

# Recommendations for Regulators – Cannabis Operations

**Developed by:**  
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**This document includes the following Recommendations for Regulators:**

- **Manufacturing, Packaging, Labeling, and Holding Operations**

## 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 adult use of these either for medical purposes only or for any adult personal use.

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

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

This document is specific to the area of Cannabis Manufacturing, Packaging, Labeling and Holding Operations, and is presented in the form of a draft regulation. These recommendations are intended to establish a basis for oversight of entities that are engaged in any of these 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, plants and grounds, relevant controls, recordkeeping, and other matters that can contribute to best practice in these operational settings.

This Revision 1 of the document incorporates minor editorial changes to definitions and clarifies the definition of hemp. Other minor revisions and clarifications have been added throughout the document.

The AHPA Cannabis Committee offers this document to states and local municipalities where use of *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 this document further.

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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<sup>1, 2</sup>.
- (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 pre-defined step of manufacture or packaging of a particular cannabis-derived product.

*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

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

<sup>2</sup> 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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assure that the cannabis-derived product meets appropriate safety requirements; or (4) fails to meet appropriate safety requirements; 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 to intentionally 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.

*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.

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*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 an effective yield of not more than 0.3 (three-tenths) percent delta-9-tetrahydrocannabinol on a dry weight basis<sup>3</sup>.

*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.

*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*.

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<sup>3</sup> The term "hemp" as used in this document is intended to be consistent with the exclusions provided in the Controlled Substances Act (21 USC 801) definition of "marijuana", specifically the following: "Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination."

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*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.

*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.



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*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.

*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.

*Scientifically valid method* means an analytical method that has been subjected to accepted method validation processes and has been demonstrated to be fit for purpose in the analysis for cannabis, cannabis-derived products, hemp, or hemp-derived products.

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*Should* is used to state recommended or advisory procedures.

*Strength* means the potency of cannabis or a cannabis-derived product expressed as the amount or percent of specific chemical constituents or groups of chemical constituents.

*Theoretical yield* means the quantity that would be produced at any pre-defined 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**

### **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.

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**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.

**Section 2.4 Quality systems**

- (a) Manufacturing, packaging, labeling and holding operations must establish a quality system sufficient to ensure that all cannabis and cannabis-derived products supplied by the operation comply with established specifications.
- (b) The quality system must include a process for the creation and maintenance of product specifications.
- (c) A system for reporting any non-conformance to quality control personnel must be established.

**SUBPART C – PERSONNEL**

**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

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- (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, 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, using e-cigarettes or vaporizers, 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,

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- cannabis-derived products, or contact surfaces with microorganisms, filth, or 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 safety data sheets (SDS); 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 Safety and Health 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.
- (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 a manner that provides 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.
- (d) One or more qualified personnel should be assigned to supervise quality control activities as defined in this part. Each of these supervisors must be qualified by

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education, training, or experience to oversee implementation of the operation's quality system.

**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 mix-ups 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.
  - (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 mix-ups of components, cannabis, or cannabis-derived products during any of the 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;

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- (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
  - (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;

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- (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:
- (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.
  - (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,

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- 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.
- (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.

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**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-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

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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
  - (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
    - (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.

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- (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.
  - (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 of 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,

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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.
- (f) 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.

**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;

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- (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;
- (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:
  - (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;



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- (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.
- (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;

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- (3) Preventing cross-contamination and mix-ups 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.
- (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;

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- (2) Batch, lot, or control number of the item sampled;
  - (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.
  - (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:

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- (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 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.

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**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 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 actual 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**

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**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.
- (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 of 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 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

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deviation must be documented, justified, and approved by quality control personnel.

- (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<sup>4</sup>.

**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.

**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

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<sup>4</sup> It is adequate to differentiate gang-printed labeling using one parameter, such as printing label text in different colors to differentiate multiple strengths of the same product.

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- (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;
  - (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;



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- (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.
  - (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 mix-ups 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;

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- (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;
  - (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<sup>5</sup>;
  - (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).
- (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

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<sup>5</sup> Appropriate warnings may be applicable for cannabis and cannabis-derived products that should not be used by sensitive subpopulations of compliant individuals, and warnings to keep cannabis and cannabis-derived products from being accessible to children and pets.

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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 mix-ups. 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;
  - (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.

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- (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;
  - (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.

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- (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.

**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;
  - (2) Inspection, sampling, testing, and examinations performed on the batch or lot by the operation, and the conclusions derived therefrom;

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- (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 8.3 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 8.4 Record retention**

- (a) Except as required in sections 8.4(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.
- (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:

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- (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;
  - (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.

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**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 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 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 probability that



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

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
  - (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<sup>6</sup>, as necessary and appropriate.
- (c) Manufacturing, packaging, labeling, and holding operations may consider periodically conducting a mock recall to assess the effectiveness of the recall plan.

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<sup>6</sup> This may include social media channels, if utilized by the operation.