of the type of extraction method including any solvents, gases, or other chemicals used (if applicable)

BioTrackTHC's label creation tool enables licensees to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

The following list contains the fields already integrated into BioTrackTHC. Should the State desire additional fields, BioTrackTHC will create and implement those fields per request.

- Custom Text Fields
- Images
- Lines
- Additives
- Barcode
- Batch #
- Custom Batch #
- Customer MMJ #
- Customer Name
- Date
- Date and time
- Employee Name
- Employee License #
- Grow License #
- Harvest Date
- Inventory Grade
- License #
- MITS ID
- Package Date
- Package Weight
- Plant Birthdate
- Product Expiration
- Product Ingredients
- Product Name

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- Strain
- Strain Type
- Testing Date
- Testing Lab
- Usable Weight
- Weight
- Test Results
  - All Available
  - CBC
  - CBD
  - CBD-A
  - CBG
  - CBN
  - D8-THC
  - D9-THC
  - D9-THC-A
  - H2O
  - Heavy Metals
  - Mold
  - Mildew
  - Total THC
  - Total Cannabinoids

(11) A plan for secure disposal of marijuana and manufactured marijuana products;

The BioTrackTHC MMJ Tracking System tracks and reports on all disposal of marijuana and marijuana products within a licensed facility. The System allows for the adjustment of inventory quantities as the result of both non-sales operational activities (such as disposal, wastage, moisture loss, mistakes, and inventory audits) and external factors (such as theft and seizure by law enforcement). Data related to disposal information may include, but is not limited to: the amount disposed, reasons for disposal, day/time, identity of the employee(s) conducting the disposal, and manner of disposal in addition to all product-related data such as inventory classification, etc.

(12) Ability to ensure product safety, in accordance with Chapter 11-850 and Sections 329D-8, 329D-10, 329D-11, HRS.

After a testing laboratory has entered sample test results into the System, the licensee retrieves the testing laboratory results and the System applies those results to the original lot from which

the sample came. Only if the inventory item has a status of "Passed QA" can it be placed on a manifest. A registered organization user cannot, under any circumstance, place an item on transportation manifest if that item requires testing and does not have a "Passed QA" status (e.g. not yet tested or failed testing).

Why PFC?

Patient Focused Certification (PFC) is a non-profit, third-party certification for the medical cannabis industry offered by Americans for Safe Access (ASA). ASA has been fighting for the rights of patients and for safe and legal access to medical cannabis for over decade. As an independent organization, we are able to work with regulators, industry, healthcare professionals and patients to set industry standards nationwide.

PFC is the only certification based on the new quality standards for medical cannabis products and businesses issued by the American Herbal Products Association and the American Herbal Pharmacopoeia. The program was established to help medical cannabis businesses ensure the production of quality products & services while giving patients, caregivers, healthcare providers, and regulators a way to easily identify them.

Where Do I Find PFC Certified Companies & Products?

Visit: patientfocusedcertification.org/companies

Companies participating in the PFC program can be found on our website above. If there is not a company near you, take this brochure to your local provider and ask them to enroll!

ASA PFC Patient Focused Certification

Look for the PFC Seal

Choose Your Medicine with Confidence

1806 Vernon St. NW - Washington, DC 20009
202.857.4272 - pfc@safeaccessnow.org
www.patientfocusedcertification.org

ASA PFC

PATIENT FOCUSED CERTIFICATION

a project of Americans for Safe Access Foundation

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What does the PFC Seal tell you?

When you see the PFC seal at a distribution center or on a product label, it tells you that the quality of products and services has been verified through the rigorous Patient Focused Certification Program.

Patient Focused Certification means:

- Company staff are well trained
- Products and services have been tested for contaminates
- Products and services meet legal requirements as well as AHPA and AHP standards
- Companies have recall protocols in place

ASA PFC Cultivation · ASA PFC Manufacturing · ASA PFC Distribution · ASA PFC Laboratory · ASA PFC M+D · ASA PFC M+C · ASA PFC C+D · ASA PFC M+D+C

How does PFC provide Certification?

PFC works with companies who voluntarily participate in the program and agree to adhere to local laws, AHPA and AHP standards. We verify their companies through a comprehensive evaluation process.

Our auditors:

- Perform thorough audits of the facilities.
- Test products in PFC certified laboratories.
- Conduct at least one surprise audit a year to ensure PFC standards are upheld.
- Maintain a consumer complaint database and follow up with the company for any needed corrective action.
- Only allow the PFC seal to be used on products that meet the PFC criteria.

Safety & Quality Assurance

More than one-third of the US population lives in states with medical cannabis laws, & over one million Americans are legally using medical cannabis under the care of a physician.

While many states and localities have created regulations to govern the location, size, & taxati of these businesses , they do not, for the most part, address the quality and safety of the prod ucts being sold.

Patients have the right to know how their medicine has been produced, that is free of contaminates & should be confident that the medicine they are receiving has been handled with the highest quality standards. They can now look fo the PFC seal to help them determine which proc ucts to purchase.

PFC is available to all companies cultivating, manufacturing or distributing medical cannabis products, as well as to laboratories providing analytic services to these companies. PFC includ employee training, compliance inspections, pro uct testing, ongoing monitoring, and an indeper dent complaint process for customers.

Companies certified by PFC are demonstrating a commitment to safety and quality.

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Response to Criterion 11

"Disposal or Destruction"

Launiupoko Farm

From Julie Okada, Individual Applicant, and Launiupoko Farm, LLC, Entity Applicant with the technical assistance of James Anthony Technical Assistance Consulting (JATAC), consultant.

CONTENTS

We have a comprehensive inventory system that secures disposal and destruction. 1
- Designated employees will identify marijuana for disposal or destruction 1
- BioTrackTHC specifically tracks disposal and destruction. 2
- We will use unique identifiers to account for all marijuana and MMPs, destroyed or not, in full batches or in partial batches. 3

We will use multiple methods of disposal or destruction 3
- The first method of disposal or destruction is by delivery to an authorized disposal firm. 3
- The second method of disposal or destruction is by composting 4
- The third method of disposal or destruction is by incineration. 4

We will have contamination prevention standards for disposal areas. 4

ATTACHMENTS

11-A: Endnotes
11-B: Compliance Checklist
11-C: BioTrackTHC Supporting Documents
11-D: HAR Section 23-200-20

Criterion 11 Language

A plan for secure disposal or destruction of marijuana and manufactured marijuana products; Response shall be no longer than five (5) pages.

We at Launiupoko Farm and our dedicated team of expert consultants from James Anthony Technical Assistance Consulting ("JATAC," and both collectively, "we") have a plan for secure disposal and destruction of marijuana and manufactured marijuana products (MMPs) that meets and exceeds the requirements of HAR 11-850 and HRS 329D-7, as demonstrated in this Response. Endnotes throughout the text show compliance with relevant cited HAR and HRS (Hawai'i Administrative Rules and Hawai'i Revised Statute) sections, and are listed separately as **Attachment 11-A,** and in Compliance Checklist form as **Attachment 11-B**.

We have a comprehensive inventory system that secures disposal and destruction

To ensure the safety of all patients and to prevent diversion of medical marijuana to the underground market, we at Launiupoko Farm and our expert consultants at JATAC will establish written policies for secure and legal disposal and destruction and will adhere to them at all times.[1] We will dispose of or destroy all unused, unsold, contaminated, or expired marijuana, MMPs, or waste products, as required, so that they do not become available to unauthorized persons.[2] All marijuana or MMPs that are contaminated or expired, or that are not sold within times designated in BioTrackTHC, will be scheduled for disposal or destruction (see **Attachment 11-C**: BioTrackTHC Supporting Documents). This includes all marijuana or MMPs that a certified laboratory test found to not meet established standards for quality and safety. We will schedule all products that do not meet established laboratory testing requirements for disposal or destruction.

▶ DESIGNATED EMPLOYEES WILL IDENTIFY MARIJUANA FOR DISPOSAL OR DESTRUCTION

Identification of marijuana or MMPs to be disposed of or destroyed will occur throughout each step of production from seed to sale. We will train and designate select employees in the evaluation of products to determine if quality and safety standards have been adequately met. In addition to their other duties, these individuals will examine marijuana

and MMP throughout production and at random intervals before sale. If an employee who is not so designated has reason to believe that any marijuana or MMP is contaminated, expired, or otherwise unfit to be provided to a qualified patient or caregiver, they will immediately inform a designated individual and have it inspected.

All disposal and destruction at our facilities will be performed by those individuals with clearance to make changes in BioTrackTHC. Such clearance will only be available to managers and to specifically designated employees. All employees disposing of or destroying marijuana or MMP will be accompanied by at least one other employee who also has clearance to make changes in the tracking system. All disposal or destruction will occur in full view of security surveillance cameras. This additional voluntary measure helps prevent any diversion of marijuana or MMPs.

▶ BIOTRACKTHC SPECIFICALLY TRACKS DISPOSAL AND DESTRUCTION

All disposal and destruction of marijuana and MMP will be carefully documented in the medical marijuana dispensary seed to sale tracking system, BioTrackTHC.[3] It is important that documentation be accurate and prompt so as to prevent diversion to unauthorized persons.

During or after a harvest or cure, our production center will create a batch for the "green waste," which will include broad leaf trim and stems that won't be converted into a concentrated format through a manufacturing extraction process. All waste will be weighed and will be given its own 16-digit barcode, which is permanently stored in BioTrackTHC prior to the destruction of the waste. When we send a sample for quality assurance testing and the sample does not meet minimum standards, we will either place the product into quarantine for destruction or convert the product into a different format. If we convert the non-conforming sample into a new format, the new converted product

must be retested. Only if the certificate of analysis shows that the new product meets quality and safety standards will it go on to be packaged and dispensed. Otherwise, the product will be placed into secure quarantine for destruction.

- **WE WILL USE UNIQUE IDENTIFIERS TO ACCOUNT FOR ALL MARIJUANA AND MMPS, DESTROYED OR NOT, IN FULL BATCHES OR IN PARTIAL BATCHES**

We will measure, weigh, and count all marijuana or MMP before disposal or destruction. The unique identifiers on the marijuana or MMP will be checked against the tracking system and marked as scheduled for disposal or destruction. By using the unique identifiers, the employee disposing of or destroying the product can verify that the entire batch has been accounted for. If only part of a batch of marijuana or MMP needs to be disposed of or destroyed, we will make such a note in the tracking system. A second employee will verify all measurements, weights, or counts and unique identifiers before disposal or destruction. After the proper disposal or destruction of the marijuana or MMP, the employee who executed the disposal or destruction will mark it as subtracted from the inventory[4] and as disposed of or destroyed in the tracking system.

We will use multiple methods of disposal or destruction

Once the inventory to be disposed of or destroyed is marked for disposal in the tracking system, the inventory will be disposed of or destroyed in one of three ways:

- **THE FIRST METHOD OF DISPOSAL OR DESTRUCTION IS BY DELIVERY TO AN AUTHORIZED DISPOSAL FIRM**

Hawai'i Administrative Rules, Title 23 Department of Public Safety, Subtitle 3 Law Enforcement, Chapter 200 Regulation of Controlled Substances Section 20 (See **Attachment 11-D**: HAR Section 23-200-20) provides "procedures for disposal of controlled substances."[5] This section specifically provides that "any registrant desiring

to dispose of control substances … may do so in the following manner … 3) By delivery to an authorized United States Department of Justice, Drug Enforcement Administration registered disposal firm."

Assuming that we can qualify as a "registrant" with Department of Public Safety and that we can find such a registered disposal firm on Maui willing to serve us, we would prefer to use, and will use, this existing controlled substances disposal or destruction procedure.

▶ THE SECOND METHOD OF DISPOSAL OR DESTRUCTION IS BY COMPOSTING

Our composting process with have four steps: 1) the shredding of the marijuana or MMP into water, 2) the mixing of the shredded material with either a compostable absorbent material to control odor and prevent diversion, 3) the careful tending of the compost to assure proper decomposition and that no pests gain access to the compost, and 4) the reintroduction of the compost into our propagation media.

▶ THE THIRD METHOD OF DISPOSAL OR DESTRUCTION IS BY INCINERATION

Any materials that cannot be composted, or if composting becomes impractical, will be disposed of using an incinerator specifically designed for the disposal of drugs.[6] Upon completion of the disposal or destruction of the marijuana or MMP, the employees shall make the appropriate BioTrackTHC entries.

We will have contamination prevention standards for disposal areas

To prevent unnecessary waste, we will teach contamination prevention standards during employee training. Such training will include the prompt disposal of all litter and waste and

t[redacted]

F[redacted]

[redacted] The clearing and cleaning of disposal areas will serve to minimize the development of odor and potential for the waste to become an attractant, harborage, or breeding place for pests.[8] All facilities will have adequate screening or other protection against the entry of pests to prevent contamination between products and disposal areas.[9]

1. HAR §11-850-43(c)
2. HAR §11-850-43(a)
3. HAR §11-850-43(a)
4. HAR §11-850-43(a)
5. HAR §23-200-20
6. http://drugterminator.elastec.com/
7. HAR §11-850-75(f)
8. HAR §11-850-75(i)
9. Ibid

HAR COMPLIANCE CHECKLIST

CRITERION 11 "Disposal or Destruction"

A plan for secure disposal or destruction of marijuana and manufactured marijuana products;

Response shall be no longer than five (5) pages.

Relevant HAR sections	Endnote Number
HAR §11-850-43(a)	2,3,4
HAR §11-850-43(c)	1
HAR §11-850-75(f)	7
HAR §11-850-75(i)	8
HAR §23-200-20	5

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1/12/2015

Reference: BioTrackTHC Support Document and Letter of Intent
Lau Niu Poko

Dear James,

BioTrackTHC provides effective cutting -edge technology solutions for the emerging legal marijuana industry. Solutions that not only prevent product theft, but assist business owners in running their cultivation, processing, packaging, and retail operations more profitably and more legally compliant. Furthermore, this is all done without leaving sensitive business and consumer data vulnerable in the cloud. Specifically, BioTrackTHC is the industry's only true seed--to--sale software system with enterprise resource planning, complete inventory tracking, point--of--sale, marketing, financial reporting and regulatory compliance features. Subsequently, because it is a server -based system with advanced security features, customers can rest assured that no one,- not even the BioTrackTHC team,- can access their business or consumer information without their permission.

This document confirms BioTrackTHC's intentions to enter into a formal agreement with Lau Niu Poko to provide software solutions guaranteed to meet published Hawaii Department of Health reporting, regulation, and compliance guidelines for cannabis production facilities in the event that an authorized license is obtained.

Thank you for your consideration of BioTrackTHC. We are eager to assist you in your efforts to acquire a license and look forward to entering into a software solution agreement with you upon receipt of that license.

Best Regards,

[redacted]

Moe Afaneh
Chief Operating Officer

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Hawaii HB 321

(A) Secure inventory tracking and control;
(B) Protecting confidential customer information;
(1) Ability to comply with the requirements in this chapter and chapters 329 and 3290, HRS, for inventory tracking, security, and sales limits for qualifying patients;
(1) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;
(2) Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 3290-7 and 3290-8, HRS;
(3) Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;
(4) A plan for secure disposal or destruction of marijuana and manufactured marijuana products;

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

(a) A dispensary licensee shall not transfer any marijuana or manufactured marijuana products to any other dispensary.

(b) A dispensary licensee shall not accept any marijuana or manufactured marijuana products from any other dispensary.

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NO pre-rolls, no samples, no paraphernalia

§11-850-35 Employee records

(a) A dispensary licensee shall have available at each dispensary facility a time clock or other adequate method to record the month, day, year, and time that each employee arrives at and leaves the facility.

(b) Time record entries shall be made at the time an employee reports for duty and again when the employee goes off duty and at any time the employee leaves and returns to the premises for any reason.

(c) A dispensary licensee shall maintain all employee records, including the specific employee training provided and hours worked.

The Time Clock function within BioTrackTHC records the date and time that every employee clocks into and out of the system. A manager can be granted the permission within the system to modify the clock in/out times for an employee in the event of an error or someone forgetting to clock out.

§11-850-36 Transport

(a) A dispensary may transport marijuana and manufactured marijuana products between its facilities, and between its facilities and a laboratory for testing.

(b) Only employees designated by the dispensary licensee, who are trained and knowledgeable on the transportation protocols required by this chapter, shall transport marijuana and manufactured marijuana products. Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.

(c) Each time marijuana and manufactured marijuana products are transported, the dispensary licensee shall prepare a manifest on a form prescribed by the department that lists the elements required by the department's tracking system. A dispensary licensee shall only transport marijuana or manufactured marijuana products that are listed on the manifest. A dispensary licensee shall transport marijuana or manufactured marijuana products in secured containers . The dispensary licensee shall include a copy of the manifest in the interior and on the exterior of the container.

(b) Upon receipt of marijuana and manufactured marijuana products the dispensary licensee or the laboratory shall immediately report to the department any discrepancies between what is received and what is on the manifest.

(c) The designated employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest.

(d) The dispensary licensee shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion.

(e) A dispensary licensee shall not transport marijuana or manufactured marijuana products:

(1) Off site to qualifying patients or to primary caregivers;
(2) To another county or another island within the same county; or
(3) To, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

BioTrackTHC provides functionality for Cultivators, Processors and Dispensary Licensees to create transfer manifest documents. Transfer manifests will be stored and tracked by the System. Input data may include, but is not limited to, the following fields: ship from name, license number and route description. For each item include destination address, destination name, license number, address, product description, product ID and lot number, quantity and units of measure. Transfer manifests will be used as shipping documents for transfers between locations within an organization or sales between Licensees.

(b) A dispensary licensee shall give the department access to all parts of the dispensary property, equipment, records, documents, and any other substance, material, or information relevant to ensure the dispensary licensee's compliance with this chapter, upon request.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-38 Reports.

(a) A dispensary licensee shall submit quarterly reports on January 15, April 15, July 15, and October 15.

If the due date for submitting a quarterly report falls on a Saturday, Sunday, or State holiday, the report will be on time if it is submitted on the next day that is not a Saturday, Sunday, or State holiday. Reports shall be submitted on a form and in a manner prescribed by the department.

(b) Reports shall include but not be limited to:

1. Records of entry and exit for all individuals who entered a dispensary facility;

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2. Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
3. Amounts by category of marijuana and manufactured marijuana products sold;
4. A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
5. A summary financial statement;
6. Laboratory results of all tests conducted;
7. Description of any breach or halt in its security system and tracking system; and
8. Any other information requested by the department.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-39 Audits

(a) A dispensary licensee shall obtain an independent financial audit annually, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.
(b) The report shall be completed and submitted to the department no later than sixty days prior to the end of the license expiration date, or at another time as the department may direct.
(c) When a license is revoked, suspended, surrendered, or expires, a dispensary licensee shall file a final report thirty days following revocation, suspension, surrender, or expiration.

In the course of doing business, a user can perform inventory audits to confirm or adjust what's showing in your inventory and what the user actually has on hand. After clicking on the Inventory Audit Icon a list will populate showing all of the items for inventory in the current inventory room. If the user wishes to run a "Blind Audit" this will prevent the employee from seeing the original weights or any differences. The Inventory Shrinkage report allows you to total loss across various products for a given time period with a threshold to ignore adjustments outside of a certain increment (mistakes).

§11-850-41 Record retention.

(a) A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:

(1) Inventory tracking including transport of marijuana and manufactured marijuana products;

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(2) Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
(3) Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
(4) Logs of entry and exit for dispensary facilities; and
(5) Employee records.

(b) A dispensary licensee shall retain for a minimum of one year all security recordings.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity. All inventory records, patient records, recall reports, sales/transaction records, product disposal records, and all scanned documents can be accessed at any time (real time), either in-system or through the report creation tool. Though system actions can be adjusted or voided, at no time is any data ever fully deleted as BioTrackTHC™ maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

§11-850-42 Allowed quantities for dispensing.

(a) A dispensary licensee may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four ounces of marijuana during a period of fifteen consecutive days, and shall not exceed eight ounces of marijuana during a period of thirty consecutive days .

(b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter.

Within "Sales Limits" a user can regulate the permissible quantities allotted to a patient or caregiver.

§11-850-43 Disposal or destruction.

(a) A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the

cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.

(b) A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.

(c) A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired marijuana and manufactured marijuana products.

During or after a Harvest or Cure, a user would create a batch for the "green waste" which would include broad leaf trim, and stems that weren't going to be converted into a concentrated format. All waste would be weighed, given it's own 16-digit barcode, which is permanently stored in the system prior to it being destroyed. When a BioTrackTHC user sends a sample for Quality Assurance testing and the sample does not meet minimum standards, a user may; 1) Place the product into quarantine for destruction, or, 2) Convert the product into a different format. If the user converts the non-conforming sample and originating lot, the new converted product must be retested.

§11-850-61 Tracking requirements

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

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(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable . The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

PRODUCTS AND PRODUCT STANDARDS

§11-850-71 Marijuana.

(a) A dispensary licensee may dispense marijuana only in the form of dried matured processed flowers of female cannabis plants.

§11-850-72 Manufactured marijuana products.

(a) A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

§11-850-74 Equivalent weights for manufactured marijuana products.

(a) A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.

(b) A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale.

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BioTrackTHC is a complete inventory control system that also creates a searchable, secure, tamper-evident record of each and every action performed within the system. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

LABORATORY CERTIFICATION, TESTING, AND STANDARDS

§11-850-81 Laboratory testing required.

A dispensary licensee shall not dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter.

§11-850-85 Laboratory standards and testing

(a) A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-proof manner a similar sample from the same batch, for verification testing as directed by the department.

(a) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things for which it is certified. The certificate of analysis shall include the results with supporting data for the following:

(1) The chemical profile of the batch for the following compounds:
- (A) 9 (delta 9) - Tetrahydrocannabinol (THC)
- (B) Tetrahydrocannabinol Acid (THCA)
- (C) Cannabidiol (CBD)
- (D) Cannabidiolic Acid (CBDA)
- (E) Cannabigerol (CBG)
- (F) Cannabinol (CBN)

(2) The presence of the following contaminants, which shall not exceed the following levels:
- (A) Heavy metals:
  - (i) Arsenic 10.0 ppm
  - (ii) Lead 6.0 ppm
  - (iii) Cadmium 4.0 ppm (iv) Mercury 2.0 ppm

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(B) Pesticides regulated by the U.S. Environmental Protection Agency: 1.0 ppm

(C) Solvents:

(i) Butanes 800 ppm

(ii) Heptanes 500 ppm (iii) Benzene** 1 ppm

(iv) Toluene** 1 ppm (v) Hexane** 10 ppm

(vi) Total Xylenes

(m,o,p-xylene) 1 ppm

** Contaminants in solvents

(D) Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;

(E) Moisture content of plant material <15%

(F) Microbiological impurities, including but not limited to:

1. Total Viable Aerobic Bacteria:
   a. Unprocessed and Processed Materials: 105 Colony Forming Unit (CFU)/g
   b. C02 and Solvent Based Extracts: 104 CFU/g
2. Total Yeast and Mold:

(a) Unprocessed and Processed Materials: 104 CFU/g

(b) C02 and Solvent Based Extracts: 103 CFU/g

(iii) Total Coliforms:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(iv) Bile-tolerant Gram Negative Bacteria:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(v) *E. coli* (pathogenic strains) and *Salmonella spp.:* Not detected in 1 g

(vi) *Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger :* <1 CFU/g;

(vii) Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and

(3) Additional testing requested at the discretion of the department.

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The above information can all be generated within BioTrackTHC and reflected on the label for each product.

(d) The certified laboratory may retest or reanalyze ,the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense.

(e) The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of marijuana or manufactured marijuana products that remain after testing and analysis are completed.

(f) A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana products, including but not limited to:

1. The time and date the sample was obtained;
2. A description of the sample, including the amount;
3. What tests were conducted on each sample;
4. The results of the tests including the certificate of analysis; and
5. Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount;
6. and shall make all the records available to the department upon request.

(g) A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection (c), and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.

(h) A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.

(i) The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.

(j) A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon

receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c).

BioTrackTHC automatically syncs testing data upon receipt from a certified testing location. Testing will ensure the product is free of contaminants with consistent THC and/or CBD levels. Furthermore, every plant interaction is recorded, including but certainly not limited to what additives are used and when, allowing cultivators to replicate results or make applicable changes to increase plant quality and consistency. BioTrackTHC syncs testing data to the applicable plant batch or barcode for easy display and retrieval. To simplify the process that information can be directly ported onto the associated product labels.

All aspects of the marijuana plants, byproduct wastes, weights, ID numbers and associated data is stored in the system indefinitely. Destruction event information and explanations are also documented and stored within the BioTrackTHC system. This data cannot be modified or deleted by the cultivation center employees or even by BioTrackTHC.

BioTrackTHC records manual inventory adjustments through a detailed notes section. The reason for disposal and, if applicable, disposal company are recorded and archived to the 16 digit barcode associated with the disposed cannabis. As with all transactions in the BioTrackTHC system, the employee responsible for the transaction is required to enter a PIN number or biometric fingerprint recording the date, time, and reason for the transaction.

§11-850-92 Packaging and labeling for retail sale.

(b) Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:

(1) Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:

(A) Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;

(B) The concentration of tetrahydrocannabinol or 9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;

(2) The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;

(3) The batch number and date of packaging;

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(4) Includes a computer tracking inventory identification number barcode generated by tracking software;
(5) Date of harvest or manufacture and "Use by date";
(6) Instructions for use;
(7) The phrases "For medical use only" and "Not for resale or transfer to another person";
(8) The following warnings:
(A) "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";
(B) "This product has intoxicating effects and may be habit forming";
(C) "Smoking is hazardous to your health";
(D) "There may be health risks associated with consumption of this product";
(E) "This product is not reconunended for use by women who are pregnant or breast feeding";
(F) "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
(6) A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
(9) The name of the laboratory that performed the testing;
provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
(c) A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.

BioTrackTHC™'s label creation tool enables licensed producers to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale.

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[redacted]

[redacted]

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Hawaii Medical Marijuana Dispensary License Application Support Document

The format of the application asks for one's education, knowledge and experience with the sections outlined below, among others. The information contained within this document is to be used to assist an applicant with answering the questions that fall within the scope of the capabilities of BioTrackTHC; i.e. inventory tracking, sales limits, labeling, etc.

No guarantees or warranties, either expressed or implied, are associated with this document.

I) Secure inventory tracking and control

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

(4) Ability to comply with the security requirements of Chapter 11-850 and Section 329D-7, HRS;

(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;

This is the responsibility of the licensee.

(7) Ability to comply with the requirements in Chapter 11-850 and Sections 329 and 329D, HRS, for inventory tracking, security, and dispensing limits for qualifying patients;

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SUBCHAPTER 5
TRACKING REQUIREMENTS

§11-850-61 Tracking requirements.

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

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

The BioTrackTHC System issues a globally unique, non-repeating 16-digit identification number to each plant. At every stage in the product lifecycle where something needs to be differentiated, the System issues a new "child" identifier (e.g., separating flower from stems during the harvest process, separating edible batches that are going to different dispensaries, the creation of new clones or seeds from a mother plant, etc…). The System issues the identifier to prevent accidental or intentional identifier duplication by the user, and the 16-digit identifier ensure scalability and longevity—the System could generate 1,000,000 identification numbers per second and it would not run out of unique identifiers for over 317 years.

Every identifier is associated with a quantity that is measured in either discrete units or a weight depending on the item's classification; for example, plants, seeds, and infused edibles are measured in discrete units, whereas, bulk flower and stems are measured in continuous weight. This creates an unbroken audit chain. Select any identification number and both the State and the registered organization can backwards-trace the medical cannabis product's lineage all the way

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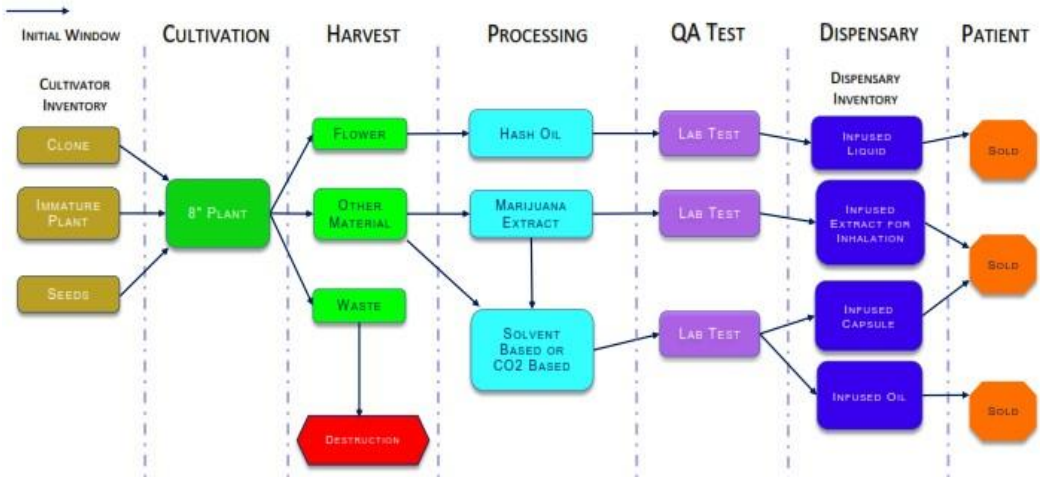
back to the plant from which it came, and also forwards-trace every gram to where it is still in inventory, where it has been dispensed, to whom it was dispensed, and where it was destroyed.

As an example, if 100 grams were harvested from plant 98765: in this case, 2 grams were consumed by the testing laboratory, 8 grams were dispensed to patient Smith, 15 grams were dispensed to patient Jones, 55 grams are still in inventory, and 20 grams have been destroyed.

Laboratory testing is built-in and tied directly into the inventory typing system. This allows for very complex or very simple rules on what needs to be tested, what the testing requirements are, the pass/fail limits, etc. This testing paradigm provides a model for ensuring that only properly tested product may be sold to a patient. The system's integrated features can be setup to prevent the sale or transfer of product that has not passed state mandated laboratory tests, if necessary.

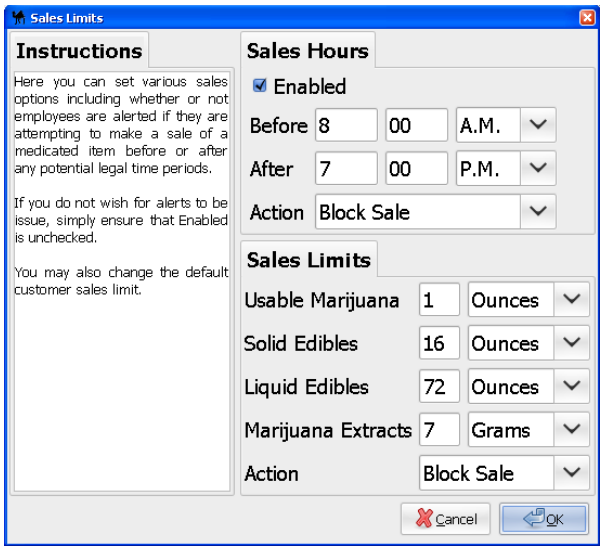


(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

Within "Sales Limits" a BioTrackTHC user can regulate the permissible quantities allotted to a patient or caregiver. The system stores patient purchases and cross-references with any Department defined limits. As the system will be recording every transaction, this data can be

parsed, filtered and reported against at any time. The system can also issue stop purchase alerts if a patient attempts to exceed said defined limits and disallow the completion of such a sale.

In the event that a patient has exceeded their purchasing limit; the retail dispensing location will be notified within the Tracking System that the patient has exceeded their sales limit; in response, the System will issue a stop purchase alert. The System does not allow for a retail dispensing location to transact with a patient that has exceeded their pre-defined sales limit.



(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

BioTrackTHC is the winner apparent to the state contract for Hawaii's computer software tracking system for the medical marijuana dispensary system based on and in compliance with Chapter 329D HRS. BioTrackTHC's commercial software provides seamless data exchange integration between a licensee and the state's marijuana tracking system. There will be integration via the application program interface (API) between the registered organization's BioTrackTHC enterprise system and the state interface utilized by the Hawaii DOH. This will

allow data to be sent in real time, not only from the registered organization to the state, but it will allow the registered organization to retrieve transferred data by Hawaii DOH.

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

In the event of a loss of internet access, BioTrackTHC has the ability to operate in Offline mode. While operating in Offline mode a facility may continue to process sales with an on-site server, even if the internet connectivity goes down. When service is restored, all changes made in Offline mode will be updated and synced within the system.

(8) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

BioTrackTHC provides record retention of patient data including purchases and medical information that is voluntarily offered by the patient. Confidentiality of a patient's medical information is the responsibility of the licensee and their staff.

(10) Ability to comply with requirements for packaging, labeling, and chain of custody of products

Labels for medical marijuana and medical marijuana products will be labeled using only black lettering on a white background with no pictures or graphics[i] and will include:

a) Net weight in ounces and equivalent physical weight of the marijuana used to produce the product.
b) The concentration of tetrahydrocannabinol or tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol; as well as the name of the laboratory that performed the testing
c) The dispensary licensee's license number and the name of the production center
d) The batch number and date of packaging
e) A computer tracking inventory identification number barcode generated by tracking software.
f) Date of harvest or manufacture and Use By Date
g) Instructions for use
h) The phrases: "For medical use only"; "Not for resale or transfer to another person"; "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law", "This product has intoxicating effects and may be habit forming"; "Smoking is hazardous to your health"; "There may be health risks associated

with consumption of this product"; "This product is not recommended for use by women who are pregnant or breast feeding"; "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"; and a disclosure of the type of extraction method including any solvents, gases, or other chemicals used (if applicable)

BioTrackTHC's label creation tool enables licensees to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

The following list contains the fields already integrated into BioTrackTHC. Should the State desire additional fields, BioTrackTHC will create and implement those fields per request.

- Custom Text Fields
- Images
- Lines
- Additives
- Barcode
- Batch #
- Custom Batch #
- Customer MMJ #
- Customer Name
- Date
- Date and time
- Employee Name
- Employee License #
- Grow License #
- Harvest Date
- Inventory Grade
- License #
- MITS ID
- Package Date
- Package Weight
- Plant Birthdate
- Product Expiration
- Product Ingredients
- Product Name

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- Strain
- Strain Type
- Testing Date
- Testing Lab
- Usable Weight
- Weight
- Test Results
  - All Available
  - CBC
  - CBD
  - CBD-A
  - CBG
  - CBN
  - D8-THC
  - D9-THC
  - D9-THC-A
  - H2O
  - Heavy Metals
  - Mold
  - Mildew
  - Total THC
  - Total Cannabinoids

(11) A plan for secure disposal of marijuana and manufactured marijuana products;

The BioTrackTHC MMJ Tracking System tracks and reports on all disposal of marijuana and marijuana products within a licensed facility. The System allows for the adjustment of inventory quantities as the result of both non-sales operational activities (such as disposal, wastage, moisture loss, mistakes, and inventory audits) and external factors (such as theft and seizure by law enforcement). Data related to disposal information may include, but is not limited to: the amount disposed, reasons for disposal, day/time, identity of the employee(s) conducting the disposal, and manner of disposal in addition to all product-related data such as inventory classification, etc.

(12) Ability to ensure product safety, in accordance with Chapter 11-850 and Sections 329D-8, 329D-10, 329D-11, HRS.

After a testing laboratory has entered sample test results into the System, the licensee retrieves the testing laboratory results and the System applies those results to the original lot from which

the sample came. Only if the inventory item has a status of "Passed QA" can it be placed on a manifest. A registered organization user cannot, under any circumstance, place an item on transportation manifest if that item requires testing and does not have a "Passed QA" status (e.g. not yet tested or failed testing).

Hawaii Administrative Rules
Title 23 Department of Public Safety
Subtitle 3 Law Enforcement
Chapter 200 Regulation of Controlled Substances

§23-200-20 Procedures for disposal of controlled substances.

(a) Any registrant desiring to dispose of controlled substances that are old, outdated, contaminated or unfit for human consumption may do so in the following manner:
    1) By delivery to an agent of the department who is authorized to dispose of controlled substances;
    2) By the destruction in the presence of an authorized agent of the department;
    3) By delivery to an authorized United States Department of Justice, Drug Enforcement Administration registered disposal firm; or
    4) By other means as the administrator may determine to assure that the controlled substance does not become available to unauthorized persons.

(b) Any registrant desiring to dispose of their controlled substances may do so by:
    1) Transferring any unopened containers to another registrant who is authorized to possess those controlled substances;
    2) Returning the controlled substances to the distributor if he so authorizes; or
    3) Any means mentioned in subsection (a).

(c) In the event that controlled substances are destroyed or transferred in accordance with subsection (a) or (b) the registrant shall prepare a list of the controlled substances listing each drug, the strength and total dosage unit or volume in duplicate. The original shall be kept with the records of the registrant or the registrant to whom the controlled substances were transferred, and the duplicate forwarded to the department or turned over to the authorized agent disposing of the substance. [Eff April 15, 2000] (Auth: HRS §§329-31, 353C-2) (Imp: HRS §329-36)

§23-200-21 Production of controlled substance bearing plants.

(a) It-shall be unlawful for any person to engage in or be associated in any manner with or permit another to engage in the cultivation of controlled substance bearing plants or in the production, manufacturing or processing of controlled substances unless such person holds a currently effective certificate of registration issued by the department.

(b) A certificate of registration may be renewed upon the filing of an application on a form furnished by the director, stating either that there has been no changes in the status of matter set forth in the registrant's original application or in a supplementary application, or, if .any changes have occurred, setting forth such changes.

(c) A certificate of registration shall be renewed annually.

(d) A certificate of registration may be revoked immediately by the director upon any violation by the registrant of any of the terms of the certificate of laws of the United States and this State governing controlled substances.

(e) Disposal of controlled substance-bearing plants. Any controlled substance bearing plant that is cultivated or any substance from such plant that is produced, manufactured, or processed by the registrant and used for a specific scientific or educational use shall be disposed of 23-200-20. [Eff April 15, 2000] (Auth: HRS §§329-31, 353C-2) (Imp: HRS §329-32, 329-42)

Response to Criterion 12

"Product Safety"

Launiupoko Farm

From Julie Okada, Individual Applicant, and Launiupoko Farm, LLC, Entity Applicant with the technical assistance of James Anthony Technical Assistance Consulting (JATAC), consultant.

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ATTACHMENTS

12-A: Endnotes
12-B: Compliance Checklist
12-C: BioTrackTHC Supporting Documents
12-D: Patient Focused Certification Information

Criterion 12 Language

Ability to ensure product safety, in accordance with this chapter and sections 329D-8, 329D-10, 329D-11, HRS. Response shall be no longer than five (5) pages

We at Launiupoko Farm with our dedicated team of expert consultants from James Anthony Technical Assistance Consulting ("JATAC," and both collectively, "we") will ensure product safety, and will meet and exceed all requirements, in accordance with sections 329D-8, 329D-10, 329D-11, HRS., as demonstrated in this Response. Endnotes throughout the text show compliance with relevant cited HAR and HRS (Hawai'i Administrative Rules and Hawai'i Revised Statute) sections, and are listed separately as **Attachment 12-A**, and in Compliance Checklist form as **Attachment 12-B**.

We will use the certified laboratory Steep Hill Halent, or an equivalent, to ensure product safety

Every batch of our marijuana and manufactured marijuana products (MMPs) will be tested by the Department certified laboratory, Steep Hill Halent, or an equivalent that will meet all required standards for laboratory testing for content, contamination, and consistency. Steep Hill Halent will analyze each batch of all our marijuana and MMPs and will issue a Certificate of Analysis delineating the levels of cannabinoids and of contaminants present in the product including heavy metals, pesticides regulated by the US Environmental Protection Agency, solvents and contaminates in solvents, any visible foreign or extraneous material, and microbiological impurities. Should any batch exceed the HAR limits, the batch will be slated for re-testing or destruction. Our patients will be safe from contamination, and confident in our contents and consistency. See Criteria 9 Response for more information about our laboratory testing procedures and Criteria 11 Response for disposal and destruction procedures. The chemical profile provided in the Certificate of Analysis will allow our employees to provide strain specific profiles to qualified patients and caregivers to aid in their selection of the medicine to best serve their medical condition. See Criteria 5 Response.

We will restrict the type and packaging of marijuana and MMPs in accordance with HRS and HAR to best ensure the safety of our qualified patients

To ensure the safety of the qualified patients that we serve, we will only dispense marijuana in the form of dried, matured processed flowers of female cannabis plants[1] and we will only manufacture MMPs in the form of capsules, lozenges, pills, oils and oil extracts, tinctures, ointments and skin lotions, and other products as specified by the Department.[2] Moreover, we will not alter marijuana or MMPs to change their appearance, flavor, or smell in a way that would appeal to minors.[3]

We will package all marijuana and MMPs safely. Any capsule, lozenge or pill, will be packaged so that one dose or single wrapped item does not exceed ten milligrams of tetrahydrocannabinol (THC) and no product or product pack will exceed 100 milligrams of THC per pack or container.[4] This will help patients safely adjust and titrate their own individual dosage levels. We will work with our team of expert consultants from James Anthony Technical Assistance Consulting (JATAC) to calculate the equivalent physical weight of the marijuana used to manufacture any MMPs.[5] Our JATAC extraction expert consultant will determine the appropriate equivalency calculations and formulas, which we will then use in BioTrackTHC for label making and to make them available to the Department and consumers.[6] **See Attachment 12-C**: BioTrackTHC Supporting Documents. For all MMPs we will include this equivalent weight on the label, [7] along with all other required information.[8] See Criteria 10 Response.

We will establish policies and procedures to ensure patient safety

Beyond limiting the type and amounts of marijuana and MMPs dispensed, we are dedicated to ensure that our production of MMPs is safe and in accordance with all laws and regulations. This includes having written policies and procedures for both marijuana and

MMPs that include safe and appropriate use of equipment, safe and appropriate storage of materials used to produce MMPs, effective training and monitoring of employees who participate in production, adequate protocols for laboratory testing, and safe and appropriate storage and disposal or destruction of marijuana at all stages of production and sale.[9] These policies and procedures are located throughout our Responses, including but not limited to Criteria 7, 9, 10, 11, and this Response.

Our expert consultants at JATAC will ensure that all of our policies and procedures directly address both the regulatory and practical requirements of production, processing, testing, and disposal. Furthermore, all of our employees will go through Patient Focused Certification training, which includes compliance and best practice instruction by the Cannabis Training Institute. See **Attachment 12-D**: Patient Focused Certification Information.

Our production centers will report all required information to the Department

Our commitment to providing the Department all required information begins prior to any production of marijuana or MMPs. All of the strains we cultivate will be reported to the Department prior to marijuana production,[10] just as all strains of marijuana to be used by the dispensary to produce MMPs will be reported prior to production.[11] Our production center will also report all types of MMPs to be produced and the manufacturing processes.[12]

Our reporting duties are not limited to information about our strains and products. We will determine what state or county permits or licenses are required for our particular manufacturing activity, and shall obtain and maintain all that are required.[13] We will provide the Department with copies of them and will post them at all facilities as required.[14] If any permit is suspended or revoked, we will immediate cease production or manufacture and notify the Department.[15]

We will comply with all quality control, health, safety, and sanitation standards required under HAR section 11-850-75

We are dedicated to ensuring that the marijuana and MMPs we produce are safe for use or consumption by qualifying patients.[16] To ensure this safety we will comply with state and county health, safety, and sanitation regulations. [17] We understand that we may be subject to unannounced inspection to confirm that no health or safety concerns are present which may contaminate the products.[18] We will comply with such regulations by following our policies and procedures, and by having properly built and equipped facilities and trained employees.

Our product safety policy and procedure will be instituted to maintain our buildings, fixtures, and other facilities in a sanitary condition.[19] Our JATAC experts will help us create the comprehensive facility and operations policies and procedures to achieve these goals. This will include contamination prevention. For example, any person who has or appears to have an illness will not be allowed any contact with marijuana or MMPs.[20] Healthy employees will have hand washing facilities[21] where they will be required to wash their hand thoroughly before starting work and at any other time when the hands may have become soiled or contaminated.[22] Hygienic practices, including maintaining adequate personal cleanliness, will be required of all persons working in direct contact with marijuana and MMPs.[23]

Beyond employee behavior, contamination prevention will include policies that require all litter and waste to be properly removed so that it will not be a source of contamination for marijuana or MMPs[24] or be left to become an attractant, harborage, or breeding place for pests.[25] Similarly, the use and maintenance of any toxic cleaning compounds, sanitizing agents, and pest control measures will be in accordance with law and protect against contamination of marijuana and MMPs.[26] To further prevent any pest or animal based contamination, we will screen against the entry of pests[27] and animals will not be allowed in any dispensary facility, except for services animals in accordance with section 347-2.5, HRS.28

A properly built and equipped facility is as crucial to compliance with health, safety, and sanitation regulations as policy is. We will provide proper facilities by ensuring that all floors, walls, and ceilings of our facilities are constructed so that they can be cleaned and that they are kept clean and in good repair.[29] Additionally, we will provide adequate lighting in all areas that marijuana and MMPs are stored or sold, and where equipment or utensils are cleaned.[30]

We have labeling and packaging plans in accordance with HRS and HAR

We understand that the proper packaging and labeling of marijuana and MMPs is crucial to the safety of qualified patients and caregivers and the Maui community. We have a comprehensive packaging and labeling plan which utilizes the BioTrackTHC system. Our packaging plan includes compliance with all legal regulations and our internal requirements.[31] Our labeling plan includes that all labels will be black letters on white background, without graphics,[32] and will have all requisite information and warnings.[33] If the product is a MMP the equivalent physical weight of the marijuana used to manufacture the product will also be included.[34] For a more detailed description of our labeling and packaging plans, please see Criteria 10 Response.

Our only advertising will be the operation of our webpage

The only form of advertising that we will use will be the establishment of a website. This website is not targeted at increasing sales or attracting a wide customer base, but rather to provide information to qualified patients and caregivers, and to provide an anonymous means for patients and caregivers to leave feedback and suggestions. We shall provide only general information on our contact information, the location of our retail dispensing location, and a list of products available for dispensing.[35] Our list of available products will also include information about the products, but will be limited to the information that we have on our labels and no prices. See Criteria 10 Response.

1. HAR §11-850-71(a)
2. HRS §329D-10
3. HAR §11-850-75(m)
4. HRS §329D-11(b)
5. HAR §11-850-74(a)
6. HAR §11-850-74(a)
7. HAR §11-850-74(b)
8. HAR §11-850-92(B)
9. HAR §11-850-71(b) and 72(b)
10. HAR §11-850-71(c)
11. HAR §11-850-71(c)(1)
12. HAR §11-850-71(c)(2)-(3)
13. HAR §11-850-73(a)
14. HAR §11-850-73(b)-(c)
15. HAR §11-850-73(d)
16. HRS §11-850-75(a)
17. HAR §11-850-75(b)
18. HAR §11-850-75(b)
19. HAR §11-850-75(k)
20. HAR §11-850-75(c)
21. HAR §11-850-75(d)
22. HAR §11-850-75(e)(2)
23. HAR §11-850-75(e)(1)
24. HAR §11-850-75(f)
25. HAR §11-850-75(i)
26. HAR §11-850-75(l)
27. HAR §11-850-75(i)
28. HAR §11-850-75(j)
29. HAR §11-850-75(g)
30. HAR §11-850-75(h)
31. HRS §329D-11(A)(1)
32. HRS §329D-11(A)(2)
33. HRS §329D-11(A)(3)-(8)
34. HRS §329D-11(A)(9)
35. HAR §11-850-93(a)

HAR COMPLIANCE CHECKLIST
CRITERION 12 "Product Safety"

Ability to ensure product safety, in accordance with this chapter and sections 329D-8, 329D-10, 329D-11, HRS. Response shall be no longer than five (5) pages

Relevant HAR sections	Endnote Number
HAR §11-850-71(a)	1
HAR §11-850-71(b)	9
HAR §11-850-71(c)	10, 11, 12
HAR §11-850-72(b)	9
HAR §11-850-73(a)	13
HAR §11-850-73(b)	14
HAR §11-850-73(c)	14
HAR §11-850-73(d)	15
HAR §11-850-74(a)	5,6
HAR §11-850-74(b)	7
HAR §11-850-75(a)	16
HAR §11-850-75(b)	17, 18
HAR §11-850-75(c)	20
HAR §11-850-75(d)	21
HAR §11-850-75(e)	22, 23
HAR §11-850-75(f)	24
HAR §11-850-75(g)	29
HAR §11-850-75(h)	30
HAR §11-850-75(i)	25, 27
HAR §11-850-75(j)	28
HAR §11-850-75(k)	19
Relevant HAR sections	Endnote Number
HAR §11-850-75(l)	26
HAR §11-850-75(m)	3
HAR §11-850-92(b)	8
HAR §11-850-93(a)	35

CONFIDENTIAL & PROPRIETARY. **DO NOT DISCLOSE.** January 29, 2016.

BioTrackTHC™
The Only Seed to Sale Solution

1/12/2015

Reference: BioTrackTHC Support Document and Letter of Intent
Lau Niu Poko

Dear James,

BioTrackTHC provides effective cutting -edge technology solutions for the emerging legal marijuana industry. Solutions that not only prevent product theft, but assist business owners in running their cultivation, processing, packaging, and retail operations more profitably and more legally compliant. Furthermore, this is all done without leaving sensitive business and consumer data vulnerable in the cloud. Specifically, BioTrackTHC is the industry's only true seed--to--sale software system with enterprise resource planning, complete inventory tracking, point--of--sale, marketing, financial reporting and regulatory compliance features. Subsequently, because it is a server -based system with advanced security features, customers can rest assured that no one,- not even the BioTrackTHC team,- can access their business or consumer information without their permission.

This document confirms BioTrackTHC's intentions to enter into a formal agreement with Lau Niu Poko to provide software solutions guaranteed to meet published Hawaii Department of Health reporting, regulation, and compliance guidelines for cannabis production facilities in the event that an authorized license is obtained.

Thank you for your consideration of BioTrackTHC. We are eager to assist you in your efforts to acquire a license and look forward to entering into a software solution agreement with you upon receipt of that license.

Best Regards,

[redacted]

Moe Afaneh
Chief Operating Officer

BioTrackTHC™
The Only Seed to Sale Solution

Hawaii HB 321

(A) Secure inventory tracking and control;
(B) Protecting confidential customer information;

(1) Ability to comply with the requirements in this chapter and chapters 329 and 3290, HRS, for inventory tracking, security, and sales limits for qualifying patients;

(1) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

(2) Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 3290-7 and 3290-8, HRS;

(3) Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;

(4) A plan for secure disposal or destruction of marijuana and manufactured marijuana products;

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

(a) A dispensary licensee shall not transfer any marijuana or manufactured marijuana products to any other dispensary.

(b) A dispensary licensee shall not accept any marijuana or manufactured marijuana products from any other dispensary.

BioTrackTHC™
The Only Seed to Sale Solution

NO pre-rolls, no samples, no paraphernalia

§11-850-35 Employee records

(a) A dispensary licensee shall have available at each dispensary facility a time clock or other adequate method to record the month, day, year, and time that each employee arrives at and leaves the facility.

(b) Time record entries shall be made at the time an employee reports for duty and again when the employee goes off duty and at any time the employee leaves and returns to the premises for any reason.

(c) A dispensary licensee shall maintain all employee records, including the specific employee training provided and hours worked.

The Time Clock function within BioTrackTHC records the date and time that every employee clocks into and out of the system. A manager can be granted the permission within the system to modify the clock in/out times for an employee in the event of an error or someone forgetting to clock out.

§11-850-36 Transport

(a) A dispensary may transport marijuana and manufactured marijuana products between its facilities, and between its facilities and a laboratory for testing.

(b) Only employees designated by the dispensary licensee, who are trained and knowledgeable on the transportation protocols required by this chapter, shall transport marijuana and manufactured marijuana products. Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.

(c) Each time marijuana and manufactured marijuana products are transported, the dispensary licensee shall prepare a manifest on a form prescribed by the department that lists the elements required by the department's tracking system. A dispensary licensee shall only transport marijuana or manufactured marijuana products that are listed on the manifest. A dispensary licensee shall transport marijuana or manufactured marijuana products in secured containers . The dispensary licensee shall include a copy of the manifest in the interior and on the exterior of the container.

(b) Upon receipt of marijuana and manufactured marijuana products the dispensary licensee or the laboratory shall immediately report to the department any discrepancies between what is received and what is on the manifest.