Recommendations for Regulators – Cannabis Operations

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This document includes the following Recommendations for Regulators:

• Cultivation and Processing Operations

Introduction

The legal status of products derived from *Cannabis* spp. is in a transitional phase in many states in the United States. Where products that contain marijuana and its derivatives were formally illegal throughout the U.S., many state laws now allow adult use of these either for medical purposes only or for adult personal use.

The American Herbal Products Association (AHPA) chartered a Cannabis Committee in 2010 with an express purpose to address issues related to the safe use and responsible commerce of legally-marketed products derived from *Cannabis* species.

To meet its purpose, the AHPA Cannabis Committee has developed recommendations to regulators for best practice rules to address four operational stages of *Cannabis* production and distribution: cultivation and processing; manufacturing and related operations; laboratory practice; and dispensing.

This document is specific to the area of Cannabis Cultivation and Processing Operations, and is presented in the form of a draft regulation. These recommendations establish a basis for oversight of entities that cultivate cannabis in either outdoor or indoor facilities. The document address such topics as cultivation practices, facility requirements, management of water resources, recordkeeping and information disclosure. It also establishes best practices for operations that provide post-harvest processing of cannabis, for either distribution to dispensing operations, or to manufacturing operations for the production of cannabis-derived products.

This Revision 2 of the document incorporates additional definitions and clarifies the definition of hemp. It incorporates new recommendations for the establishment of quality control systems and record retention. Other minor revisions and clarifications have been added throughout the document.

The AHPA Cannabis Committee offers this document to states and local municipalities where use of marijuana is allowed under local law such that regulatory authorities can consider the adoption of these recommendations, in whole or in part, as the basis for development of jurisdiction-specific regulations.

Please contact AHPA for further information or to discuss this document further.

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

- (a) Except as provided by paragraph (b) of this section, any person, group of persons, non-profit entity, or business entity that cultivates cannabis for retail or wholesale transactions in the jurisdiction in which this part applies¹ is engaged in a cultivation operation, and is subject to this part.
- (b) A compliant individual who cultivates cannabis in accordance with local and state law for personal use is not subject to this part.
- (c) Except as provided by paragraph (d) of this section, any person, group of persons, or business entity that processes cannabis for retail or wholesale transactions in the jurisdiction in which this part applies¹ is engaged in a processing operation, and is subject to this part.
- (d) A compliant individual who processes cannabis in accordance with local and state law for personal use is not subject to this part.
- (e) Operations subject to this part are subject only to those sections of this part that directly apply to the operations conducted, such that:
 - A cultivation operation is not subject to the processing sections of this part unless processing operations are also conducted by the cultivation operation; and
 - (2) A processing operation is not subject to the cultivation sections of this part unless cultivation operations are also conducted by the processing operation.

Section 1.2 Other statutory provisions and regulations

In addition to this part, cultivation operations and processing operations must comply with all other applicable statutory provisions and regulations related to cannabis cultivation and processing in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting the cultivation operation or processing operation.

Section 1.3 Definitions

The following definitions apply to this part:

Adverse event means a health-related event associated with use of cannabis or a cannabis-derived product that is adverse, and that is unexpected or unusual.

Batch means a specific quantity of cannabis harvested during a specified time period from a specified cultivation area.

Cannabis means any of the aerial parts of a plant in the genus *Cannabis*, and does not mean hemp.

Cannabis planting material means cannabis seeds, seedlings, cuttings, clones, etc. used by a cultivation operation to grow cannabis.

¹ This term "in the jurisdiction where this part applies" may be replaced throughout with the name of the specific jurisdiction.

Cannabis waste means cannabis discarded by the cultivation operation or processing operation.

Compliant individual means an individual who has met all legal requirements to obtain and use cannabis or cannabis-derived products in the jurisdiction where this part applies.

Contamination means the presence of unsafe levels of bacteria, mold, or yeasts, chemicals, or foreign matter.

Cultivate means to grow, harvest, dry, and cure cannabis. A person, group of persons, non-profit entity, or business entity that cultivates is a *cultivator*, and a facility where cannabis plants are cultivated is a *cultivation operation*.

Cultivation area means the physical location of a structure or property at which cannabis is cultivated.

Curing means the process by which dried cannabis is properly and safely preserved, to retain the volatile oil content in the dried plant material, while allowing the plant's chlorophyll content to breakdown over time.

Direct-from-garden or *caregiver operation* means a dispensing operation whereby compliant individuals obtain cannabis or cannabis-derived product directly from a cannabis cultivator.

Dispensing operation means a person, group of persons, non-profit entity, or business entity that provides cannabis or cannabis-derived product to compliant individuals and includes delivery services, direct-from-garden operations, growing co-ops, and storefront operations².

Drying means the dehydration of harvested cannabis to a moisture content below 15% water weight.

Firewall assembly means a fireproof barrier used to prevent the spread of fire between or through buildings or structures.

Freezing means a method for long-term storage of harvested cannabis at temperatures below 32° F (0° C).

Greenhouse means a permanent structure located outdoors that is completely covered by a material that allows a controlled level of light transmission.

Greenhouse cultivation means the cultivation of cannabis inside of a greenhouse utilizing natural sun and possible supplemental artificial lighting.

Harvest means to gather cannabis plants from cultivation medium or to gather specific aerial parts of cannabis plants.

² Different jurisdictions may have other terminology for the type of operation that is defined as a dispensing operation in this document.

Hemp means any part of a plant in the genus *Cannabis*, whether growing or not, with an effective yield of not more than 0.3 (three-tenths) percent delta-9 tetrahydrocannabinol on a dry weight basis³.

High intensity discharge lamps (HID lamps) means a type of electrical gasdischarge lamp which produces light by means of an electric arc between tungsten electrodes housed inside a translucent or transparent fused quartz or fused alumina arc tube.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics as stated on the label or other labeling.

Indoor cultivation means cultivation of cannabis grown in a fully enclosed location in which the only light source is artificial.

Lot means a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.

Manufacture means to compound, blend, grind, extract, or otherwise make or prepare cannabis-derived product. A person, group of persons, non-profit entity, or business entity that manufactures is a *manufacturer*, and a facility where manufacture occurs is a *manufacturing operation*.

May is used to indicate an action or activity that is permitted.

Medium means the nutritive substrate that the cultivator is using to establish a root system.

Must is used to state a requirement.

Nursery facility means an indoor, greenhouse, or outdoor cultivation operation that produces cannabis plants for the purpose of providing planting material to other cultivation operations.

Outdoor cultivation means cultivation of cannabis out of doors utilizing natural sunlight and possibly supplemental artificial lighting.

Pack (verb) means to place cannabis or cannabis-derived product into containers for distribution, other than to package the cannabis or cannabis-derived product; and includes the placement of cannabis into any type of container by cultivation operations, processing operations, and dispensing operations, as well as the

³ The term "hemp" is intended to be consistent with the exclusions provided in the Controlled Substances Act definition of "marijuana", specifically the following: Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

placement of filled primary packaging containers into other containers such as for storage or transport.

Personal use means cannabis that is produced for a compliant individual's personal medical needs and is not sold or distributed in any manner.

Planting means to place cannabis seeds or young plants in soil or medium.

Process means to trim, inspect, grade, or pack cannabis. A person, group of persons, non-profit entity, or business entity that processes cannabis is a *processor*, and a facility where cannabis is processed is a *processing operation*.

Processing loss means cannabis that, for any reason, during processing is deemed unfit for human consumption.

Propagation materials means all substances used in the cultivation of cannabis.

Pruning means cutting away cannabis leaves, branches or stems from unharvested plants.

Should is used to state recommended or advisory procedures.

Supplemental lighting means artificial lighting used to help or extend the vegetative life cycle of a cannabis plant.

Trimming means the removal of leaves and stems from harvested cannabis.

Variety means a specific cultivar, stock, line, or breed of cannabis, also commonly referred to as strain.

Vendor means a person, group of persons, non-profit entity, or business entity that supplies cannabis or cannabis-derived product to storefront or delivery service dispensing operations, and may be either the direct representative of a cultivation or manufacturing operation, or may function independently of such operations by purchasing cannabis or cannabis-derived product from such operations and reselling it to other operations.

SUBPART B – CULTIVATION AND PROCESSING OPERATIONS

Section 2.1 Types of cultivation and processing operations

- (a) Cannabis may be cultivated by any of the following types of cultivation operations, as defined in section 1.3 in this part:
 - (1) Indoor cultivation operations;
 - (2) Greenhouse cultivation operations;
 - (3) Outdoor cultivation operations; and
 - (4) Nursery operations.
- (b) Cultivation operations may do the following, as allowed by applicable legislation and regulation:
 - (1) Produce their own cannabis planting material; and
 - (2) Obtain cannabis planting material from any of the following:
 - (i) Other cultivation operations;

- (ii) Nursery operations; and
- (iii) Compliant individuals.
- (c) Processing operations may obtain cannabis from any of the following, as allowed by applicable legislation and regulation:
 - (1) Cultivation operations;
 - (2) Compliant individuals, and
 - (3) Vendors.
- (d) Cultivation operations and processing operations may distribute cannabis to any of the following, as allowed by applicable legislation and regulation:
 - (1) Other cultivation operations;
 - (2) Other processing operations;
 - (3) Dispensing operations;
 - (4) Manufacturing operations;
 - (5) Vendors; and
 - (6) Compliant individuals.

Section 2.2 Ancillary operations

- (a) Cultivation operations and processing operations may also engage in other operations, including:
 - (1) Manufacturing, packaging, labeling, and holding of cannabis-derived product;
 - (2) Laboratory operations;
 - (3) Dispensing of cannabis and cannabis-derived product; and
 - (4) Cultivation and marketing of products other than cannabis.
- (b) The ancillary operations identified in section 2.2(a) may be conducted:
 - At the same location as cultivation or processing, so long as such operations are permitted at this location in the jurisdiction in which this part applies; or
 - (2) At another location at which such operations are permitted in the jurisdiction in which this part applies.
- (c) The ancillary operations identified in section 2.2(a) must be conducted in compliance with all regulations relevant to such operations in the jurisdiction in which this part applies.

Section 2.3 Cultivation practices

- (a) Propagation materials
 - (1) Propagation materials used in cultivation operations must be appropriate for use in agricultural food production.
 - (2) Cultivation operations must follow the manufacturer's usage, storage, and disposal recommendations for the propagation material.
- (b) Pesticides
 - (1) Pesticides used in cultivation operations must be approved by the jurisdiction in which they will be used, or in the absence of an approved pesticide list, must be one of the following:

- (i) Subject to a tolerance established for application to cannabis by the US Environmental Protection Agency (EPA)⁴;
- (ii) Identified by EPA regulation as exempted from tolerance⁴;
- (iii) Subject to a Section 18 emergency exemption under FIFRA⁵; or
- (iv) Permitted for application to cannabis in other countries as long as the pesticide is also permitted for application to one or more food crops in the United States.
- (2) Cultivation operations must follow the manufacturer's application and storage recommendations, and disposal recommendations for the pesticide product.
- (3) Cultivation operations must follow the EPA Worker Protection Standard⁶ when preparing and applying pesticides.
- (4) Indoor cultivation operations must comply with the pesticide manufacturer's published re-entry interval time periods when applying pesticides.
- (5) Application of pesticides should be avoided following the flowering of cannabis plants.
- (c) Nutrients
 - (1) Nutrients used in cultivation operations must be appropriate for use in agricultural food production.
 - (2) Cultivation operations must follow the manufacturer's application, storage, and disposal recommendations for the nutrient product.
 - (3) Cultivation operations must not return unused rooting hormone to the source container.
 - (4) Nitrate-based and other oxidizing fertilizers must be stored away from solvents, fuels and pesticides.
- (d) Carbon dioxide
 - Indoor cultivation facilities utilizing carbon dioxide must maintain levels under 2000 ppm in cultivation areas when facility personnel may be present.
 - (2) Indoor cultivation facilities utilizing carbon dioxide at levels above 2000 ppm in a sealed room must prohibit personnel from entering the cultivation area unless personal protective equipment is provided.
 - (3) All regulators and environmental control systems that regulate carbon dioxide emissions must be maintained in good working order and be serviced in accordance with the manufacturer's recommendations.
 - (4) Compressed gases must be securely stored and appropriate signage and safety warnings provided.

⁴ See <u>40 CFR 180</u> for the list of EPA approved pesticide tolerances and exemptions; it is noted that as of the date of this document no pesticides have established tolerances for use on cannabis.

⁵ Section 18 of the <u>Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)</u> authorizes EPA to allow an unregistered use of a pesticide for a limited time if EPA determines that an emergency condition exists.

⁶ The EPA Worker Protection Standard can be accessed at the following website -<u>http://www.epa.gov/pesticide-worker-safety/revisions-worker-protection-standard</u> (accessed February 2, 2016)

- (e) Equipment and tools
 - (1) Equipment used for measuring, regulating, or recording temperatures, pH, humidity, or other conditions related to the cultivation and processing of cannabis must be accurate and adequately maintained.
 - (2) Cultivation and processing tools that come in direct contact with cannabis plants should be disinfected as needed to protect plant health.
 - (3) Scales used for the weighing of cannabis must be calibrated at regular intervals.

Section 2.4 Processing practices

- (a) Processing operations must be maintained in a clean and sanitary condition including all work surfaces and equipment.
- (b) Processing operations must implement protocols which prevent contamination.
- (c) Employees handling cannabis in processing operations must utilize facemasks and gloves in good operable condition as applicable to their job function.
- (d) Employees must wash hands sufficiently when handling cannabis.
- (e) Cannabis intended to be packaged for short or long-term storage must be adequately dried or frozen prior to packaging.
- (f) Cured cannabis must be maintained in containers that allow for:
 - (1) Proper preservation of constituents in the cured product; and
 - (2) Periodic monitoring of the cannabis during the curing process.

Section 2.5 Distribution practices

- (a) A process for reviewing relevant documentation and test results prior to distribution should be established.
- (b) Cannabis meeting specifications and requirements may be released for the next phase of processing or into distribution. An indication of approval should be placed on the cannabis.
- (c) Cannabis not meeting specifications and requirements may not be released to the next phase of processing or into distribution. An indication of rejection should be placed on the cannabis.
- (d) Cannabis distributed by cultivation operations and processing operations must be accompanied by the following information:
 - (1) Cultivation or processing operation's name;
 - (2) Identity of contents;
 - (3) Net weight of contents; and
 - (4) Sufficient information to trace the cannabis to its batch and/or lot.

Section 2.6 Quality systems

(a) Cultivation and processing operations must establish a quality system sufficient to ensure that all cannabis supplied by the operation complies with established specifications.

- (b) The quality system must include a process for the creation and maintenance of product specifications.
- (c) A system for reporting any non-conformance to quality control personnel should be established.

SUBPART C – PERSONNEL

Section 3.1 Personnel training

(a) Cultivation and processing operations must:

- (1) Ensure that each person engaged in the operation has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.
- (2) Maintain records of any training provided to employees for the performance of all assigned functions, including but not limited to application of pesticides.
- (b) Cultivation and processing operations should provide all employees with training that includes:
 - (1) Instructions regarding regulatory inspection preparedness and lawenforcement interactions; and
 - (2) Information on applicable local, state, and U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.
- (c) Cultivation and processing operations must implement employee hygiene protocols and training, which at a minimum address:
 - (1) Policies which prohibit employees who are showing signs of illness, open wounds, sores or skin infections from handling cannabis.
 - (2) Hygiene training for employees who handle cannabis with specific attention to preventing microbial contamination.
 - (3) Hand washing requirements including washing hands with soap and hot water before beginning work, after using the bathroom and after meal breaks.
 - (4) Instructive hand washing signage must be in appropriate areas such as bathrooms, kitchens, and lunch areas, and in multiple languages as needed.

Section 3.2 Employee safety

- (a) Cultivation operations and processing operations must implement safety protocols and provide all employees with adequate safety training relevant to their specific job functions, which may include:
 - (1) Emergency action response planning as necessary;
 - (2) Employee accident reporting and investigation policies;
 - (3) Fire prevention;
 - (4) Hazard communication policies, including maintenance of safety data sheets (SDS);
 - (5) Materials handling, spill, and disposal policies;

- (6) Job hazard analyses; and
- (7) Personal protective equipment policies, including but not limited to use of eye protection, respiratory protection, and ergonomic supports, such as back braces.
- (b) Cultivation operations must provide and maintain at least one emergency eye flushing station readily accessible and visible to all employees, and access to adequate eye flushing water for each employee working in field operations.
- (c) Cultivation operations and processing operations must visibly post and maintain an emergency contact list which includes at a minimum:
 - (1) Operation manager contacts;
 - (2) Emergency responder contacts;
 - (3) Poison control contacts;
 - (4) Fire department contacts; and
 - (5) Spill response team contacts.

SUBPART D – FACILITIES

Section 4.1 General compliance

- (a) Cultivation operations must comply with all legal requirements pertaining to the following as applicable:
 - (1) Restrictions on the size of the cultivation area;
 - (2) Restrictions on the number of cannabis plants allowed or other quantitative limits;
 - (3) Light pollution restrictions; and
 - (4) Odor control restrictions.
- (b) Location of cultivation operations:
 - (1) Indoor cultivation operations may be located on any property that is zoned for such use and must be located in a fully permitted, nonresidential structure that:
 - (i) Was constructed in compliance with local building code;
 - (ii) Has a complete roof enclosure supported by connecting walls extending from the ground to the roof;
 - (iii) Is secure against unauthorized entry; and
 - (iv) Minimizes unnecessary visual, auditory or olfactory evidence of indoor cannabis cultivation.
 - (2) Outdoor cultivation operations and greenhouse cultivation operations may be located on any property that is zoned for such use.
 - (3) Outdoor cultivation operations and greenhouse operations must be located within any setbacks that pertain to the property where the cultivation is taking place.
 - (4) Greenhouse cultivation structures must be fully permitted and built to code at the time of construction.
- (c) Location of processing operations
 - (1) Processing operations may be located on any property that is zoned for such use.

- (2) Processing operations must be located within any setbacks that pertain to the property where the processing is taking place.
- (3) Processing operation structures must be fully permitted and constructed in compliance with local building code.
- (d) Outdoor cultivation or greenhouse cultivation operations must shield or downcast supplemental lighting.
- (e) Cultivation operations and processing operations that transport cannabis must provide for the following:
 - (1) Cannabis must be placed in a secured enclosed container or secured trunk of the delivery vehicle.
 - (2) The transport vehicle must be maintained in a sanitary condition.
 - (3) Packaging must be sufficient to prevent cross-contamination of the cannabis.
 - (4) Proper environmental controls for temperature and humidity must be provided to maintain the integrity of the fresh or dried cannabis.

Section 4.2 Fire prevention

- (a) Any room in an indoor cultivation operation in which operational supplemental lighting, ballasts, or electrical control panels are located must be constructed with a minimum of a one-hour firewall assembly.
- (b) Indoor cultivation operations must have adequate fire suppression systems in compliance with jurisdictional requirements, such as:
 - (1) At least one operating fire extinguisher, and
 - (2) Additional fire extinguishers in a number proportional to the watts of supplemental lighting used in the facility (one fire extinguisher per every 10,000 watts of lighting), or in accordance with local fire code.
- (c) Fire extinguishers must be:
 - (1) Easily accessible to employees from every room and in each hallway of the facility;
 - (2) Maintained annually or as otherwise specified by the manufacturer; and
 - (3) Of the appropriate class rating for the type of fire associated with the functions being performed in the facility (i.e., electrical, chemical).
- (d) Flammable products must be stored in a properly marked fire containment cabinet or area.
- (e) Signage that complies with National Fire Protection Association (NFPA) standard 704 must be placed at entrances to exposure areas.
- (f) Cultivation and processing operations may provide a fire prevention plan for review by the local fire protection authority.

Section 4.3 Sanitation practices

- (a) Cultivation operations and processing operations must provide employees with adequate and readily-accessible toilet facilities.
 - (1) Toilet facilities must be maintained in a sanitary condition;
 - (2) Toilet facilities must be adequately stocked with toilet paper, soap, and single use paper towels or other hand-drying devices; and

- (3) Toilet facilities must be kept in good repair at all times.
- (b) Cultivation operations and processing operations must provide adequate and convenient hand-washing stations.
 - (1) Hand washing stations must be provided with running water of suitable temperature;
 - (2) Hand washing stations must be provided with effective hand cleaning or sanitizing preparations and single use paper towels or other handdrying devices;
 - (3) Hand washing stations must be located at points in the facility where good sanitary practices require employees to wash or sanitize their hands; and
 - (4) Outdoor and greenhouse cultivation operations must provide handwashing stations at field locations as appropriate.
- (c) Cultivation operations and processing operations must implement sanitation practices, which at a minimum address:
 - (1) Removal of debris, and control of the growth of mold, mildew and algae in the cultivation area or processing area;
 - (2) Pest control practices, including maintenance and repair of caulk cracks and drain areas;
 - (3) Identification of hoses dedicated for use in cultivation;
 - (4) Maintenance and cleaning of irrigation systems;
 - (5) Control of the introduction of potential contamination into the cultivation or processing area by personnel; and
 - (6) Design of operational areas to protect the work process and minimize the risk of contamination or adulteration.
- (d) Processing operations must protect cannabis from contact with birds, rodents, insects, and other animals and from exposure to the elements.

Section 4.4 Electrical system

- (a) The cultivation operation's electrical system must be of sufficient capacity to handle the actual electrical load and be installed in accordance with an approved electrical permit.
- (b) All electrical work and upgrades at cultivation operations must be performed with proper permitting.
- (c) All electrical equipment used by a cannabis cultivation operation should be connected to the electrical system in accordance with the equipment manufacturer's recommendations.

Section 4.5 Ventilation system

- (a) Enclosed cultivation operations and processing operations must be equipped with adequate ventilation to maintain proper humidity and temperature.
- (b) For indoor cultivation operations:
 - (1) If a mechanically propelled air intake system is used, a filter capable of removing 99.97% of particles with a diameter of 0.3 micrometers (μm) must also be utilized, as necessary to control potential contamination with pathogenic organisms.

(2) If a non-mechanically propelled or passive intake system is being utilized, a grate and filter sufficient to reduce the intrusion of rodents and insects must be installed.

Section 4.6 Disposal and waste practices

- (a) Cannabis waste must be composted or disposed of in a manner which prevents unauthorized use and such disposal must be documented. Disposal should not violate any other ordinance, code section or provision of law regarding disposal of cannabis.
- (b) Medium, bulbs and ballasts utilized during the cultivation of cannabis must be disposed of in accordance with manufacturer's recommendations, or recycled when feasible.
- (c) Nutrients, pesticides, and other chemicals used in cultivation and processing operations must be disposed of in accordance with manufacturer's recommendations.

Section 4.7 Security provisions

- (a) Outdoor and greenhouse cultivation operations should be enclosed by a secure perimeter fence at least six (6) feet in height. The fence should include a lockable gate that is locked when a qualified employee is not in the immediate area. The fence must not violate any other ordinance, code section or provision of law regarding height and location restrictions.
- (b) Indoor cultivation facilities and processing facilities must implement facility security measures sufficient to deter the risk of unauthorized access while allowing for emergency ingress and egress in accordance with applicable regulations.
- (c) Cultivation operations and processing operations must implement and communicate security protocols to all personnel and on-site contractors.
- (d) Visitors must be accompanied by an employee at all times.
- (e) Cultivation and processing operations should have a system for review of relevant records (see Section 6.1) as a means of preventing diversion.

SUBPART E – WATER RESOURCE MANAGEMENT

Section 5.1 Cultivation water management

- (a) In the absence of local or state water district regulations for cannabis production, cultivation operations must create and implement a cultivation water management plan to address the following:
 - (1) Erosion prevention;
 - (2) Effluent and agricultural discharges; and
 - (3) Water conservation.
- (b) Chemical solutions must be disposed of in accordance with applicable laws and regulations.

(c) Application of nutrients or pesticides through an irrigation system (chemigation), must be performed in accordance with state or local agricultural regulations.

Section 5.2 Potable water for employee use

- (a) Cultivation operations not utilizing a municipal source of potable water must test the potable water supply at least two times per year to ensure compliance with state primary drinking water standards.
- (b) Chemicals, fertilizers, pesticides, media and other products must be stored away from the potable water supply.

SUBPART F – RECORDKEEPING

Section 6.1 Recordkeeping practices

- (a) Cultivation operations must record the identity and source of all cannabis propagation material with sufficient specificity to ensure that the material can be traced to its source. Such records must be created whether the propagation material is obtained off-site or produced on-site.
- (b) For each batch of cannabis, cultivation operations must maintain cultivation records that include at a minimum:
 - (1) Planting records:
 - (i) Form of cannabis planted (e.g., seed, clone, seedlings, etc.);
 - (ii) Date(s) that planting took place;
 - (iii) Variety(ies) planted;
 - (iv) Size of the cultivation area; and
 - (v) Location of the cultivation area.
 - (2) Propagation records:
 - (i) Media used, and whether the media was reused or new product;
 - (ii) Description of all actions taken to prevent or treat the cannabis for disease or pest issues;
 - (iii) Soil amendments added, date of application, and strength of the application;
 - (iv) Nutrients added, date of application, and strength of the application;
 - (v) All substances applied to the plant(s) surface or used as a fumigant in the cultivation and/or nursery area and date of application; and
 - (vi) Pruning or other physical technique(s).
 - (3) Pesticide use records:
 - (i) Pesticide chemical name;
 - (ii) Brand name and manufacturer name;
 - (iii) Amount of pesticide applied;
 - (iv) Date pesticide applied;
 - (v) Cultivation stage at application;

- (vi) Identification or location of plants to which pesticide was applied; and
- (vii) Name of applicator if required.
- (4) Harvest records:
 - (i) Identity of each variety harvested;
 - (ii) Date of harvest;
 - (iii) Gross weight of the cannabis harvested for processing (generally recorded after drying);
 - (iv) Total weight of cannabis waste resulting from the harvest, and
 - (v) Net weight of harvested cannabis (gross weight less waste).
- (c) Processing operations must maintain records for processed cannabis that include at a minimum:
 - (1) Identity of the variety processed;
 - (2) Sufficient information to trace the processed cannabis to its cultivation source;
 - (3) Date of processing;
 - (4) Initial weight; and
 - (5) Total weight of any processing loss (based on wet or dry weight).
- (d) Cultivation operations and processing operations must maintain records of the commercial sale of cannabis to other cultivation and processing operations, to manufacturing operations, and to dispensing operations that include at a minimum:
 - (1) Identity of the variety distributed;
 - (2) Total weight of each variety distributed;
 - (3) Date of distribution;
 - (4) Identity of the receiving operation; and
 - (5) Amount of and the batch or lot number of any variety returned due to product spoilage, recalls, etc.
- (e) Cultivation operations and processing operations are not required to retain records of cannabis distributed for the following purposes:
 - (1) Samples provided for informational testing;
 - (2) Samples provided to other operations at no charge; and
 - (3) Samples provided to compliant individuals at no charge.

Section 6.2 Record retention

- (a) Except as required in sections 6.2(b) and (c), cultivation and processing operations must retain the records required by this part for a period of three years past date of creation of the record, or one year past the expiration date of the related product, whichever is longer, as applicable to the operation.
- (b) Product complaint records must be retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the complaint, whichever is longer.
- (c) Records for returned products must be retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the return, whichever is longer.

SUBPART G – INFORMATION DISCLOSURE

Section 7 Information disclosure

- (a) Cultivation and processing operations must provide relevant records as established in Section 6.1 to regulatory authorities upon request.
- (b) Cultivation and processing operations should provide relevant records as established in Section 6.1 to other cultivation operations, processing operations, manufacturing operations, dispensing operations, and compliant individuals receiving cannabis from the operation, upon receipt of a product complaint, product recall, or as needed to satisfy an investigation.
- (c) Information provided by a cultivation operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.
- (d) Cultivation operations and processing operations must disclose the extent and type of testing and analysis conducted on the cannabis it provides, including, but not limited to:
 - (1) The type of test, analysis or examination used, if any, to determine the particular strain or cultivar of each batch of cannabis provided;
 - (2) Any tests to determine the quantitative levels of contained constituents, such as individual cannabinoids and terpenes, and if so, the type of testing used;
 - (3) Any tests to determine the absence or presence of specific classes of potential contaminants, and if so, the type of testing used. The information required by this paragraph must be disclosed for each of the following:
 - (i) Common or known pesticides;
 - (ii) Yeasts and molds;
 - (iii) Other microbiological contaminants; and
 - (iv) Heavy metals.
 - (4) Whether the testing was conducted by the cultivation or processing operation, or by an external laboratory.

SUBPART H – PRODUCT COMPLAINTS, ADVERSE EVENTS AND RECALLS

Section 8.1 Product complaints

- (a) Cultivation and processing operations should establish policies for receiving and recording product complaints associated with the distribution and use of the cannabis it provides. Such policies should include:
 - (1) Process for submittal of a product complaint to the operation;
 - (2) Identification of the minimum data elements to record for a product complaint;
 - (3) Review of product complaints by a qualified person;
 - (4) A procedure for determining whether to investigate a product complaint; and

(5) A procedure for the review and approval of the findings and follow-up action of any investigation performed.

Section 8.2 Adverse event records

- (a) Cultivation and processing operations should establish policies for receiving and recording adverse event reports associated with use of the cannabis it provides. Such policy should include:
 - (1) Identification of the minimum data elements to record for any adverse event report, which could include:
 - (i) An identifiable individual who is reported to have experienced the adverse event;
 - (ii) An initial reporter, who may be the same as the identifiable individual or another person;
 - (iii) The identity of the specific cannabis used, if known; and
 - (iv) A description of the adverse event.
 - (2) A procedure for determining if an adverse event should:
 - (i) Be reported to any public health authority;
 - (ii) Be reported to the physician of record for the compliant individual reported to have experienced the adverse event, if known;
 - (iii) Require a product recall.
 - (3) Procedures for communicating the policy to:
 - (i) Employees of the cultivation and processing operation with task assignments that require knowledge of the policy;
 - (ii) Compliant individuals who are provided with cannabis by the cultivation and processing operation; and
 - (iii) Other cultivation operations, processing operations, manufacturing operations, and dispensing operations receiving cannabis from the operation.
- (b) For purposes of this section, an adverse event report recorded under a policy established by a cultivation and/or processing operation may not be construed as an admission or as evidence that the cannabis involved caused or contributed to the adverse event.

Section 8.3 Recall plan

- (a) Each cultivation operation and processing operation must develop and implement a recall plan addressing at a minimum:
 - (1) Factors which necessitate a recall procedure;
 - (2) Personnel responsible for a recall; and
 - (3) Notification protocols.
- (b) Each cultivation operation and processing operation must establish a policy for communicating a recall of cannabis that has been shown to present a probability that the use of or exposure to the product will cause serious adverse health consequences, or could cause temporary or medically reversible adverse health consequences. This policy should include:

- A mechanism to contact all customers who have, or could have, obtained the cannabis from the cultivation operation or processing operation, which communication must include information on the policy for return or proper disposal of the recalled product;
- (2) A mechanism to contact the cultivation or processing operation; and
- (3) Communication and outreach via media, as necessary and appropriate.
- (c) Any recalled cannabis that is returned to a cultivation operation or processing operation must be disposed of in a manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person.
- (d) Cultivation and processing operations should periodically conduct a mock recall to assess the effectiveness of the recall plan.