**ATTACHMENT 1B**

**Cultivation and Operations Plan**

# CMMLUO/OPERATIONS OVERVIEW- Apps# 12933

**Modification to permit request**
**CUP 16-927 & SP/APN 223-171-001**
**1560 Bear Canyon Road**
**Garberville, CA 95542**
**V4.0 revised 10/6/2022**



Due to the unresolved situation with PG&E and the lack of power service to the subject parcel, the applicant is seeking a resurrection and modification of the original interim permit, which granted permission for 8,000 square feet of mixed light cultivation on the subject property. The applicant requests conversion of said original permit to that of a micro-business designation. Under this micro-business designation, 8,000 square feet of outdoor cultivation would take place, as well as distribution and infusion centered manufacturing activities. The distribution and manufacturing activities would have to be phased in as County approved structures become available on the property. County approved structures could be either some portion of the existing metal building being brought up to finished code compliance, or a self-contained office unit. Either of these two options would be powered by a combination of solar and generator. We request that the County allow us to take this phased approach so that we can apply with the State for the micro-business designation, as opposed to applying only for the cultivation and then reapplying later for a different permit.

The applicant acknowledges that the commercial cannabis activity approval being sought under the aforementioned conditional use permit, pursuant to CMMLUO, is subject to compliance with all other applicable Humboldt County zoning and land use regulations, as well as other applicable provisions of the Humboldt County code and applicable state laws. Determination of compliance will require multi-agency review of proposed activity/development described in the aforementioned special permit and, may also require site inspections by personnel from various governmental agencies.

If development and/or activities on the subject parcel are determined, for some reason, to be out of compliance with any applicable State of County code, regulation or policy, a compliance agreement can be formulated between the applicant and relevant agency or agencies, which includes a compliance timeline whereby operations may continue under a "provisional clearance or permit" and corrective action is initiated to achieve compliance under agreed upon terms.

**Parcel Information:** The subject parcel (223-171-001) is approximately 8 acres, zoned MH and is located near Garberville, CA.

**Topography/Landscape:** The ground surface and the cultivation areas are nearly level, as the subject parcel is situated on an alluvial terrace alongside of the South Fork of the Eel River. Much of the parcel is covered with native tree species.

**Surface Water Features:** The subject parcel borders the South Fork of the Eel River and an unnamed Class 1 watercourse runs through the NE portion of the parcel.

**Roads/Stream Crossings/Easements:** The subject parcel borders Redwood Drive. A single driveway off the county road provides access to an interior clearing. Road conditions including stream crossings were assessed in the development of a site-specific Water Resources Protection Plan (WRPP) by Timberland Resource Consultants. The road accessing the parcel interior did not exhibit signs of erosion or sediment delivery to the nearby receiving waters when

assessed, Assessment and/or work prescribed within a WRPP does not preclude the need to comply with other state and county road requirements applicable to the aforementioned permit application.

**Utilities:** Electrical power will be supplied by a combination of solar and generator backup, and water is provided from Garberville CSD. A portable toilet equipped with hand washing facilities is available on site. Garberville Sanitary district provides water service to the property in the form of two meters, one agricultural and one commercial. A will serve letter specific to the project has been provided to the County. If/when the PG&E situation is resolved, power supply will be reevaluated.

**Water Storage:** Currently consists of two 300 gallon mixing tanks located on the existing lower flat. There are plans to add an additional 50,000 gallons of storage this cultivation season, consisting of ten 5,000 gallon rain catchment poly tanks. It is estimated that the peak months of water usage (July and August) will require up to 36,000 gallons (in total for both months) to service the cultivation operation. These tanks are proposed to be located North of the driveway and outside the streamside management area. This additional storage is in anticipation of potential water shutoff for Ag projects by Garberville CSD when river flows drop below the allowable threshold. These tanks will be installed as resources allow, likely in groups of five tanks at a time. Ag service for the parcel was not interrupted during the 2022 season.

**Cultivation Area(s) and/or other graded flats:** Proposed cultivation on the subject parcel would consist of the following:

5- PVC hoop greenhouses measuring 20'x80' for a total of 8,000 square feet.

Proposed cultivation areas and surrounding ground surfaces were evaluated in the development of a site-specific Water Resources Protection Plan (WRPP) prepared by Timberland Resource Consultants. If deemed necessary, the WRPP will prescribe corrective measures to address conditions which may adversely impact water resources and it will establish a timeline in which to achieve compliance with the RWQCB Order No.2015-0023. Corrective measures prescribed in the WRPP do not preclude the need for Cultivation Areas or other manmade features to be brought into compliance with all applicable state and local grading, excavation and erosion/sediment control requirements.

**Peak Water Demand:** The peak monthly water demand anticipated to maintain cultivation associated with the project during the hottest summer months is 18,000 gallons.

The monthly water usage table below shows water use at different periods of the grow season. Water demand for potential distribution and/or manufacturing activities is considered negligible, and should be easily serviced by the second water meter that Garberville Sanitary District is requiring us to maintain.

## Monthly Water Usage Estimates in Gallons

| Month | Cultivation |
|---|---|
| January | 1000 |
| February | 1000 |
| March | 6000 |
| April | 8000 |
| May | 10000 |

| | |
|---|---|
| June | 13000 |
| July | 18000 |
| August | 18000 |
| September | 14000 |
| October | 7000 |
| November | 4000 |
| December | 4000 |
| Totals | 104000 |

**Irrigation Method(s):** Irrigation is accomplished by use of conventional garden hoses (hand watering). Different methods of drip irrigation shall be experimented with to identify additional methods of water conservation. Mulch shall also be employed in the greenhouses to optimize soil water retention.

**Irrigation Runoff/Erosion Control:** The use of carefully applied hand watering precludes the occurrence of unattended water discharge. Experimental drip irrigation methods shall be closely monitored to mitigate or eliminate runoff entirely. In the unlikely event that residual discharge did occur it would contact permeable soil on nearly level ground in and around cultivation areas and be rapidly absorbed. Movement or runoff of any irrigation solution away from the point of ground contact is very unlikely. The ground surface in and around cultivation areas is proactively managed year-round to prevent any unwanted migration of entrained constituents such as fine sediment, fertilizer or other organic particles.

**Watershed Protection:** Watershed protection is accomplished through implementation of BMP's and corrective measures prescribed in a site-specific Water Resources Protection Plan developed by Timberland Resource Consultants, a RWQCB approved Third Party Program Administrator.

**MEASURES TO COMPLY WITH FLOOD DAMAGE PREVENTION:** It has been determined by Omsberg and Preston engineering that the site is elevated above the 100 year flood zone, which should alleviate the need for such measures. Please see attached, signed and stamped flood elevation certificates.

Once enrolled under R1-2015-0023, participants are required to engage in ongoing monitoring, reporting and maintenance including periodic site inspections and reviews of operational practices to ensure regulatory requirements related to the following items are being met.

- Site maintenance, erosion control, and drainage features
- Riparian and wetland protection and management
- Water storage and use
- Fertilizers and soil amendments
- Petroleum products and other chemicals
- Refuse and human waste
- Stream crossing maintenance
- Irrigation runoff
- Pesticides and herbicide management
- Cultivation related wastes

Additionally, participants ensure that management measures and controls are effectively protecting water resources, and that any newly developing problems representing a water quality concern are identified and corrected quickly.

**Fertilizers, Pesticides, and other Regulated products:** The pest/fungicides to be used on the premises for cultivation are listed below. They are all organic products, certified by their OMRI listing. Employees are trained in the use of protective equipment such as eyewear and gloves before being allowed to apply any pest/fungicides. Any and all fertilizers used in cultivation shall be organic in nature, thereby subject to minimal regulation. These products shall be stored in one of the unfinished units of the existing metal building.

| Pest/Fungicides | | | Active Ingredient |
|---|---|---|---|
| Azatrol | Pesticide | OMRI | Azadirachtin |
| Serenade | Fungicide | OMRI | Bacilus Subtilis |
| Green Cure | Fungicide | OMRI | Potassium Bicarbonate |

**List and describe machinery and equipment used for cultivation and associated activities:**

**Greenhouse cultivation**: Circulation fans, exhaust fans, dehumidifiers, and submersible pumps, as well as control systems for all appliances.

**Drying/Curing**: Fans and dehumidifiers

**Processing portion of cultivation operation**: Electric drive trimming machines, weighing devices (scales), standard cleaning equipment such as scissors and trim trays.

**Describe equipment service and maintenance:**

Equipment service/maintenance is done by qualified service providers from the nearest available location.

**List and describe compressed gases, cleaners, solvents and sanitizers; indicate amounts normally stored and how/where they are stored:**

**Domestic cleaning products** (Simple Green, Rubbing Alcohol) in normal domestic amounts are kept inside on shelves in the partially completed existing metal building. Up to 10 gallons of Isopropyl Alcohol shall be stored in the metal building for cleaning the trimming machines. This larger quantity of alcohol shall be kept in an approved flammables cabinet.

**Fertilizers:** The fertilizers/amendments listed below are used throughout the grow season; only quantities needed are purchased and brought to the site. Annual reporting of fertilizer/amendment use is required under RWQCB Order No. R1-2015-0023 and the data is provided on page 4, Appendix C (RWQCB Order No. R1-2015-0023). Mixing of the products below takes place only within a small area near cultivation sites and the products are kept protected from accidental spillage or disturbance from wildlife while mixing takes place.

Age Old- Grow

Age Old- Bloom

Composted Organic Chicken Manure

"Spare Time Supply" Bat Guano

Kelp Meal

Mycorrhizae

Any unused amendments and/or liquid fertilizers shall be stored in the metal building, as indicated on the plot plan. Liquids shall be stored in an approved containment device such as a plastic tote.

The applicant acknowledges that the storage and/or use of certain materials in specified volumes and/or weights will be subject to regulation through Humboldt County Division of Environmental Health CUPA and may require: submittal of inventories for those materials, documentation of emergency and training procedures, maintenance of hazardous waste disposal records, obtaining an EPA generator ID number, and be subject to site inspections.

**Cultivation related wastes:** These wastes are sorted such that compostable materials are recycled or composted on site within a small area equipped with perimeter and top containment to prevent unwanted movement of materials due to weather conditions or animals/pests. Other materials, unsuitable for composting, are stored in conventional trash containers with tight fitting lids and serviced by the local garbage company, Recology. As it becomes necessary, exhausted soil will be removed from the cultivation area and placed in a soil containment area to initiate microbial reconditioning and prevent unwanted constituent migration. These soil reconditioning areas would consist of wattles and/or silt fences, as well as waterproof coverings to prevent unwanted disbursement of soils into native soils.

**Human Waste:** Temporarily, a portable toilet equipped with a hand washing station will service the subject property. Fully compliant ADA bathrooms will service the facility after the construction of the proposed buildings is completed. These will be serviced by an approved septic system. Omsberg & Preston will be performing septic testing and design to accommodate the proposed buildings.

**Cultivation Operations/Practices:** The applicant intends to cultivate 8,000 square feet of outdoor cannabis in five 1,600 square foot hoop style greenhouses.

**Schedule of Cultivation Activities**

| | |
|---|---|
| January | Site and infrastructure maintenance |
| February | Site and infrastructure maintenance |
| March | Site and infrastructure maintenance |
| April | Obtain clones from licensed nursery and begin propagating for the season. |
| May | Plant clones into greenhouses |

| | |
|---|---|
| June | Ongoing plant care and site infrastructure maintenance, propagate clones for second round |
| July | Ongoing plant care and site infrastructure maintenance, propagate clones |
| August | Ongoing plant care and site infrastructure maintenance, propagate clones. Harvest first round of plants. |
| September | Ongoing plant care and site infrastructure maintenance |
| October | Ongoing plant care and site infrastructure maintenance, harvest second round of plants. |
| November | Site and infrastructure maintenance |
| December | Site and infrastructure maintenance |

**Harvesting and Processing:** Plants from the greenhouses shall be dried and cured in one of the partially completed units of the existing metal building. Processing shall likely be completed by the applicant using mechanized trimming machines, which will be powered by a combination of solar and generator. If the applicant does not perform the processing, it shall be performed by a licensed processing facility.
All equipment, surfaces, and tools which come into contact with harvested cannabis are washed and sanitized throughout the day in a manner consistent with The National Organic Program's (NOP) Organic Standards (USDA organic regulations 7 CFR 205.272). These standards require that an organic handling operation takes measures to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances and list acceptable and prohibited compounds.

Individuals involved with processing/trimming utilize personal protective equipment (PPE) including disposable face masks, hair nets, and latex gloves. Ample potable water for hand washing along with restroom facilities equipped with potable water, first aid kits, and an eye-wash station shall be readily available.

**Security:** Access to the subject parcel is restricted by placement of locked metal gates at entrance roads. There shall be a cyclone style security fence encircling all processing and cultivation related activities. This fence shall tie into the locked gate for ingress/egress to the subject property. Motion activated cameras shall be employed to cover the cultivation area, ingress/egress, and other areas such as parking and any buildings.

**Local law enforcement and fire departments shall be provided with all access codes and/or keys to insure access to the property in the event of an emergency.**

## HEALTH AND SAFETY

Employees shall implement the use of appropriate health and safety equipment during performance of tasks. Equipment shall include but not be limited to: latex gloves, dust masks, hair and beard nets, and safety glasses. All management shall wear appropriate safety equipment as necessary. In the event of an accident or injury, employees shall notify the acting manager and take appropriate measures. The severity of the incident will be assessed by staff

to determine a course of action. If minor, any injuries such as cuts or scratches will be treated using supplies available in the on-site first aid kit. If the injury is more serious, the employee will either be transported to an appropriate medical facility or 911 will be called. All accidents and injuries will be documented on the accident report form and kept on record.

**TOILET AND HANDWASHING FACILITIES:** Eventually, the facility will be equipped with ADA compliant restrooms, as well as additional utility sinks for handwashing. There shall be an emergency eye wash station and first aid kit permanently installed on site. The lack of power places a nearly insurmountable obstacle in terms of completing the existing metal building for commercial use. We request that the County allow us to operate with an ADA compliant portable toilet.

**PLUMBING AND SEPTIC**: Eventually, the facility shall be serviced by a septic system designed by Whitchurch Engineering.

**DRINKING WATER:** Drinking water for employees shall be provided by the Garberville Sanitary District.

**ROAD USAGE:** Road usage shall be minimal, as the proposed scope of the operation has drastically changed. We anticipate the only traffic originating from the applicant(s) and their business partners (i.e. distributors). Any increased road usage due to activities at the processing facility shall be mitigated by installation of asphalt on the roadways as resources allow.

**ON-SITE HOUSING:** No farmworker or employee housing shall exist on site.

**PARKING SPACES:** Since we will not be opening the existing metal building to the public, we would defer to the County in regards to parking. In the event that the metal building is completed to allow access by the public, there shall be twenty-four parking spaces, two ADA spaces, and one loading space to service the facility.

**WATER STORAGE:** See measures described above.

**MEASURES TO ENSURE WATERSHED PROTECTION:** See measures described above.

**MEASURES TO COMPLY WITH FLOOD DAMAGE PREVENTION:** It has been determined by Omsberg and Preston engineering that the site is elevated above the 100 year flood zone, which should alleviate the need for such measures. Please see attached, signed and stamped flood elevation certificates.

**EQUIPMENT AND SUPPLIES**

2- triminator dry trim machines
2- weighmaster approved certified scales

Miscellaneous hand tools such as scissors

**TROUBLESHOOTING**

If an error occurs in recording during any point in the processing chain, records will be reviewed by facility managers/owners until the error is found and reconciled. See SOP's below for a more detailed description of this protocol. Mechanical problems with equipment will be evaluated by the facility manager to determine whether they can be fixed in-house or will require the help of a professional.

## Applicant Facility Maintenance and Product Intake SOPS: Distribution and Manufacturing

### 10101 BR - Batch Production Record Checklist

The applicant will complete this checklist every time a written batch production record is prepared when a batch of cannabis product is manufactured. The applicant will use this checklist to confirm the batch production record contains complete information regarding the manufactured batch.

### 10102 BR Master Manufacturing Protocol Checklist

The applicant will complete this checklist for every master manufacturing protocol written for each unique formulation of cannabis product, and each batch size, that the applicant manufactures. This checklist will be used to verify comprehensive detail and complete information for each master manufacturing protocol, which should mitigate against the potential for adulteration through the incorporation of incorrect amounts of cannabinoids, unintended ingredients, or hazards that were identified in the product quality plan, as well as against the potential for misbranding through the incorporation of ingredients that are not identified on the label or the mislabeling of the product. The master manufacturing protocol should additionally ensure uniformity in finished batches and across all batches that are produced.

### 10103 BR Product Quality Plan Checklist

The applicant will complete this checklist for each product quality plan created for every type of product the applicant manufactures. This checklist will be used to verify comprehensive detail and complete information for each product quality plan, which should address the hazards associated with the premises or the manufacturing process that, if not properly mitigated, could cause the product to be adulterated or misbranded, or cause the product to fail laboratory testing or quality assurance review.

For each product quality plan, the applicant will conduct a comprehensive assessment of the overall manufacturing process, identify each step from the intake of product components to the transfer of the product from the manufacturing premises, and determine all potential risks associated with each step in the manufacture of the product. The applicant will then identify the preventative measures necessary to mitigate the potential risks and the methods needed to monitor and evaluate the effectiveness of each preventative measure, as well as the action to take if a preventative measure is unsuccessful.

The applicant will maintain all product quality plans and any documentation of preventative measures, monitoring results, and corrective actions on-site at all times in a way that can be provided to the Department upon request.

Citations: CCR 17-01-13 40253(a) (2019), CCR 17-01-13 40253(b) (2019), CCR 17-01-13 40253(g) (2019)."

**10104 BR Recordkeeping & Electronic Access to Records**

The applicant will secure and back up electronic records that prevents unauthorized access and that ensures the integrity of the records is maintained. These tasks will be completed when conducting any activity that is required to be recorded under state or local law and regulation. The applicant may elect to contract with a third party for record custodial or management services. All persons with recordkeeping responsibilities must be informed that a contract with such a service does not relieve the applicant of the recordkeeping responsibilities described here and in applicable state and local laws and regulations. All documentation will be maintained in English; although other languages are allowed. Outdated SOPs will not be accessible to on-site employees.

Policy Citation: CCR 17-01-13 40500(b) (2019); CCR 17-01-13 40500(c) (2019)."

**10105 BR - Sales Invoices & Receipts Checklist**

The applicant will complete this checklist for every sales invoice or sales receipt generated. The applicant will generate a sales invoice or sales receipt for every sale, transport, or transfer of cannabis products to another licensee. This checklist will be used to confirm comprehensive detail and complete information when creating sales invoices and receipts

Sales invoices and receipts can be maintained electronically but must be readily accessible for examination by the Department and its inspectors and agents upon demand. The applicant will not commingle sales invoices and receipts for the sale, transport, or transfer of cannabis or cannabis products with those invoices concerning other commodities.

Citations: CCR 17-01-13 40505(a) (2019), CCR 17-01-13 40505(d) (2019)"

**10111 BR-R Actions Requiring Notification to Department**

The applicant must notify the Department within 48 hours of the following circumstances:

- Criminal conviction of any owner;
- Civil penalty or judgement;
- Revocation of local authorization; or
- An administrative order for violation of labor standards

The applicant will keep and maintain all notifications to the Department in on-site records. In addition to notifying the Department within 48 hours, the applicant will also provide this information in its annual license renewal.

Policy Citation: CCR 17-01-13 40184 (2019)."

**10201 EMPL - Sanitation and Health**

All employees are required to abide by Employee Health and Sanitation procedures at all times while engaging in commercial cannabis activities at the applicant's licensed premises. The applicant is committed to ensuring all cannabis products are manufactured in a safe and sanitary manner and to ensuring the identity, strength, quality and purity of cannabis products are maintained. All employees will:

• Report to work wearing clean garments;

• Wash hands thoroughly in an adequate hand-washing area before starting work, prior to engaging in the production or manufacture of marijuana products, and any other time when hands may have become soiled or contaminated; and

• Maintain good personal hygiene, including but not limited to, keeping fingernails manicured and long hair away from the face, etc.; and

• Refrain from having direct contact with the cannabis and wear hair nets, beard nets, face masks, and rubber gloves in good repair when appropriate.

An employee will notify the Manufacturing Manager as soon as he or she becomes aware that he or she may have a sickness or injury. If the Manufacturing Manager suspects an employee may be ill or have an injury, he or she will exclude employee from any operations which may be expected to result in contamination until the condition is corrected. Depending on the seriousness of the condition, the supervisor, under the discretion of the Human Resource Manager, may require the employee have documentation from a physician certifying his or her health prior to commencing working at the facility again.

In addition to general daily sanitary requirements, any employee who engages in the preparation, handling, and packaging of edible products will successfully complete a California food handler certificate course from an entity accredited by the American National Standards Institute (ANSI) within 90 days of working for the applicant and again every three years during employment. The applicant will obtain documentation evidencing the fulfillment of this requirement.

It is the responsibility of the Human Resource Manager to ensure all employees engaged in the manufacture of edible marijuana product engage in the above food safety training.

Policy Citations: CCR 17-01-13 40246(a) (2019); CCR 17-01-13 40246(a) (2019); CCR 17-01-13

40280(a)(3) (2019)."

**10202 EMPL - Manufacturing Training**

All personnel, within 30 days of engaging in any cannabis manufacturing process, will take part in the required training program. This program consists of:

• An overview of the cannabis manufacturing process and standard operating procedure(s);

• Quality control procedures;

• Product quality plans;

• Proper and safe usage of equipment or machinery;

• Safe work practices applicable to an employee's job tasks, including appropriate use of any necessary safety or sanitary equipment;

• Cleaning and maintenance requirements;

• Emergency operations, including shutdown; and

• Any additional information reasonably related to an employee's job duties.

Additionally, manufacturing employees who prepare, handle, or package edible products will:

• Successfully complete a food handler course accredited by the American National Standards Institute (ANSI) within 90 days of commencing employment at the premises and again every three years during employment; and

• Provide documentation evidencing the fulfillment of this requirement shall be given to their supervisor.

Since the Director of Manufacturing will have the education, training, and experience necessary to ensure the production of quality cannabis product by all personnel, he/she will be the designated training personnel. The Director of Manufacturing will sign and date a document on an annual basis attesting that he or she has received and understands all information that will be provided to employees in the manufacturing training program. This documentation will be maintained in applicant records.

For more information regarding general employee training, please see the New Employee and Training SOP.

For more information regarding quality control employee training, please see the Quality Control Training SOP.

Policy Citation: CCR 17-01-13 40280(a)(2) (2019); CCR 17-01-13 40280(a)(3) (2019); CCR 17-01-13 40280(c) (2019)."

**10203 EMPL - New Employee and Annual Training**

The applicant will only hire employees that have the education, training, and experience, or any combination thereof, to enable the them to perform all assigned functions. Employees shall not be allowed to report to work prior to receiving orientation training or when any required critical training is eight weeks or more past due.

Additionally, the applicant will ensure that that the assigned supervisory personnel, the Director of Human Resources and the Director of Manufacturing, have the education, training, experience, or combination thereof necessary to train new employees. The Human Resources Director and the Director of Manufacturing will sign and date a document on an annual basis

attesting that he or she has received and understands all information that will be provided to employees in the training program. This documentation will be maintained in applicant records.

The applicant will ensure that all personnel receive annual refresher training that at minimum covers all topics listed in the "tasks" section of this standard operating procedure SOP. This annual refresher training will be completed within 12 months of the previously recorded training completion date.

For more information regarding manufacturing training, please see the Manufacturing Training SOP.

For more information regarding quality control employee training, please see the Quality Control Training SOP.

Policy Citations: CCR 17-01-13 40280(a)(4) (2019); CCR 17-01-13 40280(c) (2019); CCR 17-01-13"

**10204 EMPL - Quality Control Training**

The applicant will ensure that all manufacturing employees are given training on quality control procedures prior to independently engaging in any cannabis manufacturing process. This quality control training will be conducted in addition to the applicant's general employee training.

Since the Quality Assurance Director will have the education, training, and experience necessary to ensure the production of quality cannabis product by all personnel, he/she will be the designated training personnel. The Quality Assurance Director will sign and date a document on an annual basis attesting that he or she has received and understands all information that will be provided to employees in the quality control training program. This documentation will be maintained in applicant records.

For more information regarding general employee training, please see the New Employee and Training SOP.

For more information regarding manufacturing training, please see the Manufacturing Training SOP. Policy Citation: CCR 17-01-13 40280(a)(2)(B) (2019); CCR 17-01-13 40280(a)(2)(C) (2019); CCR 17-01-13 40280(c) (2019).

**10301 - FCLTY Facility Construction and Design**

The applicant's premises, including any fixtures, will be maintained in a clean and sanitary condition in order to prevent cannabis products from becoming adulterated. The applicant will ensure the facility is constructed in such a manner:

• That floors, walls, and ceilings are of smooth, nonporous, easily cleanable, corrosion-resistant, and suitable to the activities conducted at the facility;

• That drip or condensate from fixtures, ducts, and pipes does not contaminate cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials;

• So as to provide adequately wide and unobstructed aisles or working spaces between equipment and walls that permit employees to bother perform their duties and protect against

the contamination of cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials via clothing or personal contact.

The applicant will ensure a janitorial facility is located at the facility and meets the requirements of the Health and Safety Code.

Policy Citations: CCR 17-01-40240(b)(1) (2019); CCR 17-01-40240(b)(5) (2019); CCR 17-01-40 240(b)(5)(A)(2019).

**10302 FCLTY Facility Grounds**

The applicant will:

• Properly store equipment, remove litter and waste, and cut weeds or grass within the immediate vicinity of the facility so that the premises will not constitute an attractant, breeding place, or harborage for pests;

• Properly maintain roads, yards, and parking lots so that these areas will not constitute a source of contamination in areas where cannabis products are handled or transported;

• Provide adequate drainage areas in order to prevent pooled or standing water, contamination by seepage, or the breeding of pests due to unsanitary conditions;

• Provide and maintain waste treatment systems so as to prevent contamination in areas where cannabis products may be exposed to such system's waste or waste by-products; and

• Screen, seal, or otherwise protect openings in the building, such as windows, exhaust fans, ventilation ducts, or plumbing vets.

If the applicant's facility grounds are bordered by grounds outside of its control, that are not maintained in the same manner described above, the applicant will inspect, exterminate, and exercise any other reasonable care within the facility in order to eliminate any pests, dirt, and/or filth that poses a source of contamination.

The applicant will ensure that all insecticides, rodenticides, or any other pesticides used meet the requirements of California's Health and Safety Code, section 114254.

Policy Citation: CCR 17-01-13 40240(a) (2019)."

**10401 IM - Daily Inventory Management**

The Director of Manufacturing will oversee manufacturing employees and ensure that these tasks are completed each day. The applicant will ensure a standard of measurement supported by the Statewide Track and Trace System and approved by the Department is used when recording quantities for inventory tracking purposes. The applicant will measure, record, and report cannabis weight in pounds, ounces and fractions thereof, and in metric units wherever possible. The applicant will only use scales that are Department-approved, certified Legal-for-Trade, and NTEP approved. The applicant will maintain all documentation of approved scales and provide a copy to the Department, upon request.

METRC is a web-based tool coupled with UID technology that gives both the user and the Department the ability to identify and account for all cannabis and cannabis products. Through the use of UID technology, a licensed cultivator will tag either the seed or immature plant with

an individualized number, which will follow the cannabis through all phases of production and final sale to a customer. This will allow the Department and the METRC user to monitor and track cannabis inventory. METRC will also provide a platform for the Department to exchange information and provide compliance notifications to the applicant.

It is the responsibility of the Director of Manufacturing to ensure that all applicant company personnel shall:

• Use batch numbers in conjunction with UID tags to track cannabis inventory through every stage of production to maintain the distribution chain;

• Create and maintain batch production records at the time of performance for each production batch. The batch production records shall accurately follow the appropriate master manufacturing protocol, and each step of the protocol shall be performed in the production of the batch;

• Store cannabis and cannabis products on the premises in an enclosed, locked area within the limited access area;

• Designated areas within the premises that are compartmentalized based on function, such as the manufacturing area; and

• Control access between areas of the premises.

• All bags of cannabis trim/harvested cannabis will have the respective UID attached; and

• All cannabis production batches will have the respective UID tag attached.

All records related to daily inventory management shall be maintained on the premises for 7 years and shall be made available to the Department upon request.

Policy Citations: CCR 17-01-13 40500(b) (2019), CCR 17-01-13- 0500(a)(11) (2019), CCR 17-01-13 40258(a) (2019)"

**10402 IM - Inventory Audits**

The applicant will regularly conduct physical inventory audits. The applicant will reconcile on-hand inventory at least once every 30 days, and assign the same personnel to recurring inventory groups whenever possible. At least one employee shall be a Quality Assurance Specialist or the Compliance Manager.

The applicant will:

• Ensure that inventory audits are completed on schedule with minimal impact on regular operations.

• Report any discrepancies identified during inventory audits to the Director of Manufacturing.

• Follow good handling practices when conducting inventory audits to minimize risks of microbial contamination. Be free of infectious illnesses and wear protective clothing and hair coverings.

• Review and maintain all audit logs. Audit logs will be kept on the premises for 7 years and be made available to the Department upon request.

The applicant will establish an inventory audit schedule that includes all of the following:

• Shift audits – in process cannabis.

• Weekly audits – bulk cannabis storage containers, in process cannabis, and finished cannabis products.

• Monthly audits – complete inventory count.

• Semi-annual audits – complete inventory with second count.

• Annual audits – complete inventory with second count witnessed by the Director of Manufacturing.

Policy Citation: CCR 17-01-13 40282(b) (2019); CCR 17-01-13 40282(a) (2019); CCR 17-01-13 40500(a)(11) (2019); CCR 17-01-13 40500(b) (2019)."

**10403 IM - Handling Inventory Discrepancies**

All manufacturing personnel will report all discrepancies identified during inventory audits, including diversion, theft, loss, or any criminal action to the Director of Manufacturing, Director of Compliance and Regulatory Affairs, and the Director of Security. The employee who discovered the discrepancy shall provide audit findings or other records that evidence or otherwise pertain to the discrepancy. If required or desired by the Department, a complete Incident Log and all relevant Post-Incident Reports shall be submitted to the Department as soon as possible after unlawful activity is determined to be the cause of an inventory discrepancy.

The applicant's physical inventory track-and- trace system account should be reconciled at least once every 30 days. Any discrepancies that are left over after the applicant's internal reconciliations should be accounted for, documented, and communicated to the board or department using the "Package Adjustments" feature in the Statewide Track-and-Trace system.

If the discrepancy is discovered to be the result of criminal activity, such as theft or diversion:

• Notify local law enforcement;

• Report the discrepancy to the Department within 24 hours; and

• Report the discrepancy to the Department as needed.

A response plan will be created upon discovering a discrepancy. This response plan will include, but will not be limited to:

• Corrective actions with responsible personnel;

• Communication to be had with any other licensees who are involved; and

• Corrective actions made to the Statewide Track-and-Trace system.

Policy Citations: CCR 17-01-13 40282(b) (2019); CCR 17-01-13 40282(c) (2019)."

**10404 IM - Storage and Transfer of Material**

Facility staff will ensure that all movement of cannabis into, throughout, and out of the facility are recorded in METRC within 24 hours of the activity. These activities include:

Receipt of cannabis material.

The transfer to or receipt from another licensed manufacturer of cannabis products for further manufacturing.

All changes in disposition of cannabis or cannabis products where a change in disposition includes, but is not limited to, processing of the cannabis or further processing of the cannabis products or packaging and labeling, or storage of cannabis products.

Use of cannabis or cannabis product for internal quality control testing or product research development. Transfer of cannabis products to a distributor.

Any other commercial cannabis activities

For each recorded event, we ensure the following is entered into the system:

• The licensed entity from which the cannabis material or product is received, including that entity's license number, and the licensed entity to which the cannabis product is transferred, including that entity's license number.

• The name and license number of the distributor who transported the cannabis material or cannabis product.

• The type of cannabis material or cannabis product received or transferred.

• The weight of the cannabis material or cannabis product received or transferred.

• The date of receipt or transfer.

• The unique identifier assigned to the cannabis material or cannabis product.

• Name and employee ID number of facility employee receiving the cannabis.

• Copies of purchase order, employees' ID cards, and other supporting documentation.

• Any other information required by other applicable licensing authorities.

While operating prior to Annual Licensing and Access to METRC - CA State Track and Trace System, all such documentation shall be written on Manifests and internal records.

Policy Citation: CCR 17-01-13 40512(a) (2019); CCR 17-01-13 40512(b) (2019)."

**10405 IM - Inventory Control Overview**

The applicant will order UID tags within 5 business days of receiving access to the Track and Trace System. The applicant will record receipt of the UID tags in the Track and Trace System within 3 business days of receipt. After access to the Track and Trace System is granted, the applicant will input all inventory into it no later than 30 calendar days after receipt of UID tags. The applicant will maintain copies of any documentation required by the Department for at least 7 years after the event. Reconciliation shall be performed by one person and independently

verified by a second person. Upon discovering a problem in inventory control procedures, ensure all necessary changes are made to them and employees are retrained immediately. The applicant will ensure a standard of measurement supported by the Track and Trace System and approved by the Department is used when recording quantities. The applicant will only use scales that are Department-approved, certified Legal-for- Trade, and NTEP approved. The applicant will maintain all documentation of approved scales and provide a copy to the Department upon request. The applicant will conduct an audit if a discrepancy between the inventory and the Track and Trace System is found. Notify the Department within 24 hours if the audit turns up a discrepancy that's not within 5% of the documented inventory and/or evidence of theft or diversion.

Policy Citations: CCR 17-01-13 40517(a) (2019); CCR 17-01-13 40517(b) (2019); CCR 17-01-13 40500(b) (2019); CCR 17-01-13 40282(b) (2019); CCR 17-01-13 40277(a) (2019); CCR 17-01-13 40282(c) (2019); CCR 17-01-13 40282(d) (2019).

**10406 IM - Loss of Access to the Track and Trace System**

The Director of Manufacturing will confirm that procedures are in place upon loss of access to the company's chosen computerized seed to sale system and/or the statewide track and trace system, or as directed.

It is the responsibility of the Director of Manufacturing to ensure all facility personnel are trained in how to respond to a loss of access to the statewide track and trace system.

The applicant's Director of Manufacturing shall implement the following procedures in the event that there is a loss of access to the statewide track-and-trace system:

• Prepare and maintain comprehensive records detailing all required inventory tracking activities during the loss of access.

• Document the date and time when access to the track-and-trace system was lost, when it was restored, and the cause for each loss of access.

Policy Citations: CCR 17-01-13 40513(a) (2019); CCR 17-01-13 40513(c) (2019)."

**10407 IM - Required Inventory Tracking & Reporting**

The Director of Manufacturing will oversee manufacturing personnel and ensure that these tasks are completed each day. The applicant will ensure a standard of measurement supported by the Statewide Track and Trace System and approved by the Department is used when recording quantities for inventory tracking purposes. The applicant will measure, record, and report cannabis weight in pounds, ounces and fractions thereof. The applicant will only use scales that are Department- approved, certified Legal-for-Trade, and NTEP approved. The applicant will maintain all documentation of approved scales and provide a copy to the Department, upon request.

The Track-and-Trace-System is a web-based tool coupled with UID technology that gives both the user and the Department the ability to identify and account for all cannabis and cannabis products. Through the use of UID technology, a licensed cultivator will tag either the seed or immature plant with an individualized number, which will follow the cannabis through all phases

of production and final sale to a customer. This will allow the Department and the Track-and-Trace-System user to monitor and track cannabis inventory. The Track-and-Trace-System will also provide a platform for the Department to exchange information and provide compliance notifications to the applicant.

The Director of Manufacturing will ensure that all commercial cannabis activities are being entered into the statewide track-and-trace system. All authorized facility personnel, under the condition of employment, will complete the following activities:

• Record all commercial cannabis activities into the track-and-trace system within 24 hours of the activity; and
• Maintain comprehensive records for all required inventory tracking activities in the event of loss of access to the track-and-trace system.

Policy Citations: CCR 17-01-13 40513(a) (2019); CCR 17-01-13 40512(a) (2019)."

**10408 IM - Statewide Track and Trace System Access**

The Director of Operations will establish a premises account in the statewide track and trace system prior to commencement of any commercial cannabis activities associated with the applicant's manufacturing license. The applicant's manufacturing operation will maintain an active account while licensed. If the Director of Operations does not complete the required training prior to the applicant receiving their annual license, this individual will complete the training within 5 business days of the license being issued.

Each statewide track and trace system account manager and user will have a unique log-on, consisting of a username and password, which will not be used by any other person. Employees will only use their own credentials to log into the statewide track and trace system. Applicant representatives will not share their log-on information, including their username or password, with anyone for any reason.

The Track and Trace System Authorized Users Log will be maintained on-site. The applicant will order UID tags within 5 business days of receiving access to the track and trace system and record the receipt in the system within 3 business days of receipt. If the applicant is in operation at the time access to the track and trace system is granted it will input all inventory into the system no later than 30 days after UID tag receipt.

The Director of Manufacturing is responsible for designating track-and-trace users as needed, and shall ensure that designated users are trained in the proper and lawful use of the track-and-trace system before the users are permitted to access the track-and-trace system.

The applicant will maintain an accurate and complete list of all track-and-trace designated users and update the list immediately when changes occur.

Policy Citations: CCR 17-01-13 40510(d)(3) (2019); CCR 17-01-13 40510(d)(3) (2019); CCR 17-01-1340517(a) (2019); CCR 17-01-13 40517(b) (2019); CCR 17-01-13 40510(c)(2) (2019); CCR 17-01-1340510(c)(3) (2019).

**10420 IM - Receiving Bulk Cannabis Product at Facility**

These tasks will be performed only upon a previously scheduled and approved delivery of a shipment of inventory by a licensed distributor to the applicant's licensed premises. Unscheduled and unapproved deliveries may not be accepted. The applicant will not accept any delivery of cannabis or cannabis products without receiving a copy of a shipping manifest from the licensed distributor responsible for making the delivery at least 24 hours prior to the delivery. Shipments of cannabis goods may only be accepted from a licensed distributor. Shipments of cannabis goods must be inspected for freshness. Cannabis goods that have exceeded their expiration or sell-by date may not be accepted. If a facility employee discovers there is a defect or non- conformity in an inventory shipment, they will refuse it.

Policy Citations: 16-42-5049(a)(4); 16-42-5049(a)(5); 16-42-5049(b)(6)(B); 16-42-5314(b); 16-42-5406(b); 16-42-5412; 16-42-5422.

**10501 MFG - Manufacturing Operations**

The applicant will:

• Conduct all cannabis product manufacturing under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of cannabis products, and deterioration of cannabis products; and

• Create and implement a written product quality plan for each type of product manufactured at the premises. The Director of Manufacturing is responsible for implementing and maintaining manufacturing processes and procedures that ensure cannabis product quality.

When raw materials, ingredients, or waste are unprotected, they will not be handled simultaneously in a receiving, loading, or shipping area if such handling could result in allergen cross-contact or contaminated cannabis products.

Adulterated cannabis products, raw materials, or other ingredients will be either disposed of in a manner that protects against the contamination of other cannabis products or ingredients or reprocessed, if appropriate, using a method that has been proven to be effective and subsequently reexamined and found to be unadulterated.

When the applicant uses ice or water that comes into contact with cannabis products, the water used must be safe, potable, and of adequate sanitary quality.

Policy Citations: CCR 17-01-13 40248(a) (2019); CCR 17-01-13 40250(a) (2019); CCR 17-01-13 40253(a) (2019); CCR 17-01-13 40250(a) (2019); CCR 17-01-13 40240(b)(3)(A) (2019)."

**10502 MFG- Good Manufacturing Processes Overview**

The applicant will ensure all personnel properly completes the tasks listed in this SOP. Open lesions, boils, and/or infected wounds will be adequately covered (e.g., by an impermeable cover). Personnel shall be instructed to report any relevant health conditions to their supervisors. All employees working in direct contact with cannabis products, cannabis product-contact surfaces, and cannabis product- packaging materials will conform to hygienic practices to the extent necessary to protect against allergen cross-contact and contamination of cannabis

products while on duty. The applicant will ensure that the grounds of the premises it controls are kept in a condition that prevents contamination.

Policy Citation: CCR 17-01-13 40246(a) (2019); CCR 17-01-13 40240(a)(2) (2019)."

**10503 MFG - Permissible Extractions Overview**

The applicant will only conduct cannabis processing and extraction using the following methods:

• Oil infusion: extraction of biomass into oils or butter by heating on a heating element.

No solvent extraction operations will occur.

Mechanical systems will be commercially manufactured, and bear a permanently affixed and visible serial number.

The applicant will establish and implement written procedures to document that the equipment is maintained in accordance with the manufacturers' specifications and to ensure routine verification that it is operating in accordance with specifications and continues to comply with fire, safety, and building code requirements.

The applicant is responsible for developing standard operating procedures (SOPs), good manufacturing practices, and a training plan to produce extracts. No solvents or hazardous materials will be used in the manufacturing process.

Policy Citation: CCR 17-01-13 40220(a)(1) (2019); CCR 17-01-13 40220(a)(2) (2019); CCR 17-01-13 40220(a)(3) (2019); CCR 17-01-13 40220(a)(4) (2019); CCR 17-01-13 40220(a)(5) (2019); CCR 17-01-13 40223(a) (2019); CCR 17-01-13 40222(c) (2019); CCR 17-01-13 40225(a) (2019); CCR 17-01-13 40225(c) (2019); CCR 17-01-13 40225(d) (2019); CCR 17-01-13 40225(e) (2019)."

**10504 MFG - Failed Product Batches**

A finished cannabis product batch that fails any required testing shall be destroyed unless the product batch may be remediated by relabeling pursuant to, or a corrective action plan is approved by the Department.

Policy Citation: CCR 17-01-13 40330(a)(1) (2019); CCR 17-01-13 40330(a)(2) (2019); CCR 17-01-13 40330(c) (2019)."

**10505 MFG - Product Standards & Prohibited Products**

The applicant will not sell the following types of cannabis products:

• Alcoholic beverages, except for properly packaged and delivered tinctures;

• Any product containing any non-cannabinoid additive that would increase potency, toxicity, or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives include nicotine and caffeine. (Except for products containing naturally-occurring caffeine, e.g. coffee and tea.);

• Any product that must be held at or below 41 degrees F to keep it safe for human consumption. (Except for juice that must be held at or below 41 degrees F if it was processed in accordance with the Special Processing Requirements SOP.);

• Any thermally-processed low-acid cannabis product packed in a hermetically sealed container that, if it did not contain cannabis, would be subject to the manufacturing requirements of Title 21, Code of Federal Regulations, Part 113;"

"• Any acidified cannabis product that, if it did not contain cannabis, would be subject to the manufacturing requirements of Title 21, Code of Federal Regulations, Part 114;

• Any juice that is not shelf-stable or was not processed in accordance with the Special Processing

Requirements SOP;

• Dairy products, except that butter purchased from a licensed plant or location that is subsequently infused/mixed with cannabis may be sold as a cannabis product;

• Meat products, other than meat products prepared in accordance with the Special Processing

Requirements SOP;

• Seafood products;

• Any product attractive to kids, including products shaped like a human, animal, insect, or fruit;

• Any product manufactured by applying an extract or concentrate to commercially available food. Except that food product may be used as an ingredient in a cannabis product as long as the original product is rendered unrecognizable and is not listed on the label as the commercial product.

Policy Citation: CCR 17-01-13 40300 (2019); CCR 17-01-13 40308 (2019).

**10506 MFG - Topical, Concentrated & Other Cannabis Products**

Except for cannabis, cannabis concentrate, or terpenes, topical cannabis products shall only contain ingredients permitted for cosmetic manufacturing in accordance with Title 21, Code of Federal Regulations, Part 700, subpart B (section 700.11 et seq.) (Rev. March 2016), which is hereby incorporated by reference.

A topical cannabis product or cannabis concentrate shall not contain more than 1,000 milligrams THC per package.

A topical cannabis product or cannabis concentrate may contain more than 1,000 milligrams THC per package, but not more than 2,000 milligrams THC per package, if the product is labeled for "FOR MEDICAL USE ONLY" and is only available for sale to a medicinal use customer.

Any orally-consumed product that contains more than .5% alcohol by volume as an ingredient, and is not otherwise an alcoholic beverage shall be packaged in a container no larger than two (2) fluid ounces and shall include a calibrated dropper or other similar device capable of accurately measuring servings.

Policy Citation: CCR 17-01-13 40306(c) (2019); CCR 17-01-13 40315(c) (2019); CCR 17-01-13 40315(d) (2019); CCR 17-01-13 40308 (2019); CCR 17-01-13 40306(c) (2019).

**10601 QC - Quality Control Program Overview**

The applicant will implement a Quality Control Program to ensure that cannabis products manufactured at the facility are not adulterated or misbranded. The quality control operations outlined in the applicant's Quality Control Program will be supervised by the Quality Assurance Director, in coordination with the director of Manufacturing, and performed by quality control personnel. The applicant's Quality Control Program will encompass the following:

- The grounds, building, and manufacturing premises;
- Equipment and utensils;
- Employee health and sanitation;
- Raw materials and other cannabis product components; and
- Manufacturing processes and procedures.

Policy Citations: CCR 17-01-13 40235(a) (2019); CCR 17-01-13 40235(b) (2019).

**10602 QC - Hazard Analysis**

As part of the applicant's Product Quality Plan, quality control personnel, under the direction of the Quality Assurance Director, will conduct a hazard analysis to identify or evaluate known or reasonably foreseeable hazards to the consumer for each type of cannabis product produced at the facility. Types of hazards include:

- Biological hazards, including microbiological hazards;
- Botanical hazards, including cannabis
- Chemical hazards, including radiological hazards, pesticide contamination, solvent or other residue, natural toxins, decomposition, or allergens; and
- Physical hazards, such as stone, glass, metal fragments, hair, or insects.

Quality control personnel will also analyze the layout of the workplace and any other sources of identified potential hazard.

If hazards are identified, preventative measures outlined in the applicant's Product Quality Plan will be implemented. These preventative measures will be observed and measured to assess whether they are operating as intended.

In order to carry out all hazard waste procedures, facility quality control personnel and other employees will be trained on the applicant's quality control policies and procedures, referencing the Quality Control Training SOP.

Please see the Product Quality Plan Checklist to confirm all information needed when creating a product quality plan for each type of product the applicant manufactures.

Policy Citations: CCR 17-01-13 40253(a) (2019); CCR 17-01-13 40253(c) (2019).

**10603 QC - Material Receiving Process**

All deliveries of manufacturing materials, including cannabis materials, will be scheduled and approved by the Manufacturing Manager prior to delivery.

Upon arrival at the applicant's facility, all deliveries will be verified by security personnel at the front entrance to the facility before being allowed access to the loading areas. This verification process will be under video surveillance.

**10604 QC - Incoming Cannabis Product Components**

The Manufacturing Manager will work with the Quality Assurance Director and two quality control personnel to check and maintain the quality of product components in order to prevent the adulteration of cannabis products received by the applicant.

Raw materials and other components that have been received by the applicant will be washed or cleaned as necessary to remove soils and other contaminants. Raw materials and other components will not contain levels of microorganisms that render the cannabis product injurious to human health, or will be pasteurized or otherwise treated during manufacturing so that they no longer contain levels of microorganisms that would cause the cannabis product to be adulterated.

Raw material and other components susceptible to contamination with aflatoxin or other natural toxins, pests, or extraneous material will not exceed generally acceptable limits set by the U.S. FDA in the Feb. 2005 revised Defect Levels Handbook, before these raw materials or ingredients are incorporated into finished cannabis products.

The applicant will hold raw materials and other components in containers designed and constructed to protect against allergen cross-contact or contamination, and will be held at such temperature and relative humidity and in such a manner as to prevent the cannabis products from being adulterated.

Policy Citation: CCR 17-01-13 40248(b) (2019).

**10605 QC - Preventative Measures**

The implementation of preventative measures at the applicant's manufacturing facility is a component of the applicant's Product Quality Plan. This plan is put in place in order to address hazards associated with the premises or the manufacturing process that, if not properly mitigated, may cause the product(s) to be adulterated or misbranded, or may cause the product(s) to fail laboratory testing or quality assurance review.

As part of the Product Quality Plan(s), preventative measures will be implemented to reduce each potential risk or hazard identified during the hazard analysis (please see the Hazard Analysis SOP for more information on this process). These preventative measures will be monitored at all times while on the manufacturing premises or conducting manufacturing activities.

The applicant's preventative measures, as indicated in applicant Product Quality Plan, will include:

1. The identification of critical control points; and

2. The establishment of critical limits for each critical control point.

In order to carry out the implementation of the applicant's preventative measures during the quality control process, applicant quality control personnel and other employees will be trained on the applicant's quality control policies and procedures, referencing the Quality Control Training SOP.

Please see the Product Quality Plan Checklist to confirm all information needed when creating a product quality plan for each type of product the applicant manufactures.

Policy Citations: CCR 17-01-13 40253(a) (2019); CCR 17-01-13 40253(d) (2019).

**10606 QC - Quality Control Evaluations**

As part of the applicant's Product Quality Plan, quality control personnel, under the direction of the Quality Assurance Director, will conduct quality control evaluations. This plan is put in place in order to address hazards associated with the premises or the manufacturing process that, if not properly mitigated, may cause the product(s) to be adulterated or misbranded, or may cause the product(s) to fail laboratory testing or quality assurance review.

In addition to quality control monitoring, to be performed at all times while on the manufacturing premises, quality control evaluations will be done at least monthly, but as frequently as the applicant sees fit. While monitoring tasks are more specific, evaluations will be more general and will be done on a grander scale.

Quality control evaluations consider:

• Observations or measurements used to assess whether preventive measures are operating as intended; and

• Corrective actions taken if preventative measures indicate that risks were not properly mitigated.

In order to carry out all quality control evaluation procedures, applicant quality control personnel and other employees will be trained on the applicant's quality control policies and procedures, referencing the Quality Control Training SOP.

Please see the Product Quality Plan Checklist to confirm all information needed when creating a product quality plan for each type of product the applicant manufactures.

Policy Citation: CCR 17-01-13 40253(a) (2019).

**10607 QC - Consent to Sample Collection**

If the applicant transfers possession but not title of cannabis to a licensed distributor, the applicant will allow the Bureau or the Department, upon their request, to collect samples for purpose of conducting oversight of licensed testing laboratories.

Policy Citation: CCR 17-01-13 40292 (2019).

**10608 QC - Quality Control Monitoring**

Quality control monitoring at the applicant's manufacturing facility is a component of the applicant's Product Quality Plan. This plan is put in place in order to address hazards associated with the premises or the manufacturing process that, if not properly mitigated, may cause the product(s) to be adulterated or misbranded, or may cause the product(s) to fail laboratory testing or quality assurance review.

As part of the Product Quality Plan(s), preventative measures will be implemented to reduce each potential risk or hazard identified during the hazard analysis (please see the Hazard Analysis SOP for more information on this process). These preventative measures will be monitored at all times while on the manufacturing premises or conducting manufacturing activities.

Quality control personnel, under the direction of the Quality Assurance Director, will:

• Approve or reject all components, product containers, closures, in-process materials, packaging materials, labeling, and cannabis;

• Approve all materials, packaging components, in-process material, and finished product specifications impacting product identity, strength, quality and purity; and

• Review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated and resolved.

The applicant will approve or reject all procedures or specifications, which may impact the identity, strength, quality and purity of the applicant's cannabis products or protecting any containers or packaging from contamination.

In order to carry out all quality control monitoring procedures, applicant quality control personnel and other employees will be trained on the applicant's quality control policies and procedures, referencing the Quality Control Training SOP.

Please see the Product Quality Plan Checklist to confirm all information needed when creating a product quality plan for each type of product the applicant manufactures.

Policy Citation: CCR 17-01-13 40253(a) (2019); CCR 17-01-13 40253(e) (2019).

**10609 QC - Recalling a Product**

In the event of a recall of cannabis product, the applicant's Chief Financial Officer (CFO) will contact the applicant's insurance provider and determine coverage of the recall, if any. If the event is covered, the CFO will file all documentation necessary after the completion of the recall. The CFO will notify legal counsel and maintain communication with them throughout the

recall procedures. Any recommendations by legal counsel for alternative procedures must be approved by the Chief Executive Officer (CEO).

The applicant will develop a Product Recall Plan, used for recalling cannabis products that are determined to be misbranded or adulterated that maximizes the recall effect and minimizes risks to public health and safety, including:

• Factors which necessitate a recall;

• Personnel responsible for implementing the recall procedures;

• Notification protocols; and

• Process for the collection and destruction of any called product. Examples of factors that may necessitate a recall include:

• Falsification of test results;

• Traces of contaminants found in the applicant's products;

• The use of packaging that is not tamper-evident, opaque, or child-resistant; and

• Non-compliance with the standards set forth by the California Department of Public Health, the California Bureau of Cannabis Control, and the California Department of Food and Agriculture."

Notification protocols will include:

• A mechanism to notify all customers that have, or could have, obtained the product, including communication and outreach via media, as necessary and appropriate;

• A mechanism to notify any licensees that supplied or received the recalled product;

• Instructions to the general public and other licensees for the return or destruction of the recalled product; and

• Any side effects, injuries, or illnesses resulting from product use.

Recall notifications will be carefully crafted and worded so as to minimize whatever liability the product recall may create for the applicant. This may include crafting a press release. If so, legal counsel will be consulted prior to doing so.

The applicant will immediately execute a recall upon any request or mandate from any regulatory body with authority to do so. The applicant will initiate a mandatory recall if any cannabis product in which the consequences of use of or exposure to the cannabis product are life threatening or involve a serious adverse health consequence and will take all reasonable steps to ensure consumer safety.

The applicant will document every effort made in recalling products and will record all communications with consumers and vendors.

Policy Citation: CCR 17-01-13 40297(a) (2019).

**10610 QC - Handling Cannabis Product Complaints**

The applicant will establish a feedback loop with the licensed distributors who the applicant distributes products to in order for the applicant to promptly receive comprehensive product complaints from vendors, customers, or the Department.

Upon receiving a product complaint, the Quality Assurance Director will:

• Review the complaint;

• Determine whether such complaints involve a possible failure of a cannabis product to meet any of its specifications; and

• Determine whether or not to investigate.

If the Quality Assurance Director determines an investigation is necessary, he or she is to get the investigation approved by the Director of Operations.

Policy Citations: CCR 17-01-13 40295(a)(1) (2019); CCR 17-01-13 40295(a)(2) (2019).

**10611 QC- Voluntary Withdrawals**

The applicant may voluntarily remove or correct a distributed product which involves only a minor issue that would not normally be subject to action by the Department or which doesn't involve any violation at all.

In the event of a voluntary withdrawal of cannabis product, the applicant's Chief Financial Officer (CFO) will contact the applicant's insurance provider and determine coverage, if any.

If the event is covered, the CFO will file all documentation necessary after the completion of the withdrawal. The CFO will notify legal counsel and maintain communication with them throughout the withdrawal procedures.

Any recommendations by legal counsel for alternative procedures shall be approved by the Chief Executive Officer (CEO).

Examples of factors that may necessitate a voluntary withdrawal include:

• Quality-related issues;

• Non-hazardous packaging; or

• Labeling mistakes.

The applicant's Product Recall Plan will include a section dedicated to voluntary withdrawals, which will include:

• Factors which necessitate a voluntary withdrawal;

• Personnel responsible for implementing the voluntary withdrawal procedures;

• Notification protocols; and

• Processes for the collection and destruction of any voluntarily withdrawn product. Notification protocols will include:

• A mechanism to notify all customers that have, or could have, obtained the product, including communication and outreach via media, as necessary and appropriate;

• A mechanism to notify any licensees that supplied or received the recalled product;

• Instructions to the general public and other licensees for the return or destruction of the voluntarily withdrawn product; and

• Any side effects, injuries, or illnesses resulting from product use.

Withdrawal notifications will be carefully crafted and worded so as to minimize whatever liability the product withdrawal may create for the applicant. This may include crafting a press release. If so, legal counsel will be consulted prior to doing so.

The applicant will document every effort made in voluntarily withdrawing products and will record all communications with consumers and vendors.

Policy Citation: CCR 17-01-13 40297(a) (2019).

**10612 QC - Salvaging Products**

The applicant will ensure that any cannabis that has been subjected to adulteration due to improper storage conditions, including, extremes in temperature, humidity, smoke, fumes, pressure, age or radiation due to natural disasters, fires, accidents or equipment failures, shall not be salvaged and may not be distributed.

Salvaging operations may only be conducted if there is:

• Evidence from laboratory tests that say the cannabis meets all applicable standards of identity, strength, product quality and purity; and

• Evidence from inspection of the premises that the cannabis and its associated packaging was not subjected to improper storage conditions as a result of a disaster or accident, if any.

**10613 QC - Weights and Measures**

Weighing devices used by the applicant will be approved, tested, and sealed by the California's Department of Food and Agriculture's Division of Measurement Standards and in accordance with the requirements of Chapter 5 of Division 5 of the Business and Professions Code.

Weighing devices used by the applicant will be registered with the county sealer consistent with Chapter 2 (commencing with 12240) of Division 5 of the Business and Professions Code.

The applicant will use the weighing device for commercial purposes as defined in Section 12500 of the Business and Professions Code.

The applicant will hire a licensed weighmaster to determine the weight, measure, or count of cannabis and cannabis products.

Calibration and testing of weighing equipment will be performed in accordance with the manufacturer's instructions and state regulations for cannabis weighing equipment. Professional

calibration and testing will be completed by a Department-approved third-party tester at least annually, or as required by the Department.

Cleaning and maintenance of weighing and measuring equipment will be performed according to manufacturer's instructions. Policy Citations: CCR 17-01-13 40277(a) (2019); CCR 17-01-13 40277(a)(4) (2019); CCR 17-01-13 40277(c) (2019)

**10701 SAN - Environmental Controls**

Environmental controls are important to the applicant, because they ensure a space of comfort for employees and authorized individuals, minimize intrusive odors, and help ensure cannabis batches are protected from environmental factors that might negatively affect their quality and cause overall degradation and contamination.

Environmental controls at the applicant's manufacturing facility include:

• Heating;

• Cooling

• Ventilation;

• Lighting; and

• Dehumidification.

It is the responsibility of the Manufacturing Manager to adopt, implement, and monitor the enforcement of the environmental control policies and procedures.

It is the responsibility of the Facility Maintenance Manager to ensure that environmental controls are being maintained daily, weekly, monthly, and yearly, to delegate tasks to personnel, and to document the findings and any corrective actions in the Facility Maintenance Log. This involves the cleaning and maintenance of heating and cooling systems, the dehumidifier, and the ventilation system as well as checking the facility's lighting for burnt out bulbs, cleaning fixtures, lamps, and lenses, inspecting all environmental controls to ensure efficiency, and maintaining all environmental controls in accordance with the system manufacturer's recommendations.

Policy Citations: CCR 17-01-13 40240(b)(5) (2019); CCR 17-01-13 40240(b)(4) (2019)."

**10702 SAN - Daily Facility Cleaning**

The Facility Maintenance Manager will ensure the interior and exterior of the applicant's manufacturing facility is maintained in a sanitary condition to ensure the safety of employees and authorized visitors and to prevent the deterioration and contamination of marijuana and marijuana products. Additionally, it is the responsibility of the Facility Maintenance Manager to document the findings and any corrective actions regarding facility maintenance and cleaning in the Facility Maintenance Log.

Routine maintenance practices of the exterior facility, as outlined in the applicant's Facility Grounds SOP, include:

• Removing litter from the grounds;

• Filling cracks, window and door frames, drain areas, and floor joints with sealant to limit pest movement;

• Eradicating any weeds or pest habitats surrounding the facility;

• Inspecting the facility for mold and having a mold expert address any mold found in the facility immediately;

• Checking that any pipes within 20 feet of the building are closed-ended and not leaking;

• Cutting grass and weeds to minimize harborage areas for pests;

• Removing any food or water supply outside of the facility that could attract and support a pest population;

• If pests are found on the facility, capturing and removing them or contacting your pest control service provider to capture and remove the pests; and

• Checking that all waste receptacles are closed to exclude pests. Close any dumpsters that are open.

For information regarding the applicant's contamination prevention policies, please see the Preventing Contamination SOP. For information regarding the cleaning and maintenance of the applicant's HVAC system, please see the applicant's Environmental Controls SOP. For information regarding the applicant's equipment maintenance and cleaning, please see the applicant's Equipment Cleaning and Maintenance SOP.

In addition to daily cleaning tasks performed by facility employees, the applicant. will hire a third-party cleaning service to deep-clean the interior of the facility after business hours as needed to ensure cleanliness and sanitation.

Policy Citation: CCR 17-01-13 40240(b)(5) (2019).

**10703 SAN - Employee Facilities**

Employee facilities include hand-washing facilities, toilet facilities, and, if applicable, eye-flushing facilities.

All employee facilities are to meet the requirements of California's Health and Safety Code. This includes:

• Providing clean toilet facilities in good repair;

• Providing a sufficient amount of hand-washing and toilet facilities;

• Conveniently locating all hand-washing and toilet facilities;

• Making all hand-washing and toilet facilities accessible to all employees during all hours of operation.

Please see the applicant's Employee Sanitation and Health SOP for information regarding policies and procedures employees are to follow to maintain their health and hygiene to prevent contamination or adulteration of the applicant's inventory.

Policy Citation: CCR 17-01-13 40240(b)(3)(D) (2019); CCR 17-01-13 40240(b)(3)(E) (2019); CCR17-01-13 40240(b)(5) (2019).

## 10704 SAN - Equipment and Utensils Overview

Policy: the applicant will only use equipment and utensils to manufacture cannabis products that are designed and made of materials that do not allow the migration of deleterious substances or impart colors, odors, or tastes to products. Equipment and utensils will be safe, durable, corrosion-resistant, and nonabsorbent under normal use conditions, and will be capable of withstanding repeated washing.

Equipment will be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces. The applicant's equipment that is considered fixed because it is not easily movable will be installed so that it is:

• Spaced to allow access for cleaning along the sides, behind, and above the equipment;

• Spaced from adjoining equipment, walls, and ceilings a distance of not more than one millimeter or one thirty-second inch; and

• Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

Any floor-mounted equipment that is not easily movable at the applicant's facility will be sealed to the floor or elevated on legs that provide at least a six-inch clearance between the floor and the equipment.

Any table-mounted equipment that is not easily movable at the applicant's facility will be installed to allow cleaning of the equipment and areas underneath and around the equipment by being sealed to the table or elevated on legs that provide at least a four-inch clearance between the table and the equipment.

Product-contact surfaces will be corrosion-resistant, made of nontoxic materials, and designed to withstand the environment of their intended use, and, if applicable, cleaning products and procedures. Seams on product-contact surfaces will be smoothly bonded or maintained so as to minimize accumulation of particles, dirt, and organic matter.

Equipment in areas where cannabis products are manufactured that don't come into contact with cannabis products, as well as all holding, conveying, and manufacturing systems (including gravimetric, pneumatic, closed, and automated systems) will be constructed so that they may be kept clean and sanitary.

Policy Citations: CA BPC 114130.1 (2007); CA BPC 114130.3 (2007); CA BPC 114169(a) (2007); CA BPC114169(b) (2007); CA BPC 114169(d) (2007); CCR 17-01-13 40243(a) (2019); CCR 17-01-13 40243(b) (2019).