

California Code of Regulations, Title 17

Division 1

Chapter 13. Manufactured Cannabis Safety

SUBCHAPTER 1. General Provisions and Definitions

Article 1. Definitions

§40100. Definitions.

In addition to the definitions in Business and Professions Code section 26001, the following definitions shall govern the construction of this chapter:

(a) "A-license" means a license issued for commercial cannabis activities involving cannabis and cannabis products that are intended for individuals 21 years of age and older and who do not possess physician's recommendations.

(b) "Act" means the Medicinal and Adult-Use Cannabis Regulation and Safety Act, codified at Business and Professions Code section 26000, et seq.

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

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

(e) "Adult-use Market" means the products intended for sale at an A-licensed retailer or microbusiness to individuals 21 years of age and older and who do not possess physician's recommendations.

(f) "Adulterated" or "adulteration" has the meaning stated in section 26131 of the Business and Professions Code.

(g) "Allergen" means a major food allergen including any of the following: (1) Milk, eggs, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. (2) A food ingredient that contains protein derived from a food specified in (1), except the following: Any highly refined oil derived from a food specified in (1) and any ingredient derived from such highly refined oil.

(h) "Allergen cross-contact" means the unintentional incorporation of a food allergen into a cannabis product.

(i) “Applicant” means the owner that is applying on behalf of the commercial cannabis business for a license to manufacture cannabis products.

(j) “Batch” or “production batch” means either:

(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.

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

(l) “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 resin obtained from cannabis, whether crude or purified, tinctures, capsules, suppositories, extracts, and vape cartridges.

(m) “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 product containing cannabis or concentrated cannabis and other ingredients.

(n) “Cannabis product quality,” “quality cannabis product,” or “quality” means that the cannabis product consistently meets the established specifications for identity, cannabinoid concentration (as defined in Section 5724 of Title 16 of the California Code of Regulations) , composition, and limits on contaminants (as defined in Section 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.

(o) “Cannabis waste” is waste that contains cannabis or cannabis products.

(p) “CBD” means the compound cannabidiol.

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

(r) “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” may include cannabis, cannabis products used as ingredients, other ingredients, and processing aids.

(s) “Contact surface” means any surface that contacts cannabis products and cannabis product components and those surfaces from which drainage, or other transfer, onto the cannabis product or cannabis product components, occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, and equipment.

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

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

(v) “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” does not include any product otherwise defined as “cannabis concentrate.”

(w) “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.

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

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

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

(aa) “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.

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

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

(dd) “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.

(ee) “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.

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

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

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

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

(jj) “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 processes;
- (B) Infusion processes;
- (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 dispensary 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 purpose of complying with section 26070.1 of the Act; or

(C) The collection of the glandular trichomes that are dislodged from the cannabis plant incident to cultivation activities.

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

(ll) “Microorganisms” means yeasts, molds, bacteria, viruses, protozoa, and/or 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.

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

(nn) “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.

(oo) “Package” or “packaging” means any container or wrapper that may be used for enclosing or containing any cannabis products. The term “package” does not include any shipping container or outer wrapping used solely for the transportation of cannabis products in bulk quantity to another licensee or licensed premises.

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

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

(rr) “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.

(ss) "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.

(tt) "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 subdivision (k) of section 26001 of the Business and Professions Code) will be or is conducted. The premises shall be a contiguous area and shall only be occupied by one licensee.

(uu) "Preventive controls" 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.

(vv) "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.

(ww) "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.

(xx) "Product Identity" or "identity of the product" means the generic name of the product type by which it is most commonly known. For edible products, the product identity shall not contain any trademarked identity of a traditional food product or the term "candy" or "candies."

(yy) "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.

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

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

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

(ddd) “Quarantine” means the storage or identification of a product, to prevent distribution or transfer of the product.

(eee) “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.

(fff) “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.

(ggg) “Serving” means the designated amount of cannabis product established by the manufacturer to constitute a single unit.

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

(iii) “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.

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

(kkk) “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.

(III) “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.

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

(nnn) “Validation” 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 effectively controlling the identified hazard.

(ooo) “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.

(ppp) “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.

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

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

Section 11018.1, Health and Safety Code.

§40101. Applicability.

(a) Unless otherwise specified, the requirements of this chapter apply to licensed manufacturers and to the manufacture of cannabis products for either the medicinal-use market or the adult-use market.

(b) The requirements of subchapters 3, 4, and 5 shall apply to licensed microbusinesses conducting manufacturing operations.

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

Reference: Sections 26050; and 26106, Business and Professions Code.

§40102. Owners and Financial Interest Holders.

(a) An owner shall mean any of the following:

(1) Any person that has an aggregate ownership interest, other than a security interest, lien, or encumbrance, in a commercial cannabis business of 20 percent or more;

(2) The chief executive officer of a commercial cannabis business;

(3) If a non-profit entity, each member of the Board of Directors;

(4) Any individual that will be participating in the direction, control, or management of the licensed commercial cannabis business. An owner who is an individual participating in the direction, control, or management of the commercial cannabis business includes any of the following:

(A) Each general partner of a commercial cannabis business that is organized as a partnership;

(B) Each non-member manager or managing member of a limited liability company for a commercial cannabis business that is organized as a limited liability company; and

(C) Each officer or director of a commercial cannabis business that is organized as a corporation.

(b) Persons that hold an ownership interest of less than 20 percent in a commercial cannabis business are considered to be financial interest holders for purposes of subsection (d) of section 26051.5 of the Act and shall be disclosed on the application for licensure. A financial interest means an investment into a commercial cannabis business, a loan provided to a commercial cannabis business, or any other equity interest in a commercial cannabis business.

(c) The following persons are not considered to be owners or financial interest holders:

(1) A bank or financial institution whose interest constitutes a loan;

(2) Persons whose only ownership interest in the commercial cannabis business is through an interest in a diversified mutual fund, blind trust, or similar instrument;

(3) Persons whose only financial interest is a security interest, lien, or encumbrance on property that will be used by the commercial cannabis business; and

(4) Persons who hold a share of stock that is less than 5 percent of the total shares in a publicly traded company.

Authority: Sections 26012; and 26013, Business and Professions Code. Reference: Sections 26001; and 26051.5, Business and Professions Code.

Article 2. General Provisions

§40115. License Required.

(a) Every person who manufactures cannabis products shall obtain and maintain a valid manufacturer license from the Department for each separate premises at which cannabis products will be manufactured.

(b) No person shall manufacture cannabis products without a valid license from the Department.

(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.

(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

(e) Licenses shall not be transferrable.

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

Reference: Sections 26053, Business and Professions Code.

§40116. Personnel Prohibited from Holding Licenses.

(a) A license authorized by the Act and issued by the Department may not be held by, or issued to, any person holding office in, or employed by, any agency of the State of California or any of its political subdivisions when the duties of such person have to do with the enforcement of the Act or any other penal provisions of law of this State prohibiting or regulating the sale, use, possession, transportation, distribution, testing, manufacturing, or cultivation of cannabis or cannabis products.

(b) This section applies to, but is not limited to, any persons employed in the State of California Department of Justice as a peace officer, in any district attorney's office, in any city attorney's office, in any sheriff's office, or in any local police department.

(c) All persons listed in subsection (a) or (b) may not have any ownership interest, directly or indirectly, in any business to be operated or conducted under a cannabis license.

(d) This section does not apply to any person who holds a license in the capacity of executor, administrator, or guardian.

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

Reference: Sections 26010 and 26012, Business and Professions Code.

§40118. Manufacturing License Categories and Types.

(a) Manufacturing licenses may be issued for either the adult-use market or the medicinal-use market.

(b) The following license types are available from the Department:

(1) "Type 7," for extractions using volatile solvents as defined by Section 40100. A Type 7 licensee may also:

(A) Conduct extractions using nonvolatile solvents or mechanical methods on the licensed premises provided that the extraction process is noted on the application form and the relevant information pursuant to Section 40131 is provided to the Department;

(B) Conduct infusion operations on the licensed premises, provided that the infusion method is noted on the application form and that the relevant information pursuant to Section 40131 is provided to the Department; and

(C) Conduct packaging and labeling of cannabis products on the licensed premises.

(2) "Type 6," for extractions using mechanical methods or nonvolatile solvents as defined by Section 40100. A Type 6 licensee may also conduct infusion operations and packaging and labeling of cannabis products on the licensed premises provided that the infusion method is noted on the application form and that the relevant information pursuant to Section 40131 is provided to the Department.

(3) “Type N,” for manufacturers that produce edible products or topical products using infusion processes, or other types of cannabis products other than extracts or concentrates. A Type N licensee may also package and label cannabis products on the licensed premises.

(4) “Type P,” for manufacturers that only package or repackage cannabis products or label or relabel the cannabis product container or wrapper. Manufacturers that engage in packaging or labeling of cannabis products as part of the manufacturing operation do not need to hold a separate Type P license.

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

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

SUBCHAPTER 2 – MANUFACTURING LICENSES

Article 1. Applications for Licensure

§40126. Temporary Licenses.

(a) To request a temporary license, an applicant shall submit to the Department the following:

(1) Form CDPH-9041 (10/17), which is hereby incorporated by reference.

(2) A copy of a local license, permit, or other authorization, issued by a local jurisdiction, that enables the applicant to conduct commercial cannabis business at the location requested for the temporary license. 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.

(b) A temporary license shall be valid for 120 days from the effective date. No temporary license shall be effective prior to January 1, 2018.

(c) A temporary license may be extended by the Department for additional 90-day periods if the holder of a temporary license submits a complete application for annual licensure to the Department pursuant to Section 40128 prior to the initial expiration date of the temporary license.

(d) A temporary license is a conditional license and authorizes the holder thereof to engage in commercial cannabis activity as would be permitted under the privileges of the license for which the applicant may submit an application to the licensing authority.

(e) Refusal by the Department to issue or extend a temporary license shall not entitle the applicant to a hearing or appeal of the decision. Chapter 2 (commencing with Section 480) of Division 1.5 and Chapter 4 (commencing with Section 26040) of the Business and Professions Code shall not apply to temporary licenses.

(f) A temporary license does not obligate the Department to issue an annual license to the temporary license holder, nor does the temporary license create a vested right in the holder to either an extension of the temporary license or to the granting of a subsequent annual license.

Authority: Sections 26013, and 26130, Business and Professions Code. Reference: Section 26050.1, Business and Professions Code.

§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 online submission, which includes all of the following information:

(A) Business information specified in Section 40129;

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

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

(2) The nonrefundable application fee as specified in Section 40150.

(b) The application shall be signed by the applicant under penalty of perjury that the information provided 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) If the licensed premises has 20 or more employees, the applicant will enter 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. A copy of the agreement shall be sent to the Department. If the applicant has not yet entered into a labor peace agreement, a notarized statement indicating the applicant will enter into and abide by the terms of a labor peace agreement shall be sent to the Department;

(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.

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 without a federal tax identification number, the applicant shall submit the social security number of the sole proprietor;

(3) The name(s) under which the business will operate (“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 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). A commercial cannabis business that is a foreign corporation shall include in its application the certificate of qualification issued by the Secretary of State of California;

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

(9) A list of financial interest holders, as defined in Section 40102;

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

(11) The license type applied for and whether the application is for medicinal or adult-use manufacturing.

(b) Pursuant to section 26055(e) of the Act, applicants may voluntarily submit a copy of a license, permit, or other authorization to conduct commercial cannabis manufacturing activities issued by the local jurisdiction. 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 that is an individual shall submit all of the following information:

(1) Name;

(2) Title or position held;

(3) Social security 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; and

(8) Disclosure of all of the following, including 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 citation, penalty or license sanction that is substantially related to the qualifications of a manufacturer as identified in Section 40162, subsections (f) and (g), 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.

(b) The owner form shall be signed by the owner under penalty of perjury that the information provided is complete, true, and accurate.

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

§40131. Annual License Application Requirements – Manufacturing Premises and Operations Information.

The applicant shall submit all of the following information regarding the manufacturing premises and operation:

(a) The physical address of the manufacturing premises;

(b) Whether the premises manufactures medicinal-use and/or adult-use cannabis products;

(c) The type of activity conducted at the premises (extraction, infusion, packaging, and/or labeling);

(d) The types of products that will be manufactured, packaged, or labeled;

(e) The name, title and phone number of the on-site individual who manages the operation of the premises;

(f) The name, title and phone number of an alternate contact person for the premises;

(g) The number of employees at the premises;

(h) The anticipated gross annual revenue from products manufactured at the premises. An applicant for an M-license shall submit the anticipated gross annual revenue from the sale of medicinal-use products manufactured at the premises and an applicant for an A-license shall submit the anticipated gross annual revenue from the sale of adult-use products manufactured at the premises;

(i) A premises diagram. The diagram shall be specific enough to enable ready determination of the bounds of the property and the proposed premises to be licensed, showing all boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows, and common or shared entryways. The diagram must show the areas in which all commercial cannabis activities will be conducted. The diagram shall be to scale. If the proposed premises consists of only a portion of a property, the diagram shall be labeled to indicate which part of the property is the proposed premises and identifying what the remaining property is used for.

(j) The following information:

(1) A description of inventory control procedures sufficient to demonstrate how the applicant will comply with the requirements of Section 40282, or a copy of the standard operating procedure addressing inventory control;

(2) A description of quality control procedures sufficient to demonstrate how the applicant will comply with all of the applicable requirements specified in Sections 40232-40268 or a copy of the standard operating procedure addressing quality control;

(3) A description of the transportation process to be used by the applicant that is in compliance with state law, or a copy of the standard operating procedure addressing transportation;

(4) A description of security procedures sufficient to demonstrate how the applicant will comply with the requirements of Section 40200, or a copy of the standard operating procedure addressing security procedures;

(5) A description of the waste disposal procedures sufficient to demonstrate how the applicant will comply with the requirements of Section 40290, or a copy of the standard operating procedure addressing waste management.

(k) A written statement signed by the owner of the property, or the owner's agent, identifying the physical location of the property and acknowledging and consenting to the manufacture of cannabis products on the property. The name, address and contact phone number for the owner or owner's agent shall be included.

(l) Any manufacturer submitting operating procedures and protocols to the Department pursuant to the Act and this chapter may claim such information as a trade secret or confidential by clearly identifying such information as "confidential" on the document at the time of submission. Any claim of confidentiality by a manufacturer must be based on the manufacturer's good faith belief that the information marked as confidential constitutes a trade secret as defined in Civil Code section 3426.1(d), or is otherwise exempt from public disclosure under the California Public Records Act in Government Code section 6250 et seq.

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

Reference: Sections 26050; 26050.1; 26055; and 26130, Business and Professions Code.

§40133. Limited Waiver of Sovereign Immunity.

(a) Any applicant or licensee that may fall within the scope of sovereign immunity that may be asserted by a federally recognized tribe or other sovereign entity must waive any sovereign immunity defense that the applicant or licensee may have, may be asserted on its behalf, or may otherwise be asserted in any state administrative or judicial enforcement actions against the applicant or licensee, regardless of the form of relief sought, whether monetary or otherwise, under the state laws and regulations governing commercial cannabis activity. The applicant or licensee must submit a written waiver of sovereign immunity to the Department with any license application or renewal, which is valid for the period of the license. The written waiver shall include that the applicant or licensee has the lawful authority to enter into the waiver required by this

section, the applicant or licensee hereby waives sovereign immunity, and the applicant or licensee agrees to do all of the following:

(1) Provide documentation to the Department that establishes that the applicant or licensee has the lawful authority to enter into the waiver required by this section;

(2) Conduct all commercial cannabis activity in full compliance with the state laws and regulations governing commercial cannabis activity, including submission to all enforcement provisions thereof;

(3) Allow access as required by state statute or regulation by persons or entities charged with duties under the state laws and regulations governing commercial cannabis activity to any premises or property at which the applicant conducts any commercial cannabis activity, including premises or property where records of commercial cannabis activity are maintained by or for the applicant or licensee;

(4) Provide any and all records, reports, and other documents as may be required under the state laws and regulations governing commercial cannabis activity;

(5) Conduct commercial cannabis activity with other state commercial cannabis licensees only, unless otherwise specified by state law;

(6) Meet all of the requirements for licensure under the state laws and regulations governing the conduct of commercial cannabis activity, and provide truthful and accurate documentation and other information of the applicant's qualifications and suitability for licensure as may be requested;

(7) Submit to the personal and subject matter jurisdiction of the California courts to address any matter related to the waiver or the commercial cannabis application, license, or activity, and that all such matters and proceedings shall be governed, construed, and enforced in accordance with California substantive and procedural law, including but not limited to the Medicinal and Adult-Use Cannabis Regulation and Safety Act and the Administrative Procedure Act;

(b) The Department shall not approve an application for a state license if approval of the license would violate the provisions of any local ordinance or regulation adopted in accordance with Section 26200 of the Act that is issued by the county or, if within a city, the city, within which the licensed premises is to be located.

(c) Any applicant or licensee must immediately notify the Department of any changes that may materially affect the applicant and licensee's compliance with subdivision (a).

(d) Any failure by an applicant or licensee to comply with the requirements of subdivisions (a) or (c) shall be a basis for denial of an application or renewal or discipline of a licensee.

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

Reference: Section 26011.5, Business and Professions Code.

§40135. Incomplete Applications.

(a) Incomplete applications will not be processed. Applications will only be considered complete if all of the information requested under Sections 40128 to 40131 is included. The Department shall issue a written notice to the applicant informing them of any information missing from the application.

(b) If the applicant fails to submit the required information within 180 days from the date of notice, the application shall be deemed abandoned.

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

Reference: Section 26050, Business and Professions Code.

§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 online submission.

(b) An applicant may reapply for annual licensure at any time subsequent to the withdrawal of an application.

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

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

Article 3. Fees

§40150. Application and License Fees.

Manufacturer application fees and annual license fees shall apply to all manufacturer applicants and licensees, as follows:

- (a) A nonrefundable application processing fee of \$1,000 for each new application submitted.
- (b) The annual license fee, based upon a sliding scale, calculated as follows:
 - (1) For a licensed premises with an annual gross revenue of up to \$100,000 (Tier I), the fee shall be \$2,000.
 - (2) For a licensed premises with annual gross revenue of \$100,001 to \$500,000 (Tier II), the fee shall be \$7,500.
 - (3) For a licensed premises with annual gross revenue of \$500,001 to \$1,500,000 (Tier III), the fee shall be \$15,000.
 - (4) For a licensed premises with annual gross revenue of \$1,500,001 to \$3,000,000 (Tier IV), the fee shall be \$25,000.
 - (5) For a licensed premises with annual gross revenue of \$3,000,001 to \$5,000,000 (Tier V), the fee shall be \$35,000.
 - (6) For a licensed premises with an annual gross revenue of \$5,000,001 to \$10,000,000 (Tier VI), the fee shall be \$50,000.
 - (7) For a licensed premises with an annual gross revenue of over \$10,000,000 (Tier VII), the fee shall be \$75,000.

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

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

Article 4. Approval or Denial of Application for Licensure

§40155. New License Approval.

- (a) The Department shall notify the applicant upon approval of a license application.
- (b) The applicant shall pay the applicable license fee specified in Section 40150(b) within 30 calendars days of notification.
- (c) The license shall become effective on the date the Department receives the applicable license fee in full.

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

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

§40156. Priority License Issuance.

(a) Priority in issuance of licenses shall be given to applicants that can demonstrate that the commercial cannabis business was in operation under the Compassionate Use Act of 1996, Health and Safety Code sections 11362.5 et seq., as of September 1, 2016.

(b) Eligibility for priority in application processing shall be demonstrated by any of the following, dated prior to September 1, 2016:

(1) Local license or permit or other written authorization;

(2) Collective or Cooperative Membership Agreement;

(3) Tax or business forms submitted to the Board of Equalization or Franchise Tax Board;

(4) Incorporation documents; or

(5) Any other business record that demonstrates the operation of the business prior to September 1, 2016.

(c) Any applicant identified by the local jurisdiction pursuant to section 26054.2(b) of the Act shall be considered eligible for priority issuance.

(d) The Department may request additional documentation to verify the applicant's date of commencement of operations.

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

Reference: Sections 26012; 26054.2; and 26130, Business and Professions Code.

§40159. Denial of License.

(a) The Department may deny an application for a new or renewal license for any reason specified in section 26057 (b) of the Act. Further, the Department may deny a new or renewal license application for any of the following additional reasons:

(1) The applicant, an owner, or licensee made a material misrepresentation in the application for the license;

(2) An owner of the commercial cannabis business has been convicted of a crime or has committed a violation of law substantially related to the qualifications, functions, or duties of a manufacturer as identified in Section 40162;

(3) The applicant or licensee has been denied a license to engage in commercial cannabis activity by a state licensing authority; or

(4) The applicant or licensee has denied the Department access to the premises.

(b) The Department shall deny an application for new or renewal license if the proposed manufacturing operation or premises would violate the applicable local ordinance.

(c) A conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere.

(d) Prior to denial of a license based upon paragraph (2) of subsection (a), the Department shall consider any evidence of rehabilitation as provided in Section 40165.

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

Reference: Section 26057, Business and Professions Code.

§40162. Substantially Related Acts.

For the purpose of denial of a license, a conviction or violation from any jurisdiction that is substantially related to the qualifications, functions, and duties of the business for which the application is made include:

(a) A violent felony conviction, as specified in subdivision (c) of Section 667.5 of the Penal Code;

(b) A serious felony conviction, as specified in subdivision (c) of Section 1192.7 of the Penal Code;

(c) A felony conviction involving fraud, deceit, or embezzlement;

(d) A felony conviction for hiring, employing, or using a minor in transporting, carrying, selling, giving away, preparing for sale, or peddling any controlled substance to a minor, or offering, furnishing, or selling any controlled substance to a minor;

(e) A felony conviction for drug trafficking with enhancements pursuant to Health and Safety Code sections 11370.4 or 11379.8;

(f) A violation of section 110620, 110625, 110630, 110760, 110765, 110770, 110775, 111290, 111295, 111300, 111440, 111445, 111450, or 111455 of the Health and Safety Code (Sherman Food, Drug, and Cosmetic Law) that resulted in suspension or revocation of a license, administrative penalty, civil proceeding or criminal conviction;

(g) A violation of sections 111950-112130 of the Health and Safety Code (California Food Sanitation Act) that resulted in suspension or revocation of a license, administrative penalty, civil proceeding or criminal conviction;

(h) A conviction of section 382 or 383 of the Penal Code; or

(i) A violation of law identified in subsections (f) or (g) committed by a business entity in which an owner was an officer or had an ownership interest is considered a violation that is substantially related to the owner's qualifications for licensure.

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

Reference: Sections 26011.5; and 26057, Business and Professions Code.

§40165. Criteria for Evidence of Rehabilitation.

(a) When evaluating whether a license should be issued or denied when an owner has been convicted of a criminal offense or committed a violation of law that is substantially related to the qualifications, functions, or duties of the business for which the application is made, the Department shall consider the following criteria in its evaluation of evidence of rehabilitation:

- (1) The nature and severity of the act or offense, including the actual or potential harm to the public;
- (2) The owner's criminal record as a whole;
- (3) Evidence of any act committed subsequent to the act or offense under consideration that could be considered grounds for denial, suspension, or revocation of a manufacturing license;
- (4) The time elapsed since commission of the act or offense listed in Section 40162, or in section 26057, subdivision (b)(4) of the Business and Professions Code;
- (5) The extent to which the owner has complied with any terms of parole, probation, restitution, or any other sanctions lawfully imposed against the applicant or licensee;
- (6) If applicable, evidence of expungement proceedings under Penal Code section 1203.4 or a similar law in another state;
- (7) If applicable, a certificate of rehabilitation obtained under Penal Code section 4852.01 or a similar law in another state; and
- (8) Other evidence of rehabilitation submitted by the owner.

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

Reference: Sections 26011.5; 26055; and 26057, Business and Professions Code.

§40167. Appeal of License Denial.

(a) Upon denial of an application for a license, the Department shall notify the applicant in writing of the reasons for the denial and the right to a hearing to contest the denial.

(b) The applicant may request a hearing by filing a written request with the Department within 30 calendar days of service of the notice of denial. The written request for hearing must be postmarked within the 30-day period. If a request is not filed within the 30-day period, the applicant's right to a hearing is waived.

(c) Upon receipt of the request for hearing, the Department shall commence proceedings in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

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

Reference: Sections 26058, Business and Professions Code.

§40169. Notification of Criminal Acts, Civil Judgments, and Revocation of a Local License, Permit, or Other Authorization after Licensure.

(a) A licensee shall notify Department in writing of a criminal conviction of any owner, either by mail or electronic mail, within 48 hours of the conviction. The written notification to the Department shall include the date of conviction, the court docket number, the name of the court in which the licensee was convicted, and the specific offense(s) for which the licensee was convicted.

(b) A licensee shall notify the Department in writing of a civil penalty or judgment rendered against the licensee or any owner in their individual capacity, either by mail or electronic mail, within 48 hours of delivery of the verdict or entry of judgment, whichever is sooner. The written notification to the Department shall include the date of verdict or entry of judgment, the court docket number, the name of the court in which the matter was adjudicated, and a description of the civil penalty or judgement rendered against the licensee.

(c) A licensee shall notify the Department in writing of the revocation of a local license, permit, or other authorization, either by mail or electronic mail, within 48 hours

of receiving notice of the revocation. The written notification shall include the name of the local agency involved, a written explanation of the proceeding or enforcement action, and the specific violation(s) that led to revocation.

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

Reference: Section 26031, Business and Professions Code.

Article 5. Licensing

§40175. License Constraints.

(a) A manufacturer licensee shall not manufacture, prepare, package or label any products other than cannabis products at the licensed premises. For purposes of this section, the term “cannabis products” also includes products that do not contain cannabis, but are otherwise identical to the cannabis-containing product, and are intended for use as samples.

(b) No licensee shall employ an individual under 21 years of age.

(c) A M-licensee shall only conduct commercial cannabis activities with M-licensees.

(d) An A-licensee shall only conduct commercial cannabis activities with A-licensees.

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

Reference: Sections 26050; and 26140, Business and Professions Code.

§40177. Change in Licensed Operations.

(a) At any time after issuance of a license and prior to submission of an application to renew the license, a licensee may request to change the manufacturing operations conducted at the licensed premises. To request approval for additional manufacturing operations, the licensee shall submit the following:

(1) The information required under Section 40131; and

(2) A non-refundable \$1,000 application processing fee to review all documents.

(b) The information submitted under subsection (a) shall be evaluated on a case-by-case basis by the Department, and upon approval of the request by the Department, the

licensee may begin conducting the additional manufacturing operation. The existing license shall be amended to reflect the change in operations, but the date of expiration shall not change.

(c) Pursuant to section 26055, subdivision (c) of the Act, the licensee shall also obtain approval from the Department prior to making any material or substantial changes to the premises. The request describing the proposed material or substantial change shall be submitted in writing to the Department and shall be evaluated on a case-by-case basis.

(d) Licensees that choose to cease operation of any licensed activity shall notify the Department within 10 days of cessation of the activity. License fees shall not be prorated or refunded upon cessation of any activity.

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

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

§40178. Add or Remove Owner(s).

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

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

Reference: Sections 26050; and 26057, Business and Professions Code.

§40180. License Renewal.

(a) An application for renewal of a manufacturing license shall be submitted to the Department at least 30 calendar days prior to the expiration date of the current license. No renewal application shall be accepted by the Department more than 60 calendar days prior to the expiration date of the current license.

(b) If a complete renewal application is submitted in a timely manner, the licensee may continue to operate until the Department approves or denies the renewal application. For purposes of this section, “timely manner” means postmarked no later than, or submitted through the online database no later than 11:59 pm on, the expiration date of the current license.

(c) After expiration of the license, a licensee shall submit a late fee of \$500 to be paid in addition to the required annual renewal fee in order to renew the license.

(d) A licensed manufacturer that does not submit a complete license renewal application, including, if applicable, the required late fee, to the Department within 30 calendar days after the expiration of the license shall forfeit their eligibility to apply for a license renewal and, instead, shall be required to submit a new license application.

(e) To apply for a license renewal, the licensee shall submit any changes to their original license information (as required by Section 40128) on a form prescribed by the Director, or through online submission; and shall sign the renewal form under penalty of perjury. Upon approval of the renewal application, the licensee shall submit the annual license fee as specified in subsection (b) of Section 40150.

(f) All owners shall also provide the information required by Section 40130, include any change in information, and sign the form under penalty of perjury.

(g) Licensees and owners applying for license renewal are not required to submit fingerprints to the Department of Justice if they have previously submitted fingerprints with an application for a cannabis manufacturer license.

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

Reference: Sections 26050; 26051.5; and 26180, Business and Professions Code.

§40182. Disaster Relief.

(a) If a licensee is unable to comply with any licensing requirement due to a disaster, the licensee may notify the Department of this inability to comply and request relief from the specific licensing requirement.

(b) The Department may exercise its discretion to provide temporary relief from specific regulatory requirements in this chapter and from other licensing requirements when allowed by law.

(c) Temporary relief from specific licensing requirements shall be issued for a reasonable amount of time in order to allow the licensee to recover from the disaster.

(d) The Department may require that certain conditions be followed in order for a licensee to receive temporary relief from specific licensing requirements.

(e) A licensee shall not be subject to an enforcement action for a violation of a licensing requirement in which the licensee has received temporary relief.

(f) For purposes of this section, “disaster” means fire, flood, storm, tidal wave, earthquake, or similar public calamity, whether or not resulting from natural causes.

(g) Notwithstanding subsection (a) of this section, if a licensee needs to move cannabis or cannabis products stored on the premises to another location immediately to prevent loss, theft, or degradation of the cannabis or cannabis products from the disaster, the licensee may move the cannabis or cannabis products without obtaining prior approval from the Department if the following conditions are met:

(1) The cannabis or cannabis products are moved to a secure location where access to the cannabis or cannabis products can be restricted to the licensee, its employees, and its contractors;

(2) The licensee notifies the Department in writing that the cannabis or cannabis products have been moved and that the licensee is requesting relief from complying with the specific licensing requirements pursuant to subsection (a) of this section within 24 hours of moving the cannabis or cannabis products;

(3) The licensee agrees to grant the Department access to the location where the cannabis or cannabis products have been moved;

(4) The licensee submits in writing to the Department within 10 days of moving the cannabis or cannabis products a request for temporary relief that clearly indicates what

statutory and regulatory sections relief is requested from, the time period for which the relief is requested, and the reasons relief is needed for the specified amount of time.

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

Reference: Section 26012, Business and Professions Code.

SUBCHAPTER 3. REQUIREMENTS OF OPERATION

Article 1. Safety and Security

§40200. Security Plan.

Every applicant and licensee shall develop and implement a security plan. At a minimum, the security plan shall include a description of the security measures to be taken to:

(a) Prevent access to the manufacturing premises by unauthorized personnel and protect the physical safety of employees. This includes, but is not limited to:

(1) Establishing physical barriers to secure perimeter access and all points of entry into a manufacturing premises (such as locking primary entrances with commercial-grade, non-residential door locks, or providing fencing around the grounds, driveway, and any secondary entrances including windows, roofs, or ventilation systems);

(2) Installing a security alarm system to notify and record incident(s) where physical barriers have been breached;

(3) Establishing an identification and sign-in/sign-out procedure for authorized personnel, suppliers, and/or visitors;

(4) Maintaining the premises such that visibility and security monitoring of the premises is possible; and

(5) Establishing procedures for the investigation of suspicious activities.

(b) Prevent against theft or loss of cannabis and cannabis products. This includes but is not limited to:

(1) Establishing an inventory system to track cannabis and cannabis products and the personnel responsible for processing it throughout the manufacturing process;

(2) Limiting access of personnel within the premises to those areas necessary to complete job duties, and to those time-frames specifically scheduled for completion of job duties;

(3) Supervising tasks or processes with high potential for diversion (including the loading and unloading of cannabis transportation vehicles); and

(4) Providing designated areas in which personnel may store and access personal items.

(c) Secure and back up electronic records in a manner that prevents unauthorized access and that ensures the integrity of the records is maintained.

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

Reference: 26011.5; and 26051.5, Business and Professions Code.

§40205. Video Surveillance.

(a) At a minimum, 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) The video surveillance system shall be accessible via remote access by the licensee.

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

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

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

(2) Limited-access areas;

(3) Security rooms;

(4) Areas containing surveillance-system storage devices 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.

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

(f) All recording and monitoring equipment shall be located in secure rooms or areas of the premises in an access-controlled environment.

(g) All surveillance recordings shall be kept on the licensee's recording device for a

minimum of 90 days.

(h) All video surveillance recordings are subject to inspection by the Department and shall be copied and sent, or otherwise provided, to the Department upon request.

(i) 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.

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

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

Article 2. Extractions

§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 food-grade glycerin. Nonhydrocarbon-based solvents shall be food grade;

(3) Chemical extraction using a professional closed loop CO₂ gas extraction system;

(4) Chemical extraction using a volatile solvent, as defined in Section 40100; or

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

(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.

§40222. Volatile Solvent Extractions.

Chemical extractions using volatile solvents shall be subject to the following requirements:

- (a) Hydrocarbon-based solvents shall be at least 99 percent purity;
- (b) All extractions shall be performed in a closed loop extraction system as described in Section 40225;
- (c) No volatile solvent extraction operations shall occur in an area zoned as residential; and
- (d) The extraction operation shall be approved by the local fire code official and shall be operated in accordance with all relevant state and local requirements.

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

Reference: Sections 26011.5; 26105; and 26130, Business and Professions Code.

§40223. Ethanol Extractions.

(a) Ethanol used for extractions or for post-extraction processing shall be food-grade.

(b) The extraction operation shall be approved by the local fire code official and shall be operated in accordance with Division of Occupational Health and Safety (Cal/OSHA) regulations and any other relevant state and local requirements.

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

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

§40225. Closed-Loop Extraction System Requirements.

(a) Chemical extractions using CO₂ or a volatile solvent shall be conducted in a professional closed loop extraction system. The system shall be commercially manufactured and bear a permanently affixed and visible serial number. The system shall be certified by a California-licensed engineer that the system was commercially manufactured, safe for its intended use, and built to codes of recognized and generally accepted good engineering practices, such as:

- (1) The American Society of Mechanical Engineers (ASME);
- (2) American National Standards Institute (ANSI);
- (3) Underwriters Laboratories (UL); or
- (4) The American Society for Testing and Materials (ASTM).

(b) Professional closed loop systems, other equipment used, the extraction operation, and facilities must be approved for use by the local fire code official and comply with any required fire, safety, and building code requirements related to the processing, handling and storage of the applicable solvent or gas.

(c) The certification document required pursuant to subsection (a) shall contain the signature and stamp of a California-licensed professional engineer and the serial number of the extraction unit being certified.

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

Reference: Section 26011.5, Business and Professions Code.

Article 3. Good Manufacturing Practices

§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 their health condition is corrected. Open lesions, boils, and/or 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/or 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.

(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 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 facility so that the premises shall 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.

(d) The provision and maintenance of waste treatment 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 grounds of the cannabis manufacturing facility are 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 cannabis manufacturing facility in order to eliminate any pests, dirt, and/or 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.

§40236. Facility Construction and Design.

At minimum, a cannabis manufacturing facility 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 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/or 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) Buildings, fixtures, and other physical facilities on the premises are maintained in a clean and sanitary condition and are kept in good repair so as to prevent cannabis products from becoming adulterated.

(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 facility where cannabis products are processed or exposed:

- (1) Those required to maintain clean and sanitary conditions;
- (2) Those necessary for facility and equipment maintenance and operation; and
- (3) Those necessary for use in the cannabis manufacturing facility's 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 facility in all areas where cannabis components and/or products may be at risk of contamination by pests. The use of pesticides to control pests in the cannabis manufacturing facility 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 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 facility 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.

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

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

§40240. Sanitary Facilities and Controls.

The facility 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/or 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 facility.

(2) Properly convey sewage and liquid disposable waste from the facility.

(3) Avoid the creation of unsanitary conditions and/or 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 facility shall provide employees with adequate, readily accessible toilet facilities. Toilet facilities shall be kept clean 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 facility 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.

§40242. Equipment and Utensils.

(a) All cannabis 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.

(c) Equipment shall be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(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, including prohibited additives specified in Section 40300.

(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 accurate, precise, adequately maintained and calibrated, and be provided in an adequate number for their designated use(s).

(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.

Article 4. Production and Process Controls

§40250. General Provisions.

(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 and to 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.

(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.

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 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 contains 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 bulk, or 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.

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 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 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, breadings, 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 a_w 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 or and evaluate known or reasonably foreseeable hazards for each type of cannabis product produced at their facility in order to determine whether there exist any hazards requiring a preventive control. The hazard analysis shall include:

(a) The identification of potential 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/or

(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;

(2) The product formulation;

(3) The design, function and condition of the manufacturing facility 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/or 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. The points, steps or procedures in a given process in 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. 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 occurrence of an identified hazard. For example: the establishment of specific limits on temperature, humidity, or pH.

(c) The establishment and implementation of monitoring procedures in order to use monitoring results to adjust a given process and maintain control. This shall include specifying the frequency and documentation requirements for monitoring.

(d) The establishment and implementation of corrective actions to be taken when monitoring indicates there is a deviation from an established critical limit. 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;

(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.

(e) The establishment and implementation of record keeping procedures to document hazard analyses and control plans, identify the person responsible for each step, and identify the corrective actions that were taken upon of the discovery of a deviation. These records shall be subject to review by the Department.

(f) 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.

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

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

§40260. Equipment and Machinery Qualification.

(a) The licensee shall establish and implement written procedures to ensure that each piece of equipment and machinery is suitable for its intended use prior to operation. These procedures include, but are not limited to:

(1) Procedures for validating that all equipment and machinery has design specifications, operating procedures, and performance characteristics appropriate for its intended use by the licensee.

(2) Procedures for validating that all equipment and machinery are built as designed with proper materials, capacity, and functions, and properly installed, connected, and calibrated.

(3) Procedures for validating that all equipment and machinery perform in accordance with quality requirements in all anticipated operating ranges using the licensee's standard operating procedures. Operating ranges shall be shown to be capable of being held as long as would be necessary during routine production.

(4) The establishment of a schedule for routine re-verification of all equipment and machinery.

(b) The licensee shall maintain verification records for all equipment and machinery, which contain at minimum:

(1) Documentation of successful verification of each piece of equipment and machinery, dated and signed by the person conducting the verification.

(2) Documentation of successful re-verifications of each piece of equipment and machinery upon any modification to the equipment or machinery, intended use, or standard operating procedure.

(3) A log documenting the verification and re-verification of all equipment and machinery in operation on the licensed premises.

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

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

§40262. Master Manufacturing Protocol.

The licensee shall establish and follow a written master manufacturing protocol for each unique formulation of cannabis product manufactured, and for each batch size, 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 per serving 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;

(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 expected yield of the finished product, including the maximum and minimum percentages of theoretical yield beyond

which a deviation investigation of a batch is necessary and material review is conducted and disposition decision 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;

(B) Procedures for product and/or batch sampling and a cross-reference to procedures for tests or examinations of products and/or 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, or other law enforcement agencies. The licensee may consider the master manufacturing protocol 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.

§40264. 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 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 (or, when applicable, to a cannabis product received from a supplier for packaging or labeling as a cannabis product), packaging, and label used;

(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 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

(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 required monitoring operation(s) required by this article;

(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.

(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 history of work performed; including:

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

- (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 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.

§40266. 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;

(c) Pursuant to subdivisions (a) and (b) in this section, any review and/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/or 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; and
- (6) Any findings of the investigation and/or follow-up action taken when an investigation is performed.

(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 incorrect concentration of cannabinoids, or cannabis products 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.

§40268. 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/or other licensees for the return and/or destruction of 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 in accordance with Section 40290, and do so on

video surveillance in accordance with Section 40205. A recalled cannabis product that has been rendered unusable and unrecognizable is considered cannabis waste and shall be disposed of in accordance with Section 40290.

(3) A licensee shall dispose of chemical, dangerous, or hazardous waste in a manner consistent with federal, state, and local laws. This requirement shall include but is not limited to recalled products containing or consisting of pesticide or other agricultural chemicals, solvents or other chemicals used in the production of manufactured cannabis batches, and cannabis soaked in a flammable solvent for the purpose of producing manufactured cannabis batches.

(4) A licensee shall not dispose of recalled cannabis product in an unsecured area or waste receptacle that is not in the possession and/or control of the licensee.

(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. For recalled cannabis products, the licensee shall enter the following details into the track and trace database: the weight 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.

Article 5. Special Processing Requirements

§40270. Juice Processing.

(a) Requirements of this section shall apply to manufacturers of cannabis-infused juice to be sold as either 100% juice or to be used as an ingredient in other products. The requirements of this section do not apply to manufacturers of infused beverages that use non-infused juice as an ingredient.

(b) Manufacturers of juice shall prepare a written juice hazard analysis and control plan in accordance with the requirements of 21 CFR, Part 120, subpart B, (Rev. January 2001), which is hereby incorporated by reference.

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

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

§40272. Dried Meat Processing.

Manufacturing of cannabis-infused dried meat products shall be conducted in accordance with the United States Department of Agriculture *FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments: 2014 Compliance Guideline* (Rev. 2014), which is hereby incorporated by reference. Meat for processing into dried meat products shall be acquired from a commercially-available source.

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

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

Article 6. Other Responsibilities

§40275. Standard Operating Procedures.

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:

(a) Any policies or procedures developed in accordance with the security plan required by Section 40200;

(b) Emergency response procedures;

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

- (d) Policies and procedures developed in accordance with Article 4 of this subchapter (Production and Process Control);
- (e) Procedures for complying with the track-and-trace requirements established in Article 2 of subchapter 5;
- (f) Inventory control procedures in compliance with Section 40282; and
- (g) Waste management procedures in compliance with Section 40290.

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

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

§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) Bulk shipments of cannabis and cannabis products shall be weighed by a licensed weighmaster, and shall be issued a certificate consistent with the requirements in Chapter 7 (commencing with section 12700) of Division 5 of Business and Professions Code.

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

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

§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:

(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 material safety data sheet for each solvent or chemical;

(C) Emergency procedures;

(D) Security procedures;

(E) Record keeping requirements; and

(F) Training requirements.

(2) 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;

(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 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. For licensees in operation

pursuant to Section 40126, applicable personnel shall complete the ANSI-accredited food handler course no later than 90 days after the effective date of the annual license. 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 section. This annual refresher training must be completed within 12 months of the previous training completion date.

(b) The licensee shall maintain a record 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 the individual personnel and the licensee verifying receipt and understanding of each training or refresher training completed by the personnel; 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 designated training personnel shall sign and date a document on an annual basis attesting that he or she has received and understands all information and training provided in the training program. This documentation shall be maintained as part of the record requirements.

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

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

§40282. Inventory Control – Cannabis and Cannabis Products.

(a) A licensee shall establish and implement a written inventory control plan capable of tracking the location and disposition of all cannabis and cannabis products at the licensed premises.

(b) A licensee shall reconcile the on-hand inventory of cannabis and cannabis products at the licensed premises with the records in the track-and-trace database least once every thirty (30) calendar days. Reconciliation shall be performed by one person and independently verified by a second person.

(c) If a licensee finds a discrepancy between the inventory and the track-and-trace database, the licensee shall conduct an audit.

(d) The licensee shall notify the Department within 24 hours of the completion of the audit if the audit reveals a discrepancy that is not within five percent of the documented inventory.

(e) If a licensee finds evidence of suspected theft or diversion, the licensee shall report the suspected theft or diversion to the Department within 24 hours of the discovery.

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

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

§40290. Waste Management.

(a) A licensee shall dispose of all waste, including cannabis waste, in accordance with applicable state and local laws and regulations. It is the responsibility of the licensee to properly evaluate waste to determine if it should be designated a hazardous waste under 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 local government, or private waste hauler permitted by the local government only. Public access to the designated receptacle or area shall be strictly prohibited.

(c) No cannabis product shall be disposed of in its packaging, and all cannabis products shall be 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.

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

(1) Provide the Department with the name of the entity hauling the waste;

(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

(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 to one, or more, of the solid waste facilities in subsection (e)(3) of this section, a licensee shall obtain for each delivery of cannabis waste by the licensee a copy of a certified weight ticket or receipt documenting delivery 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.

§40292. Consent to Sample Collection.

A manufacturer licensee that transfers possession but not title of cannabis products to a licensed distributor shall allow the Bureau, upon the Bureau's request, to collect samples for purposes of conducting oversight of licensed testing laboratories.

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

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

SUBCHAPTER 4. PRODUCTS

Article 1. Cannabis Product Standards

§40299. Applicability.

The requirements of this subchapter shall apply to cannabis products manufactured on or after January 1, 2018.

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

Reference: Section 26130, Business and Professions Code.

§40300. Prohibited Products.

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

(a) Alcoholic beverages, as defined in section 23004 of the Business and Professions Code. For purposes of this section, “alcoholic beverage” does not include tinctures.

(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; or 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;

(d) Any low-acid cannabis product with a finished equilibrium pH greater than 4.6 and water activity greater than 0.85, packed in a hermetically sealed container in a reduced oxygen package (e.g. vacuum packed);

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

(f) Dairy products of any kind, as prohibited by subdivision (t) of section 26001 of the Business and Professions Code, 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;

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

(h) Seafood products of any kind;

(i) 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;

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

(k) 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.

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

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) Edible cannabis products shall not contain more than ten (10) milligrams of THC per serving.

(b) Edible cannabis products shall not contain more than one hundred (100) milligrams of THC per package.

(c) 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>.

(d) Edible cannabis products that consist of more than a single serving shall 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.

(e) Each serving of an edible cannabis product in a multi-serving package shall be homogenized to contain the same concentration of THC, within the variance established by the Bureau through regulation in Section 5716 of Title 16 of the California Code of Regulations.

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

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

§40306. Requirements for Topical Cannabis Products, Concentrates, and Other Cannabis Products.

(a) A cannabis product that is not an edible cannabis product and that is manufactured for the adult-use market shall not contain more than 1,000 mg of THC per package.

(b) A cannabis product that is not an edible cannabis product and that is manufactured for the medicinal market shall not contain more than 2,000 mg of THC per package.

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

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

Reference: Section 26011.5, Business and Professions Code.

§40310. Failed Product Batches.

(a) No finished cannabis product shall contain a contaminant identified in Section 26100 of the Act at a level set by the Bureau in Section 5718 to 5723, inclusive, of Title 16 of the California Code of Regulations. Any cannabis product batch that fails a laboratory testing requirement required by section 26100 of the Act is adulterated and may be embargoed pursuant to section 26133 of the Act.

(b) Any cannabis product batch that fails quality assurance review required pursuant to section 26100 of the Act is misbranded and may be embargoed pursuant to section 26133 of the Act.

(c) Failed product batches shall be destroyed unless a corrective action plan for remediation or reprocessing is approved by the Department. Corrective action plans shall be approved by the Department on a case-by-case basis.

(d) Remediation or reprocessing of failed product batches or the use of harvest batches that have failed any laboratory test shall comply with any requirements and procedures established by the Bureau in Sections 5727 and 5728 of Title 16 of the California Code of Regulations, in addition to the requirements of this chapter.

(e) Edible products that fail laboratory testing requirements shall not be remediated or reprocessed and shall be destroyed. If any edible product that has failed laboratory testing is remediated, reprocessed, or otherwise mixed with another batch of cannabis product, such action shall render the final cannabis product adulterated, regardless of the defect level of the final cannabis product.

(f) Notwithstanding subsection (e), a cannabis product that is determined through laboratory testing to be labeled with an incorrect amount of THC per package or per serving may be relabeled with the correct information in accordance with a corrective action plan approved by the Department, provided that the THC limits under Sections 40305 and 40306 are met.

(g) Prior to any remediation or reprocessing of a failed product batch or the use of a failed harvest batch, the licensee shall submit a corrective action plan to the Department

to include, at minimum, a description of how the product or harvest batch will be remediated such that the product or any product produced therefrom will meet all laboratory testing and quality assurance requirements. A failed product or harvest batch shall not be remediated or reprocessed by a licensee unless the Department has approved the licensee's corrective action plan. Remediation or reprocessing of edible products shall not be approved.

(h) Any remediation or reprocessing of a product batch that has failed laboratory testing or quality assurance review or the use of a failed harvest batch by a licensee shall be documented in the manufacturing records. All remediated product batches and 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.

SUBCHAPTER 5. LABELING AND PACKAGING REQUIREMENTS

Article 1. General Provisions

§40400. Applicability.

(a) The requirements in this subchapter shall apply to finished cannabis products and shall not apply to cannabis or cannabis products that are transferred between licensees for purpose of further processing or packaging.

(b) Except as otherwise provided in Section 40601, the requirements of this subchapter shall apply to any cannabis product manufactured on or after January 1, 2018.

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

Reference: Section 26130; Business and Professions Code.

§40401. Release to Distributor as Finished Product.

Prior to release of a 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.

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

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

Article 2. Labeling Requirements

§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.

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

Reference: Section 26120, Business and Professions Code.

§40405. Primary Panel Labeling Requirements: All Products.

(a) The label for a 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;

(3) The net weight or volume of the contents of the package;

(4) The THC content and CBD content for the package in its entirety, expressed in milligrams per package.

(b) Nothing in this section prohibits the inclusion of additional information on the primary panel. 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.

§40406. Additional Primary Panel Labeling Requirements: Edible Products.

In addition to the requirements of Section 40405, the primary panel of an edible cannabis product shall include the following information:

(a) The words “cannabis-infused” immediately above the identity of the product in bold type and a text size larger than the text size used for the identity of the product.

(b) The THC content and CBD content per serving, expressed in milligrams per serving.

Authority: Sections 26012; 26013; 26120; and 26130, Business and Professions Code.

Reference: Section 26120, Business and Professions Code.

§40408. Informational Panel Labeling Requirements.

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

(1) The licensed manufacturer 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) If the cannabis product is intended for sale in the medicinal-use market, the statement "FOR MEDICAL USE ONLY;"

(5) A list of all product ingredients in descending order of predominance by weight or volume;

(6) If the edible 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) If an edible cannabis product, the names of any artificial food colorings contained in the product;

(8) If an edible cannabis product, the amount, in grams, 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; and

(11) The UID and, if used, the batch number.

(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, unless there is insufficient area on the container available to print all the required information in a text size of no less

than 6 point font. In such a case, the label shall include the warning statements required by paragraph (3) in a text size of no less than 6 point font, and the product shall be accompanied by a supplemental labeling that includes all of the information required by this section. The text of the supplemental labeling shall be no less than 8 point font.

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

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

§40410. Labeling Restrictions.

The label shall not contain any of the following:

- (a) Claims that the cannabis product was produced from cannabis grown in a California county when the cannabis was not grown there.
- (b) The name of a California county unless the cannabis used in the product was grown there.
- (c) Content that is or 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.”
- (d) Any information that is false or misleading.
- (e) 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.

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

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

§40411. Statement of Characteristic Anticipated Effects.

A cannabis product may include information on the characteristic anticipated effects of the cannabis product if the manufacturer has substantiation that the information is truthful and not misleading. Such information may be located on the informational panel of the label or as an insert included in the product package. For purposes of this section, “characteristic anticipated effect” includes any physiological effect (a temporary effect on the body related to the consumption of cannabis) that is common to or expected from the particular cannabis strain, but excludes any claim of health benefits (i.e. claims of therapeutic action as a result of the consumption of cannabis).

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

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

§40412. Universal Symbol.

The primary panel of a cannabis product shall be marked, stamped, or otherwise imprinted with the universal symbol.

(a) The symbol shall replicate the following in form and shall be black in color:



(b) The symbol shall be no smaller in size than half (.5) inch by half (.5) inch and shall be printed legibly and conspicuously. For packaging that is dark in color, the symbol may be made conspicuous by printing the symbol on, or outlining the symbol with, a contrasting color.

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

Reference: Sections 26120; 26121; and 26130, Business and Professions Code.

Article 3. Packaging

§40415. Packaging.

A package used to contain a cannabis product shall adhere to 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 shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.

(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.

(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.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

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

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

SUBCHAPTER 6. COMPLIANCE

Article 1. Records

§40500. Record Keeping Requirements.

(a) The licensee shall have the following documents available on the premises at all times and shall make the documents available to the Department and any enforcement agency upon request:

- (1) The valid state license issued by the Department;
- (2) Any other valid license issued by a state cannabis licensing agency;
- (3) The valid license, permit, or other approval issued by the local jurisdiction;
- (4) The premises diagram, as specified in Section 40131;
- (5) The current standard operating procedures as defined in Section 40275;
- (6) Shipping manifests;

(7) Employee records, including evidence of employee qualifications and training procedures and logs, as specified in Section 40280; and

(8) Any other record or documentation required to be kept pursuant to this Chapter or the Act.

(b) The records required pursuant to subsection (a) shall be maintained on the premises in a manner immediately accessible to the Department and any enforcement agencies upon request for a period of seven (7) years. Outdated standard operating procedures shall not be accessible to onsite employees.

(c) All documentation shall be maintained in English.

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

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

Article 2. Track-and-Trace System

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

(a) A licensee shall enter all commercial cannabis activities into the track-and-trace system within 24 hours of occurrence.

(b) Within ten (10) calendar days of notification from the Department that the annual license application fee has been processed, a licensee shall register for track-and-trace system training provided by the Department of Food and Agriculture or its designee.

(c) If a licensee has not registered for track-and-trace system training pursuant to subsection (b), the licensee shall register for training within five (5) business days of notification from the Department that the annual license has been approved.

(d) A licensee shall designate at least one owner to be the track-and-trace system account manager. The track-and-trace system account manager shall have the following responsibilities:

(1) Designate authorized track-and-trace system users and require designated users to be trained in the proper and lawful use of the track-and-trace system before the designated user can access the system;

(2) Maintain an accurate and complete list of all track-and-trace system account managers and users and update the list within three (3) business days upon any change;

(3) Ensure that each track-and-trace account manager and user has a unique log-on, consisting of a username and password, which shall not be shared with or used by any other person;

(4) Immediately cancel any track-and-trace system account manager or user from a track-and-trace system account if the individual is no longer a licensee representative;

(5) 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;

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

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

(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.

(e) 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 not corrected.

(f) The licensee is responsible for all actions that a track-and-trace system account manager or user acting as a licensee representative takes while logged into the track-and-trace system or otherwise conducting commercial cannabis activities.

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

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

§40512. Track-and-Trace System Reporting Requirements.

(a) A system account manager or user shall record all of the following activities in the track-and-trace system within 24 hours of the activity:

(1) Receipt of cannabis material;

(2) The transfer to or receipt of cannabis products for further manufacturing from another licensed manufacturer; and

(3) All changes in the disposition of cannabis or cannabis products. A change in disposition includes, but is not limited to:

(A) Processing of the cannabis or further processing of the cannabis product; and

(B) Packaging of the cannabis products.

(4) Transfer of cannabis products to a distributor.

(b) The following information shall be recorded for each activity entered into the track-and-trace system:

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

(2) The name and license number of the distributor that transported the cannabis material or cannabis product.

(3) The type of cannabis material or cannabis product received, processed, manufactured, or transferred.

(4) The weight or count of the cannabis material or cannabis product received, processed, packaged, or transferred.

(5) The date and time of receipt, processing, packaging, or transfer.

(6) The UID assigned to the cannabis material or cannabis product.

(7) Any other information required by other applicable licensing authorities.

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

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

§40513. Track-and-Trace System – Loss of Access.

(a) If a licensee loses access to the track-and-trace system for any reason, the licensee shall prepare and maintain comprehensive records detailing all required inventory tracking activities conducted during the loss of access.

(b) Upon restoration of access to the track-and-trace system, all inventory tracking activities that occurred during the loss of access shall be entered into the track-and-trace system within three (3) business days.

(c) A licensee shall document the date and time when access to the track-and-trace system was lost and when it was restored and the cause for each loss of access.

(d) A licensee shall not transfer cannabis products to a distributor until such time as access to the track-and-trace system is restored and all information is recorded into the track-and-trace system.

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

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

§40515. Track-and-Trace System – Temporary Licenses.

(a) A licensee operating under a temporary license issued pursuant to Section 40126 is not required to record commercial cannabis activity in the track-and-trace system as otherwise required by this article. Temporary licensees shall track all commercial cannabis activities on a paper sales receipt or invoice that includes the following information:

- (1) Name, address, and license number of the seller;
- (2) Name, address, and license number of the purchaser,
- (3) Date of sale or transfer and invoice number;
- (4) Description or type of cannabis or cannabis product;
- (5) Weight or quantity of cannabis or cannabis product sold or transferred;
- (6) Cost to the purchaser of the cannabis or cannabis product.

(b) After issuance of an annual license, the licensee may continue to conduct commercial cannabis activities with temporary licensees in accordance with subsection (a). Any commercial cannabis activity conducted between annual license holders shall be recorded in the track-and-trace system.

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

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

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

(a) A licensee shall order UID tags within five (5) business 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 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.

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

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

Article 3. Advertising and Marketing

§ 40525. Advertising and Marketing.

(a) A licensee shall ensure that all advertising and marketing of its cannabis products meet the requirements of Chapter 15 (commencing with section 26150) of the Act. Any health-related statement shall also meet the requirements of section 40410.

(b) A licensee shall accurately and legibly include its name and license number on all advertising and marketing for its products.

(c) A licensee shall maintain records and documentation to establish that its advertising and marketing meet the requirements of Chapter 15 (commencing with section 26150) of the Act. The records shall be maintained in accordance with section 26160 of the Act and Section 40500 of this chapter.

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

Reference: Section 26150, Business and Professions Code.

Article 4. Inspections

§40550. Inspections.

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

(b) The Department and its inspectors or agents shall have access at reasonable times to the manufacturing premises, 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 shall include 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 promptly 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 including the ability to enter and inspect any place where any cannabis product is suspected of being manufactured or held in violation of the Act or these regulations.

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.

SUBCHAPTER 7. TRANSITIONAL PERIOD

§40600. License Designations.

Notwithstanding any other provision, until July 1, 2018, licensees may conduct commercial cannabis activities with any other licensee, regardless of the A or M designation on the license.

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

Reference: Section 26050, Business and Professions Code.

§40601. Packaging and Labeling.

Any cannabis product that is in possession of a manufacturer prior to January 1, 2018, and that does not meet all applicable requirements of Subchapter 5 may enter into the commercial cannabis market provided that all of the following conditions are met:

(a) The cannabis product is packaged in child-resistant packaging that meets the requirements of subsection (c) of Section 40415. A secondary package that is child-resistant shall be sufficient to meet the requirements of this subsection.

(b) The cannabis product contains the government warning required pursuant to paragraph (3) of subsection (a) of Section 40408. A sticker with the required statement that is placed on the outside of the package or secondary package shall be sufficient to meet the requirements of this subsection.

(c) The cannabis product meets the applicable THC limits under Sections 40305 or 40306.

(d) The cannabis product contains the amount of THC and, if applicable, CBD per serving and per package. A sticker with the THC and CBD amount that is placed on the outside of the package or secondary package shall be sufficient to meet the requirements of this subsection.

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

Reference: Sections 26011.5; 26050; 26120; and 26130, Business and Professions Code.