

Recommendations for Regulators – Cannabis Operations

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This document includes the following Recommendations for Regulators:

- Cultivation and Processing Operations
- Manufacturing, Packaging, Labeling, and Holding Operations
- Laboratory Operations
- Dispensing Operations

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Introduction

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

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. The implementation of all four best practice rules provides a framework for the oversight of *Cannabis* production and distribution practices from seed to the consumer.

To facilitate the utilization of these recommendations, they are presented in the form of draft regulations. The following paragraphs provide a brief overview of the content of each document.

- Cultivation and processing operations

These recommendations are intended to establish a basis for oversight of entities that cultivate cannabis in either outdoor or indoor facilities. The document addresses 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.

- Manufacturing and related operations

These recommendations are intended to establish a basis for oversight of entities that are engaged in manufacturing, packaging, labeling, and holding operations with regard to *Cannabis* and *Cannabis*-derived products. These recommendations are modeled generally after federal current good manufacturing practice for foods and dietary supplements, and focus on personnel, product acquisition, physical plant and

grounds, relevant controls, recordkeeping, and other matters that can contribute to best practice in these operational settings.

- Laboratory operations

These recommendations are intended to establish a basis for oversight of entities performing analysis of marijuana and hemp products. Developed as a complement to existing good laboratory practices, these recommendations focus on the personnel, security, sample handling and disposal, and data management and reporting activities that may be unique to laboratories analyzing cannabis samples.

- Dispensing operations

These recommendations are intended to establish a basis for oversight of entities that provide marijuana products directly to compliant adult consumers in a dispensary setting. These recommendations focus on personnel, security, product acquisition, record keeping, customer policies, and other matters that can contribute to best practice in the dispensary setting.

Use of these documents

The AHPA Cannabis Committee offers these documents to states and local municipalities where use of *Cannabis* and *Cannabis*-derived products 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 these documents 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:
 - (1) 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:

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.

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

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

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.

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 cannabis is prepared, preserved, or finished.

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.

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

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.

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

High intensity discharge lamps (HID lamps) means a type of electrical gas-discharge 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.

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

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

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 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 dead or overgrown cannabis leaves, branches or stems.

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 stock, line, or breed of cannabis, also commonly referred to as strain.

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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 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.

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- (b) The ancillary operations identified in section 2.2(a) may be conducted:
 - (1) 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 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 one of the following:
 - (i) Subject to a tolerance established for application to cannabis by the US Environmental Protection Agency (EPA);
 - (ii) Identified by EPA regulation as exempted from tolerance;
 - (iii) Subject to a Section 18 emergency exemption under FIFRA³; 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 Standard⁴ 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.

(c) Nutrients

- (1) Nutrients used in cultivation operations must be appropriate for use in 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.

³ Section 18 of the [Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#) authorizes EPA to allow an unregistered use of a pesticide for a limited time if EPA determines that an emergency condition exists.

⁴ The EPA Worker Protection Standard can be accessed at the following website - <http://www.epa.gov/agriculture/twor.html> (accessed September 9, 2013)

- (d) Carbon dioxide
 - (1) 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.
- (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 processing contamination and mold and mildew growth on cannabis.
- (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 or use gloves.

Section 2.5 Distribution practices

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.

SUBPART C – PERSONNEL

Section 3.1 Personnel training

- (a) Cultivation and processing operations must:

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- (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.
- (b) Cultivation and processing operations should provide all employees with training that includes:
- (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
 - (2) Information on 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 material safety data sheets (MSDS);
 - (5) Materials handling, spill, and disposal policies;
 - (6) Job hazard analyses; and
 - (7) Personal protective equipment policies, including respiratory protection.
- (b) Cultivation operations must provide and maintain at least one emergency eye flushing station readily accessible 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;

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- (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; and
 - (3) Light pollution 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, non-residential 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 do so in a secured enclosed container or secured trunk of the delivery vehicle.

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:
 - (1) Provide at least one operating fire extinguisher, and
 - (2) Provide 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.

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 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 drying 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 hand-washing 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;

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- (3) Identification of hoses dedicated for use in cultivation; and
- (4) Maintenance and cleaning of irrigation systems.
- (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 disposed of in a manner which prevents unauthorized use and such disposal must be documented.
- (b) Bulbs and ballasts utilized during the cultivation of cannabis 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 have locking doors and windows which allow emergency ingress and egress in accordance with applicable regulations.
- (c) Cultivation operations and processing operations must implement and communicate security protocols to all personnel.
- (d) Visitors must be accompanied by an employee at all times.

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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; and
 - (2) Effluent and agricultural discharges.
- (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 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, and strength of the application;
 - (iv) Nutrients added, 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
 - (vi) Pruning or other physical technique(s).

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- (3) Pesticide use records:
 - (i) Pesticide chemical name;
 - (ii) Brand name and manufacturer name;
 - (iii) Amount of pesticide applied;
 - (iv) Date pesticide applied;
 - (v) Identification or location of plants to which pesticide was applied; and
 - (vi) 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; and
 - (4) Identity of the receiving operation.
- (e) Cultivation operations and processing operations are not required to retain records of cannabis distributed for the following purposes:
 - (1) Samples provided for testing;
 - (2) Samples provided to other operations at no charge; and
 - (3) Samples provided to compliant individuals at no charge.

SUBPART G – INFORMATION DISCLOSURE

Section 7 Information disclosure

- (a) Cultivation operations must provide the following records to other cultivation operations, processing operations, manufacturing operations, and dispensing operations receiving cannabis from the cultivation operation, upon the receiving operation's request:
 - (1) Nutrients used during cultivation;

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- (2) All substances applied to the plant(s) surface or used as a fumigant in the cultivation area;
 - (3) Pesticides applied during cultivation; and
 - (4) Other substances used during cultivation that may result in a residue on cannabis.
- (b) Information provided by a cultivation operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.
- (c) Cultivation operations and processing operations must disclose the extent and type of testing and analysis conducted on the cannabis it provides, including:
- (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, 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) Pesticides;
 - (ii) Yeasts and molds; and
 - (iii) Other microbiological contaminants.
 - (4) Whether the testing was conducted by the cultivation or processing operation, or by an external laboratory.

SUBPART H – RECALLS

Section 8 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 reasonable or a remote 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:
- (1) A mechanism to contact all customers who have, or could have, obtained the cannabis from the cultivation operation or processing operation;
 - (2) Information on the return or destruction of any recalled product;
 - (3) A mechanism to contact the cultivation operation; and

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- (4) 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.

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

- (a) Except as provided by paragraphs (b), (c), and (d) of this section, any person, group of persons, non-profit entity, or business entity is subject to this part if engaged in manufacturing, packaging, labeling, or holding operations for cannabis or cannabis-derived products in the jurisdiction in which this part applies^{1, 2}.
- (b) A compliant individual that manufactures, packs, labels or holds cannabis or cannabis-derived products in accordance with local and state law for personal use; or for another compliant individual at no charge, is not subject to this part.
- (c) Cultivation and processing operations are not subject to this part; however, this exemption does not apply to any off-site warehouse or storage facility that serves the cultivation or processing operation.
- (d) Dispensing operations are not subject to this part; however, this exemption does not apply to any off-site warehouse or storage facility that serves the dispensing operation.
- (e) Each operation subject to this part is responsible to comply with only those sections that apply to the activities conducted by that operation.

Section 1.2 Other statutory provisions and regulations

In addition to this part, manufacturing, packaging, labeling and holding operations must comply with all other applicable statutory provisions and regulations related to these operations in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting these operations.

Section 1.3 Definitions

The following definitions apply to this part:

Actual yield means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular cannabis-derived product.

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

² These requirements are intended to apply to subject operations having multiple personnel and that manufacture, package, label, or hold some hundreds of ounces (thousands of grams) of cannabis per year for commercial purposes rather than personal use. State and local jurisdictions may consider this limitation in determining applicability of these requirements to subject operations.

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Adulteration means that a cannabis-derived product (1) consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) bears or contains any poisonous or deleterious substance which may render it injurious to health; except that (A) such product shall not be considered adulterated if the quantity of such substance does not ordinarily render it injurious to health and (B) the cannabis content of the product shall not be considered injurious to health; (3)(A) has been manufactured, packaged, labeled, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (B) has been manufactured, packaged, labeled, or held by methods, in facilities, or using controls that do not conform to or are not operated or administered in conformity with this part to assure that the cannabis-derived product meets appropriate requirements as to safety; or (4) fails to meet appropriate requirements as to safety; or (5) is in a container composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (6) bears or contains, for purposes of coloring, a color additive which is not approved in the United States for use in a comparable food product; or (7) (A) has been mixed or packaged with any substance so as to reduce its quality or strength or (B) has been substituted wholly or in part with any substance.

Batch means, with regard to cannabis, a specific quantity of cannabis harvested during a specified time period from a specified cultivation area; and means, with regard to cannabis-derived product, a specific quantity that is uniform, that is intended to meet specifications for identity, strength, purity and composition, and that is manufactured, packaged and/or labeled during a specified time period according to a single manufacturing, packaging, and/or labeling batch record.

Batch number, lot number, or control number means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, or holding of a batch or lot of cannabis or cannabis-derived products can be determined.

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

Cannabis-derived product means a product, other than cannabis itself, which contains or is derived from cannabis by manufacturing as defined herein, and does not mean a product that contains or is derived from hemp.

Cannabis waste means cannabis or cannabis-derived product discarded by a manufacturing, packaging, labeling, or holding operation.

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

Composition means the aggregate mixture which results from the manufacture of a cannabis-derived product according to the formula and process defined in the product's manufacturing protocol.

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Component means any substance or item intended for use in the manufacture of a cannabis-derived product, including those that do not appear in the batch of the cannabis-derived product. Component includes cannabis, cannabis-derived products used as ingredients, other ingredients, and processing aids.

Contact surface means any surface that directly contacts cannabis, components, or cannabis-derived product, and any surface from which drainage onto cannabis, components, or cannabis-derived product, or onto surfaces that contact cannabis, components, or cannabis-derived product, may occur during the normal course of operations.

Controlled access area means an area in the physical plant designed to prevent entry by anyone except authorized personnel.

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*.

Dispense means to provide cannabis or cannabis-derived product to compliant individuals.

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 operations.

Disposition means review and approval or rejection of a batch, lot, or other item by quality control personnel.

Gang-printed label means a label for one product that is printed simultaneously on the same sheet of paper as labels for other products.

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

Hold means to store or warehouse cannabis or cannabis-derived product in any context by an operation that is subject to this rule. A person, group of persons, non-profit entity, or business entity that holds is a *holder*, and a facility where holding occurs is a *holding operation*.

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. In the case of cannabis-derived products, identity means the product name, strength, key features of its form or composition, grade, and/or other characteristics as applicable.

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Ingredient means any substance that is used in the manufacture of a cannabis-derived product and that is intended to be present in the batch of the cannabis-derived product.

In-process material means any material that is compounded, blended, ground, extracted, sifted, sterilized, or prepared in any other way by the operation for use in its manufacturing, packaging, or labeling of cannabis or a cannabis-derived product.

Label (verb) means to affix labeling on packaged cannabis or cannabis-derived product. A person, group of persons, non-profit entity, or business entity that labels is a *labeler*, and a facility where labeling occurs is a *labeling operation*.

Labeling (noun) means all labels and other written, printed or graphic matter on or accompanying any article or any of its containers or wrappers.

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; or, in the case of a cannabis-derived product produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner 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; the term does not apply to cannabis. 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; *may not* is used to indicate an action or activity that is not permitted.

Microorganism means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes species that may cause a component or cannabis or cannabis-derived product to decompose; may indicate that the component or cannabis or cannabis-derived product is contaminated with filth; or otherwise may cause the component, cannabis or cannabis-derived product to be adulterated.

Must is used to state a requirement.

Package (verb) means to place cannabis or cannabis-derived product into primary packaging for bulk or retail distribution when performed by an operation subject to this part. A person, group of persons, non-profit entity, or business entity that packages is a *packager*, and a facility where packaging occurs is a *packaging operation*.

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

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Packaging component means any item intended for use in the primary packaging or labeling of cannabis-derived products.

Personnel means any worker engaged in the performance of operations subject to this rule and includes full and part-time employees, temporary employees, contractors, and volunteers.

Pest means any objectionable insect or other animal at any life stage.

Physical plant means all or any part of a building or facility used for or in functional connection with manufacturing, packaging, labeling, or holding a cannabis-derived product.

Primary packaging means items used in packaging that serve to directly contain, contact, and/or label the product.

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

Product complaint means any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a product that could be related to its manufacture, packaging, or labeling.

Production means manufacturing, packaging, and/or labeling, as applicable to the firm's operations.

Purity means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.

Quality means that the product consistently meets the established specifications for identity, purity, strength, composition, packaging, and labeling, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration.

Quality control means a planned and systematic operation or procedure for ensuring the quality of a product.

Quality control personnel means any person, persons, or group, within or outside of a manufacturing, packaging, labeling or holding operation, which is designated to be responsible for the operation's quality control operations.

Quarantine means to segregate and withhold from use lots, batches, or other portions of components, packaging components, in-process materials, cannabis, or products whose suitability for use must be determined by quality control personnel.

Representative sample means a sample that consists of an adequate quantity of material or number of units that is collected in a manner intended to ensure that the sample accurately portrays the material being sampled.

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Reprocessing means the performance of a treatment, adjustment, repackaging, relabeling, or other deviation from standard procedures or from the applicable manufacturing protocol, in order to render a nonconforming material suitable for use.

Reserve sample means a representative sample of component, packaging component, or product that is held for a designated period of time.

Sanitize means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.

Should is used to state recommended or advisory procedures.

Strength means the potency of cannabis or a cannabis-derived product, whether expressed as (a) the amount or percent of specific chemical constituents or groups of chemical constituents; (b) the concentration or amount of cannabis present in a cannabis-derived product; or (c), in the case of cannabis extracts, the ratio of the input quantity of crude cannabis, on a dry weight basis, to the output quantity of finished extract.

Theoretical yield means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular cannabis-derived product, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

Water activity (a_w) is a measure of the free moisture in a component or product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Vendor means a person, group of persons, non-profit entity, or business entity that supplies cannabis or cannabis-derived product to manufacturing, packaging, labeling or holding operations, and may be either the direct representative of a cultivation, processing, 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 – GENERAL REQUIREMENTS

FOR DISCUSSION. Prepared for consideration by state or local regulatory agencies in states within the United States.

Section 2.1 Acquisition of cannabis and cannabis-derived products

Manufacturing, packaging, labeling, and holding operations may obtain cannabis or cannabis-derived product from any of the following as allowed by applicable legislation and regulation:

- (1) Cultivation operations;
- (2) Processing operations;
- (3) Vendors;
- (4) Other manufacturing, packaging, labeling or holding operations; and
- (5) Any other legal entity as allowed in this jurisdiction.

Section 2.2 Distribution of cannabis and cannabis-derived products

(a) Manufacturing, packaging, labeling and holding operations may distribute cannabis and cannabis-derived products to any of the following as allowed by applicable legislation and regulation:

- (1) Dispensing operations;
- (2) Other manufacturing, packaging, labeling or holding operations subject to this section;
- (3) Vendors; and
- (4) Any other legal entity as allowed in this jurisdiction.

(b) Manufacturing, packaging, labeling and holding operations that transport cannabis or cannabis-derived products must do so in a secured enclosed container and/or secured cargo area of the delivery vehicle.

Section 2.3 Ancillary operations

In addition to the manufacturing of cannabis-derived product and the packaging, labeling or holding of cannabis or cannabis-derived product, an operation described in section 1.1 may also engage in other operations, so long as such operations are permitted at this location in the jurisdiction in which this part applies.

SUBPART C – PERSONNEL

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Section 3.1 Personnel training

(a) Manufacturing, packaging, labeling and holding 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) Provide personnel with training in the applicable requirements of this part; and
- (3) Maintain records of any training provided to personnel for the performance of all assigned functions.

(b) Personnel training should include:

- (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
- (2) Information on U.S. federal, state and local laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such personnel.

Section 3.2 Personnel responsibilities

(a) Measures must be taken to exclude from any operation any person that might be a source of microbial contamination due to a health condition through contact with any material, including components, packaging components, in-process materials, cannabis, cannabis-derived products, and contact surfaces used in manufacturing, packaging, labeling, and holding operations. Such measures include the following:

- (1) Excluding from working in any operations that may result in contamination any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces, until the health condition no longer exists; and
- (2) Instructing personnel to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that could result in microbial contamination of any components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surface.

(b) Personnel working in an operation during which adulteration of components, packaging components, cannabis, cannabis-derived products, or contact surfaces could occur must use hygienic practices to the extent necessary to protect against such contamination of components, packaging components, in-process materials,

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cannabis, cannabis-derived products, or contact surfaces. These hygienic practices include the following:

- (1) Wearing outer garments in a manner that protects against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surface;
- (2) Maintaining adequate personal cleanliness;
- (3) Washing hands thoroughly with soap (and sanitizing if necessary to protect against contamination with microorganisms):
 - (i) Before starting work;
 - (ii) After using the restroom; and
 - (iii) At any other time when the hands may have become soiled or contaminated;
- (4) Removing all unsecured jewelry and other objects that might fall into components, packaging components, cannabis, cannabis-derived products, equipment, or packaging, and removing hand jewelry that cannot be adequately cleaned during periods in which components, packaging components, in-process materials, cannabis, or cannabis-derived products are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces;
- (5) Maintaining gloves used in handling components, packaging components, in-process materials, cannabis, or cannabis-derived products in an intact, clean, and sanitary condition. The gloves should be of an impermeable material;
- (6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;
- (7) Not storing clothing or other personal belongings in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surfaces are exposed or where contact surfaces are washed;
- (8) Not eating food, chewing gum, drinking beverages, or using tobacco products in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surfaces are exposed, or where contact surfaces are washed;
- (9) Taking any other precautions necessary to protect against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces with microorganisms, filth, or

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- any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin;
- (10) Taking all precautions necessary to maintain the security of the physical plant, to prevent unauthorized access to controlled access areas, and to maintain strict control of in-process materials, cannabis, cannabis-derived products, and cannabis waste; and
 - (11) Entering controlled access areas only as authorized by supervisory personnel.

Section 3.3 Personnel safety

- (a) Policies must be implemented to protect personnel in all operations and provide personnel with adequate safety training to comply with these policies. Such policies should be similar to personnel safety policies in comparable industries, such as food processors, and may include, for example:
 - (1) Personnel accident reporting and investigation policies;
 - (2) Fire prevention and response plans;
 - (3) Materials handling and hazard communications policies, including maintenance of material safety data sheets (MSDS); and
 - (4) Personal protective equipment policies.
- (b) An emergency contact list must be visibly posted and maintained 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.
- (c) Compliance must also be ensured with all other applicable standards of the federal Occupational Health and Safety Administration and any applicable state or local worker safety requirements.

Section 3.4 Supervisor requirements

- (a) Qualified personnel should be assigned to supervise the manufacturing, packaging, labeling, or holding of cannabis and cannabis-derived products.

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- (b) Each person responsible for supervising the manufacture, packaging, labeling, or holding of a cannabis or cannabis-derived product must have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the cannabis or cannabis-derived product has the identity, purity, strength, and composition that it purports or is represented to possess.
- (c) One or more qualified personnel should be assigned to supervise overall sanitation. Each of these supervisors must be qualified by education, training, or experience to develop and supervise sanitation procedures.

SUBPART D – PHYSICAL PLANT AND GROUNDS

Section 4.1 Design and construction

- (a) The physical plant used in the manufacture, packaging, labeling, or holding of cannabis and cannabis-derived products must be suitable in size, construction, and design to facilitate maintenance, cleaning and/or sanitizing, as applicable to the operation.
- (b) Any such physical plant must have adequate space for the orderly placement of equipment and materials to prevent mixups of components, packaging components, in-process materials, cannabis, or cannabis-derived products during manufacturing, packaging, labeling, or holding.
- (c) Any such physical plant must be designed to reduce the potential for contamination of components, packaging components, cannabis, cannabis-derived products, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. The design and construction must include:
 - (1) Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair;
 - (2) Fixtures, ducts, and pipes that do not contaminate components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces by dripping or other leakage, or condensate;
 - (3) Aisles or working spaces between equipment and walls that are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces with clothing or personal contact.

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- (4) Safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials must be used when the light bulbs, fixtures, skylights or other glass or glass-like materials are suspended over exposed components, packaging components, in-process materials, or cannabis or cannabis-derived products, unless the physical plant is otherwise constructed in a manner that will protect against contamination of components, packaging components, in-process materials, or cannabis or cannabis-derived products in case of breakage of glass or glass-like materials.
- (d) Any such physical plant must have separate or defined areas, or other control systems such as computerized inventory controls or automated systems of separation, to prevent cross-contamination and mixups of components, cannabis, or cannabis-derived products during any of following operations that take place in the physical plant:
- (1) Receipt, identification, storage, and withholding from use of quarantined components, packaging components, in-process materials, cannabis, or cannabis-derived products pending disposition by quality control personnel;
 - (2) Storage of approved components, packaging components, cannabis, or cannabis-derived products;
 - (3) Storage of rejected components, packaging components, in-process materials, cannabis, cannabis-derived products, and cannabis waste pending return to their supplier or destruction;
 - (4) Storage of in-process materials pending normal further processing;
 - (5) Storage of components, packaging components, in-process materials, and products pending reprocessing;
 - (6) Manufacturing operations;
 - (7) Packaging and labeling operations;
 - (8) Separation of the manufacturing, packaging, labeling, and holding of different product types including different types of cannabis or cannabis-derived products and other products handled in the same physical plant;
 - (9) Performance of laboratory analyses and storage of laboratory supplies and samples, as applicable;
 - (10) Cleaning and sanitation of contact surfaces.
- (e) Water must be provided that is:
- (1) Safe and sanitary, at suitable temperatures, and under pressure as needed, for all uses where water does not become a component of the cannabis-derived product; and

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- (2) Compliant with applicable state and local potable water requirements and with other requirements as necessary to ensure the water does not contaminate the cannabis-derived product, for all uses where such water may become a component of the cannabis-derived product, e.g., when such water contacts components, packaging components, in-process materials, cannabis or cannabis-derived products, or any contact surface.
- (f) Heating, ventilating, cooling, and air filtration must be installed and maintained in the physical plant as needed to ensure the quality of the product.
- (1) Ventilation equipment such as filters, fans, exhausts, dust collection, and other air-blowing equipment must be provided in areas where odors, dust, and vapors (including steam and noxious fumes) may contaminate components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces.
 - (2) When fans, compressed air, or other air-blowing equipment are used, such equipment must be designed, located, and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces.
 - (3) Equipment that controls temperature, humidity, and/or microorganisms must be provided, when such equipment is necessary to ensure the quality of the product.
- (g) The plumbing in the physical plant must be of an adequate size and design and be adequately installed and maintained to:
- (1) Carry sufficient amounts of water to required locations throughout the physical plant;
 - (2) Properly convey sewage and liquid disposable waste from the physical plant;
 - (3) Avoid being a source of contamination to components, packaging components, in-process materials, cannabis or cannabis-derived products, water supplies, or any contact surface, or creating an unsanitary condition;
 - (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
 - (5) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing cannabis-derived products, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.
- (h) Personnel must be provided with adequate, readily accessible toilet facilities that are:

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- (1) Maintained in a clean and sanitary condition;
 - (2) Adequately stocked with toilet paper, soap, and single use paper towels or other drying devices;
 - (3) Kept in good repair at all times;
 - (4) Equipped with signage advising personnel of the necessity of washing hands prior to returning to work;
 - (5) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.
- (i) Airborne contamination from toilet facilities must be prevented from contacting components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces, for example by providing adequate physical separation of toilet facilities from manufacturing, packaging, labeling, and holding operations, or by use of negative air pressure within the toilet facility.
- (j) Adequate and convenient hand-washing facilities must be provided that are:
- (1) Provided with running water of suitable temperature;
 - (2) Provided with effective hand cleaning and/or sanitizing preparations and single use paper towels or other drying devices;
 - (3) Located at points in the facility where good sanitary practices require personnel to wash their hands;
 - (4) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.
- (k) Adequate lighting must be provided in:
- (1) All areas where components, packaging components, in-process materials, cannabis, or cannabis-derived products are examined, manufactured, packaged, labeled, or held;
 - (2) All areas where contact surfaces are cleaned; and
 - (3) Hand-washing areas, dressing and locker rooms, and toilet facilities.

Section 4.2 Sanitation requirements

- (a) The grounds of the physical plant must be kept in a condition that protects against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces. The methods for adequate ground maintenance include:

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- (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical plant so that it does not attract pests, harbor pests, or provide pests a place for breeding;
 - (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces are exposed;
 - (3) Adequately draining areas that may contribute to the contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests;
 - (4) Adequately operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces are exposed; and
 - (5) If the plant grounds are bordered by grounds not under the operation's control, and if those other grounds are not maintained in the manner described in this section, care should be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous materials that may be a source of contamination.
- (b) The physical plant must be maintained in a clean and sanitary condition and must be maintained in repair sufficient to prevent components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces from becoming contaminated.
- (c) Cleaning compounds, sanitizing agents, pesticides, and other toxic materials must be appropriately stored, handled, and controlled.
- (1) Cleaning compounds and sanitizing agents must be free from microorganisms of public health significance and be safe and adequate under the conditions of use.
 - (2) Toxic materials must not be used or held in a physical plant in which components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces are manufactured or exposed, unless those materials are necessary as follows:
 - (i) To maintain clean and sanitary conditions;
 - (ii) For use in laboratory testing procedures, where applicable;
 - (iii) For maintaining or operating the physical plant or equipment; or
 - (iv) For use in the plant's operations.

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- (3) Cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials must be identified, stored, and used in a manner that protects against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces.
- (d) Adequate pest control must be provided.
- (1) Animals or pests must not be allowed in any area of the physical plant, except that guard or guide dogs may be allowed in some areas of the physical plant if the presence of the dogs will not result in contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces;
 - (2) Effective measures must be taken to exclude pests from the physical plant and to protect against contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, and contact surfaces on the premises by pests; and
 - (3) Insecticides, fungicides, or rodenticides must not be used in or around the physical plant, unless they are registered with EPA and used in accordance with the label instructions, and effective precautions are taken to protect against the contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces.
- (e) Trash must be regularly conveyed, stored, and disposed in order to:
- (1) Minimize the development of odors;
 - (2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;
 - (3) Protect against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, any contact surface, water supplies, and grounds surrounding the physical plant; and
 - (4) Control hazardous waste to prevent contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, and contact surfaces.
- (f) Manufacturing, packaging, labeling, or holding operations must have and follow written procedures for sanitation that address the following:
- (1) Responsibility for sanitation;
 - (2) Detailed description of the cleaning schedules, methods, equipment, and materials to be used in cleaning the grounds and buildings; and
 - (3) Records of cleaning and sanitation that must be kept.

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- (g) Manufacturing, packaging, labeling, and holding operations must have and follow written procedures for use of rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents that address the following:
 - (1) Prevention of the contamination of components, packaging components, in process materials, cannabis, cannabis-derived products, or contact surfaces; and
 - (2) Records of the use of rodenticides, insecticides, fungicides, fumigating agents, and cleaning or sanitizing agents must be kept.
- (h) Sanitation procedures must apply to work performed by all personnel during the ordinary course of operations.
- (i) All operations must be conducted in accordance with adequate sanitation principles, including, but not limited to:
 - (1) Cleaning and/or sanitizing production equipment, containers, and other contact surfaces, as needed;
 - (2) Controlling airborne contamination as needed where components, packaging components, in-process materials, product, or contact surfaces are exposed;
 - (3) Using sanitary handling procedures.

Section 4.3 Equipment and utensils

- (a) Production operations must use equipment and utensils that are of appropriate design, construction, and workmanship.
 - (1) Equipment and utensils must be suitable for their intended use;
 - (2) Equipment and utensils must be able to be adequately cleaned and properly maintained; and
 - (3) Use of equipment and utensils must not result in the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces.
- (b) All equipment and utensils used in production operations must be:
 - (1) Installed and maintained to facilitate cleaning of the equipment, utensils, and adjacent spaces;
 - (2) Constructed so that contact surfaces are nontoxic and corrosion-resistant, and neither reactive nor absorptive;
 - (3) Designed and constructed to withstand the environment in which they are used, the action of components, in-process materials, cannabis, or cannabis-

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derived products and, if applicable, cleaning compounds and sanitizing agents; and

- (4) Maintained to protect components, in-process materials, cannabis, and cannabis-derived products from being contaminated by any source.
- (c) Equipment and utensils must be designed and maintained to minimize accumulation of dirt, filth, organic material, particles of components, in-process materials, cannabis, and cannabis-derived products, or any other extraneous materials or contaminants.
- (d) Compressed air or other gases introduced mechanically into or onto a component, packaging component, in-process material, cannabis or cannabis-derived product, or contact surface or used to clean any contact surface must be filtered or otherwise treated such that the component, packaging component, in-process material, cannabis or cannabis-derived product, or contact surface is not contaminated.
- (e) Each freezer, refrigerator, and other cold storage compartment used to hold components, in-process materials, or cannabis or cannabis-derived products:
 - (1) Must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that indicates and records, or allows for recording by hand, the temperature accurately within the compartment; and
 - (2) Must have an automated device for regulating temperature and/or an automated alarm system to indicate a significant temperature change.
- (f) Instruments or controls used in manufacturing, packaging, labeling, holding, or testing, and instruments or controls that are used to measure, regulate, or record conditions that control or prevent the growth of microorganisms or other contamination, must be suitably accurate and precise, and adequately maintained.
- (g) Where appropriate, instruments and controls used in manufacturing, packaging, holding, or testing components, packaging components, in-process materials, cannabis, and cannabis-derived products must be calibrated, inspected, or otherwise verified before first use and at routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument or control, and the resulting data must be periodically reviewed by quality control personnel. Instruments or controls that are past their calibration, inspection, or verification due date, or which cannot be adjusted to provide suitable accuracy and precision, must be removed from use until they are repaired or replaced.
- (h) Production operations must establish and use appropriate controls for automated, mechanical, and electronic equipment (including software for a computer controlled process) to ensure that:
 - (1) Any changes to the equipment are approved by quality control personnel and instituted only by authorized personnel; and

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- (2) The equipment functions in accordance with its intended use.
- (i) Equipment and utensils, and any other contact surfaces used in production operations must be maintained, cleaned, and sanitized, as necessary.
 - (1) Equipment and utensils must be taken apart as necessary for thorough maintenance, cleaning, and sanitizing.
 - (2) All contact surfaces used for manufacturing, packaging, or holding low-moisture components, in-process materials, or cannabis or cannabis-derived products, must be in a dry and sanitary condition when in use. When the surfaces are wet-cleaned, they must be sanitized, when necessary, and thoroughly dried before subsequent use.
 - (3) If wet processing is used during production, all contact surfaces must be cleaned and sanitized, as necessary, to protect against the introduction of microorganisms into components, packaging components, in-process materials, or cannabis or cannabis-derived products.
 - (4) When cleaning and sanitizing is necessary, all contact surfaces must be cleaned before use and after any interruption during which the contact surface may have become contaminated.
 - (5) If contact surfaces are used in a continuous production operation or in consecutive operations involving different batches of the same product, the contact surfaces must be adequately cleaned and sanitized, as necessary.
 - (6) Surfaces that do not come into direct contact with components, packaging components, in-process materials, or cannabis or cannabis-derived products must be cleaned as frequently as necessary to protect against contaminating components or products.
 - (7) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored in appropriate containers, and handled, dispensed, used, and disposed of in a manner that protects against contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or any contact surface.
 - (8) Cleaning compounds and sanitizing agents must be adequate for their intended use and safe under their conditions of use.
 - (9) Cleaned and sanitized portable equipment and utensils that have contact surfaces must be stored in a location and manner that protects them from contamination.
 - (j) There must be written procedures for calibration, maintenance, cleaning, and sanitation of equipment, instruments, and utensils, and records of these activities must be kept.

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Section 4.4 Security requirements

- (a) Security procedures must be established and implemented for authorized access to the physical plant and any controlled access areas therein.
- (b) Access to the physical plant and controlled access areas must be limited to current personnel and contractors as appropriate to their job function.
- (c) The physical plant must be equipped with one or more controlled access areas for storage of the following:
 - (1) Labels and other packaging components;
 - (2) Cannabis and cannabis-derived products;
 - (3) Cannabis waste;
 - (4) Quarantined components, packaging components, in-process materials, and cannabis or cannabis-derived products;
 - (5) Rejected components, packaging components, in-process materials, cannabis, or cannabis-derived products.
- (d) There must be written procedures for security.

SUBPART E – MANUFACTURING PROCESS CONTROLS

Section 5.1 Manufacturing protocol

- (a) Manufacturing operations must prepare and follow a manufacturing protocol for each unique formulation of cannabis-derived product to be produced. The manufacturing protocol must include the following, as applicable:
 - (1) Identity of the product;
 - (2) For each formulation of product:
 - (i) Nominal batch size;
 - (ii) Identity of each component to be used in the batch;
 - (iii) Weight or measure of each component to be used in the batch, including the unit of measure and a statement of any range or variation in the weight or measure;
 - (iv) A statement of any intentional overage amount of a component; and

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- (v) Name and amount of each ingredient that will be declared on the product's labeling.
- (3) A statement of theoretical yield for each significant process step and at the end of manufacture, including the acceptable maximum and minimum percentages of theoretical yield;
- (4) Written instructions or cross references to standard procedures for the following:
 - (i) The execution of each process step;
 - (ii) Production process specifications per section 5.5;
 - (iii) Monitoring of production process specifications;
 - (iv) In-process material specifications per section 5.8;
 - (v) In-process material sampling, testing, and/or examination;
 - (vi) Cannabis-derived product sampling, testing, and/or examination; and
 - (vii) Additional applicable procedures to be followed, if any.
- (5) Cannabis-derived product specifications, or a cross-reference to cannabis-derived product specification documents.
- (b) Manufacturing protocols must be written with the intent to provide not less than 100 percent of the labeled or specified amount of cannabis and any other ingredient for which a quantitative label claim is made, throughout the shelf life of the product.
- (c) The production process described in the manufacturing protocol must ensure that cannabis-derived product specifications are consistently met.

Section 5.2 Manufacturing component control requirements

- (a) Manufacturing operations must have written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, review, and approval or rejection of components.
- (b) Each container or grouping of containers for components must be identified with a distinctive code (i.e. lot or control number) for each lot in each shipment received, which allows the lot to be traced backward to the supplier, the date received, and the name of the component; and forward to the cannabis-derived product batches manufactured or distributed using the lot. This code must be used in recording the disposition of each lot.
- (c) Specifications for each component must be established as follows, to the extent they are necessary to ensure that manufactured batches of cannabis-derived product meet specifications.

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- (1) An identity specification for the component must be established;
 - (2) Specifications for the strength and composition of the component must be established as necessary to ensure the strength and composition of cannabis-derived products manufactured with the component;
 - (3) Specifications for the purity of the component must be established as necessary to ensure the purity of cannabis-derived products manufactured with the component, including limits on those types of contamination that may adulterate or may lead to adulteration of cannabis-derived products manufactured with the component, such as filth, insect infestation, microbiological contamination, or other contaminants.
- (d) Components must be received and stored pending approval as follows:
- (1) Upon receipt and before acceptance, each container or grouping of containers must be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination, to determine whether the container condition may have resulted in contamination or deterioration of the components.
 - (2) The supplier's documentation for each shipment must be examined to ensure the components are consistent with what was ordered.
 - (3) Components must be stored under quarantine until they have been sampled, reviewed, and approved or rejected by quality control personnel.
- (e) Components must be approved or rejected as follows:
- (1) Each lot of components must be withheld from use until the lot has been sampled, reviewed, and released for use by the quality control personnel.
 - (2) Compliance of the lot with established specifications must be ensured either through review of the supplier's certificate of analysis or other documentation, or through appropriate tests and/or examinations. Any tests and examinations performed must be conducted using appropriate scientifically valid methods.
 - (3) Any lot of a component that meets its specifications may be approved and released for use for use by quality control personnel.
 - (4) Any lot of a component that does not meet its specifications must be rejected by quality control personnel, unless quality control personnel approve a treatment, process adjustment, reprocessing, or other deviation that will render the component or packaging component suitable for use, and will ensure the finished cannabis product batches manufactured with the affected lot will meet all specifications for identity, purity, strength, and composition and will not be otherwise contaminated or adulterated. Any such treatment, process adjustment, reprocessing, or other deviation must be documented, justified, and approved by quality control personnel.

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Section 5.3 Manufacturing batch record

- (a) The manufacturing operation must prepare a manufacturing batch record for each batch of cannabis-derived product manufactured.
- (b) The manufacturing batch record must:
 - (1) Cross-reference or reproduce the appropriate manufacturing protocol; and
 - (2) Form a complete record of the manufacturing and control of the batch.
- (c) Each batch must be assigned a batch, lot, or control number which allows the complete history of the production and distribution of the batch to be determined. This code must be used in recording the disposition of each batch.
- (d) The manufacturing batch record must include, as applicable to the process:
 - (1) Identity of the cannabis-derived product;
 - (2) The batch, lot, or control number of the cannabis-derived product;
 - (3) Batch size;
 - (4) For each component used in production of the batch:
 - (i) Identity of each component used in the batch;
 - (ii) Batch, lot, or control number of each component used in the batch;
 - (iii) Actual weight or measure of each batch or lot of component used in the batch, including the unit of measure;
 - (5) Date(s) on which, and where applicable the time(s) at which, each step of the manufacturing process was performed;
 - (6) Actual results obtained during monitoring of production process parameters;
 - (7) Identity of processing lines and major equipment used in producing the batch;
 - (8) Date and where applicable the time of the maintenance, cleaning, and/or sanitizing of the major equipment used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is recorded;
 - (9) If manufacture of the batch uses equipment or instruments requiring periodic calibration, inspection, or verification, the date and where applicable the time of the last calibration, inspection, or verification or the date on which such is next due; or a cross-reference to records, such as individual equipment logs, where this information is recorded;
 - (10) A statement of the actual yield and a statement regarding whether the actual yield is within the acceptable range of the theoretical yield as per section 5.1(a)(3) after each significant process step and at the end of manufacturing;

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- (11) Records of any cannabis waste generated during production of the batch;
 - (12) Records of any treatment, process adjustment, reprocessing, or other deviation that occurred during production of the batch;
 - (13) Records of the date, time where applicable, quantity, and person responsible for any sample removed during or after production;
 - (14) Actual results of any testing or examination of in-process material or cannabis-derived product, or a cross-reference to such results;
 - (15) Documentation that the cannabis-derived product meets its specifications for identity, purity, strength, and composition, in accordance with the requirements of the manufacturing protocol;
 - (16) Identity of each person performing each process step in production of the batch, including but not limited to:
 - (i) Weighing or measuring each component and verifying the weight or measure of each component used in the batch per section 5.4;
 - (ii) Adding each component to the batch and verifying the addition of each component to the batch per section 5.4;
 - (iii) Monitoring production process parameters;
 - (iv) Performing and verifying calculations of the actual yield and any other mathematical calculations;
 - (v) Directly overseeing each stage of production of the batch;
 - (vi) Performing any other checks or verifications in production of the batch, as needed; and
 - (vii) Releasing the batch from one stage of production to the next.
- (e) All data in the manufacturing batch record must be recorded at the time at which each action is performed.
- (f) The completed manufacturing batch record for each batch must be reviewed and signed by quality control personnel to determine compliance with all applicable specifications and other requirements of the manufacturing protocol before a batch is approved.

Section 5.4 Allocation and charge-in of components

- (a) Manufacturing operations must weigh, measure, or subdivide components to be used in a cannabis-derived product batch as appropriate for the batch.
- (b) If a component is removed from the original container to another, the new container must be identified with the following information:

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- (1) Component identity;
 - (2) Batch, lot, or control number;
 - (3) Weight or measure in the new container; and
 - (4) Batch for which component was dispensed, including its identity and batch, lot, or control number.
- (c) Each container of component dispensed to manufacturing must be examined by a second person or verified by automated equipment to assure that:
- (1) The component was released by quality control personnel;
 - (2) The weight or measure is correct as stated in the manufacturing protocol; and
 - (3) The containers are properly identified.
- (d) Each component must either be added to the batch by one person and verified by a second person or, if the components are added by automated equipment, verified by one person.

Section 5.5 Process monitoring and controls during manufacturing

- (a) Process specifications must be established for production process parameters at or during any point, step, or stage where control is necessary to ensure the quality of the batch of cannabis-derived product, and to detect any unanticipated occurrence that may result in contamination, adulteration, or a failure to meet specifications. The process parameters to be monitored may include, but are not limited to, the following as appropriate:
- (1) Time;
 - (2) Temperature;
 - (3) Pressure; and
 - (4) Speed.
- (b) Production process parameters must be monitored at or during any point, step, or stage where process specifications have been established.
- (c) Any deviation from the specified process parameters must be documented and justified, and the associated in-process material or product must be quarantined. The deviation must be reviewed and approved or rejected by quality control personnel. Such deviations must not be approved unless quality control personnel determine that the resulting cannabis-derived product will meet all specifications for identity, purity, strength, and composition and is not otherwise contaminated or adulterated.

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- (d) If a deviation is rejected, the resulting in-process or finished cannabis-derived product must be rejected, unless quality control personnel approve a treatment, process adjustment, reprocessing, or other deviation that will ensure the cannabis-derived product batches manufactured with the affected material will meet all specifications for identity, purity, strength, and composition and will not be otherwise contaminated or adulterated. Any such treatment, process adjustment, reprocessing, or other deviation must be documented, justified, and approved by quality control personnel.
- (e) Manufacturing operations must properly identify all compounding and storage containers, processing lines, and major equipment used during the production of a batch of cannabis-derived product at all times to indicate their contents and, when necessary, the phase of processing of the batch.
- (f) Operations on one component, product, or batch must be physically, spatially, or temporally separated from operations on other components, products, or batches.
- (g) All necessary precautions must be taken during the manufacture of a cannabis-derived product to prevent contamination of components and products. These precautions include, but are not limited to:
 - (1) Washing or cleaning components that contain soil or other contaminants;
 - (2) Holding components, in-process materials, and cannabis or cannabis-derived products appropriately;
 - (3) Preventing cross-contamination and mixups between contaminated components, in-process materials, and cannabis or cannabis-derived products and uncontaminated items;
 - (4) Using effective measures to protect against the inclusion of metal or other foreign material in components or cannabis products, by, for example:
 - (i) Filters, strainers, or sieves;
 - (ii) Traps;
 - (iii) Magnets;
 - (iv) Electronic metal detectors.

Section 5.6 Manufacturing sampling requirements

- (a) A representative sample of each batch or lot of component, cannabis, or cannabis-derived product must be collected by removing and compositing portions of material or units from throughout the containers in the batch or lot.

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- (b) In addition to representative samples, other samples may be taken as appropriate to:
 - (1) Monitor the quality of in-process materials during production;
 - (2) Examine the degree of variability of materials or products; and
 - (3) Investigate known or suspected non-conformances.
- (c) The number of containers and the amount of material or units to be removed from each container must be based on appropriate criteria such as:
 - (1) Quantity needed for testing, examination, and reserve;
 - (2) Past quality history of the item;
 - (3) Expected variability of the material or units being sampled; and
 - (4) Degree of confidence and precision required.
- (d) The containers selected for sampling must be based on rational criteria such as random sampling; directed sampling may be used where appropriate.
- (e) Samples must be collected in accordance with the following procedures:
 - (1) The containers selected for sampling must be cleaned when necessary in a manner to prevent introduction of contaminants into the component, in-process material, cannabis or cannabis-derived product.
 - (2) The containers must be opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, in-process materials, cannabis or cannabis-derived product.
 - (3) Sterile equipment and aseptic sampling techniques must be used when necessary.
 - (4) Where appropriate for the purpose of the sample and the nature of the material being sampled, sample portions are removed from the top, middle, and bottom of containers. Such sample portions may be composited in forming the representative sample, or may be tested separately, as appropriate to the purpose.
 - (5) Containers from which samples have been taken must be marked to indicate that samples have been removed from them.
- (f) Sample containers must be identified with the following information:
 - (1) Name of the item sampled;
 - (2) Batch, lot, or control number of the item sampled;

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- (3) Container from which the sample was taken, or for samples taken directly from the production line, the equipment line and time at which the sample was taken, unless such information is documented separately;
 - (4) Date on which the sample was taken;
 - (5) Name of the person who collected the sample; and
 - (6) Quantity and unit of measure of the sample.
- (g) Each sample removed from a batch or lot must be recorded in the inventory or manufacturing batch record for the batch or lot.
 - (h) The quantity of sample used for each test or examination must be of sufficient size or number to ensure the results are representative of the batch or lot.
 - (i) A reserve sample must be prepared from the representative sample of each batch or lot of shelf-stable component, cannabis or cannabis-derived product.
 - (j) Reserve samples should consist of at least twice the quantity necessary for tests and examinations to determine whether the shelf-stable component, cannabis or cannabis-derived product meets established critical quality specifications. However, where state law limits the amount of cannabis and cannabis-derived product permitted to be kept on hand, operations may keep smaller amounts in reserve if necessary.
 - (k) Reserve samples of shelf-stable components should:
 - (1) Be stored using an appropriate container-closure to protect against contamination or deterioration during storage;
 - (2) Be stored under conditions consistent with the conditions under which the component is stored at the manufacturing operation; and
 - (3) Be retained for one year past the expiration date of the last batch of cannabis-derived product manufactured from the lot. However, where state law limits the amount of cannabis and cannabis-derived product permitted to be kept on hand, operations may keep reserve samples for shorter periods of time if necessary.
 - (l) Reserve samples of cannabis-derived product should:
 - (1) Be stored using the same container-closure system in which the packaged and labeled cannabis-derived product is distributed, or for bulk products, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which the bulk product is distributed;
 - (2) Be stored under conditions consistent with the storage conditions recommended on the product label or, if no storage conditions are recommended on the label, under ordinary storage conditions.

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- (3) Be retained for one year past the expiration date of the batch or lot. However, where state law limits the amount of cannabis and cannabis-derived products permitted to be kept on hand, operations may keep reserve samples for shorter periods of time if necessary.

Section 5.7 Cannabis-derived product specifications

- (a) Manufacturing operations must establish specifications for each cannabis-derived product as follows:
 - (1) Manufacturing operations must establish specifications for the identity purity, strength, and composition of each cannabis-derived product manufactured by the operation.
 - (2) Manufacturing operations which receive cannabis-derived product for further processing must establish specifications to provide sufficient assurance that the product received is adequately identified and is consistent with the purchase order.
- (b) For each batch or lot of cannabis-derived product manufactured by the operation, the conformance of the batch or lot to established specifications must be confirmed as follows:
 - (1) For every batch or lot, or for a subset of cannabis-derived product batches or lots identified through sound statistical sampling plan, the operation must verify that the batch or lot meets product specifications for identity, purity, strength, and composition, to the extent that scientifically valid test methods exist for these specifications.
 - (2) In lieu of testing every established strength and composition specification for which scientifically valid test methods exist, one or more strength and/or composition specifications may be selected for testing, where it can be established that testing for this reduced panel of specifications is sufficient to ensure that the production and process control system is producing product that meets all specifications.
 - (3) Where no scientifically valid test method exists for a product specification, compliance with the specification must be established through component and/or in-process testing, examinations, or monitoring and/or review of manufacturing batch records.
 - (4) Quality control personnel must document and approve the justification for reduced product testing under section 5.7(b)(2) or section 5.7(b)(3) of this part.
- (c) Cannabis-derived product which fails to meet its specifications must be rejected, unless quality control personnel approve a treatment, process adjustment, reprocessing, or other deviation that will ensure the cannabis-derived product

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batches manufactured with the affected material will meet all specifications for identity, purity, strength, and composition, and will not be otherwise contaminated or adulterated. Any such treatment, process adjustment, reprocessing, or other deviation must be documented in the manufacturing batch record, justified, and approved by quality control personnel.

- (d) Any unexplained occurrence or discrepancy, and any failure of the cannabis-derived product to meet its specifications or requirements, must be documented and investigated. The investigation must extend to any related batches that may have been associated with the same specific failure, discrepancy, or problem; this may include, but is not limited to, batches of the same cannabis-derived product, other batches processed on the same equipment or during the same time period, and other batches produced using the same lots of components.
- (e) Manufacturing operations must have written procedures describing in sufficient detail the storage, handling, sampling, testing, and approval or rejection of cannabis and cannabis-derived products.

Section 5.8 In-process material specifications, sampling, and testing

- (a) In-process specifications must be established for any point, step, or stage in the manufacturing protocol where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the cannabis-derived product. Such specifications may include, but are not limited to, the following as appropriate:
 - (1) Weight or fill of tablets, capsules, or other units;
 - (2) Weight or fill variation of tablets, capsules, or other units;
 - (3) Hardness or friability of tablets;
 - (4) Disintegration time of unit dosages;
 - (5) Clarity, viscosity, specific gravity, total dissolved solids, or pH of solutions;
 - (6) Loss on drying, moisture content, or solvent residue;
 - (7) Microbiological characteristics; and
 - (8) Organoleptic characteristics.
- (b) In-process specifications for such characteristics must be consistent with the cannabis-derived product specifications.
- (c) In-process materials must be sampled and tested or examined for conformance with in-process specifications as appropriate during the production process, e.g., at commencement or completion of significant process stages or after storage for long

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periods, and where appropriate must be approved or rejected by quality control personnel.

- (d) In-process material which fails to meet its specifications must be rejected, unless quality control personnel approve a treatment, process adjustment, reprocessing, or other deviation that will ensure the cannabis-derived product batches manufactured with the affected material will meet all specifications for identity, purity, strength, and composition and will not be otherwise contaminated or adulterated. Any such treatment, process adjustment, reprocessing, or other deviation must be documented in the manufacturing batch record, justified, and approved by quality control personnel.

Section 5.9 Calculation of yield

- (a) Actual yields must be determined at the conclusion of each appropriate phase of manufacturing of the cannabis-derived product. Such calculations must either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment, be independently verified by one person.
- (b) If the percentage of theoretical yield at any process step or at the end of production falls outside the maximum or minimum percentage of theoretical yield allowed in the manufacturing protocol, quality control personnel must conduct an investigation of the batch and determine, to the extent possible, the source of the discrepancy. The deviation must be documented, explained, and approved by quality control personnel.

SUBPART F – PACKAGING AND LABELING PROCESS CONTROLS

Section 6.1 General considerations for packaging components, including labels

- (a) Cannabis to be packaged without undergoing manufacturing to a cannabis-derived product must be received, identified, stored, handled, sampled, reviewed, and approved or rejected as per sections 5.2 and 5.6 above.
- (b) Specifications for packaging components must be established as necessary to ensure the identity, purity, strength, and composition of the packaged products. Packaging components that may come into contact with products must be safe and suitable for their intended use and must not be reactive or absorptive or otherwise affect the safety, purity, or quality of the product.

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- (c) Packaging and labeling operations must establish written procedures describing in sufficient detail the receipt, identification, storage, handling, and approval or rejection of packaging and labeling components.
- (d) Labels and other packaging components must be received and stored pending approval as follows:
 - (1) Upon receipt and before acceptance, each container or grouping of containers of packaging components must be visually examined for appropriate labeling as to contents, container damage or broken seals, and contamination, to determine whether the container condition may have resulted in contamination or deterioration of the packaging components; and
 - (2) The supplier's documentation for each shipment must be examined to ensure the packaging components are consistent with what was ordered.
 - (3) Each container or grouping of containers for packaging components must be identified with a distinctive code (i.e. lot or control number) for each lot in each shipment received, which allows the lot to be traced backward to the supplier, the date received, and the name of the component; and forward to the product batches packaged or labeled using the lot. This code must be used in recording the disposition of each lot.
 - (4) Labels and other packaging components must be stored under quarantine until they have been examined and approved or rejected by quality control personnel.
- (e) Packaging components must be approved or rejected as follows:
 - (1) Each lot of packaging components must be withheld from use until the lot has been reviewed and released for use by the quality control personnel.
 - (2) Compliance of the lot with established specifications must be ensured through examination of the components received, and/or review of the supplier's documentation.
 - (3) Any shipment of a packaging component that meets its specifications may be approved and released for use for use by quality control personnel.
 - (4) Any packaging component that does not meet its specifications, including any incorrect labels, must be rejected by quality control personnel, unless quality control personnel approve a treatment or other deviation that will render the packaging component suitable for use, and will ensure the product batches packaged and labeled with the affected component will meet all specifications for identity, purity, strength, composition, packaging, and labeling and will not be otherwise contaminated or adulterated. Any such treatment or other deviation must be documented, justified, and approved by quality control personnel.

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- (f) Use of gang-printed labeling for different products, or different strengths or net contents of the same product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color.

Section 6.2 Packaging and/or labeling protocol

- (a) Packaging and labeling operations must prepare and follow a written protocol for each unique product to be packaged and/or labeled to assure that correct packaging and labeling components are used for each product packaged or labeled by the operation. Where appropriate, the packaging and/or labeling protocol may be combined with the manufacturing protocol for the product. The protocol must:
 - (1) Identify the product to be packaged and/or labeled;
 - (2) Identify each packaging component to be used;
 - (3) Provide a specimen of the label and other labeling to be used, or a cross-reference to the labeling (such as by label number and version number);
 - (4) Provide a statement of the acceptable maximum and minimum percentages of theoretical yield; and
 - (5) Include written instructions or cross references to standard procedures for the following:
 - (i) Inspection of packaging and labeling equipment before and after use to assure that all products and packaging and labeling materials from previous operations have been removed;
 - (ii) Issuance of labels and labeling to a packaging and/or labeling batch;
 - (iii) Careful examination of labels and labeling issued to each batch prior to use, to ensure conformity to the labeling specified in the packaging and/or labeling protocol;
 - (iv) Each packaging and/or labeling process step;
 - (v) Monitoring of packaging and/or labeling process steps; and
 - (vi) Additional applicable procedures to be followed, if any.
- (b) Packaging and/or labeling protocols must be written with the intent to provide not less than 100 percent of the labeled amount of product.
- (c) The packaging and/or labeling process described in the protocol must ensure that product specifications are consistently met.

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Section 6.3 Packaging and/or labeling batch record

- (a) The packaging and/or labeling operation must prepare a packaging and/or labeling batch record for each batch or lot of product packaged and/or labeled by the operation. Where appropriate, the packaging and labeling batch record may be combined with the manufacturing batch record for the batch or lot.
- (b) The packaging and/or labeling batch record must:
 - (1) Cross-reference or reproduce the appropriate packaging and/or labeling protocol; and
 - (2) Form a complete record of the packaging and/or labeling and sampling of the batch.
- (c) The packaging and/or labeling batch record must include, as applicable to the process:
 - (1) Identity of the product;
 - (2) Batch, lot, or control number of the product;
 - (3) Packaging and/or labeling batch size;
 - (4) For each packaging component used in production of the batch:
 - (i) Identity of each packaging component;
 - (ii) Batch, lot, or control number of each packaging component used in the batch;
 - (iii) Quantity of each lot of packaging components used, including the unit of measure.
 - (5) Date(s) on which, and where applicable the time(s) at which, each step of the packaging and/or labeling protocol was performed;
 - (6) Identity of packaging lines and major equipment used in packaging and/or labeling the batch;
 - (7) Date and time of the maintenance, cleaning, and/or sanitizing of the packaging lines and major equipment used in packaging and labeling of the batch, or a cross-reference to records, such as individual equipment logs, where this information is recorded;
 - (8) If packaging or labeling of the batch uses equipment or instruments requiring periodic calibration, inspection, or verification, the date and time of the last calibration, inspection, or other verification of instruments or equipment or the date on which such is next due; or a cross-reference to records, such as individual equipment logs, where this information is recorded;

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- (9) Statement of the actual yield and a statement regarding whether the actual yield is within the acceptable range of the theoretical yield as per section 6.2(a)(4) at the end of packaging and/or labeling;
- (10) When the actual yield falls outside the allowed limits, quality control personnel must conduct an investigation of the batch and determine, to the extent possible, the source of the discrepancy. The deviation must be documented, explained, and approved by quality control personnel.
- (11) Label reconciliation, as per section 6.3(f) of this part;
- (12) Records of any labeling scrap or cannabis waste generated during packaging and/or labeling of the batch;
- (13) Identity of each person performing each process step in packaging and/or labeling of the batch, including but not limited to:
 - (i) Inspecting labels and other packaging components to ensure suitability and correctness prior to use in the batch;
 - (ii) Inspecting packaging and labeling areas before and after use;
 - (iii) Reconciling label issuance and usage and verifying the reconciliation of label issuance and usage;
 - (iv) Examining packaged and labeled products to ensure proper labeling and coding;
 - (v) Performing any other checks or verifications in packaging and/or labeling of the batch as needed; and
 - (vi) Releasing the batch from one stage of packaging and/or labeling to the next.
- (d) All data in the packaging and/or labeling batch record must be recorded at the time at which each action is performed.
- (e) Printing devices located on, or associated with, production lines must be monitored to assure that all printing conforms to the requirements of the packaging and/or labeling protocol when used to imprint labeling or coding directly on the following:
 - (1) Primary packaging for the product; or
 - (2) Secondary packaging (e.g., a case containing several individual packages of product).
- (f) Packaging and labeling operations must reconcile the quantities of labels or labeling issued, used, and returned to storage.
 - (1) Narrow limits for the labeling reconciliation must be established, based where possible on historical operating data, for the amount of allowed variation in the labeling reconciliation.

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- (2) When a labeling reconciliation falls outside the allowed limits, quality control personnel must conduct an investigation of the batch and determine, to the extent possible, the source of the discrepancy. The deviation must be documented, explained, and approved by quality control personnel.
 - (3) Labeling reconciliation is waived for cut or roll labels if a 100-percent examination for correct labels is performed, either manually or by appropriate electronic or electromechanical equipment during or after completion of finishing operations.
 - (4) All excess labeling bearing batch, lot, or control numbers must be destroyed.
 - (5) Care must be taken when returning labeling to storage, to prevent mixups and ensure proper identification.
- (g) Representative and reserve samples of each batch or lot of retail packaged and/or labeled product must be collected as per section 5.6 of this part.
- (h) The completed packaging and/or labeling batch record for each batch or lot must be reviewed and signed by quality control personnel to determine compliance with all applicable specifications and other requirements of the packaging and/or labeling protocol before a batch or lot is approved.
- (i) Packaged or labeled product which fails to meet its packaging or labeling specifications or other packaging requirements must be rejected, unless quality control personnel approve repackaging, relabeling, or other deviation that will ensure the product batch or lot will meet all packaging and labeling specifications and other packaging requirements, and will not be otherwise contaminated or adulterated. Any such repackaging, relabeling, or other deviation must be documented, justified, and approved by quality control personnel.

Section 6.4 Label content for cannabis and cannabis-derived products

- (a) Each packaged and labeled product must bear on the label of its primary packaging:
- (1) Name and place of business of the manufacturer or distributor;
 - (2) Identity of the product;
 - (3) Net quantity of contents in terms of weight, numerical count, or other appropriate measure;
 - (4) A batch, lot, or control number;
 - (5) Either a production date or an expiration date. Products capable of supporting the rapid and progressive growth of infectious, toxigenic, or spoilage microorganisms must bear a "use by" date and/or a "freeze by" date. Any shelf life or expiration period indicated on the label of an edible product must be supported by appropriate data;

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- (6) Instructions for use, including any types of compliant individuals for whom the product is recommended, as appropriate;
 - (7) Appropriate warnings for use, including any types of compliant individuals for whom the product is contraindicated, as appropriate;
 - (8) Instructions for appropriate storage; and
 - (9) Any other statements or information required by state regulators.
- (b) For edible products, each product label must contain a "Product Facts" box listing quantitative content and nutrient information relevant to the product, including, as applicable to the product's content:
- (1) Cannabis ingredient;
 - (2) Cannabinoid and/or terpenoid content;
 - (3) Total calories and fat calories (when greater than 5 calories per serving);
 - (4) Total fat, saturated fat, and trans fat (when greater than 0.5 g per serving);
 - (5) Cholesterol (when greater than 2 mg per serving);
 - (6) Sodium (when greater than 5 mg per serving);
 - (7) Total carbohydrates (when greater than 1 g per serving);
 - (8) Dietary fiber (when greater than 1 g per serving);
 - (9) Sugars (when greater than 1 g per serving);
 - (10) Protein (when greater than 1 g per serving); and
 - (11) Vitamin A, vitamin C, calcium, and iron (when present at greater than 2% of the recommended daily intake).

SUBPART G – HOLDING CONTROLS

Section 7.1 Identification

- (a) Each container of component, packaging component, in-process material, and product must be appropriately identified at all times with the following:
- (1) Identity of the item;
 - (2) Batch, lot, or control number;
 - (3) Status (e.g., quarantined, approved, recalled, rejected).

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- (b) Product packages that are held in unlabeled condition for future labeling operations must be identified and handled to preclude mislabeling of individual containers, lots, or batches. Identification need not be applied to each individual container but must be sufficient to determine the identity of the product, quantity of contents, and batch, lot, or control number of each container.
- (c) Identification information required in sections 7.1(a) and (b) may be:
 - (1) Affixed to the individual container or to an appropriate grouping of containers;
or
 - (2) Assigned to the room or other defined physical location of the container(s).

Section 7.2 Storage and handling

- (a) Components, packaging components, in-process materials, and products must at all times be handled, stored, and distributed in a manner to avoid deterioration, prevent contamination, and avoid mixups. Where necessary, appropriate conditions of temperature, humidity, and light must be established and maintained so that the identity, purity, strength, and composition of components, in-process materials, and products are not affected and that adulteration is prevented.
- (b) Containers of components, packaging components, in-process materials, and product must be stored off the floor and suitably spaced to permit cleaning and inspection.
- (c) Components, in-process materials, and products that can support the rapid growth of microorganisms of public health significance must be held in a manner that prevents them from becoming adulterated.
- (d) Labels, labeling, cannabis, cannabis-derived products, and cannabis waste must be stored in a controlled access area.
- (e) Components, packaging components, and products must be used or distributed in a manner whereby the oldest batches or lots are used or distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

Section 7.3 Withholding materials from use or distribution

- (a) Manufacturing, packaging, and labeling operations must establish and implement written procedures for quarantine of any lot, batch, or other portion of component, packaging component, in-process material, or product whose suitability for use or distribution is in question, to prevent its use and distribution pending disposition by quality control personnel. This includes:
 - (1) Newly received components and packaging components for use in manufacturing, packaging and/or labeling;

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- (2) Batches newly completed in production;
 - (3) Product returned to the operation for any reason;
 - (4) Components, packaging components, in-process materials, or products that are or may be contaminated or adulterated; or
 - (5) Components, packaging components, in-process materials, or products that are under investigation by quality control personnel for any other reason.
- (b) Rejected components, packaging components, in-process materials, finished product, cannabis waste, and rejected labels and labeling (including any excess labeling bearing lot, batch, or control numbers which is not immediately destroyed after packaging operations are complete) must be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.
- (c) Cannabis waste other than cannabis and cannabis-derived product that is rejected and returned to the vendor, and rejected labels and other labeling, must be destroyed in a manner which prevents unauthorized use. Destruction of any cannabis waste must be documented and witnessed by at least two workers, one of whom must be supervisory, managerial, or quality control personnel; except that if video surveillance is used, only one worker is necessary. Destruction may include composting.

SUBPART H – INVENTORY AND RECORDKEEPING

Section 8.1 Materials inventory

- (a) Manufacturing, packaging, labeling and holding operations must keep written records for each shipment of component, packaging component, cannabis, and cannabis-derived product received from another company or individual.
- (b) Records must be kept of the following:
- (1) Identity of the received item, as applicable to the item; and any component number or product number if such are in use by the supplier;
 - (2) Supplier or vendor from which the shipment was received;
 - (3) Original cultivation operation, processing operation, or manufacturing operation, if known and where applicable;
 - (4) The cultivation operation's, processing operation's, manufacturing operation's, or supplier's batch, lot, or control number, if known and where applicable;

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- (5) Date of receipt; and
 - (6) Shipment delivery method, including where applicable the name of the commercial or private carrier.
- (c) Additionally, manufacturing, packaging, and labeling operations must keep records, or establish cross references to other records such as manufacturing batch records, of the following information:
- (1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the shipment;
 - (2) Inspection, sampling, testing, and examinations performed on the batch or lot, and the conclusions derived therefrom, as applicable to the scope of the operation;
 - (3) Any treatment, reprocessing, or other deviation performed by the operation on the batch or lot prior to use;
 - (4) Disposition of the batch or lot by quality control personnel, including the date and the signature of the person responsible for approving or rejecting the batch or lot and any treatment, reprocessing, or other deviation performed thereon;
 - (5) A record of each use of the batch or lot in production, including:
 - (i) Quantity used, including unit of measure;
 - (ii) Name and batch, lot, or other control number of the product batch in which the batch or lot is used; and
 - (iii) Initials of the person(s) responsible for removing from storage the necessary quantity for use in the designated batch.
 - (6) A record of any portion of the batch or lot returned from production to storage, including:
 - (i) Quantity returned, including unit of measure;
 - (ii) Name and batch, lot, or other control number of the batch or lot from which the portion is returned; and
 - (iii) Initials of the persons responsible for verifying the quantity returned.
 - (7) A record of any portion of the batch or lot disposed of from storage, including the quantity, unit of measure, reason, and persons responsible for measuring the quantity.

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Section 8.2 Distributed materials

- (a) Manufacturing, packaging, labeling and holding operations must keep written records for each batch or lot of cannabis or cannabis-derived product distributed by the operation.
- (b) Records must be kept of the following:
- (1) Identity of the cannabis or cannabis-derived product, and any item code or product number if such are in use by the manufacturing, packaging, labeling, or holding operation;
 - (2) A record of each distribution of the batch or lot, including:
 - (i) Quantity distributed, including unit of measure;
 - (ii) Name and address of each company or non-profit entity to which, or individual to whom, the batch is distributed, unless a system exists to unambiguously cross-reference the name to the corresponding address maintained on file separately;
 - (iii) Shipping method by which each shipment is distributed, including where applicable the name of the commercial or private carrier;
 - (iv) Initials of the persons responsible for removing from storage the necessary quantity for each shipment. Each distribution must be verified by a second person.
 - (3) A record of any portion of the batch or lot returned to storage, including:
 - (i) Quantity returned, including the unit of measure;
 - (ii) Company, non-profit entity, individual, or location from which the portion is returned;
 - (iii) Shipment return method, including where applicable the name of the commercial or private carrier;
 - (iv) Initials of the person(s) responsible for verifying the quantity returned;
 - (4) A record of any portion of the batch or lot disposed of from storage, including the quantity, unit of measure, reason, and persons responsible for measuring the quantity.
- (c) Additionally, manufacturing, packaging, and labeling operations must keep records or establish cross references to other records such as manufacturing batch records, for the following:
- (1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the batch or lot;

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- (2) Inspection, sampling, testing, and examinations performed on the batch or lot by the operation, and the conclusions derived therefrom;
- (3) Any treatment, reprocessing, or other deviation performed on the batch or lot by the operation prior to distribution; and
- (4) Disposition of the batch or lot by quality control personnel, including the date and the signature of the person responsible for approving the batch or lot for distribution; and the date and the signature of the person responsible for approving or rejecting any treatment, reprocessing, or other deviation performed thereon.

Section 8.4 Reconciliation

- (a) Records of receipt, use or distribution, return, and disposal of each batch or lot of components, packaging components, cannabis or cannabis-derived products must be kept chronologically, and the quantities must be recorded with an appropriate level of precision.
- (b) After each batch or lot is used or distributed, manufacturing, packaging, labeling, and holding operations must perform a reconciliation of the quantity received into storage against the quantity used, distributed, returned, and/or disposed. Such calculations must be performed by one person and independently verified by a second person.
- (c) Narrow limits must be established, based where possible on historical operating data, for the amount of allowed variation in the reconciliation.
- (d) When a reconciliation falls outside the allowed limits, quality control personnel must conduct an investigation to determine, to the extent possible, the source of the discrepancy. The deviation must be documented, explained, and approved by quality control personnel.

Section 8.5 Record retention

- (a) Except as required in sections 8.5(b) and (c), manufacturing, packaging, labeling, and holding operations must retain the records required by this part for a period of at 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.

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- (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 I – COMPLAINTS, RETURNS, AND RECALLS

Section 9.1 Complaint files

- (a) Manufacturing, packaging, labeling, and holding operations must establish written procedures describing the handling of product complaints received regarding a cannabis or cannabis-derived product.
- (b) A qualified person must:
 - (1) Review product complaints to determine whether the product complaint involves a possible failure of a product to meet any of its specifications, or any other requirements, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury; and
 - (2) Investigate any product complaint that involves a possible failure of a product to meet any of its specifications, or any other requirements of this part, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury.
- (c) Quality control personnel must review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed.
- (d) The review and investigation of the product complaint, and the review by quality control personnel about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, must extend to all related batches and relevant records. Related batches may include, but are not limited to, batches of the same product, other batches processed on the same equipment or during the same time period, or other batches produced using the same batches or lots of components or packaging components.
- (e) A written record of the complaint and where applicable its investigation must be kept, including:
 - (1) Identity of the product;
 - (2) Batch, lot or other control number of the product;
 - (3) Date the complaint was received and the name, address, or telephone number of the complainant, if available;
 - (4) Nature of the complaint including, if known, how the product was used;

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- (5) Names of personnel who do the following:
 - (i) Review and approve the decision about whether to investigate a product complaint;
 - (ii) Investigate the complaint, and
 - (iii) Review and approve the findings and follow-up action of any investigation performed.
- (6) Findings of the investigation and follow-up action taken when an investigation is performed; and
- (7) Response to the complainant, if applicable.
- (f) Manufacturing, packaging, labeling, and holding operations must establish a procedure for a product complaint that includes a report of an adverse event. For purposes of this section, an adverse event is a health-related event associated with use of a product that is undesirable, and that is unexpected or unusual. The procedure must address whether the adverse event requires the following:
 - (1) Reporting to any public health authority;
 - (2) Reporting to the physician of record for the individual reported to have experienced the adverse event, if known; and
 - (3) Product recall.

Section 9.2 Returned products

- (a) Manufacturing, packaging, and/or labeling operations must establish written procedures describing the receipt, handling, and disposition of returned cannabis or cannabis-derived products.
- (b) Returned products must be identified as such and be quarantined upon receipt.
- (c) Returned product must be reviewed and approved or rejected by quality control personnel.
- (d) If the conditions under which returned product has been held, stored, or shipped before or during its return, or if the condition of the product, its containers, or labeling, as a result of storage or shipping, casts doubt on the identity, purity, strength, composition, or freedom from contamination or adulteration of the product, the returned product shall be rejected unless examination, testing, or other investigations prove the product meets appropriate standards of identity, purity, strength, and composition and its freedom from contamination or adulteration.
- (e) If the reason a product is returned implicates associated batches, an appropriate investigation must be conducted and must extend to all related batches and relevant records. Related batches may include, but are not limited to, batches of the same

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product, other batches processed on the same equipment or during the same time period, or other batches produced using the same components or packaging components.

- (f) Rejected returned product returned to the manufacturing, packaging, labeling, and holding operation must be destroyed as per section 7.3(c).
- (g) A written record must be kept of the return, and where applicable its investigation, including:
 - (1) Identity of the product;
 - (2) Batch, lot or other control number of the product;
 - (3) Date the returned product was received;
 - (4) Name and address from which it was returned, and the means by which it was returned;
 - (5) Reason for the return;
 - (6) Results of any tests or examinations conducted on the returned product, or on related batches, if any;
 - (7) Findings of the investigation and follow-up action taken when an investigation is performed;
 - (8) Any reprocessing performed on the returned product;
 - (9) The ultimate disposition of the returned product, and the date of disposition; and
 - (10) Names of the quality control personnel who do the following:
 - (i) Review the reason for the product return;
 - (ii) Review and approve any reprocessing, as applicable, and
 - (iii) Review and approve the findings and follow-up action of any investigation performed.

Section 9.3 Recall procedures

- (a) Manufacturing, packaging, labeling, and holding operations must establish a procedure for recalling a product that has been shown to present a reasonable or remote probability that the use of the product will cause serious adverse health consequences or could cause temporary or medically reversible adverse health consequences. This procedure should include:
 - (1) Factors which necessitate a recall;
 - (2) Personnel responsible for a recall; and

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- (3) Notification protocols.
- (b) Manufacturing, packaging, labeling, and holding operations must establish a procedure for communicating a recall of product distributed by the operation. This procedure should include:
 - (1) A mechanism to contact all customers that have, or could have, obtained the product from the operation;
 - (2) A mechanism to contact the vendor that supplied the recalled product to the operation, if applicable;
 - (3) Instructions for the return or destruction of any recalled product by customers;
 - (4) Instructions for contacting the relevant manufacturing, packaging, labeling, and/or holding operations; and
 - (5) Communication and outreach via media, as necessary and appropriate.

PART [X] – Cannabis laboratory operations

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

- (a) Except as provided in paragraph (b) of this section, any person, group of persons, non-profit entity, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products in the jurisdiction in which this part applies¹ is a laboratory operation and is subject to this part.
- (b) A cannabis cultivation, manufacturing, or dispensing operation which performs analytical testing solely as a function of its internal operations is not subject to this part.

Section 1.2 Other statutory provisions and regulations

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

Section 1.3 Definitions

The following definitions apply to this part:

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

Cannabis-derived product means a product, other than cannabis itself, which contains or is derived from cannabis, and does not mean a product that contains or is derived from hemp.

Cannabis waste means cannabis or cannabis-derived product discarded by a laboratory operation.

Compliant business means a business that has met all legal requirements to obtain, possess, manufacture, distribute, or sell cannabis and cannabis-derived products in the jurisdiction where this part applies.

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

Controlled access area means an area in a laboratory facility designed to physically prevent entry by anyone except authorized personnel.

Controlled substance means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of 21 U.S.C. 802. It does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

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

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

Hemp-derived product means a product, other than hemp itself, which contains or is derived from hemp.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and hemp, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics and as stated on the label or other labeling. In the case of cannabis-derived products or hemp-derived products, identity means the product name, strength, key features of its form or composition, grade, and other characteristics as applicable and as stated on the label or other labeling.

Laboratory facility means the physical location(s) of a laboratory operation.

Laboratory operation means a person, group of persons, non-profit entity, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.

Macroscopic examination means using the naked eye or minor magnification (e.g., with a 10x magnifying glass) to observe and/or measure a sample or object.

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

Microscopic examination means using a microscope to view samples and objects that cannot be seen with the unaided eye (objects that are not within the resolution range of the normal eye).

Must is used to state a requirement.

Organoleptic examination means testing by using sense organs to evaluate flavor, aroma, appearance, or texture.

Primary reference standard means a reference standard whose purity is determined with a high degree of confidence through comprehensive analysis using multiple test methods based on differing principles, such as HPLC or GC, MS, NMR, Karl-Fisher, etc.

Purity means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.

Secondary reference standard means a reference standard whose purity is established by assaying it against a primary standard.

Should is used to state recommended or advisory procedures.

Strength means the potency of cannabis or a cannabis-derived product, whether expressed as (a) the amount or percent of specific chemical constituents or groups of chemical constituents; (b) the concentration or amount of cannabis present in a cannabis-derived product; or (c), in the case of cannabis extracts, the ratio of the input quantity of crude cannabis, on a dry weight basis, to the output quantity of finished extract.

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Test sample means the specific portion of cannabis, cannabis-derived product, hemp, or hemp-derived product submitted for analysis.

Volumetric solution means a solution used for volumetric analysis, such as titration, wherein the content of analyte is determined by reacting the analyte with a known quantity of standardized reagent.

SUBPART B – LABORATORY FUNCTIONS

Section 2 Scope of laboratory functions

- (a) Laboratory operations may conduct any analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.
- (b) Analytical testing of cannabis or hemp may include, among other things, analysis for:
 - (1) Identity;
 - (2) Purity, such as analysis of:
 - (i) Heavy metals;
 - (ii) Microbiological organisms (e.g., total plate count; pathogens; yeasts; molds; etc.) or microbial toxins;
 - (iii) Residues of pesticide or plant growth regulators;
 - (iv) Residual solvents;
 - (v) Foreign matter.
 - (3) Strength, such as analysis of:
 - (i) Cannabinoid content;
 - (ii) Terpenoid content.
 - (4) Other quality factors, such as weight loss on drying, oil content, ash, acid-insoluble ash, etc.
- (c) Analytical testing of cannabis-derived products may include, among other things:
 - (1) Any of the analyses identified in paragraph (b) of this section that are relevant to such product;
 - (2) Determination of any factor of a product's composition or nutritional content.
- (d) Laboratory operations may utilize any appropriate tests and examinations in its analyses, including:
 - (1) Gross organoleptic analysis;
 - (2) Macroscopic analysis;
 - (3) Microscopic analysis;
 - (4) Chemical analysis;

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- (5) Genetic (DNA) analysis; or
- (6) Other scientifically valid methods.

SUBPART C – PERSONNEL

Section 3 Personnel training

- (a) Each person engaged in a laboratory operation must:
 - (1) Have education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.
 - (2) Have records of any training received for the performance of all assigned functions.
- (b) Laboratory operations should provide all employees with training that includes:
 - (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
 - (2) Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.

SUBPART D – FACILITIES

Section 4.1 Physical facilities

- (a) Laboratory operations must:
 - (1) Be operated in adherence with any regulation in the jurisdiction in which this part applies that is relevant to its specific operations, including:
 - (i) Locations and zoning;
 - (ii) Business hours;
 - (iii) Parking;
 - (iv) Drive-through services; and
 - (v) Signage.
 - (2) Be maintained in a clean and orderly condition;
 - (3) Be equipped with such utensils and equipment as are necessary to conduct all operations that occur at the laboratory facility; and
 - (4) Provide adequate space for laboratory operations, sample storage, and document storage.

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Section 4.2 Security

- (a) Laboratory operations must establish and adhere to such security procedures as are provided by applicable regulation in the jurisdiction in which this part applies.
- (b) Laboratory operations should:
 - (1) Provide additional security as needed to protect the employees during working hours and in a manner appropriate for the community where it operates; and
 - (2) Provide training to make all employees aware of the operation's security procedures, and each individual employee's security roles and responsibilities.
- (c) Laboratory operations analyzing cannabis, cannabis-derived product, hemp, or hemp-derived product samples must be equipped with one or more controlled access areas for storage of the following:
 - (1) Cannabis and cannabis-derived test samples;
 - (2) Cannabis waste;
 - (3) Reference standards for analysis of cannabinoids; and
 - (4) Any other controlled substances.
- (d) Access to controlled access areas must be limited by locks, electronic badge readers, biometric identifiers, or other means.
- (e) Appropriate steps must be taken to ensure access privileges to the laboratory facility and to controlled access areas, as applicable, are revoked for personnel who are no longer employed by the operation.
- (f) There must be written procedures for security.

SUBPART E – SAMPLE RECEIPT, HANDLING, AND DISPOSITION

Section 5.1 Sample receipt

- (a) Laboratory operations may receive test samples from any compliant business or compliant individual, or may be contracted to collect test samples on behalf of those entities.
- (b) Laboratory operations should establish and implement policies for:
 - (1) Collecting test samples in a manner that ensures that the test sample accurately represents the material being sampled; and
 - (2) Other parameters affecting sample preparation, documentation, and transport, including, if applicable:
 - (i) Accepted test sample types;
 - (ii) Minimum test sample size;

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- (iii) Recommended test sample container;
- (iv) Test sample labeling;
- (v) Transport and storage conditions, such as refrigeration if required;
- (vi) Other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and
- (vii) Use of sample chain of custody forms.

(c) Laboratory operations must:

- (1) Record each receipt of a test sample. This record must include:
 - (i) The name and contact information of any compliant business or compliant individual that was the source of the sample;
 - (ii) An appropriately complete and specific description of the sample;
 - (iii) The date of receipt of the sample;
 - (iv) A statement of the quantity (weight, volume, number, or other amount) of the sample; and
 - (v) A unique sample identifier for the sample.
- (2) Inform each compliant business and compliant individual that submits test samples of the policies established in paragraph (b) of this section.

Section 5.2 Sample handling and disposal

- (a) Laboratory operations must establish sample handling procedures for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent any diversion.
- (b) Laboratory operations must store each test sample under the appropriate conditions to protect the physical and chemical integrity of the sample.
- (c) Analyzed test samples consisting of cannabis or cannabis-derived product must be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.
- (d) Any portion of a cannabis or cannabis-derived test sample that is not destroyed during analysis must be:
 - (1) Returned to the same compliant individual or compliant business that provided the sample;
 - (2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or
 - (3) Destroyed in a manner which prevents unauthorized use. Such destruction must be documented and witnessed by at least two employees, one of whom must be supervisory, managerial, or quality control personnel; except that if video surveillance is used, only one employee is required.

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- (e) Any portion of a hemp or hemp-derived product test sample that is not destroyed during analysis may be:
 - (1) Returned to the same compliant individual or compliant business that provided the sample;
 - (2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or
 - (3) Disposed of in any appropriate manner.

SUBPART F – EQUIPMENT AND REAGENTS

Section 6.1 Equipment

- (a) Equipment used for the analysis of test samples must be adequately inspected, cleaned, and maintained. Equipment used for the generation or measurement of data must be adequately tested and calibrated on an appropriate schedule, as applicable.
- (b) Laboratory operations must document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and must specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures must designate the personnel responsible for the performance of each operation.
- (c) Records must be maintained of all inspection, maintenance, testing, and calibrating operations. These records must include the date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. Records must be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records must document the nature of the repair, how and when the need for the repair was discovered, and any remedial action taken in response to the repair.
- (d) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions should ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Section 6.2 Reagents, solutions, and reference standards

- (a) Analytical reagents, solutions, and reference standards must be:
 - (1) Labeled to indicate identity, date received or prepared, and expiration or requalification date, and, where applicable, concentration or purity, storage requirements, and date opened.

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- (2) Stored under appropriate conditions to minimize degradation or deterioration of the material.
 - (3) Be within their expiration or requalification dates at the time of use.
- (b) Deteriorated or outdated reagents and solutions must be properly discarded.
- (c) Laboratory operations may acquire commercial reference standards for cannabinoids including, but not limited to:
- (1) Tetrahydrocannabinolic acid (THC-acid);
 - (2) Delta-9 tetrahydrocannabinol (Δ^9 THC);
 - (3) Cannabidiolic acid (CBD-acid);
 - (4) Cannabidiol (CBD);
 - (5) Cannabichromene (CBC);
 - (6) Cannabigerol (CBG);
 - (7) Cannabinol (CBN); and
 - (8) Delta-8 tetrahydrocannabinol (Δ^8 THC).
- (d) Laboratory operations may elect to internally produce reference standards. When internally produced, laboratory operations should utilize standard analytical techniques to document the purity and concentration of the internally produced reference standards.
- (e) Laboratory operations must obtain or, for internally-produced standards, create a certificate of analysis (COA) for each lot of reference standard. Each COA must be kept on file and the lot number of the reference standard used should be recorded in the documentation for each analysis, where applicable.

SUBPART G – ANALYSIS OF SAMPLES

Section 7.1 Analytical procedures

- (a) Laboratory operations must:
- (1) Utilize analytical methods that are fit for purpose in their testing of cannabis, cannabis-derived products, hemp, and hemp-derived products.
 - (2) Require analysts to demonstrate proficiency in the performance of the analytical methods used.
 - (3) Have written procedures for the analytical method used for the analysis of each test sample, including for each of the following:
 - (i) Sample preparation;
 - (ii) Reagent, solution, and reference standard preparation;
 - (iii) Instrument setup, where applicable;
 - (iv) Standardization of volumetric reagent solutions, as applicable;

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- (v) Data acquisition; and
 - (vi) Calculation of results.
- (4) Specify, as applicable to each analytical method used, requirements for accuracy, precision, linearity, specificity, limit of detection, limit of quantitation, and other data quality parameters.
 - (5) Ensure that no deviations from approved protocols or standard operating procedures are made during any analytical process without proper authorization and documentation.
- (b) Laboratory operations should use only primary standards or secondary standards for quantitative analyses.

Section 7.2 Recording of analytical data

- (a) All data generated during the testing of a test sample, except those that are generated by automated data collection systems, must be recorded directly, promptly, and legibly in ink. All data must be annotated with the date of entry and signed or initialed by the person recording the data. Any change in entries must be made so as not to obscure the original entry, must indicate the reason for such change, and must be dated and signed or initialed at the time of the change.
- (b) In automated data collection systems, the individual responsible for direct data input must be identified at the time of data input. Any change in automated data entries must be made so as not to void or delete the original entry, must indicate the reason for change, must be dated, and the responsible individual must be identified.

Section 7.3 Data review

For each final result reported, laboratory operations must verify that:

- (1) Any calculations or other data processing steps were performed correctly;
- (2) The data meet any data quality requirements such as for accuracy, precision, linearity, etc.;
- (3) Any reference standards used were of the appropriate purity and within their expiration or requalification dates;
- (4) Any volumetric solutions were properly standardized before use;
- (5) Any test or measuring equipment used has been properly tested, verified, and/or calibrated and is within its verification or calibration period.

Section 7.4 Data storage

- (a) All raw data, documentation, protocols, and final reports associated with analysis of a test sample must be retained for two years from the date of the completion of analysis.
- (b) Laboratory operations must maintain the records identified in paragraph (a) of this section, either on the laboratory operation's premises or remotely. Such records must be maintained:

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- (1) In a manner that allows retrieval as needed;
 - (2) Under conditions of storage that minimize deterioration throughout the retention period; and
 - (3) In a manner that prevents unauthorized alteration.
- (c) Laboratory operation must designate an individual as responsible for records maintenance.
- (d) Only authorized personnel may enter or access the maintained records.

Section 7.5 Data reporting

- (a) All analytical results related to any test sample are the property of the compliant business or compliant individual which provided the sample, unless contracts or other written agreements specify otherwise.
- (b) A laboratory report given to a compliant business or compliant individual must contain the following information:
- (1) Date of receipt of the test sample;
 - (2) Description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.);
 - (3) The unique sample identifier as established in accordance with subparagraph 5.1 (b)(1)(v) of this part;
 - (4) Information on whether sampling was performed by the laboratory operation, by the compliant business or individual which submitted the test sample, or by a third-party;
 - (5) Date on which analysis occurred;
 - (6) The analytical method used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);
 - (7) The analytical results, including units of measure where applicable;
 - (8) The identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met;
 - (9) The name, address, and contact information of the laboratory operation.
- (c) If a laboratory operation reports cannabinoid values other than those directly measured in the test sample, the laboratory report must include the following:
- (1) All calculations or conversion factors used to determine the reported non-measured results; and
 - (2) Written explanation of any assumptions, if any, associated with the reported non-measured results, such as the route of consumption of the product represented by the test sample.

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(d) The laboratory report must state that reported analytical results apply only to the test sample received.

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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 provides cannabis or cannabis-derived product to compliant individuals in the jurisdiction in which this part applies¹ is engaged in a cannabis dispensing operation², and is subject to this part.
- (b) A compliant individual who transfers or gives cannabis or cannabis-derived product to another compliant individual at no charge is not a cannabis dispensing operation and is not subject to this part.

Section 1.2 Other statutory provisions and regulations

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

Section 1.3 Definitions

The following definitions apply to this part:

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

Cannabis-derived product means a product, other than cannabis itself, which contains or is derived from cannabis, and does not mean a product that contains or is derived from hemp.

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

Co-owned operation means a cultivation or manufacturing operation that has the same ownership as a dispensing operation.

Cultivate means to grow plants in the genus *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*.

Delivery service means a dispensing operation that delivers cannabis or cannabis-derived product to compliant individuals.

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

Dispense means to provide cannabis or cannabis-derived product to compliant individuals.

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

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

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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.

Growing co-op means a dispensing operation that consists of a group of compliant individuals who grow cannabis collectively on property belonging to, leased or rented by, or otherwise authorized for use by the entire group, or by a member of the group, or who cooperatively produce cannabis-derived product for use by members of the group.

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

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; *may not* is used to indicate an action or activity that is not permitted.

Must is used to state a requirement.

Oral cannabis or *edible* means cannabis or cannabis-derived product that is ingested through the mouth and into the digestive system.

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

Provide means to offer for sale or to sell, including by barter, cannabis or cannabis-derived product to compliant individuals.

Should is used to state recommended or advisory procedures.

Smoked cannabis means cannabis or cannabis-derived product that is burned and inhaled into the lungs.

Storefront operation means a dispensing operation that provides cannabis or cannabis-derived product to compliant individuals at a physical location.

Topical cannabis or *topical* means a cannabis-derived product intended to be rubbed on the skin and not intended for oral consumption.

Vaporized cannabis means cannabis or a cannabis-derived product that is heated to a temperature at which the contained constituents are released into a vapor without combustion of the material.

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

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purchasing cannabis or cannabis-derived product from such operations and reselling it to dispensing operations.

SUBPART B – DISPENSING OPERATIONS

Section 2.1 Types of dispensing operations

- (a) Except as provided by paragraph (c) of this section, cannabis or cannabis-derived product may be provided by any of the following types of dispensing operations, as defined in section 1.3, that are in compliance this part:
- (1) Storefront operations, which may also operate a delivery service operation from the same physical location;
 - (2) Delivery service operations, which may operate either with or without a storefront operation; and
 - (3) Direct-from-garden operations, which may:
 - (i) Operate either with or without a storefront operation; and
 - (ii) Be located either at the same location as cultivation occurs, or at another location.
 - (4) Growing co-op operations.
- (b) Dispensing operations may provide:
- (1) Cannabis that is cultivated by:
 - (i) The dispensing operation itself;
 - (ii) A co-owned cultivation operation; or
 - (iii) A cultivation operation that is not co-owned, which may be obtained by the dispensing operation either:
 - (A) Directly from the cultivation operation; or
 - (B) From a vendor of the cannabis;
 - (2) Cannabis-derived product that is manufactured by:
 - (i) The dispensing operation itself;
 - (ii) A co-owned manufacturing operation; or
 - (iii) A manufacturing operation that is not co-owned, which may be obtained by the dispensing operation either:
 - (A) Directly from the manufacturing operation; or
 - (B) From a vendor of the cannabis-derived product.
- (c) Notwithstanding paragraph (a) of this section, dispensing operations must be in compliance with all other legal requirements in the jurisdiction where this part applies.

Section 2.2 Ancillary operations

- (a) In addition to providing cannabis or cannabis-derived product, a dispensing operation described in section 2.1 may also engage in other operations, including:
- (1) Cultivation of cannabis;
 - (2) Manufacturing, packaging, holding, and labeling of cannabis-derived product;
 - (3) Laboratory operations; and
 - (4) Sale and marketing of products other than cannabis or cannabis-derived product.

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- (b) The ancillary operations identified in section 2.2(a) may be conducted:
 - (1) At the same location as providing cannabis or cannabis-derived product, 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 Personnel

- (a) All dispensing operation employees must have the education, training, or experience to perform all assigned functions.
- (b) Dispensing operations must:
 - (1) Provide employees who have any assigned functions that involve providing compliant individuals with cannabis or cannabis-derived product with training that includes:
 - (i) Specific uses of cannabis or a specific cannabis-derived product;
 - (ii) Clinical application of the specific constituents of cannabis;
 - (iii) The laws, regulations, and policies relevant to providing cannabis or cannabis-derived product to compliant individuals in the jurisdiction where this part applies.
- (c) Dispensing operations should provide all employees with training that includes:
 - (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
 - (2) The U.S. federal laws, regulations, and policies relating to individuals employed in dispensing operations, and the implications of these for employees and for compliant individuals.
- (d) Storefront operations should be prepared to administer cardiopulmonary resuscitation (CPR) at all times during which the operation is open for business. To do so, the operation should:
 - (1) Ensure that one or more employee has received adequate training to be capable of performing CPR;
 - (2) Schedule personnel to ensure that one such CPR-trained employee is on the premises at all times during which the operation is open for business.

Section 2.4 Physical facilities

- (a) Physical facilities of dispensing operations must:
 - (1) Be operated in adherence with any regulation in the jurisdiction in which this part applies that is relevant to its specific operations, including:
 - (i) Locations and zoning, which can vary depending upon the specific operation or operations undertaken at each facility.
 - (ii) Business hours;
 - (iii) Parking;
 - (iv) Drive-through services; and
 - (v) Signage;

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- (2) Be maintained in a clean and orderly condition;
 - (3) Be equipped with such utensils and equipment as are necessary to conduct all operations, including ancillary operations as described in section 2.2 of this part, that occur at the facility;
 - (4) Implement policies that ensure the privacy of financial transactions; and
 - (5) Have information available to compliant individuals regarding local and federal laws on cannabis possession.
- (b) Physical facilities of dispensing operations should:
- (1) Provide and use appropriate storage conditions to protect the physical and chemical integrity of cannabis-derived product, as needed;
 - (2) Provide and use a secure area for storage of cannabis or cannabis-derived product in inventory; and
 - (3) Provide and use a secure area to manage financial transactions.
- (c) Storefront operations must:
- (1) Maintain Americans with Disabilities Act (ADA) compliance;
 - (2) Establish a policy regarding on-site consumption of cannabis or cannabis-derived product, except that, if a statutory or regulatory requirement exists in the location of the operation with regard to this practice, the operations must comply with such requirement. Any voluntary on-site consumption policy should address:
 - (i) The type or types of consumption allowed (e.g., eating; smoking; vaporizing; or topical application);
 - (ii) A limit on the amount of time that can be spent in on-site consumption if such a time limit is advisable;
 - (iii) A ventilation plan, if needed;
 - (iv) A protocol to prevent and to address a compliant individual who is or becomes over-medicated;
 - (v) Additional issues as needed.

Section 2.5 Security

- (a) Dispensing operations must establish and adhere to such security procedures as are provided by applicable regulation in the jurisdiction in which this part applies.
- (b) Dispensing operations should:
- (1) Provide additional security as needed and in a manner appropriate for the community where it operates, and should include, as necessary:
 - (i) For storefront operations:
 - (A) In-store security personnel in sufficient number to ensure the safety of staff and served compliant individuals;
 - (B) In-store security cameras; and
 - (C) Monitoring of dedicated parking, if any, either with security personnel or with security cameras.
 - (ii) For delivery service operations:
 - (A) Security personnel at the facility where product is acquired, stored, or processed in sufficient number to ensure the safety of staff and security of all cannabis and cannabis-derived product on site.

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- (B) Training for delivery staff to ensure awareness of how to maintain personal and product safety and to provide contact information to police or other emergency personnel.
 - (C) Restriction of deliveries only to a private address and never to a public location.
 - (D) Compliance with local regulations regarding delivery areas and hours of operation.
- (iii) For direct-from-garden and growing co-op operations:
- (A) Security practices at the growing facility, and at associated locations where cannabis or cannabis-derived product or money are kept or from which money or cannabis or cannabis-derived product is transferred, sufficient to ensure the safety of staff and security of cannabis on site.
 - (2) Refrain from arming security personnel, except as allowed and in full compliance with all relevant legal requirements in the jurisdiction in which this part applies; and
 - (3) Provide training to make all staff aware of the operation's security procedures, and each individual employee's security roles and responsibilities.
- (c) Dispensing operations that are also engaged in cultivation or manufacturing operations must also comply with all security measures required for such operations, and should also establish and implement any relevant security measures recommended for such operations.

SUBPART C – CANNABIS PRODUCT

Section 3.1 Subject cannabis products

- (a) Dispensing operations that are subject to this part may provide cannabis and cannabis-derived product that meet any of the following definitions, as stated in section 1.3, and that are intended to be consumed consistent with these definitions:
- (1) Smoked cannabis;
 - (2) Vaporized cannabis;
 - (3) Oral cannabis (edibles); and
 - (4) Topical cannabis (topicals).
- (b) Each dispensing operation must keep an up-to-date record of the cannabis and cannabis-derived product it provides, including:
- (1) Identification of the cannabis and cannabis-derived product it provides, as described in section 3.1 (a)(1)-(a)(4);
 - (2) Information to indicate whether each cannabis or cannabis-derived product it offers to compliant individuals is provided or produced by a co-owned operation, or is from an operation that is not co-owned;
 - (3) For cannabis and cannabis-derived product obtained from an operation that is not co-owned:
 - (i) If obtained directly from a cultivation or manufacturing operation, the identity of the operation; or
 - (ii) If obtained from a vendor, the identity of the vendor;

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- (4) Restrictions, if any, on providing any specific cannabis or cannabis-derived product to compliant individuals, such as, for example:
 - (i) Limitations as to employees who may, or who may not, provide the specific cannabis or cannabis-derived product to compliant individuals;
 - (ii) Limitations as to compliant individuals who may, or who may not, obtain the specific cannabis or cannabis-derived product.

Section 3.2 Cannabis product acquisition

- (a) Dispensing operations that receive cannabis or cannabis-derived product from one or more cultivation or manufacturing operations, or from one or more vendors, should establish and implement policies for acquisition of such cannabis or cannabis-derived product, including policies on:
 - (1) Locations for receipt of cannabis or cannabis-derived product;
 - (2) Scheduling of deliveries, which may be made either:
 - (i) By scheduling appointments with specific vendors; or
 - (ii) By establishing open vending times, during which any vendor may make a delivery without a specific appointment.
 - (3) Any policies required of cultivation or manufacturing operations, or of vendors, if any, with regard to:
 - (i) Cultivation practices;
 - (ii) Manufacturing;
 - (iii) Packaging or labeling;
 - (iv) Chemical analysis; or
 - (v) Transport conditions, such as refrigeration.
- (b) Dispensing operations that receive cannabis or cannabis-derived product from one or more cultivation or manufacturing operations, or from one or more vendors must:
 - (1) Record each receipt of cannabis and cannabis-derived product, such record to include:
 - (i) The name of the cultivation or manufacturing operation, or of the vendor;
 - (ii) An appropriately complete and specific description of the cannabis or cannabis-derived product; and
 - (iii) A statement of the quantity of each cannabis or cannabis-derived product.
 - (2) If the operation is a storefront, minimize deliveries at times and in locations where compliant individuals are present, if space allows.
 - (3) Inform all cultivation and manufacturing operations and all vendors of the policies established in compliance with paragraph (a) of this section, and of the requirements set forth in paragraph (b) of this section.

Section 3.3 Cannabis product information

- (a) Information provided by a dispensing operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.
- (b) A dispensing operation must disclose the extent and type of testing it conducts, or causes to have conducted, on the cannabis it provides, including:
 - (1) The type of test or examination used, if any, to determine the particular strain or cultivar of each lot of cannabis provided;

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- (2) Whether or not the cannabis provided is tested to determine the quantitative levels of contained constituents, and if so, the type of testing used;
 - (3) Whether or not the cannabis provided is tested 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) Pesticides;
 - (ii) Yeasts and molds; and
 - (iii) Other microbiological contaminants.
 - (4) The information required to be disclosed by this paragraph must be made available:
 - (i) At each physical facility maintained by a storefront dispensing operation, either:
 - (A) With posted and readily visible signage; or
 - (B) With printed handouts that are provided to each compliant individual prior to purchase of any cannabis.
 - (ii) On any website at which cannabis or cannabis-derived products are available for ordering by or sale to compliant individuals, by posting the information so that compliant individuals will see the information prior to ordering and purchasing.
- (c) Information provided by a dispensing operation about cannabis-derived product it provides must:
- (1) Be provided in whatever manner is required in the jurisdiction in which this part applies, whether with labeling or with other markings, or with other written or verbal information;
 - (2) Be accurately conveyed:
 - (i) If manufactured by a co-owned operation, through labeling or other accurate markings or communications, in a manner that complies with all relevant requirements; or
 - (ii) If manufactured by another person or business entity, by providing the information as provided by each product's manufacturer, such that the dispensing operation may not modify the labeling or other information provided by such product's manufacturer.
 - (3) In the event that a dispensing operation has reason to believe that the information provided by the manufacturer of a cannabis-derived product is not accurate, the dispensing operation must seek clarification or correction of any such information.

Section 3.4 Cannabis product recalls

- (a) Each dispensing operation must establish a policy for communicating a recall of a cannabis or cannabis-derived product that has been shown to present a reasonable or a remote 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:

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- (1) A mechanism to contact all customers who have, or could have, obtained the product from the dispensing operation, which communication must include information on the policy for return or destruction of the recalled product;
 - (2) A mechanism to contact the cultivation or manufacturing operation, or the vendor which supplied the product to the dispensing operation; and
 - (3) Communication and outreach via media, as necessary and appropriate.
- (b) Any recalled cannabis or cannabis-derived product that is returned to a dispensing operation must either:
- (1) Be disposed of by the dispensing operation in manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person; or
 - (2) Be returned to its cultivator or manufacturer for such disposal.

SUBPART D – COMPLIANT INDIVIDUALS

Section 4.1 Requirements for purchase

- (a) Dispensing operations may provide cannabis or cannabis-derived product only to compliant individuals and may not provide cannabis or cannabis-derived product to any other person.
- (b) If any restrictions exist by statute or regulation in the jurisdiction in which this part applies on the health or medical conditions for which cannabis or cannabis-derived product can be recommended, dispensing operations may not recommend use of any cannabis or cannabis-derived product for any other condition.
- (c) Dispensing operation employees who have any assigned functions that involve providing compliant individuals with cannabis or cannabis-derived product must be aware of the legal requirements for becoming a compliant individual.
- (d) Dispensing operations must make available information on the regulations that apply in the jurisdiction in which this part applies to obtaining and maintaining status as a compliant individual.

Section 4.2 Purchase limits

- (a) Quantitative limitations on the amount of cannabis or cannabis-derived product obtained by a compliant individual in any given timeframe:
 - (1) Must be enforced by a dispensing operation in conformity with any statutory or regulatory restriction, if any exists in the jurisdiction in which this part applies;
 - (2) May be established by a dispensing operation in the absence of any statutory or regulatory limitation; and
 - (3) Should be clearly communicated to compliant individuals.

Section 4.3 Personal information

- (a) Dispensing operations should obtain identifying information for each compliant individual to whom cannabis or cannabis-derived product is provided, including:
 - (1) The individual's name;

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- (2) Contact information of sufficient specificity to serve as a means of contact, such as a phone number, email address, or mailing address;
 - (3) A physician of record identified by the compliant individual; and
 - (4) Health or medical conditions for which cannabis or cannabis-derived product is used.
- (b) All identifying information obtained about any compliant individual must be obtained and stored in compliance the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPAA).³

Section 4.4 Adverse event records

- (a) Dispensing operations should establish a policy for receiving and recording adverse event reports associated with use of the cannabis or cannabis-derived products 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 or cannabis-derived product 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 dispensing operation with task assignments that require knowledge of the policy; and
 - (ii) Compliant individuals who are provided with cannabis or cannabis-derived products by the dispensing operation.
- (b) For purposes of this section, an adverse event is a health-related event associated with use of cannabis or a cannabis-derived product that is adverse, and that is unexpected or unusual.
- (c) For purposes of this section, an adverse event report recorded under a policy established by a dispensing operation may not be construed as an admission or as evidence that the cannabis or cannabis-derived product involved caused or contributed to the adverse event.

Section 4.5 Rights and responsibilities of compliant individuals

- (a) Each dispensing operation should establish a policy that describes the rights and responsibilities of compliant individuals who obtain cannabis or cannabis-derived products from the dispensing operation. Such policy should include:

³ These can be found at <http://www.hhs.gov/ocr/privacy>.

- (1) How compliant individuals can expect to be treated by employees of the dispensing operation;
- (2) Information that each compliant individual will be required or requested to provide to the dispensing operation;
- (3) A procedure for providing feedback and suggestions, including procedures for communicating commendations and complaints;
- (4) Contact information for the dispensing operation, and for specific employees for a compliant individual to contact;
- (4) Hours of operation; and
- (5) The dispensing operation's policies related to:
 - (i) Payment for cannabis and cannabis-derived products;
 - (ii) Use of cannabis and cannabis-derived product on the premises;
 - (c) Any other applicable policies.