

## **Methodology to Indicate Changes to DPH-11-010 – Cannabis Manufacturing Licensing Regulations**

Changes to the proposed regulations are indicated as follows:

- \* \* \* \* \* denotes Sections omitted – no change from initially proposed text
- Text **added** to the proposed regulation is indicated in blue underline
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(1) An amount of cannabis concentrate or extract produced in one production cycle using the same extraction methods and standard operating procedures; or

(2) An amount of a type of cannabis product produced in one production cycle using the same formulation and standard operating procedures.

(h) “Bureau” means the Bureau of Cannabis Control in the Department of Consumer Affairs.

(i) “Cannabis concentrate” means cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product’s potency. For purposes of this chapter, “cannabis concentrate” includes, but is not limited to, the separated resinous trichomes of cannabis, tinctures, capsules, suppositories, extracts, ~~and~~ vape cartridges, inhaled products (such as dab, shatter, and wax), and tablets as defined in subsection (rr).

(j) “Cannabis product” as used in this chapter means cannabis that has undergone a process whereby the plant material has been transformed into a concentrate, including, but not limited to, concentrated cannabis, or an edible or topical cannabis product containing cannabis or concentrated cannabis and other ingredients.

(k) “Cannabis product quality,” “quality cannabis product,” or “quality” means that the cannabis product consistently meets the established specifications for identity, cannabinoid concentration (as specified in Section 5724 of Title 16 of the California Code of Regulations), homogeneity, composition, and limits on contaminants (as specified in Sections 5718 to 5723, inclusive, of Title 16 of the California Code of Regulations), and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration and misbranding.

(l) “Cannabis waste” means waste that contains cannabis or cannabis products but is not otherwise a hazardous waste as defined in Public Resources Code section 40141.

(m) “CBD” means the compound cannabidiol.

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(n) “Commercial-grade, non-residential door lock” means a lock manufactured for commercial use.

(o) “Department” means the State Department of Public Health.

(p) “Distribution” means the procurement, sale, and transport of cannabis and cannabis products between licensees.

(q) “Edible cannabis product” means a cannabis product intended to be used orally, in whole or in part, for human consumption. For purposes of this chapter, “edible cannabis product” includes cannabis products that resemble conventional food or beverages and cannabis products that dissolve or disintegrate in the mouth, but does not include any product otherwise defined as “cannabis concentrate.”

(r) “Extraction” means a process by which cannabinoids are separated from cannabis plant material through chemical or physical means.

(s) “Finished product” means a cannabis product in its final form to be sold at a retail premises.

(t) “Harvest batch” means a specifically identified quantity of dried flower or trim, leaves, and other cannabis plant matter that is uniform in strain, harvested at the same time, and, if applicable, cultivated using the same pesticides and other agricultural chemicals.

(u) “Informational panel” means any part of the cannabis product label that is not the primary panel and that contains required labeling information.

(v) “Infusion” means a process by which cannabis, cannabinoids, or cannabis concentrates are directly incorporated into a product formulation to produce a cannabis product.

(w) “Infused pre-roll” means a pre-roll into which cannabis concentrate (other than kief) or other ingredients have been incorporated.

(x) “Ingredient” means any substance that is used in the manufacture of a cannabis product and that is intended to be present in the product’s final form.

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(y) “Kief” means the resinous trichomes of cannabis that have been separated from the cannabis plant.

(z) “Labeling” means any label or other written, printed, or graphic matter upon a cannabis product, upon its container or wrapper, or that accompanies any cannabis product.

(aa) “Limited-access area” means an area in which cannabis or cannabis products are stored or held and is only accessible to a licensee and authorized personnel.

(bb) “M-license” means a license issued for commercial cannabis activity involving medicinal cannabis.

(cc) “Manufacturer licensee” or “licensee” means the holder of a manufacturer license issued pursuant to the Act.

(dd) “Manufacture” means to compound, blend, extract, infuse, or otherwise make or prepare a cannabis product.

(1) The term “manufacture” includes the following processes:

(A) Extraction;

(B) Infusion;

(C) Packaging or repackaging of cannabis products; and

(D) Labeling or relabeling the packages of cannabis products.

(2) The term “manufacture” does not include the following:

(A) The repacking of cannabis products from a bulk shipping container by a distributor or retailer where the product’s original packaging and labeling is not otherwise altered;

(B) ~~The placing of cannabis products into opaque packaging at a retail premises for the purpose of complying with section 26070.1 of the Act;~~ The preparation of pre-rolls by a licensed distributor in accordance with the requirements of the Bureau specified in Section 5303 of Division 42 of Title 16 of the California Code of Regulations;

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(C) The collection of the resinous trichomes that are dislodged or sifted from the cannabis plant incident to cultivation activities by a licensed cultivator in accordance with the requirements of the California Department of Food and Agriculture specified in Article 4 of Chapter 1 of Division 8 of Title 3 of the California Code of Regulations; ~~or~~

(D) The processing of non-manufactured cannabis products, as defined in Section 8000 of Title 3 of the California Code of Regulations, by a licensed cultivator in accordance with the requirements of the California Department of Food and Agriculture specified in Article 4 of Chapter 1 of Division 8 of Title 3 of the California Code of Regulations; ~~or~~ or

(E) The addition of cannabinoid content on the label of a package of cannabis or cannabis product by a distributor in accordance with Section 40409.

(ee) “Manufacturing” or “manufacturing operation” means all aspects of the extraction process, infusion process, and packaging and labeling processes, including processing, preparing, holding, and storing of cannabis products. Manufacturing also includes any processing, preparing, holding, or storing of components and ingredients.

(ff) “MCLS” means the Manufactured Cannabis Licensing System, which is the online license application system available on the Department’s website ([www.cdph.ca.gov](http://www.cdph.ca.gov)).

(gg) “Nonvolatile solvent” means any solvent used in the extraction process that is not a volatile solvent. For purposes of this chapter, “nonvolatile solvents” include carbon dioxide and ethanol.

(hh) “Orally-consumed concentrate” means a cannabis concentrate that is intended to be consumed by mouth and is not otherwise an edible product. “Orally-consumed concentrate” includes tinctures, capsules, and tablets that meet the definition of subsection (rr).

(ii) “Package” or “packaging” means any container or wrapper that may be used for enclosing or containing any cannabis product. The term “package” does not include any

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shipping container or outer wrapping used solely for the transportation of cannabis products in bulk quantity to another licensee or licensed premises.

(jj) "Personnel" means any worker engaged in the performance or supervision of operations at a manufacturing premises and includes full-time employees, part-time employees, temporary employees, contractors, and volunteers. For purposes of training requirements, "personnel" also includes owner-operators.

(kk) "Person" includes any individual, firm, partnership, joint venture, association, corporation, limited liability company, estate, trust, business trust, receiver, syndicate, or any other group or combination acting as a unit, and the plural as well as the singular.

(ll) "Pre-roll" means any combination of the following rolled in paper: flower, shake, leaf, or kief.

(mm) "Premises" means the designated structure(s) and land specified in the application that is owned, leased, or otherwise held under the control of the applicant or licensee where the commercial cannabis activity (as defined in section 26001(k) of the Act) will be or is conducted. The premises shall be a contiguous area and shall only be occupied by one licensee.

(nn) "Primary panel" means the part of a cannabis product label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

(oo) "Product identity" or "identity of the product" means the generic, common, or usual name of the product by which it is most commonly known.

(pp) "Quarantine" means the storage or identification of a product to prevent distribution or transfer of the product.

(qq) "Serving" means the designated amount of cannabis product established by the manufacturer to constitute a single unit.

(rr) "Tablet" means a solid preparation containing a single serving of THC or other cannabinoid that is intended to be swallowed whole, and that is not formulated to be

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chewable, dispersible, effervescent, orally disintegrating, used as a suspension, or consumed in a manner other than swallowed whole, and that does not contain any added natural or artificial flavor or sweetener.

(ss) “THC” means the compound tetrahydrocannabinol. For purposes of this chapter, “THC” refers specifically to delta 9-tetrahydrocannabinol.

(tt) “Topical cannabis product” means a cannabis product intended to be applied to the skin rather than ingested or inhaled.

(uu) “Track-and-trace system” means the program for reporting the movement of cannabis and cannabis products through the distribution chain established by the Department of Food and Agriculture in accordance with section 26067 of the Act.

(vv) “UID” means the unique identifier for use in the track-and-trace system established by the Department of Food and Agriculture in accordance with section 26069 of the Act.

(ww) “Universal symbol” means the symbol developed by the Department pursuant to section 26130(c)(7) of the Act to indicate a product contains cannabinoids.

(xx) “Volatile solvent” means any solvent that is or produces a flammable gas or vapor that, when present in the air in sufficient quantities, will create explosive or ignitable mixtures. Examples of volatile solvents include, but are not limited to, butane, hexane, and propane.

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#### **§40128. Annual License Application Requirements.**

(a) To apply for a manufacturer license from the Department, the applicant shall submit the following on behalf of the commercial cannabis business:

(1) A completed application form as prescribed by the Department, or through MCLS, which includes all of the following information:

(A) Business information specified in Section 40129;

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(B) Owner information as specified in Section 40130; and

(C) Manufacturing premises and operations information as specified in Section 40131;

(2) For new applications, the nonrefundable application fee as specified in Section 40150(a); for renewal applications, the nonrefundable annual license fee as specified in Section 40150(b);

(3) Evidence of compliance with or exemption from the California Environmental Quality Act (CEQA) as specified in Section 40132; and

(4) The limited waiver of sovereign immunity as specified in Section 40133, if applicable.

(b) The application shall be signed by the applicant under penalty of perjury that the information provided in and submitted with the application is complete, true, and accurate, and shall include the following attestations:

(1) The applicant is authorized to act on behalf of the commercial cannabis business;

(2) The applicant entity, when it has 20 or more employees, has entered, or will enter as soon as reasonably practicable, into a labor peace agreement and will abide by the terms of the agreement as required by section 26051.5 (a)(5)(A) of the Act. The applicant shall provide the Department a copy of the page of the labor peace agreement that contains the signatures of the union representative and the applicant.

(3) The commercial cannabis business is operating in compliance with all local ordinances; ~~and~~

(4) The proposed premises is not within a 600-foot radius of the perimeter of a school providing instruction in kindergarten or any grades 1 through 12, or a day care center, or youth center, or that the premises complies with the local ordinance specifying a different radius, as specified in section 26054(b) of the Act; ~~and~~

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(5) For an applicant entity with more than one employee, the applicant employs, or will employ within one year of receiving a license, one supervisor and one employee who have successfully completed a Cal/OSHA 30-hour general industry outreach course offered by a training provider that is authorized by an OSHA Training Institute Education Center to provide the course.

(c) The Department may request additional information and documents from the applicant as necessary to determine whether the applicant or the commercial cannabis business meets the requirements and qualifications for licensure.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26050; 26051.5; and 26054, Business and Professions Code.

#### **§40129. Annual License Application Requirements – Business Information.**

(a) The applicant shall submit the following information for the commercial cannabis business:

(1) The legal business name;

(2) The federal tax identification number. If the commercial cannabis business is a sole proprietorship, the applicant shall submit the social security number or individual taxpayer identification number of the sole proprietor;

(3) The registered name(s) under which the business will operate (Fictitious Business Name, Trade Name, “Doing Business As”), if applicable;

(4) The business’s mailing address which will serve as the address of record;

(5) The name, title, phone number and email address of the primary contact person for the commercial cannabis business;

(6) The seller’s permit number issued by the California Department of Tax and Fee Administration or notification issued by the California Department of Tax and Fee Administration that the business is not required to have a seller’s permit. If the applicant

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has not yet received a seller's permit, the applicant shall attest that the applicant is currently applying for a seller's permit;

(7) The business structure of the commercial cannabis business as filed with the California Secretary of State (e.g., limited liability company, partnership, corporation) or operation as a sole proprietor. A commercial cannabis business that is a foreign corporation or foreign limited liability company under the California Corporations Code shall include with its application the certificate of ~~qualification~~ status issued by the California Secretary of State;

(8) A list of ~~the~~ all owners, as defined in Section 40102;

(9) A list of all financial interest holders, as defined in Section 40102, which shall include:

(A) For financial interest holders that are individuals, the first and last name of the individual, and the type and number of the individual's government-issued identification (e.g., driver's license); or

(B) For financial interest holders that are entities, the legal business name and federal taxpayer identification number of the entity;

(10) Proof of having obtained a surety bond in the amount of \$5,000, payable to the State of California as obligee, to ensure payment of the cost incurred for the destruction of cannabis or cannabis products necessitated by a violation of the Act or the regulations adopted thereunder. The bond shall be issued by a corporate surety licensed to transact surety business in the State of California;

(11) The license type applied for and whether the application is for medicinal cannabis product manufacturing, adult-use cannabis product manufacturing, or both;

(12) The business formation documents, which may include, but are not limited to, articles of incorporation, bylaws, operating agreements, partnership agreements, and fictitious business name statements. If the commercial cannabis business is held in

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trust, the applicant shall provide a copy of the [certificate of trust](#) [establishing trustee authority](#);

(13) All documents filed with the California Secretary of State, which may include, but are not limited to, articles of incorporation, articles of organization, certificates of limited partnership, and statements of partnership authority.

(b) Pursuant to section 26055(e) of the Act, an applicant may voluntarily submit a copy of a license, permit, or other authorization to conduct commercial cannabis manufacturing activities issued by the local jurisdiction. When an applicant submits a local authorization, upon receipt of the application, the Department shall contact the applicable local jurisdiction to confirm the validity of the authorization. If the local jurisdiction does not respond within 10 calendar days, the Department shall consider the authorization valid.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26050; and 26051.5, Business and Professions Code.

#### **§40130. Annual License Application Requirements – Owners.**

(a) Each owner shall submit all of the following information:

(1) Name;

(2) Title or position held;

(3) Social security number or individual taxpayer identification number;

(4) Date of birth;

(5) Mailing address;

(6) Contact phone number and email address;

(7) A copy of Department of Justice form BCIA 8016, provided to the applicant by the Department of Public Health and signed by the live scan operator; ~~and~~

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(8) Disclosure of all of the following, including any actions against the owner as an individual and against a business entity in which the owner was an officer or an owner. The information provided shall include dates and a description of the circumstances, ~~if applicable:~~

(A) Any criminal conviction from any jurisdiction. Adjudications by a juvenile court and infractions do not need to be disclosed. Convictions dismissed under Penal Code section 1203.4 or equivalent non-California law must be disclosed;

(B) Any civil proceeding or administrative penalty or license sanction that is substantially related to the qualifications of a manufacturer as identified in Section 40162, ~~including proceedings, penalties or sanctions against you or against a business entity in which you were an owner or officer;~~

(C) Any fines or penalties for cultivation or production of a controlled substance on public or private land pursuant to Fish and Game Code section 12025 or 12025.1;

(D) Any sanctions by a licensing authority, city, or county for unlicensed commercial cannabis activity within 3 years preceding the date of the application;

(E) Any suspension or revocation of a cannabis license by a licensing authority or local jurisdiction within 3 years preceding the date of the application;

(F) Any administrative orders or civil judgements for violations of labor standards ~~against you or against a business entity in which you were an officer or owner~~ within the 3 years immediately preceding the date of the application.

(9) Disclosure of any ownership interest or financial interest in any other cannabis business licensed under the Act.

(b) The owner shall sign under penalty of perjury that the information provided in and submitted with the application is complete, true, and accurate.

(c) An owner disclosing a criminal conviction or other penalty or sanction pursuant to subsection (a), paragraphs (8)(A) and (B), shall submit any evidence of rehabilitation with the application for consideration by the Department. A statement of rehabilitation

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shall be written by the owner and contain all the evidence that the owner would like the Department to consider that demonstrates the owner's fitness for licensure. Supporting evidence may be attached to the statement of rehabilitation and may include, but is not limited to, evidence specified in Section 40165, and dated letters of reference from employers, instructors, or counselors that contain valid contact information for the individual providing the reference.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26012; 26013; 26050; 26055; and 26130, Business and Professions Code.

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**§40137. Application Withdrawal.**

(a) An applicant may withdraw an application for annual licensure at any time prior to the issuance or denial of the license. Requests to withdraw an application shall be submitted in writing to the Department or through MCLS.

(b) An applicant may reapply for annual licensure at any time subsequent to the withdrawal of an application; however, a new application and application fee are required.

(c) Withdrawal of an application shall not deprive the Department of its authority to institute or continue a proceeding against the applicant for the denial of the license upon any ground provided by law or to enter an order denying the license upon any such ground.

(d) The application fee paid for a new application and the annual license fee paid for a renewal application shall not be refunded ~~when~~ if an application is withdrawn.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26012; and 26050, Business and Professions Code.

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**§40152. Gross Annual Revenue Calculation.**

(a) The applicant shall calculate the gross annual revenue for the licensed premises based on the annual gross sales of cannabis products and, if applicable, the annual revenue received from manufacturing, packaging, labeling or otherwise handling cannabis or cannabis products for other licensees, in the twelve months preceding the date of application.

(b) For a new license applicant, the gross annual revenue shall be based on the gross sales and revenue expected during the first 12 months following licensure.

(c) For a manufacturer licensee that is also licensed as a distributor or retailer, and that sells or transfers cannabis products manufactured on the licensed premises in a non-arm's length transaction, the annual gross sales or revenue for such transactions shall be based on the product's fair market value ~~of the product~~ if it ~~was~~ were to be sold in an arm's length transaction at wholesale.

(d) For purposes of this section, an "arm's length transaction" means a sale entered into in good faith and for valuable consideration that reflects the fair market value in the open market between two informed and willing parties, neither under any compulsion to participate in the transaction.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26012; and 26180, Business and Professions Code.

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**§40179. Death, Incapacity, or Insolvency of a Licensee.**

(a) In the event of the death, incapacity, receivership, assignment for the benefit of creditors or other event rendering one or more owners' incapable of performing the duties associated with the license, the owner or owners' successor in interest (e.g.,

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appointed guardian, executor, administrator, receiver, trustee, or assignee) shall notify the Department in writing, within 10 business days.

(b) To continue operations or cancel the existing license, the successor in interest shall submit to the Department the following:

(1) The name of the successor in interest;

(2) The name of the owner(s) for which the successor in interest is succeeding and the license number;

(3) The phone number, mailing address, and email address of the successor in interest; and

(4) Documentation demonstrating that the owner(s) is incapable of performing the duties associated with the license such as a death certificate, or a court order, and documentation demonstrating that the person making the request is the owner or owners' successor in interest such as a court order appointing guardianship, receivership, or a will or trust agreement.

(c) The Department may give the successor in interest written approval to continue operations on the licensed business premises for a period of time specified by the Department:

(1) If the successor in interest or another person has applied for a license from the Department for the licensed premises and that application is under review;

(2) If the successor in interest needs additional time to destroy or sell cannabis or cannabis products; or

(3) At the discretion of the Department.

(d) The successor in interest is held subject to all terms and conditions under which a state cannabis license is held pursuant to the Act.

(e) The approval pursuant to subsection (c) creates no vested right to the issuance of a state cannabis license.

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[Authority: Sections 26012, 26013 and 26130, Business and Professions Code.](#)

[Reference: Section 26130, Business and Professions Code.](#)

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#### **§40192. Registration to Operate a Shared-Use Facility.**

(a) No licensee shall operate as a shared-use facility without prior approval by the Department.

(b) To register as a shared-use facility, a Type 7, Type 6, or Type N licensee shall submit the following to the Department through MCLS:

(1) A copy of the valid license, permit, or other authorization issued by the local jurisdiction that enables the licensee to operate as a shared-use facility. [The Department shall contact the applicable local jurisdiction to confirm the validity of the local authorization](#) ~~Upon receipt of the [application for](#) registration, the Department shall contact the applicable local jurisdiction to confirm the validity of the authorization.~~ If the local jurisdiction does not respond within 10 calendar days, the Department shall consider the authorization valid.

(2) A registration form prescribed by the Department, which includes the following information:

(A) The proposed occupancy schedule that specifies the days and hours the common-use area will be available for use by Type S licensees and when the common-use area will be used by the primary licensee. The occupancy schedule shall allow for ~~adequate~~ maintenance, cleaning, and sanitizing between uses by individual licensees.

(B) A diagram indicating:

(i) Each designated area for Type S licensee(s).

(ii) The common-use area, including identification of any shared equipment.

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(c) The Department shall notify the Type 7, Type 6, or Type N licensee upon approval of the registration to operate as a shared-use facility. Notification shall be made through MCLS.

(d) At least one business day prior to a Type S licensee commencing manufacturing operations at a registered shared-use facility, the primary licensee shall provide written notification to the Department. The notification to the Department shall include the Type S licensee's business name, contact person, contact phone number, and license number. The primary licensee shall also provide an updated occupancy schedule that includes the Type S licensee and an updated diagram that specifies the Type S licensee's designated area. Notification shall be provided by email or through MCLS.

(e) A primary licensee that wishes to discontinue operation as a shared-use facility may cancel its registration by providing written notice to the Department and each Type S licensee authorized to use the shared-use facility at least 30 calendar days prior to the effective date of the cancellation.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26051.5; 26055; and 26130, Business and Professions Code.

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**§40205. Video Surveillance.**

(a) At minimum, a licensed premises shall have a digital video surveillance system with a minimum camera resolution of 1280 × 720 pixels. The video surveillance system shall be able to effectively and clearly record images of the area under surveillance.

(b) To the extent reasonably possible, all video surveillance cameras shall be installed in a manner that prevents intentional obstruction, tampering with, or disabling.

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(c) Areas that shall be comprehensively recorded on the video surveillance system include the following:

(1) Areas where cannabis or cannabis products are weighed, packed, stored, quarantined, loaded and unloaded for transportation, prepared, or moved within the premises;

(2) Limited-access areas;

(3) Security rooms;

(4) Areas containing surveillance-system storage devices, which shall contain at least one camera to record the access points to such an area; and

(5) The interior and exterior of all entrances and exits to the premises.

(d) The surveillance system shall record continuously 24 hours per day and at a minimum speed of 15 frames per second.

(e) ~~Monitoring equipment and any~~ Any on-site surveillance system storage devices shall be located in secure rooms or areas of the premises in an access-controlled environment.

(f) The licensee shall ensure that all surveillance recordings are kept for a minimum of 90 days.

(g) All video surveillance recordings shall be immediately available on the licensed premises and subject to inspection by the Department and shall also be copied and sent, or otherwise provided, to the Department upon request.

(h) The video recordings shall display the current date and time of recorded events. Time is to be measured in accordance with the U.S. National Institute of Standards and Technology standards. The displayed date and time shall not significantly obstruct the view of recorded images.

(i) If multiple licensed premises are contained within the same building, a single video surveillance covering the entire building may be used by all of the licensees under the following conditions:

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(1) Each applicant or licensee shall disclose on their premises diagram where the surveillance recordings are stored;

(2) Each applicant or licensee shall include in their security operating procedures an explanation of how the video surveillance system will be shared, including who is responsible for monitoring the video footage and storing any video recordings;

(3) All licensees shall have immediate access to the surveillance recordings to produce them pursuant to the requirements of this section;

(4) All licensees shall be held responsible and subject to discipline for any violations of the video surveillance requirements.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26070, Business and Professions Code.

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**§40220. Permissible Extractions.**

(a) Except as provided in subsection (b), cannabis extraction shall only be conducted using the following methods:

(1) Mechanical extraction;

(2) Chemical extraction using a nonvolatile solvent such as a nonhydrocarbon-based or other solvent such as water, vegetable glycerin, vegetable oils, animal fats, or glycerin. Nonhydrocarbon-based solvents shall be food grade;

(3) Chemical extraction using a professional closed loop CO<sub>2</sub> gas extraction system; CO<sub>2</sub> gas used for extraction shall be food grade;

(4) Chemical extraction using a volatile solvent, as defined in Section 40100(xx), using a professional closed loop extraction system; or

(5) Any other method authorized by the Department pursuant to subsection (b).

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(b) To request authorization from the Department to conduct cannabis extraction using a method other than those specified in paragraphs (1) through (4) of subsection (a), the applicant or licensee shall submit a detailed description of the extraction method, including any documentation that validates the method and any safety procedures to be utilized to mitigate any risk to public or worker health and safety.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.  
Reference: Sections 26011.5; and 26130, Business and Professions Code.

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**§40230. Manufacturing Practices Definitions.**

In addition to the definitions in section 26001 of the Act and Section 40100 of these regulations, the following definitions shall govern the construction of this subchapter:

(a) ~~“Actual yield” means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular cannabis product.~~

~~(b) “Adequate” means that which is necessary to accomplish the intended purpose in keeping with good public health practice to ensure cannabis product quality.~~

~~(c)~~ “Allergen cross-contact” means the unintentional incorporation of a food allergen into a cannabis product.

~~(d)~~ “Component” means any substance or item intended for use in the manufacture of a cannabis product, including those substances or items that are not intended to appear in the final form of the product. “Component” includes cannabis, cannabis products used as ingredients, raw materials, other ingredients, and processing aids.

~~(e)~~ “Contact surface” means any surface that normally comes into contact ~~s~~ with cannabis products and cannabis product components and those surfaces from which drainage, or other transfer, onto the cannabis product or cannabis product components,

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occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, and equipment.

(d) “Easily cleanable” means a characteristic of a surface that allows effective removal of soil, food residue, or other organic or inorganic materials by normal cleaning methods.

(fe) “Environmental pathogen” means a pathogen capable of surviving and persisting within the manufacturing environment such that cannabis products may be contaminated and may result in illness if consumed or used without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens include *Listeria monocytogenes* and *Salmonella spp.* but do not include the spores of pathogenic spore-forming bacteria.

(gf) “Hazard” means any biological, chemical, radiological, or physical agent that has the potential to cause illness or injury.

(hg) “Holding” means storage of cannabis or cannabis products and includes activities performed incidental to storage of a cannabis product and activities performed as a practical necessity for the distribution of that cannabis product.

~~(i) “In-process material” means any material that is fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the manufacture of a cannabis product.~~

(jh) “Microorganisms” means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject a cannabis product to decomposition, that indicate that a cannabis product is contaminated with filth, or that otherwise may cause a cannabis product to be adulterated.

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(~~k~~i) “Monitor” means to conduct a planned sequence of observations or measurements to assess whether ~~control~~ preventive measures are operating as intended.

(~~j~~) “Pathogen” means a microorganism that can cause illness or injury.

(~~m~~k) “Pest” means an undesired insect, rodent, nematode (small worm), fungus, bird, vertebrate, invertebrate, weed, virus, bacteria, or other microorganism (except microorganisms on or in humans or animals) injurious to health or the environment.

(l) “Potable” means water that meets the requirements of Health and Safety Code section 113869.

(~~n~~m) “Preventive ~~controls~~ measures” means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified pursuant to a ~~hazard analysis~~ product quality plan as specified in Section 40253.

(~~e~~n) “Processing aid” means any substance that is added to a cannabis product during manufacture but is removed in some manner from the cannabis product before it is packaged in its finished form. This includes substances that are converted into constituents normally present in the product, and do not significantly increase the amount of the constituent naturally found in the product. This also includes substances that are added to a product for their technical or functional effect in the processing but are present in the finished product at insignificant levels and do not have any technical or functional effect in that product.

(~~p~~o) “Qualified individual” means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture quality cannabis products as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the licensee.

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(~~ep~~) “Quality control” means a planned and systematic operation or procedure for ensuring the quality of a cannabis product.

(~~fq~~) “Quality control operation” means a planned and systematic procedure for taking all actions necessary to prevent cannabis product(s) from being adulterated or misbranded.

(~~sr~~) “Quality control personnel” means any person, persons, or group, designated by the licensee to be responsible for quality control operations.

(~~ts~~) “Raw material” means any unprocessed material in its raw or natural state that is intended to become part of the components of a cannabis product.

(~~ut~~) “Sanitize” means to ~~adequately~~ treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(u) “Smooth” means any of the following:

(1) A contact surface that is free of pits, pinholes, cracks, crevices, inclusions, rough edges, and other surface imperfections detectable by visual or tactile inspection.

(2) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

(v) “Utensil” means an implement, tool, or container used in the storage, preparation, manufacture, or processing of cannabis and cannabis products. In addition to kitchenware, examples of utensils include, but are not limited to, gloves, screens, sieves, implements to create pre-rolls, buckets, and scissors.

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

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(w) “Validate” means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or quality control procedures as a whole, when properly implemented, is capable of ensuring the quality of a cannabis product or effectively controlling an identified hazard.

(x) “Verification” means the application of methods, procedures, tests, or other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the quality control procedures.

(y) “Yield” means the quantity of a particular cannabis product expected to be produced at a given step of manufacture or packaging, as identified in the master manufacturing protocol. The expected yield is based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production. “Actual yield” means the quantity of a particular cannabis product that is actually produced at a given step of manufacture or packaging that is recorded in the batch production record.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26001; 26120; and 26130, Business and Professions Code.

#### ~~§40232. Requirements for Personnel.~~

~~The licensee shall establish and implement written procedures to ensure the following for all personnel:~~

~~(a) Disease control. Any individual who by medical examination or supervisory observation is shown to have, or appears to have, an illness, open lesion (such as boils, sores, or infected wounds), or any other source of microbial contamination presenting a reasonable threat of contamination to cannabis products, contact surfaces, or packaging materials, shall be excluded from any related manufacturing operations until~~

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~~their health condition is corrected. Open lesions, boils, and infected wounds shall be adequately covered (e.g., by an impermeable cover). Personnel shall be instructed to report such health conditions to their supervisors.~~

~~(b) Cleanliness. All individuals working in direct contact with cannabis products, cannabis product contact surfaces, and cannabis product packaging materials shall conform to hygienic practices to the extent necessary to protect against allergen cross-contact and contamination of cannabis products while on duty. The methods for maintaining cleanliness include:~~

~~(1) Wearing appropriate outer garments to protect against allergen cross-contact and contamination of cannabis products, contact surfaces, and packaging materials;~~

~~(2) Maintaining adequate personal cleanliness;~~

~~(3) Washing hands thoroughly in an adequate hand-washing facility before starting work, after each absence from the work station, and at any time when the hands may have become soiled or contaminated, and sanitizing hands if necessary to protect against contamination with undesirable microorganisms;~~

~~(4) Removing all unsecured jewelry and other objects that might fall into cannabis products, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which cannabis products are manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the cannabis products, cannabis product contact surfaces, or cannabis product packaging materials;~~

~~(5) Maintaining any gloves, if they are used in cannabis product handling in an intact, clean, and sanitary condition;~~

~~(6) Wearing hair nets, headbands, caps, beard covers, or other hair restraints in an effective manner, where appropriate;~~

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~~(7) Storing clothing or other personal belongings in areas separate from those where cannabis products are exposed or where equipment or utensils are washed;~~

~~(8) Confining the following activities to areas separate from those where cannabis products may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, and/or using tobacco;~~

~~(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of cannabis products, cannabis product contact surfaces, or cannabis product packaging materials by microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

#### ~~§40234. Grounds.~~

~~The licensee shall establish and implement written procedures to ensure that the grounds of the premises that are controlled by the licensee are kept in a condition that prevents the contamination of components and cannabis products. The methods for adequate maintenance of the grounds shall include at minimum:~~

~~(a) The proper storage of equipment, removal of litter and waste, and cutting of weeds or grass within the immediate vicinity of the cannabis manufacturing premises so that they do not constitute an attractant, breeding place, or harborage for pests.~~

~~(b) The proper maintenance of roads, yards, and parking lots so that these areas shall not constitute a source of contamination in areas where cannabis products are handled or transported.~~

~~(c) The provision of adequate draining areas in order to prevent contamination by seepage, foot-borne filth, or the breeding of pests due to unsanitary conditions.~~

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~~(d) The provision and maintenance of waste treatment and disposal systems so as to prevent contamination in areas where cannabis products may be exposed to such a system's waste or waste by-products.~~

~~(e) If the premises is bordered by grounds outside the licensee's control that are not maintained in the manner described in subsections (a) through (d) of this section, inspection, extermination, and other reasonable care shall be exercised within the premises in order to eliminate any pests, dirt, and filth that pose a source of cannabis product contamination.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

#### **§40235. Quality Control Program**

(a) Each licensee is responsible for implementing an overall quality control program to ensure that cannabis products are not adulterated or misbranded. The quality control program shall include quality control operations for all of the following:

(1) The grounds, building, and manufacturing premises, as specified in Section 40240;

(2) Equipment and utensils, as specified in Section 40243;

(3) Personnel, as specified in Section 40246;

(4) Cannabis product components, as specified in Section 40248; and

(5) Manufacturing processes and procedures, as specified in Section 40250.

(b) Overall quality control shall be under the supervision of one or more qualified individuals assigned responsibility for this function.

(c) For purposes of this article, for those requirements that are contained in the Health and Safety Code, use of the term "food" shall include cannabis, cannabis products, components, and contact surfaces.

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Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

**~~§40236. Premises Construction and Design.~~**

~~At minimum, a cannabis manufacturing premises shall:~~

~~(a) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of quality cannabis products.~~

~~(b) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials by microorganisms, chemicals, filth, and other extraneous material.~~

~~(c) Permit the taking of adequate precautions to protect product components in installed outdoor bulk vessels by any effective means, including:~~

~~(1) Using protective coverings;~~

~~(2) Controlling areas over and around the vessels in order to eliminate harborages for pests; or~~

~~(3) Checking such vessels on a regular basis for pests and pest infestation.~~

~~(d) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair.~~

~~(e) Be constructed in such a manner that drip or condensate from fixtures, ducts and pipes does not contaminate cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials.~~

~~(f) Be constructed in such a manner so as to provide adequately wide and unobstructed aisles or working spaces between equipment and walls that permit employees to both perform their duties and protect against the contamination of~~

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~~cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials via clothing or personal contact.~~

~~(g) Provide adequate lighting in hand-washing areas; dressing and locker rooms; toilet facilities; all areas where components or cannabis products are examined, manufactured, processed, packed, or held; and in all areas where equipment or utensils are cleaned.~~

~~(h) Provide shatter-resistant light bulbs, fixtures, skylights, and other shatter-resistant glass fixtures in all areas where glass breakage may result in the contamination of exposed cannabis, components or products at any step of preparation.~~

~~(i) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contamination of cannabis products; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and contamination of cannabis products, cannabis product-packaging materials, and cannabis product-contact surfaces.~~

~~(j) Provide, where necessary, adequate screening or other protection against pests.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

#### ~~§40238. Sanitary Operations.~~

~~The licensee shall establish and implement written sanitary operation procedures to ensure the following:~~

~~(a) The premises, including any buildings, fixtures, and other physical facilities therein, are maintained in a clean and sanitary condition and are kept in good repair so as to prevent cannabis products from becoming adulterated.~~

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~~(b) The cleaning and sanitization of utensils and equipment is conducted in a manner that protects against allergen cross-contact and contamination of cannabis products or product components, cannabis product-contact surfaces, or cannabis product-packaging materials.~~

~~(c) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures are free from undesirable microorganisms and are safe and adequate under their conditions of use. Only the following toxic materials shall be used or stored in a manufacturing premises where cannabis products are processed or exposed:~~

~~(1) Those required to maintain clean and sanitary conditions;~~

~~(2) Those necessary for premises and equipment maintenance and operation; and~~

~~(3) Those necessary for use in the cannabis manufacturing premises operations.~~

~~(d) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals are identified, held, and stored in a manner that protects against contamination of product components, cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials.~~

~~(e) Measures are taken to exclude pests from the cannabis manufacturing premises in all areas where cannabis components and products may be at risk of contamination by pests. The use of pesticides to control pests in the cannabis manufacturing premises is permitted only under precautions and restrictions that protect against the contamination of cannabis products, cannabis product-contact surfaces, and cannabis product-packaging materials.~~

~~(f) All cannabis product-contact surfaces including utensils and equipment are cleaned as frequently as necessary to protect against allergen cross-contact and contamination of cannabis products.~~

~~(g) Cannabis product-contact surfaces used for manufacturing, processing, packing or holding low-moisture cannabis products shall be maintained in a clean, dry, and~~

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~~sanitary condition before use. When such surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.~~

~~(h) When cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into cannabis products during processing methods that utilize water (wet processing), all cannabis product contact surfaces shall be cleaned and sanitized before use and after any interruption during which cannabis product contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, their surfaces shall be cleaned and sanitized as necessary.~~

~~(i) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) are stored, handled, and disposed of in a manner that protects against allergen cross-contact and contamination of cannabis product, cannabis product contact surfaces, or cannabis product packaging materials.~~

~~(j) The non-cannabis product contact surfaces of equipment used in the cannabis manufacturing premises are cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and contamination of cannabis products, cannabis product contact surfaces, and cannabis product packaging materials.~~

~~(k) Cleaned and sanitized portable equipment with cannabis product contact surfaces and utensils are stored in a location and manner that protects cannabis product contact surfaces from allergen cross-contact and contamination.~~

~~(l) The sanitary operation procedures shall include maintenance, cleaning, and sanitization schedules or logs to document and ensure that the required operation has occurred.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

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**§40240. Sanitary Facilities and Controls.**

~~The manufacturing premises shall be equipped with adequate sanitary accommodations as follows:~~

~~(a) Water supply. The water supply shall be adequate for the operations intended and derived from an adequate source. Any water that contacts cannabis products, cannabis product contact surfaces, or cannabis product packaging materials shall be safe and of adequate sanitary quality. Running water shall be provided in all areas where required for the processing of cannabis products, for the cleaning of equipment, utensils, and cannabis product packaging materials, and for employee sanitary facilities.~~

~~(b) Plumbing. Plumbing systems shall be of adequate size and design and shall be adequately installed and maintained in order to:~~

~~(1) Carry adequate quantities of water to required locations throughout the manufacturing premises;~~

~~(2) Properly convey sewage and liquid disposable waste from the premises;~~

~~(3) Avoid the creation of unsanitary conditions and contamination to cannabis products, water supplies, equipment, or utensils;~~

~~(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;~~

~~(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage, and piping systems that carry water for cannabis products or cannabis product manufacturing.~~

~~(c) Sewage disposal. Sewage shall be disposed of into an adequate sewerage system or through other adequate means.~~

~~(d) Toilet facilities. Each manufacturing premises shall provide employees with access to adequate, readily accessible toilet facilities. Toilet facilities shall be kept clean~~

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~~and shall not pose a potential source of contamination of cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials.~~

~~(e) Hand-washing facilities. Each manufacturing premises shall provide hand-washing facilities designed to ensure that an employee's hands do not pose a source of contamination to cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials. Hand-washing facilities shall be adequate, convenient, and furnish running water of at least 100° F (30° C).~~

~~(f) Waste disposal. Waste shall be conveyed, stored, and disposed of so as to minimize the development of odor, minimize the potential that waste will attract, harbor, or otherwise contribute to the breeding of pests, and protect against the contamination of cannabis products, cannabis product-contact surfaces, cannabis product-packaging materials, water supplies, and ground surfaces.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Section 26011.5; and 26131, Business and Professions Code.~~

#### §40240. Grounds, Building, and Manufacturing Premises

(a) Exterior facility and grounds. The licensee shall ensure the facility exterior and grounds under the licensee's control meet the following minimum standards:

(1) Grounds are equipped with draining areas in order to prevent pooled or standing water;

(2) Weeds, grass, and vegetation shall be cut within the immediate vicinity of the cannabis manufacturing premises, litter and waste shall be removed, and equipment shall be stored in order to minimize the potential for the grounds to constitute an attractant, breeding place, or harborage for pests;

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(3) Roads, yards, and parking lots shall be maintained so that these areas do not constitute a source of contamination in areas where cannabis products are handled or transported;

(4) Openings into the building (such as windows, exhaust fans, ventilation ducts, or plumbing vent pipes) shall be screened, sealed, or otherwise protected to minimize potential for pests to enter the building;

(5) Waste treatment and disposal systems shall be provided and maintained so as to prevent contamination in areas where cannabis products may be exposed to such a system's waste or waste by-products.

(6) The licensee shall implement precautions within the premises such as inspection or extermination if the premises is bordered by grounds outside the licensee's control that are not maintained in the manner described in subsections (1) through (5) of this subsection, in order to eliminate any pests, dirt, and filth that pose a source of cannabis product contamination. Any use of insecticide, rodenticide, or other pesticide within the premises shall meet the requirements of Health and Safety Code section 114254.

(b) Interior facility. The licensee shall ensure construction, design, and maintenance of the interior of the manufacturing premises as follows:

(1) Walls, ceilings, and floors. Walls, ceilings, and floors shall be constructed of material that is smooth, nonporous, easily cleanable, corrosion-resistant, and suitable to the activity that will be conducted. Fixtures, ducts, and pipes shall not pose a source of drip or condensate that may contaminate cannabis products, contact surfaces or packaging material.

(2) Lighting. Interior facility lighting shall meet the requirements of subdivisions (a)(1) and (3), (b)(3) and (4), and (c) of section 114252 of the Health and Safety Code. Interior facility lighting shall also meet the requirements for shatter-resistant lighting in section 114252.1 of the Health and Safety Code. The requirements of Health and Safety Code section 114252.1, subdivision (a), shall also apply to all areas where glass

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breakage may result in the contamination of exposed cannabis, components or products at any step of preparation.

(3) Plumbing system and fixtures.

(A) Water supply. Running water shall be supplied as required by Health and Safety Code section 114192 in all areas where required for the processing of cannabis products, and in all areas used for the cleaning of equipment, utensils, and packaging materials, and for employee sanitary facilities. Any water that contacts cannabis, components, cannabis products, contact surfaces, or packaging materials shall be potable.

(B) Plumbing. Plumbing systems shall meet the requirements of Health and Safety Code section 114190.

(C) Sewage disposal. Sewage systems shall meet the requirements of the California Plumbing Code, contained in Part 5 of Title 24, California Code of Regulations and shall be maintained and kept in good repair so that it does not pose a potential source of contamination to cannabis products, contact surfaces, or cannabis product-packaging materials.

(D) Toilet facilities. Each manufacturing premises shall provide employees with access to toilet facilities that meet the requirements of Health and Safety Code section 114250. Toilet facilities shall be kept clean and shall not pose a potential source of contamination of cannabis products, contact surfaces, or packaging materials.

(E) Hand-washing facilities. Each manufacturing premises shall provide hand-washing facilities that meet the requirements of Health and Safety Code section 113953, subdivision (a) through (d).

(F) Waste disposal. The premises shall provide waste disposal in accordance with Health and Safety Code sections 114244(a), 114244(c), and 114245.1. Cannabis waste shall be disposed of in accordance with Section 40290 of these regulations.

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(4) Ventilation. Ventilation systems shall meet the requirements of Health and Safety Code sections 114149 and 114149.3.

(5) Cleaning and maintenance. The premises, including any fixtures, and other physical facilities therein, shall be maintained in a clean and sanitary condition and kept in good repair so as to prevent cannabis products from becoming adulterated, and shall meet the requirements of Health and Safety Code section 114257.1.

(A) The premises shall have a janitorial facility that meets the requirements of Health and Safety Code section 114279(a).

(B) Cleaning equipment and supplies shall be stored in a manner that meets the requirements of Health and Safety Code section 114281.

(C) Poisonous or toxic materials such as cleaning compounds, sanitizing agents, and pesticide chemicals that are necessary for premises and equipment maintenance and operation shall be handled and stored in a manner that meets the requirements of Health and Safety Code sections 114254.1, 114254.2 and 114254.3.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

#### **~~§40242. Equipment and Utensils.~~**

~~(a) All manufacturing equipment and utensils used in manufacturing cannabis products shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be adequately maintained to protect against allergen cross-contact and contamination.~~

~~(b) Equipment and utensils shall be designed, constructed, and used appropriately to avoid the adulteration of cannabis products with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.~~

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~~(c) Equipment shall be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces. Schedules or logs documenting the date and time of maintenance, cleaning and sanitizing of equipment shall be maintained.~~

~~(d) Cannabis product contact surfaces shall be corrosion resistant when in contact with cannabis products.~~

~~(e) Cannabis product contact surfaces shall be made of nontoxic materials, designed to withstand the environment of their intended use, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.~~

~~(f) Cannabis product contact surfaces shall be maintained to protect cannabis products from allergen cross-contact and from contamination by any source.~~

~~(g) Seams on cannabis product contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.~~

~~(h) Equipment in areas where cannabis products are manufactured and that do not come into contact with cannabis products shall be constructed so that they may be kept in a clean and sanitary condition.~~

~~(i) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in a clean and sanitary condition.~~

~~(j) Each freezer and cold storage compartment used to store and hold cannabis products, ingredients, or components capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment.~~

~~(k) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in cannabis products or components shall be~~

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~~accurate, precise, adequately maintained and calibrated, and be provided in an adequate number for their designated use(s). Schedules or logs documenting the maintenance and calibration of such instruments and controls shall be maintained to ensure the required operation has occurred.~~

~~(l) Compressed air or other gases mechanically introduced into cannabis products or used to clean cannabis product contact surfaces or equipment shall be treated in such a way that cannabis products shall not be contaminated.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

#### **§40243. Equipment and Utensils**

Licensees shall utilize equipment and utensils that meet the following minimum requirements:

(a) Design. Equipment and utensils shall be meet the requirements of Health and Safety Code sections 114130.1, 114130.2, 114130.3, and 114130.4 and shall be used in accordance with their operating instructions to avoid the adulteration of cannabis products with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(b) Installation. Equipment shall be installed so as to allow the cleaning and maintenance of the equipment and of adjacent spaces. Equipment that is not easily moveable shall meet the requirements of Health and Safety Code section 114169.

(c) Cleaning, sanitizing, and maintenance. The quality control program for cleaning, sanitizing, and maintenance of equipment and utensils shall include the following elements, at minimum:

(1) A detailed, written procedure for cleaning, sanitizing, and maintaining (including calibrating) equipment and utensils;

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(2) A schedule for cleaning, sanitizing, and maintaining equipment and utensils;

(3) A procedure, including a log, for documentation of the date and time of maintenance, cleaning, and sanitizing of equipment; and

(4) A detailed, written procedure for storing cleaned and sanitized equipment and utensils in a manner to protect the equipment and utensils from contamination.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

#### **§40246. Personnel**

A licensee shall implement written procedures for personnel that include, at minimum:

(a) Disease control. Any individual who by medical examination or supervisory observation is shown to have, or appears to have, an illness specified in Health and Safety Code section 113949.2(a), or an open lesion (such as boils, sores, cut, rash, or infected wounds) unless covered in accordance with the requirements of Health and Safety Code section 113949.2(b), shall be excluded from any manufacturing operations until their health condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All individuals working in direct contact with cannabis products, contact surfaces, and packaging materials shall maintain personal cleanliness in order protect against allergen cross-contact and contamination of cannabis products while on duty. The methods for maintaining personal cleanliness include:

(1) Wearing clean outer clothing to protect against allergen cross-contact and contamination of cannabis products, contact surfaces, and packaging materials;

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(2) Washing hands thoroughly in a hand-washing facility that meets the requirements of Section 40240 before starting work, after each absence from the work station, and at any time when the hands may have become soiled or contaminated;

(3) Removing all unsecured jewelry and other objects that might fall into cannabis products, equipment, or containers. Hand jewelry that cannot be sanitized shall be removed during periods in which cannabis products are manipulated by hand. If such hand jewelry cannot be removed, it shall be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials;

(4) Maintaining any gloves, if they are used in cannabis product handling, in an intact, clean, and sanitary condition;

(5) Wearing hair nets, caps, beard covers, or other hair restraints that are designed and worn to prevent hair contact with cannabis, cannabis product, contact surfaces, or cannabis product-packaging materials;

(6) Storing clothing and personal belongings in areas separate from those where cannabis products are exposed or where equipment or utensils are washed;

(7) Confining the following activities to areas separate from those where cannabis products may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, and using tobacco;

(c) Nothing in this section prohibits a licensee from establishing any other precautions to protect against allergen cross-contact and against contamination of cannabis products, contact surfaces, or packaging materials by microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

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Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

**§40248. Cannabis Product Components.**

(a) In order to prevent adulteration of cannabis products through incorporation of unsanitary components, the-licensee shall establish and implement written policies and procedures to ensure and maintain the quality of product components.

(b) Components are subject to the following minimum requirements:

(1) Raw materials and other ingredients shall be inspected upon intake-to ensure that they are clean and suitable for processing into cannabis products, and shall be stored under conditions that protect against allergen cross-contact and contamination, and in such a way as to minimize deterioration.

(2) Raw materials shall be washed or cleaned as necessary to remove soil and other visible contaminants. Water used for washing, rinsing, or conveying cannabis product ingredients shall be potable.

(3) Raw materials and other components shall not contain levels of microorganisms that render the cannabis product injurious to human health, or shall be pasteurized or otherwise treated during manufacturing so that they no longer contain levels of microorganisms that would cause the cannabis product to be adulterated.

(4) Raw materials and other components susceptible to contamination with aflatoxin or other natural toxins, pests, or extraneous material shall not exceed generally acceptable limits set by the U.S. Food and Drug Administration in the *Defect Levels Handbook* (Rev. February 2005), which is hereby incorporated by reference, before these raw materials or other ingredients are incorporated into finished cannabis products.

(5) Raw materials and other components shall be held in containers designed and constructed so as to protect against allergen cross-contact or contamination, and shall

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be held at such temperature and relative humidity and in such a manner as to prevent the cannabis products from becoming adulterated.

(6) Frozen raw materials and other components shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Raw materials and other ingredients that are food allergens shall be identified and held in a manner that prevents cross-contact with other raw materials or ingredients.

(c) Holding and storage of cannabis product components shall meet the requirements of section 114047, subdivisions (a) and (b), section 114049, and section 114051 of the Health and Safety Code.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

#### **~~Article 4. Production and Process Controls.~~**

#### **~~§40250. General Provisions. Manufacturing Processes and Procedures.~~**

~~(a) Appropriate quality control operations shall be employed to ensure that cannabis products are suitable for human consumption or use, and that cannabis product-packaging materials are safe and suitable.~~

~~(b) Overall sanitation of the premises shall be under the supervision of one or more qualified individuals assigned responsibility for this function.~~

~~(c) Adequate precautions shall be taken to ensure that production procedures do not contribute to allergen cross-contact or contamination from any source.~~

~~(d) Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible allergen cross-contact and cannabis product contamination.~~

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~~(e) Any cannabis product that has become contaminated to the extent that it is adulterated shall be rejected, or if appropriate, treated or processed to eliminate the contamination, as determined by a qualified individual.~~

(a) The licensee shall implement and maintain manufacturing processes and procedures that ensure cannabis product quality. Manufacturing processes and procedures shall be identified through a product quality plan, as described in Section 40253.

(b) The licensee shall maintain written master manufacturing protocols, as described in Section 40255, for each unique formulation of cannabis product manufactured to ensure only intended components are included and that the cannabis product is packaged and labeled in accordance with product specifications and these regulations.

(c) The licensee shall maintain written batch production records, as described in Section 40258, to document the production process and, if needed, to verify that the established processes and procedures, including the preventive measures and master manufacturing protocol, were implemented correctly.

(d) All manufacturing records are subject to inspection by the Department, its inspectors and agents.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

### ~~§40252. Quality of Raw Materials and Ingredients.~~

~~The licensee shall establish and implement written policies and procedures to ensure the quality of raw materials and ingredients as follows:~~

~~(a) Raw materials and other ingredients shall be inspected, segregated, or otherwise handled as necessary to ensure that they are clean and suitable for processing into~~

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~~cannabis products, and shall be stored under conditions that protect against allergen cross-contact and contamination, and in such a way as to minimize deterioration.~~

~~(b) Raw materials must be washed or cleaned as necessary to remove soils and other contaminants. Water used for washing, rinsing, or conveying cannabis product ingredients must be safe and of adequate sanitary quality.~~

~~(c) Raw materials and other ingredients shall not contain levels of microorganisms that render the cannabis product injurious to human health, or shall be pasteurized or otherwise treated during manufacturing so that they no longer contain levels of microorganisms that would cause the cannabis product to be adulterated.~~

~~(d) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins, pests, or extraneous material shall not exceed generally acceptable limits set by the U.S. Food and Drug Administration in the *Defect Levels Handbook* (Rev. February 2005), which is hereby incorporated by reference, before these raw materials or other ingredients are incorporated into finished cannabis products.~~

~~(e) Raw materials and other ingredients shall be held in containers designed and constructed so as to protect against allergen cross-contact or contamination, and shall be held at such temperature and relative humidity and in such a manner as to prevent the cannabis products from becoming adulterated.~~

~~(f) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.~~

~~(g) Raw materials and other ingredients that are food allergens shall be identified and held in a manner that prevents cross-contact with other raw materials or ingredients.~~

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~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

### **§40253. Product Quality Plan**

(a) The licensee shall create and implement a written product quality plan for each type of product manufactured at the premises. The product quality plan shall address the hazards associated with the premises or the manufacturing process that, if not properly mitigated, could cause the product to be adulterated or misbranded, or could cause the product to fail laboratory or quality assurance testing.

(b) To create the product quality plan, the licensee shall conduct a comprehensive assessment of the overall manufacturing process, identifying each step from component intake through transfer of product from the premises, to determine the potential risks associated with each step, the preventive measures to mitigate the potential risks identified, the methods to evaluate and monitor the effectiveness of the preventive measures, and action to take if a preventive measure was unsuccessful.

(c) The product quality plan shall evaluate the following potential risks to cannabis product quality:

(1) Biological hazards, including microbiological hazards;

(2) Chemical hazards, including radiological hazards, pesticide contamination, solvent or other residue, natural toxins, decomposition, or allergens;

(3) Physical hazards, such as stone, glass, metal fragments, hair, or insects.

(4) Process failures that may lead to product contamination, allergen cross-contact, packaging errors, labeling errors, or other errors affecting cannabis product quality.

(d) The product quality plan shall identify the preventive measure that will be implemented to mitigate each potential risk identified pursuant to subsection (c). Examples of preventive measures include, but are not limited to:

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(1) Cleaning and sanitizing of equipment and utensils to mitigate against risk of microbiological hazards;

(2) Conducting in-house testing of raw cannabis to mitigate against the risk of pesticide contamination;

(3) Establishing an allergen control program to ensure that allergen cross-contact does not occur between product types;

(4) Implementing procedures to ensure proper homogeneity of cannabinoids into a cannabis product to mitigate against the risk of a non-homogeneous product;

(e) The product quality plan shall identify methods to evaluate and monitor the effectiveness of the preventive measures in mitigating the potential risks identified in subsection (c). Methods for evaluation and monitoring of preventive measures include, but are not limited to, the following:

(1) Review of test results conducted to determine contamination such as pesticide residue;

(2) Maintaining and reviewing cleaning, sanitizing, or maintenance logs to verify such actions have been taken;

(3) Conducting environmental testing to determine if equipment or utensils are contaminated with undesirable pathogens;

(4) Monitoring the temperature of raw materials that need to be held below 41 F to prevent microbial contamination;

(f) The product quality plan shall identify actions to be taken if the evaluation and monitoring of the preventive measure indicates that the risk was not properly mitigated. The corrective action shall be specific to the type of product under evaluation and the specific risk to be mitigated. Examples of corrective actions that may be taken include, but are not limited to:

(1) Destruction of product components or finished product;

(2) Further processing of cannabis extract to remove impurities;

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(3) Reworking the unfinished product to further homogenize the cannabinoids;

(g) The licensee shall maintain the product quality plans and documentation of preventive measures, monitoring results, and corrective actions and make the records available to the Department upon the Department's request, including during the Department's onsite inspection of the premises. Nothing in this chapter requires the disclosure of product quality plans other than to the Department and its inspectors and agents. The licensee may consider the product quality plan subject to trade secret protection.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

#### **~~§40254. Manufacturing Operations.~~**

~~The licensee shall establish and implement written manufacturing operation procedures to ensure the following:~~

~~(a) All cannabis product manufacturing shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of cannabis products, and deterioration of cannabis products.~~

~~(b) Cannabis products capable of supporting the rapid growth of undesirable microorganisms shall be held at temperatures that prevent the cannabis product from becoming adulterated during manufacturing, processing, packing and holding.~~

~~(c) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity that are undertaken to destroy or prevent the growth of undesirable microorganisms shall be adequate under the conditions of manufacture, handling, and transfer to prevent the cannabis product from being adulterated. For purposes of this chapter, "water activity" ( $a_w$ ) is a measure of the~~

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~~free moisture in a manufactured cannabis 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.~~

~~(d) Work in process shall be handled in a manner that protects against allergen cross-contact, contamination, and growth of microorganisms.~~

~~(e) Measures shall be taken to protect finished cannabis products from allergen cross-contact and from contamination by raw materials, other ingredients, rejected components, or waste. When raw materials, other ingredients, or waste are unprotected, they shall not be handled simultaneously in a receiving, loading or shipping area if such handling could result in allergen cross-contact or contaminated cannabis products. Cannabis products transported by conveyer shall be protected against allergen cross-contact and against contamination as necessary.~~

~~(f) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work in process, or other cannabis products shall be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and contamination.~~

~~(g) Adequate measures shall be taken to protect against the inclusion of metal or other extraneous material in cannabis products.~~

~~(h) Adulterated cannabis products, raw materials, or other ingredients shall be either:~~

~~(1) Disposed of in a manner that protects against the contamination of other cannabis products or ingredients; or~~

~~(2) Reprocessed, if appropriate, using a method that has been proven to be effective and subsequently reexamined and found to be unadulterated.~~

~~(i) Steps such as washing, peeling, trimming, cutting, sorting, inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect cannabis products against allergen cross-contact and~~

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~~contamination. Cannabis products shall be protected from contaminants that may drip, drain, or be drawn into the cannabis product.~~

~~(j) When required in the preparation of cannabis products capable of supporting microbial growth, heat blanching shall be conducted by heating the cannabis product or component to a temperature to control microbial growth, holding at that temperature for an amount of time to control microbial growth, and then either rapidly cooling the cannabis product or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers shall be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitization as necessary.~~

~~(k) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time shall be treated or maintained in such a manner that they are protected against allergen cross-contact and contamination, and in a manner that minimizes the potential growth of undesirable microorganisms.~~

~~(l) Filling, assembling, packaging, and related operations shall be performed in such a way that the cannabis product is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.~~

~~(m) Cannabis products that principally rely on the control of water activity ( $a_w$ ) for preventing the growth of undesirable microorganisms (such as dry mixes, nuts, and dehydrated cannabis products) shall be processed and maintained at a safe moisture level. For purposes of this section “safe moisture level” is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing. The safe moisture level for an edible cannabis product is related to its  $a_w$ . An  $a_w$  will be considered safe for a manufactured cannabis product if adequate data is available to demonstrate that at or below the given~~

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~~aw the manufactured cannabis product will not support the growth of undesirable microorganisms.~~

~~(n) When ice is used in contact with cannabis products, the ice shall be made from water that is safe, potable, and of adequate sanitary quality.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

### ~~§40256. Hazard Analysis.~~

~~The licensee shall conduct and prepare a written hazard analysis to identify and evaluate known or reasonably foreseeable hazards that could affect cannabis product quality for each type of cannabis product produced at the manufacturing premises. The hazard analysis shall be used to determine whether there are any hazards requiring a preventive control in order to assure that cannabis products are not adulterated or misbranded. The hazard analysis shall include:~~

~~(a) The identification of reasonably foreseeable hazards, including:~~

~~(1) Biological hazards, including microbiological hazards;~~

~~(2) Chemical hazards, including radiological hazards, pesticide(s) contamination, solvent or other residue, natural toxins, decomposition, or food allergens; and~~

~~(3) Physical hazards, such as stone, glass, metal fragments, hair or insects.~~

~~(b) The evaluation of the hazards identified in order to assess the severity of any illness or injury that may occur as a result of a given hazard, and the probability that the hazard will occur in the absence of preventive controls.~~

~~(c) The hazard evaluation shall consider the effect of the following on the safety of the finished cannabis product for the intended consumer:~~

~~(1) The sanitation conditions of the manufacturing premises, including employee hygiene;~~

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- ~~(2) The product formulation;~~
- ~~(3) The design, function and condition of the manufacturing premises and its equipment;~~
- ~~(4) The raw material, ingredients and other components used in a given cannabis product;~~
- ~~(5) Product transportation and transfer practices;~~
- ~~(6) The manufacturing and processing procedures;~~
- ~~(7) The packaging and labeling activities;~~
- ~~(8) The storage of components and the finished cannabis product;~~
- ~~(9) The intended or reasonably foreseeable use of the finished cannabis product;~~
- ~~(10) Any other relevant factors.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

#### ~~§40258. Preventive Controls.~~

~~Upon completion of the hazard analysis, the licensee shall identify and implement written preventive controls to provide assurance that any hazards requiring a preventative control will be significantly minimized or prevented such that the manufactured cannabis product is not adulterated or misbranded. The preventive controls shall include the following components:~~

~~(a) The identification of critical control points, if any. Critical control points are the points, steps or procedures in a given process at which control can be applied, and as a result, a hazard can be prevented, eliminated, or reduced to acceptable levels.~~

~~(b) The establishment of critical limits for each critical control point. Critical limits are the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled in order to prevent, eliminate, or reduce to an acceptable level the~~

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~~occurrence of an identified hazard. For example: the establishment of specific limits on temperature, humidity, or pH.~~

~~(c) The identification of controls, other than those at critical control points, that are appropriate for ensuring cannabis product quality. Such controls include:~~

~~(1) Cleaning, sanitizing, and maintenance of the premises, equipment, and machinery as identified in the licensee's standard operating procedures and as may be specified by the equipment's manufacturer, as required pursuant to Subchapter 3.~~

~~(2) Supervisor, manager, and employee quality control and hygiene training, as required by sections 40232 and 40280.~~

~~(3) An environmental monitoring program for the premises to verify the effectiveness of pathogen controls in processes where a cannabis product is exposed to a possible contaminant in the manufacturing environment required pursuant to Subchapter 3.~~

~~(4) A food allergen control program to prevent allergen cross-contact as required pursuant to Subchapter 3.~~

~~(d) The establishment and implementation of monitoring procedures in order to use monitoring results to assess whether control measures are operating as intended. This shall include specifying the frequency and documentation requirements for monitoring, and routine verification that any monitoring equipment or instruments are operating in accordance with specifications.~~

~~(e) The establishment and implementation of corrective actions to be taken when monitoring indicates there is a deviation from an established critical limit or other preventative control measures are not properly implemented or are found to be ineffective. This shall include procedures for ensuring:~~

~~(1) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventative control;~~

~~(2) Appropriate action is taken, when necessary, to reduce the likelihood that a problem will recur;~~

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~~(3) All affected material(s) or product(s) are evaluated for safety;~~

~~(4) All affected material(s) or product(s) are prevented from entering into commerce if the safety or quality of that material(s) or product(s) cannot be verified.~~

~~(f) The establishment and implementation of record keeping procedures to document hazard analyses and control plans, identify the person responsible for each step, identify the corrective actions to be taken upon the discovery of a deviation, and documentation of instances of nonconformance material to product quality and corrective actions implemented. These records shall be subject to review by the Department.~~

~~(g) The establishment and implementation of verification procedures in order to validate that preventative controls are consistently implemented and are effective in minimizing or preventing identified hazards; and that monitoring activities are being conducted as required. Verification procedures shall include schedules or logs with the date and time of performance of the preventative control activity and the initials of the individual(s) completing the activity.~~

~~(h) A licensee shall conduct a re-analysis of the hazard analysis and preventive controls whenever a significant change is made in the activities conducted at the premises if the change creates a reasonable potential for a new hazard or significant increase in a previously identified hazard, and shall implement any new preventive controls as necessary to comply with this Section.~~

~~Authority: Sections 26012; 26013; and 26130, Business and Professions Code.~~

~~Reference: Sections 26011.5; and 26131, Business and Professions Code.~~

**§~~40262~~ 40255. Master Manufacturing Protocol.**

(a) The licensee shall establish and follow a written master manufacturing protocol for each unique formulation of cannabis product manufactured, and for each batch size, in order to mitigate against the potential for adulteration through incorporation of

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incorrect amounts of cannabinoids, unintended ingredients, or hazards identified in the product quality plan; against the potential for misbranding through incorporation of ingredients not identified on the label or the mislabeling of product; and to ensure uniformity in finished batches and across all batches produced.

~~(a) The master manufacturing protocol shall:~~

~~(1) Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the cannabis product and that the cannabis product is packaged and labeled as specified in the master manufacturing protocol; and~~

~~(2) Establish controls and procedures to ensure that each batch of cannabis product manufactured meets the specifications identified in accordance with subsection (a)(1) of this section.~~

(b) The master manufacturing protocol shall include:

(1) The name and intended cannabinoid(s) concentration of the cannabis product to be manufactured, ~~and the strength, concentration, weight, or measure of each ingredient for each batch size;~~

(2) A complete list of components to be used;

(3) The weight or measure of each component to be used. The master manufacturing protocol for any given product may include the ability to adjust the amount or weight of cannabinoid-containing ingredients in order to account for the variability of cannabinoid content in harvest batches;

(4) The identity and weight or measure of each ingredient that will be declared on the ingredients list of the cannabis product;

~~(5) A statement of theoretical yield of a manufactured cannabis product expected at each point, step, or stage of the manufacturing process where control is needed to ensure the quality of the cannabis product, and the~~ The expected yield of the finished product, based upon the quantity of components or packaging to be used in the

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absence of any loss or error in actual production, and including the maximum and minimum percentages of ~~theoretical~~ expected yield beyond which a deviation investigation of a batch is necessary and material review is conducted and ~~disposition-a~~ decision on the disposition of the product is made;

(6) A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label;

(7) Written instructions, ~~including the following:~~

~~(A) Specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the cannabis product and that the cannabis product is packaged and labeled as specified in the master manufacturing record;~~

(8) Written instructions for any action to mitigate an identified risk established in the product quality plan;

~~(B) Procedures for product and batch sampling and a cross-reference to procedures for tests or examinations of products and batches;~~

~~(C) Specific actions necessary to perform and validate points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the cannabis product and that the cannabis product is packaged and labeled as specified in the master manufacturing record;~~

~~(D) Special notations and precautions to be followed; and~~

~~(E) Corrective action plans for use when a specification is not met.~~

~~(8) The master manufacturing protocol for any given product may include the ability to adjust the amount or weight of cannabinoid-containing ingredients in order to account for the variability of cannabinoid content in harvest batches.~~

(c) Nothing in this chapter requires disclosure of the master manufacturing protocol to any person other than the individuals conducting activities that utilize the protocol or to the Department and its inspectors and agents. The licensee may consider the master manufacturing protocol subject to trade secret protection.

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Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

**§~~40264~~ 40258. Batch Production Record.**

(a) The licensee shall prepare a written batch production record every time a batch of a cannabis product is manufactured. The batch production record shall accurately follow the appropriate master manufacturing protocol, and each step of the protocol shall be performed in the production of the batch.

(b) The batch production record shall document complete information relating to the production and control of each batch, including all of the following details:

(1) The UID~~,~~ and ~~if used,~~ the batch or lot number~~,~~ of the finished batch of cannabis product and the UIDs of all cannabis or cannabis products used in the batch.

(2) The equipment and processing lines used in producing the batch;

(3) The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained;

(4) The identification number assigned to each component, packaging, and label used, and, if applicable, to a cannabis product received from another licensee for packaging or labeling as a cannabis product;

(5) The identity and weight or measure of each component used;

(6) A statement of the actual yield and a statement of the percentage of ~~theoretical~~ expected yield at appropriate phases of processing;

(7) The actual results obtained during any monitoring operation;

(8) The results of any testing or examination performed during the batch production, or a cross-reference to such results; and

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(9) Documentation, at the time of performance, of the manufacture of the batch, including:

(A) The date on which each step of the master manufacturing protocol was performed; and

(B) The initials of the persons performing each step, including:

(i) The initials of the person responsible for weighing or measuring each component used in the batch;

(ii) The initials of the person responsible for verifying the weight or measure of each component used in the batch;

(iii) The initials of the person responsible for adding the component to the batch; and

(iv) The initials of the person responsible for verifying the addition of components to the batch.

(10) Documentation, at the time of performance, of packaging and labeling operations, including:

(A) An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record;

(B) The expected number of packaging and labels to be used, the actual quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels; and

(C) The results of any tests or examinations conducted on packaged and labeled cannabis products (including repackaged or relabeled cannabis products), or a cross-reference to the physical location of such results.

(11) Documentation, at the time of performance, that quality control personnel:

(A) Reviewed the batch production record;

(B) Reviewed all monitoring operation(s) ~~required by this article~~;

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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(C) Reviewed the results of all tests and examinations, including tests and examinations conducted on components, ~~in-process materials~~, finished batches of cannabis product, and packaged and labeled cannabis products;

(D) Either approved and released, or rejected, the batch for distribution; and

(E) Either approved and released, or rejected, the finished cannabis product, including any repackaged or relabeled cannabis product.

(12) Documentation, at the time of performance, of any required material review and disposition decision; and

(13) The Certificate of Analysis issued for the batch by the licensed testing laboratory, which shall be added to the record after regulatory compliance testing has been completed.

(c) The batch production record shall:

(1) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

(2) Be accurate, indelible, and legible;

(3) Be created concurrently with performance of the activity documented; and

(4) Be as detailed as necessary to provide a history of work performed; including:

(A) Information to identify any associated manufacturing premises (e.g., the name, license number, and the location of the premises);

(B) The date and the time of the activity documented;

(C) The signature or initials of the person performing the activity; and

(D) The identity of the product, the UID, and the batch or lot number ~~or batch identifier, if any.~~

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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**§40275. Standard Operating Procedures.**

(a) A licensee shall establish and maintain written standard operating procedures that are easily accessible to onsite personnel. The standard operating procedures shall, at minimum, include the following:

(1) Policies or procedures developed in accordance with the security plan required by Section 40200;

(2) Emergency response procedures, including safety data sheets for any chemicals on-site;

(3) Policies and procedures developed in accordance with Section 40225;

(4) Policies and procedures developed in accordance with Article 3 of this subchapter (Good Manufacturing Practices);

(5) ~~Policies and procedures developed in accordance with Article 4 of this subchapter (Production and Process Control);~~

~~(6)~~ Procedures for complying with the track-and-trace requirements established in Article 2 of subchapter 6;

~~(7)~~ Inventory control procedures in compliance with Section 40282; and

~~(8)~~ Cannabis waste management procedures in compliance with Section 40290.

(b) Procedures shall be written in English but may be made available in other languages, as necessary for the licensee's personnel.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; 26053; 26130; and 26160, Business and Professions Code.

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**§40277. Weights and Measures.**

(a) Weighing devices used by a licensee shall be approved, tested, and sealed in accordance with the requirements in Chapter 5 (commencing with Section 12500) of Division 5 of the Business and Professions Code, and registered with the county sealer consistent with Chapter 2 (commencing with 12240) of Division 5 of the Business and Professions Code. Approved and registered devices shall be used whenever:

- (1) Cannabis or cannabis product is bought or sold by weight or count;
- (2) Cannabis or cannabis product is packaged for sale by weight or count;
- (3) Cannabis or cannabis product is weighed or counted for entry into the track-and-trace system; and
- (4) The weighing device is used for commercial purposes as defined in section 12500 of Business and Professions Code.

(b) For the purposes of this chapter, “count” means the numerical count of the individual cannabis product units.

(c) Whenever the licensee is determining the weight, or measurement measure, or count of cannabis and cannabis products ~~is determined as for the purposes~~ specified in subsection (a), ~~products the weight, measure, or count~~ shall be weighed determined by a licensed weighmaster, ~~and shall be issued a certificate consistent with the requirements in~~ as required by Chapter 7 (commencing with section 12700) of Division 5 of Business and Professions Code. The weighmaster certificate required under section 12711 of the Business and Professions Code shall not be required when cannabis or cannabis products are weighed for entry into the track-and-trace system.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26060, Business and Professions Code.

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**§40280. Training Program.**

(a) The licensee shall implement a training program to ensure that all personnel present at the premises are provided information and training that, at minimum, covers the following topics within the timeframes specified:

(1) Within 30 days of the start of employment:

(A) Health and safety hazards;

(B) Hazards presented by all solvents or chemicals used at the licensed premises as described in the safety data sheet for each solvent or chemical;

(C) Emergency procedures;

(D) Security procedures;

(E) Record keeping requirements; and

(F) Training requirements.

(2) Manufacturing and production personnel, ~~P~~prior to independently engaging in any cannabis manufacturing process:

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

(B) Quality control procedures;

(C) ~~Hazard analysis and control procedures, as appropriate~~ The product quality plans developed in accordance with Section 40253;

(D) Proper and safe usage of equipment or machinery;

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

(F) Cleaning and maintenance requirements;

(G) Emergency operations, including shutdown; and

(H) Any additional information reasonably related to an employee's job duties.

(3) Additionally, a licensee that produces edible cannabis products shall ensure that all personnel who prepare, handle, or package edible products successfully complete a

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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California food handler certificate course from an entity accredited by the American National Standards Institute (ANSI) within 90 days of commencing employment at the premises and again every three years during employment. The licensee shall obtain documentation evidencing the fulfillment of this requirement;

(4) The licensee shall ensure that all personnel receive annual refresher training to cover, at minimum, the topics listed in this [subsection](#). This annual refresher training must be completed within 12 months of the previous training completion date.

(b) The licensee shall maintain a record of training which contains at minimum:

(1) A list of all personnel at the premises, including at minimum, name and job duties of each;

(2) Documentation of training topics and dates of training completion, including refresher training, for all personnel;

(3) The signature of each individual personnel and the licensee verifying receipt and understanding of each training or refresher training completed by the individual; and

(4) Any official documentation attesting to the successful completion of required training by personnel.

(c) The licensee may assign responsibility for the training of individual personnel to supervisory personnel. Assigned supervisory personnel must have the education, training, or experience (or a combination thereof) necessary to ensure the production of quality cannabis products by all personnel. The assigned training personnel shall sign and date a document on an annual basis attesting that he or she has received and understands all information that will be provided to individual personnel in the training program. This documentation shall be maintained as part of the record requirements.

(d) For licensees in operation pursuant to Section 40126, applicable personnel shall receive required training no later than 90 days after the effective date of the annual license.

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Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; 26130; and 26160, Business and Professions Code.

\* \* \* \* \*

**§40290. Waste Management.**

(a) A licensee shall have a written cannabis waste management plan and shall dispose of all waste, including cannabis waste, in accordance with [the Public Resources Code and any other](#) applicable state and local laws, including laws regulating “organic waste” as defined in Public Resources Code section 42649.8(c). It is the responsibility of the licensee to properly evaluate waste to determine if it should be designated and handled as a hazardous waste, as defined in section 40141 of the Public Resources Code.

(b) A licensee shall dispose of any cannabis waste in a secured waste receptacle or secured area on the licensed premises. For the purposes of this section, “secured waste receptacle” or “secured area” means that physical access to the receptacle or area is restricted to the licensee, employees of the licensee, the local agency, waste hauler franchised or contracted by [the local government agency](#), or private waste hauler permitted by the local [government agency](#) only. Public access to the designated receptacle or area shall be prohibited.

(c) No cannabis product shall be disposed of in its packaging, and all cannabis waste shall be unrecognizable and unusable as cannabis or a cannabis product at the time of disposal. [Nothing in the subsection shall be construed to require waste vape cartridges to be emptied of cannabis oil prior to disposal, provided that the vape cartridge is itself unrecognizable and unusable at the time of disposal.](#)

(d) Cannabis waste shall be entered into the track-and-trace system as required under Section 40512.

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(e) Cannabis waste may be collected from a licensee in conjunction with a regular organic waste collection route used by the local agency, a waste hauler franchised or contracted by the local agency, or a private waste hauler permitted by the local agency.

If a local agency, a waste hauler franchised or contracted by the local ~~government~~ agency, or a private waste hauler permitted by the local ~~government~~ agency is being used to collect and process cannabis waste, a licensee shall do all of the following:

(1) Maintain and make available to the Department upon request the business name, address, contact person, and contact phone number of the entity hauling the waste; and

(2) Obtain documentation from the entity hauling the waste that ~~indicates the date and time of each collection of cannabis waste at the licensed premises; and evidences~~ subscription to a waste collection service.

~~(3) Obtain a copy of the certified weight ticket, or other documentation prepared by the entity hauling the waste confirming receipt of the cannabis waste at one, or more, of the following solid waste facilities:~~

~~(A) A manned fully permitted solid waste landfill or transformation facility;~~

~~(B) A manned fully permitted composting facility or manned composting operation;~~

~~(C) A manned fully permitted in-vessel digestion facility or manned in-vessel digestion operation; or~~

~~(D) A manned fully permitted transfer/processing facility or manned transfer/processing operation.~~

(f) If a licensee is self-hauling cannabis waste as allowed by the local jurisdiction to ~~one, or more, of the solid waste facilities in subsection (e)(3)~~, the licensee shall be ~~subject to all of the following requirements:~~

(1) Self-hauled cannabis waste shall only be transported by the licensee or its employees;

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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(2) Self-hauled cannabis waste shall only be transported to one or more of the following:

(A) A manned fully permitted solid waste landfill or transformation facility;

(B) A manned fully permitted composting facility or manned composting operation;

(C) A manned fully permitted in-vessel digestion facility or manned in-vessel digestion operation; or

(D) A manned fully permitted transfer/processing facility or manned transfer/processing operation.

(3) The licensee or its employee who transports the waste shall obtain for each delivery of cannabis waste by the licensee a copy of a certified weight ticket or receipt from the solid waste facility. ~~Only the licensee or its employees may transport self-hauled cannabis waste.~~

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; 26013; and 26130, Business and Professions Code.

\* \* \* \* \*

~~§40266~~40295. **Product Complaints.**

The licensee shall establish and implement written procedures to ensure that:

(a) A qualified individual shall review and investigate all product complaints to determine whether such complaints involve a possible failure of a cannabis product to meet any of its specifications;

(b) Quality control personnel shall review and approve decisions determining whether to investigate a product complaint and shall review and approve the findings and follow up action(s) of any investigation performed;

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(c) Pursuant to [subsections](#) (a) and (b) in this section, any review or investigative activities by qualified individuals and quality control personnel shall extend to all relevant batches and records.

(d) Quality control personnel shall maintain written records for every product complaint and subsequent investigation, if any. The records shall include:

- (1) The name and description of the cannabis product;
- (2) The batch number or UID of the cannabis product, if available;
- (3) The date the complaint was received and the name, address, and telephone number of the complainant, if available;
- (4) The nature of the complaint including, if known, how the product was used;
- (5) The reply to the complainant, if any;
- (6) The findings of the investigation or follow-up action taken when an investigation is performed; and
- (7) The basis for any determination not to conduct an investigation.

(e) For purposes of this section, “product complaint” means any written, electronic, or oral communication that contains any allegation expressing concern, for any reason, with the quality of a cannabis product that could be related to the manufacturing practices. Examples of product complaints may include but are not limited to: foul odor, off taste, illness or injury, disintegration time, color variation, foreign material in a cannabis product container, improper packaging, mislabeling, cannabis products that contain an incorrect concentration of cannabinoids, or cannabis products that contain an unidentified ingredient, or any form of contaminant.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

\*\*\*\*\* denotes Sections omitted – no change from initially proposed text  
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~~§40268~~40297. **Recalls.**

A licensee shall establish and implement written procedures for recalling cannabis products manufactured by the licensee that are determined to be misbranded or adulterated. These procedures shall include:

- (a) Factors which necessitate a recall;
- (b) Personnel responsible for implementing the recall procedures; and
- (c) Notification protocols, including:

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

(2) A mechanism to notify any licensees that supplied or received the recalled product;

(3) Instructions to the general public and other licensees for the return or destruction of the recalled product.

(d) Procedures for the collection and destruction of any recalled product. Such procedures shall meet the following requirements:

(1) All recalled products that are intended to be destroyed shall be quarantined for a minimum of 72 hours. The licensee shall affix to the recalled products any bills of lading, shipping manifests, or other similar documents with product information and weight. The product held in quarantine shall be subject to auditing by the Department.

(2) Following the quarantine period, the licensee shall render the recalled cannabis product unusable and unrecognizable and dispose of it in accordance with Section 40290, and do so on video surveillance in accordance with Section 40205.

(e) In addition to the tracking requirements set forth in Section 40512, a licensee shall use the track-and-trace database and on-site documentation to ensure that recalled cannabis products intended for destruction are identified, weighed, and tracked while on the licensed premises and when disposed of in accordance with this section.

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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For recalled cannabis products, the licensee shall enter the following details into the track and trace database: the weight [and count](#) of the product, reason for destruction, and the date the quarantine period will begin.

(f) The licensee shall notify the Department of any recall within 24 hours of initiating the recall.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26131, Business and Professions Code.

#### **§40300. Prohibited Products.**

The following types of products shall not be sold as cannabis products:

(a) Alcoholic beverages, as defined in section 23004 of the Business and Professions Code. This prohibition does not apply to tinctures that meet the requirements of Section 40308;

(b) Any product containing any non-cannabinoid additive that would increase potency, toxicity, or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives include, but are not limited to, nicotine and caffeine. This prohibition shall not apply to products containing naturally-occurring caffeine, such as coffee, tea, or chocolate;

(c) Any cannabis product that must be held at or below 41 degrees Fahrenheit to keep it safe for human consumption, including, but not limited to, cream or custard-filled pies; pies or pastries which consist in whole or in part of milk or milk products, or eggs; and meat-filled pies or pastries. This prohibition shall not apply to juices or beverages that need to be held below 41 degrees Fahrenheit if the juice or beverage was processed in accordance with Section 40270, or to infused butter manufactured [as](#) permitted by subsection (g);

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(d) Any thermally processed low-acid cannabis product packed in a hermetically sealed container that, if it were a food, would be subject to the manufacturing requirements of Title 21, Code of Federal Regulations, Part 113;

(e) Any acidified cannabis product that, if it were a food, would be subject to the manufacturing requirements of Title 21, Code of Federal Regulations, Part 114;

(f) Any juice that is not shelf-stable or that is not processed in accordance with Section 40270;

(g) Dairy products of any kind, as prohibited by section 26001(t) of the Act, except that butter purchased from a licensed milk products plant or retail location that is subsequently infused or mixed with cannabis may be sold as a cannabis product;

(h) Meat products other than dried meat products prepared in accordance with Section 40272;

(i) Seafood products of any kind;

(j) Any product that is manufactured by application of cannabinoid concentrate or extract to commercially available candy or snack food items without further processing of the product. Commercially available candy or snack food items may be used as ingredients in a cannabis product, provided that they are used in a way that renders them unrecognizable as the commercially available items and the label, including the ingredient list, does not note that the final cannabis product contains the commercially available item;

(k) Any cannabis product that the Department determines, on a case-by-case basis, is attractive to children, as specified in Section 40410;

(l) Any cannabis product that the Department determines, on a case-by-case basis, is easily confused with commercially available foods that do not contain cannabis;

(m) Any cannabis product in the shape of, or imprinted with the shape, either realistic or caricature, of a human being, ~~either realistic or caricature~~, animal, insect, or fruit.

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26130, Business and Professions Code; Section 37104, Food and Agricultural Code.

**§40305. Requirements for Edible Cannabis Products.**

(a) Except for cannabis, cannabis concentrate, or terpenes, no product ingredient or component shall be used in the manufacture of an edible cannabis product unless that ingredient or component is permitted by the United States Food and Drug Administration for use in food or food manufacturing, as specified in *Everything Added to Food in the United States*, available at <https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm115326.htm> or is Generally Recognized as Safe (GRAS) under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act.

(b) Edible cannabis products that consist of more than a single serving shall be either ~~be~~:

(1) Scored or delineated to indicate one serving, if the edible cannabis product is in solid form. For purposes of this section, “delineated” includes directly marking the product to indicate one serving or providing a means by which a consumer can accurately identify one serving; or

(2) If the edible cannabis product is not in solid form, packaged in a manner such that a single serving is readily identifiable or easily measurable.

(c) An edible cannabis product consisting of multiple servings shall be homogenized so that each serving contains the same concentration of THC.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26130, Business and Professions Code.

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**§40308. ~~Tinctures and~~ Orally-Consumed Products Containing Alcohol.**

Any ~~tincture or~~ orally-consumed product that contains more than 0.5% alcohol by volume as an ingredient, and is not otherwise an alcoholic beverage as defined in Business and Professions Code section 23004, shall be packaged in a container no larger than two (2) fluid ounces and shall include a calibrated dropper or other similar device capable of accurately measuring servings.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Section 26011.5, Business and Professions Code.

\* \* \* \* \*

**§40330. Failed Product Batches.**

(a) A finished cannabis product batch that fails any regulatory compliance laboratory testing requirement established by the Bureau pursuant to section 26100 of the Act shall be destroyed unless:

(1) The cannabis product batch can be remediated by relabeling pursuant to subsection (d); or

(2) A corrective action plan for remediation or reprocessing is approved by the Department pursuant to subsection (e).

(b) Remediation or reprocessing of a failed product batch or the use of a harvest batch that has failed any regulatory compliance laboratory test shall comply with the requirements and procedures established by the Bureau in Section 5727 of Title 16 of the California Code of Regulations, in addition to the requirements of this chapter.

(c) Except as provided in subsections (d) and (f), edible cannabis products that fail regulatory compliance laboratory testing ~~requirements~~ shall not be remediated or reprocessed and shall be destroyed. If any edible cannabis product that has failed

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[regulatory compliance](#) laboratory testing is remediated, reprocessed, or otherwise mixed with another batch of cannabis product [in violation of this section](#), such action shall render the final cannabis product adulterated, regardless of the defect level of the final cannabis product.

(d) A cannabis product batch that fails [regulatory compliance](#) laboratory testing for cannabinoid or terpenoid content may be remediated by relabeling the product with the correct information from the laboratory certificate of analysis, provided that the THC limits in Section 40315 are met. In addition, the following conditions apply:

(1) The manufacturer licensee shall notify the Department within 3 business days of notification by a distributor that ~~a~~[the](#) product failed cannabinoid content testing and is required to be relabeled.

[\(2\)](#) Notification shall be given to the Department by email and shall include a copy of the certificate of analysis for the batch and the name and license number of the licensee relabeling the product.

(e) Except as provided in subsection (d), a cannabis product batch or a harvest batch that fails [regulatory compliance](#) laboratory testing or quality assurance review shall not be remediated or reprocessed unless the Department has approved a corrective action plan submitted by the manufacturer licensee. The corrective action plan shall include, at minimum, a description of how the product or harvest batch will be remediated so that the product or harvest batch, or any product produced therefrom, will meet all [regulatory compliance](#) laboratory testing and quality assurance requirements. Edible cannabis products may only be remediated by relabeling [or repackaging as provided in subsection \(f\)](#). Corrective action plans will be reviewed by the Department on a case-by-case basis.

[\(f\) Edible cannabis products that fail regulatory compliance laboratory testing because the per package limit of THC has been exceeded may be remediated by repackaging under the following conditions:](#)

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- (1) The Department has approved a remediation plan for repackaging the product;
- (2) The product batch is returned to the manufacturer that packaged the product;
- (3) The product itself is not altered in any way; and
- (4) The product is labeled to accurately state the contents.

(fg) All remediation of harvest or product batches shall be documented in the manufacturing records. Remediated products, harvest batches, or products produced therefrom, shall be tested and undergo quality assurance review in accordance with the requirements established by the Bureau in Article 7 of Chapter 6 of Division 42 of Title 16 of the California Code of Regulations prior to retail sale.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Section 26131, Business and Professions Code.

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**§40401. Release to Distributor as Finished Product.**

(a) Prior to release of a cannabis product to a distributor, a licensee shall ensure that the product is in finished form and is labeled and packaged in its final form for sale.

(b) For purposes of this section, “final form” does not include:

(1) Labeling of cannabinoid content if the cannabinoid content is to be added to the label at the distribution premises after issuance of the Certificate of Analysis in accordance with section 40409; or

(2) Placing the cannabis or cannabis product into child-resistant packaging. This provision shall expire on December 31, 2019.

Authority: Section 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; and 26130, Business and Professions Code.

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#### **§40403. General Provisions.**

(a) Any information required to be listed on a label shall be written in English.

(b) A label shall be unobstructed and conspicuous so that it can be read by the consumer.

(c) All required label information shall be located on the outside container or wrapper of the finished product to be sold at a retailer. If the product container is separable from the outer-most packaging (e.g., a container placed inside of a box), the product container shall also include the following:

(1) ~~All of the information specified in Sections 40405 and 40406, for~~ For edible cannabis products, topical cannabis products, suppositories, or orally-consumed concentrates, all of the information specified in Sections 40405 and 40406, except for cannabinoid content.

(2) ~~The universal symbol as prescribed in Section 40412, for~~ For inhaled products (e.g., as dab, shatter, and wax), the universal symbol as prescribed in Section 40412.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Section 26120, Business and Professions Code.

#### **§40404. Labeling Requirements: Pre-Rolls and Packaged Flower.**

(a) The label for a package of pre-rolls or packaged flower shall include a primary panel that includes the following information in a type size no less than 6 point font and in relation to the size of the primary panel and container:

(1) Identity of the product;

(2) The net weight of cannabis in the package, listed in both metric and U.S. customary units; and

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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(3) Universal symbol;

~~(4) The cannabinoid content as specified in Section 40409.~~

(b) The label for a package of pre-rolls or packaged flower shall include an informational label that includes the following information in a type size no less than 6 point font and in relation to the size of the informational panel and container:

(1) The UID;

(2) The licensed cultivator or licensee packaging the product (either the legal business name or the registered DBA listed on the license certificate), and its contact number or website address;

(3) The date of packaging for retail sale;

(4) The following statement in bold print: "GOVERNMENT WARNING: THIS PACKAGE CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION."

(c) Nothing in this section prohibits the inclusion of additional information on the label, provided that the label does not violate the requirements of Section 40410.

(d) The cannabinoid content for a package of pre-rolls or packaged flower shall be labeled as specified in Section 40409.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Section 26120, Business and Professions Code.

\*\*\*\*\* denotes Sections omitted – no change from initially proposed text

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**§40405. Primary Panel Labeling Requirements: Manufactured Products.**

(a) The label for a manufactured cannabis product shall include a primary panel that includes the following information in a type size no less than 6 point font and in relation to the size of the primary panel and container:

(1) The identity of the product in a text size reasonably related to the most prominent printed matter on the panel;

(2) The universal symbol as prescribed in Section 40412; and

(3) The net weight or volume of the contents of the package, listed in both metric and U.S. customary units;

~~(4) Cannabinoid content as specified in Section 40409.~~

(b) Cannabinoid content may be included on the primary panel. Cannabinoid content for manufactured cannabis products shall be labeled as specified in Section 40409.

~~(c) Nothing in this section prohibits the inclusion of additional information on the primary panel, provided that the label does not violate the requirements of Section 40410. The content of other cannabinoids or terpenes may be included if such information is verified by the certificate of analysis issued by a licensed testing laboratory.~~

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Section 26120, Business and Professions Code.

\* \* \* \* \*

**§40408. Informational Panel Labeling Requirements.**

(a) The label for a manufactured cannabis product shall include an informational panel that includes the following:

\*\*\*\*\* denotes Sections omitted – no change from initially proposed text

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(1) The [name of the](#) licensed manufacturer (either the legal business name or the registered DBA listed on the license certificate) [that manufactured the cannabis product](#) and its contact number or website address;

(2) The date of the cannabis product's manufacture and packaging;

(3) The following statement in bold print: "GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS PRODUCTS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. THE INTOXICATING EFFECTS OF CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION."

(4) The statement "FOR MEDICAL USE ONLY," if:

(A) The cannabis product is intended by the manufacturer only for sale to medicinal-use customers;

(B) The product is an orally-dissolving edible product containing more than 100 milligrams THC per package, as specified in Section 40315(b); or

(C) The product is a topical cannabis product or ~~a orally-consumed~~ concentrate containing more than 1,000 milligrams THC per package, as specified in Section ~~40135~~[40315](#)(d).

(5) A list of all product ingredients in descending order of predominance by weight or volume. If any product ingredient contains subingredients, the list shall either:

(A) Include the common name of the ingredient followed by a parenthetical listing of all ingredients in descending order by weight or volume; or

(B) List all subingredients as individual ingredients in descending order of predominance.

\* \* \* \* \* denotes Sections omitted – no change from initially proposed text

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(C) This paragraph shall not apply to flavoring, which shall instead be compliant with the requirement of 21 C.F.R 101.22 (Rev. Jan 2009), hereby incorporated by reference.

(6) If the cannabis product contains an ingredient, flavoring, coloring, or an incidental additive that bears or contains a major food allergen, the word “contains,” followed by a list of the applicable major food allergens;

(7) The names of any artificial colorings contained in the product;

(8) If an edible cannabis product, the amount, in grams or milligrams, of sodium, sugar, carbohydrates, and total fat per serving;

(9) Instructions for use, such as the method of consumption or application, and any preparation necessary prior to use;

(10) The product expiration date, “use by” date, or “best by” date, if any;

(11) The UID and, ~~if used,~~ the batch or lot number; and

(12) If the cannabis product is perishable or is perishable after opening, the statement, “KEEP REFRIGERATED” or “REFRIGERATE AFTER OPENING,” as applicable.

(b) The informational panel text shall be in a text size of no less than 6 point font and in relation to the size of the primary panel and container.

(c) Except for the information required by paragraph (a)(11), the ~~The~~ requirements of subsection (a) can be fulfilled through the use of supplemental labeling, which can include, but is not limited to, a package insert, fold-out or booklet label, or a hanging tag.

(d) Cannabinoid content may be included on the informational panel. Cannabinoid content for manufactured cannabis products shall be labeled as specified in Section 40409.

(e) Nothing in this section prohibits the inclusion of additional information on the informational panel provided that the label does not violate the requirements of Section 40410. ~~The content of other cannabinoids or terpenes may be included if the~~

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~~information is verified by the certificate of analysis issued by a licensed testing laboratory.~~

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26120; and 26121, Business and Professions Code.

#### **§40409. Cannabinoid Content Labeling.**

(a) Each package for retail sale of cannabis product, cannabis, or pre-rolls shall be labeled with the cannabinoid content on either the primary panel or an informational panel. Cannabinoid content may be included on the product label at the manufacturing premises prior to release to a distributor as described in subsection (b) or it may be added to the product at the distribution premises after issuance of the regulatory compliance testing Certificate of Analysis for the batch as described in subsection (c). Cannabinoid content labelling shall include the following:

(1) ~~THC Content:~~

~~(A) For an edible product, and a cannabis concentrate for which the manufacturer has established serving designations, THC~~ and CBD ~~content, shall be~~ expressed in milligrams per serving and milligrams per package.

~~(B2) For a topical cannabis product and a cannabis concentrate without serving designations, THC~~ and CBD ~~content, shall be~~ expressed in milligrams per package.

~~(2) CBD Content:~~

~~(A) For an edible product, and a cannabis concentrate for which the manufacturer has established serving designations, CBD content shall be expressed in milligrams per serving and milligrams per package.~~

~~(B) For a topical cannabis product and a cannabis concentrate without serving designations, CBD content shall be expressed in milligrams per package.~~

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(~~c~~3) Packages of pre-rolls or cannabis flower that do not include cannabinoids other than that naturally occurring in the plant material are not required to list cannabinoid content in milligrams. Instead, such packages may be labeled with the cannabinoid content expressed as a percentage.

(~~d~~4) Packages of infused pre-rolls shall be labeled with either:

- (1) The cannabinoid content in milligrams; or
- (2) The cannabinoid content of the dried flower expressed as a percentage and the added cannabinoid content in milligrams.

(b) A manufacturer that includes the cannabinoid content on the product label prior to release to a distributor, shall label products as specified in paragraphs (1) through (4) of subsection (a), as appropriate to the product. For THC or CBD concentration that is less than two (2) milligrams per serving or per package, the THC or CBD may be labeled as “<2.0 mg per serving” or “<2.0 mg per package”.

(c) A manufacturer may arrange for cannabinoid content labeling at the distribution premises after issuance of the Certificate of Analysis in accordance with the following:

(1) Each package of cannabis product in the batch shall be labeled with the cannabinoid content as specified in subsection (a), that is indicated on the Certificate of Analysis, as well as any other cannabinoid that is 5 percent or greater of the total cannabinoid content.

(2) The manufacturer shall identify a location for the cannabinoid content label on the outer packaging of the product. The location shall be sufficient in size for the required cannabinoid content to be printed in at least 6 point font.

(3) The cannabinoid content label shall be affixed to the identified location on the outer packaging of the product and shall not obscure any other label information.

(d) Nothing in this section precludes the labeling of terpenes or additional cannabinoid content on the product, provided that such information is verified by the Certificate of Analysis.

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Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Section 26120, Business and Professions Code.

**§40410. Labeling Restrictions.**

Cannabis product labeling shall not contain any of the following:

(a) The name of a California county, including any similar name that is likely to mislead consumers as to the origin of the product, unless 100% of the cannabis used in the product was grown in that county.

(b) Content that is, or is designed to be, attractive to individuals under the age of 21, including but not limited to:

(1) Cartoons;

(2) Any likeness to images, characters, or phrases that are popularly used to advertise to children;

(3) Any imitation of candy packaging or labeling; or

(4) The terms “candy” or “candies” or variants in spelling such as “kandy” or “kandeez.”

(c) Any information that is false or misleading.

(d) Any health-related statement that is untrue or misleading. Any health-related statement must be supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims.

(e) If the product is an edible product, a picture of the product contained therein.

(f) For purposes of this section, false or misleading information includes any indication that the cannabis or cannabis product is organic, unless the National Organic

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Program (Section 6517 of the federal Organic Foods Production Act of 1990 (7 U.S.C. Section 6501 et seq.)) authorizes organic designation and certification for cannabis and the cannabis or cannabis product meets the requirements for such designation and certification. This includes use of the word “organic” on the labeling or variants in spelling such as “organix.”

[\(g\) Any labeling in violation of the requirements of the Bureau specified in Section 5040.1 of Division 42 of Title 16 of the California Code of Regulations.](#)

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26062.5; 26120; 26121; and 26154, Business and Professions Code.

\* \* \* \* \*

#### **§40415. Packaging.**

A package used to contain cannabis or a cannabis product shall comply with the following requirements:

- (a) The package shall protect the product from contamination and shall not expose the product to any toxic or harmful substance.
- (b) The package shall be tamper-evident, which means that the product packaging is sealed so that the contents cannot be opened without obvious destruction of the seal.
- (c) If the product has multiple uses, ~~#~~ the package shall be resealable.
- (d) The package shall not imitate any package used for products typically marketed to children.
- (e) If the product is an edible product, the package shall be opaque. Amber bottles shall be considered opaque for purposes of this section.

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(f) Notwithstanding subsection (e), opaque bottles used to contain a cannabis beverage product may utilize a single, vertical, clear strip of no wider than 0.25 inches for the purpose of determining serving amounts.

(g) The package shall be child-resistant, as described in Section 40417.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26120; and 26121, Business and Professions Code.

#### **§40417. Child-Resistant Packaging Requirements.**

(a) Beginning January 1, 2020, a package containing cannabis or cannabis products transferred to a distributor for retail sale shall be child-resistant, as follows:

(1) An edible product, an orally-consumed concentrate, or a suppository shall be child-resistant for the life of the product. A package that contains more than a single serving is not required to be child-resistant if each individual serving is packaged in child-resistant packaging.

(2) Cannabis or a cannabis product intended to be inhaled or a cannabis product that is applied topically may utilize packaging that is child-resistant only until first opened, if the package is labeled with the statement “This package is not child-resistant after opening.”

(b) The following packages are considered child-resistant for purposes of this chapter:

(1) Any package that has been certified as child-resistant under the requirements of the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.15(b)(1)) (Rev. July 1995), which is hereby incorporated by reference.

(2) A bottle sealed with a pry-off metal crown cork style bottle cap, provided that the bottle contains only a single serving.

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(3) Plastic packaging that is at least 4 mils thick and heat-sealed without an easy-open tab, dimple, corner, or flap, provided that the package contains a cannabis product described in Subsection (a)(2) or is a cannabis product that is only a single serving.

(c) Until the date specified in subsection (a), the child-resistant package requirement specified in section 26120 of the Act may be met through the use of a child-resistant exit package at retail sale.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; 26120; and 26121, Business and Professions Code.

\* \* \* \* \*

#### **§40510. Track-and-Trace System General Requirements.**

(a) Each applicant or licensee shall identify an owner of the commercial cannabis business to be the track-and-trace system account manager. The account manager shall register for track-and-trace system training provided by the Department of Food and Agriculture or its designee within ten (10) ~~business~~ calendar days of receiving notice from the Department of Public Health that their application for licensure has been received.

(b) Applicants approved for an annual license shall not have access to the track-and-trace system until the account manager has completed the track-and-trace training prescribed by the Department of Food and Agriculture or its designee and proof of completion has been validated by Department of Food and Agriculture or its designee.

(c) The licensee's track -and-trace system account manager shall be responsible for all the following:

(1) Complete track-and-trace system training provided by the Department of Food and Agriculture or its designee. If the account manager did not complete the track-and-trace system training prior to the licensee receiving their annual license, the account

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manager will be required to register for the track-and-trace system training provided by the Department of Food and Agriculture or its designee within five (5) ~~business~~ calendar days of license issuance;

(2) Designate track-and-trace system users, as needed, and require the designated users to be trained in the proper and lawful use of the track-and-trace system before the users are permitted to access the track-and-trace system;

(3) Maintain an accurate and complete list of all track-and-trace system designated users and update the list immediately when changes occur;

(4) Cancel any track-and-trace designated users from the licensee's track-and-trace system account if that individual is no longer authorized to represent the licensee;

(5) Correct any data that is entered into the track-and-trace system in error within three (3) ~~business~~ calendar days of discovery of the error;

(6) Obtain UID tags from the Department of Food and Agriculture, or its designee, and ensure that a sufficient supply of UIDs is available at all times;

(7) Ensure that all inventory is tagged and entered in the track-and-trace system as required by Section 40512 and 40517; ~~and~~

(8) Monitor all notifications from the track-and-trace system and resolve all issues identified in the notification. The notification shall not be dismissed by an account manager until the issue(s) identified in the notification has been resolved; ~~and~~

(9) Notify the Department of any loss of access to the track-and-trace system that exceeds 72 hours.

(d) The applicant or licensee is responsible for notifying the Department in writing of any change to the designated track and trace system account manager within forty-eight hours.

(e) The licensee is responsible for all actions its owners or employees take while logged into the track-and-trace system, or are otherwise performing track-and-trace activities.

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(f) No person shall intentionally misrepresent or falsify information entered into the track-and-trace system. The track-and-trace system shall be the system of record. The licensee is responsible for the accuracy and completeness of all data and information entered into the track-and-trace system. Information entered into the track-and-trace system shall be assumed to be accurate and may be used to take enforcement action against the licensee if incorrect information is not corrected.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26067; and 26160, Business and Professions Code

\* \* \* \* \*

**§40517. Track-and-Trace System – UID Tag Order.**

(a) A licensee shall order UID tags within five (5) ~~business~~ calendar days of receiving access to the track-and-trace system. The receipt of the UID tags by the licensee shall be recorded in the track-and-trace system within three (3) ~~business~~ calendar days of receipt.

(b) Any licensee in operation at the time access to the track-and-trace system is granted shall input all inventory into the track-and-trace system no later than 30 calendar days after receipt of the UID tags. After UID tags have been received, all commercial cannabis activity shall be recorded in the track-and-trace system by the licensee as required by this Article.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26067; 26160; and 26161, Business and Professions Code.

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**§40550. Inspections.**

(a) The Department and its inspectors or agents may conduct an on-site inspection prior to issuing a new or renewal license, and as deemed necessary by the Department.

(b) The Department and its inspectors or agents shall have access at reasonable times to the manufacturing premises, any area in which the licensee is conducting manufacturing activities, storage areas, records, production processes, labeling and packaging processes, and conveyances used in the manufacture, storage or transportation of cannabis products so that it may determine compliance with the provisions of the Act and these regulations. Departmental inspections may include, but are not limited to, all pertinent equipment, raw material, finished and unfinished materials, containers, packaging, and labeling that has a bearing on whether the cannabis product complies with the Act and these regulations.

(c) The Department may inspect any record or document that has a bearing on whether the labeling, advertising or marketing of a cannabis product complies with the requirements of Chapter 15 (commencing with section 26150) of the Act.

(d) To the extent necessary for the enforcement of the Act and this chapter, the Department may secure any sample or specimen of any cannabis product or ingredient used therein by the manufacturing operation. The Department's inspector or agent shall leave a receipt for the licensee describing any sample obtained prior to leaving the premises.

(e) The Department may analyze or examine any sample obtained. If an analysis is made of a sample, a copy of the results of the analysis shall be furnished to the licensee by the Department.

(f) The Department may conduct investigations concerning the adulteration, misbranding, false or misleading advertising or marketing, or unlicensed production of any cannabis product, and may enter and inspect any place where any cannabis

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product is suspected of being manufactured or held in violation of the Act or these regulations.

(g) The Department may collect evidence related to any alleged violation of the Act or the regulations for the purpose of preserving such evidence during the course of investigation and any subsequent enforcement proceedings.

(h) The Department may copy any materials, books, or records of any licensee or their agents pertaining to the commercial cannabis business.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; 26130; 26132; 26133; 26134; 26135; and 26160, Business and Professions Code.

#### **§40551. Notice to Comply.**

(a) The Department may issue a notice to comply to a licensee for violation(s) of the Act or regulations observed during an inspection.

(b) The notice to comply shall be in writing and describe the nature and facts of each violation, including a reference to the statute or regulation violated.

(c) The Department may serve the notice to comply prior to leaving the licensed premises on an owner, manager or other individual on the premises designated by the licensee to accept the notice, or may mail the notice to comply to the licensee within 15 ~~calendar~~ business days of the last date of inspection.

(d) The department shall specify a reasonable timeframe in the notice to comply for the licensee to correct the violation(s). Within the specified timeframe, the licensee shall notify the department of the corrective action(s) taken for each violation and describe how compliance was achieved. The Department may require the licensee to provide a corrective action plan for review and approval by the Department.

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(e) Failure to correct the violation(s) in the notice to comply may result in a disciplinary action or additional enforcement action by the Department.

Authority: Sections 26012; 26013; and 26130, Business and Professions Code.

Reference: Sections 26011.5; 26130; 26132; 26133; 26134; 26135; and 26160, Business and Professions Code.

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