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 19300.5, the following definitions shall govern the construction of this division, unless the provision or context otherwise requires:

"Act" means the Medical Cannabis Regulation and Safety Act, Business and Professions Code section 19300, et seq.

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

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

"Adulterated" or "adulteration" has the meaning stated in section 19347.6 of the Business and Professions Code.

"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.

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

"Applicant" means the individual or business entity that is applying for a license to manufacture medical cannabis products and in whose name the license will be issued. The applicant will be considered the licensee upon issuance of a license.

"Batch" means either:

(a) An amount of cannabis concentrate or extract produced in one production cycle using identical input materials, extraction methods, and standard operating procedures, and intended to have uniform character and quality; or

(b) An amount of a type of manufactured cannabis produced in one production cycle using identical formulation and standard operating procedures that is intended to have uniform character and quality.

"Bureau" means the Bureau of Medical Cannabis Regulation in the Department of Consumer Affairs.

"Cannabis product" as used in this division includes "manufactured cannabis" as defined by subdivision (ac) of section 19300.5 of the Business and Professions Code and "medical cannabis, medical cannabis product, or cannabis product" as defined by subdivision (af) of section 19300.5 of the Business and Professions Code.

"Cannabis product symbol" means the image established by the Department to indicate that a manufactured product contains THC.

"CBD" means the compound cannabidiol.

"Commercial-grade, non-residential door lock" means a lock manufactured for commercial use.

"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 can include cannabis, cannabis products used as ingredients, other ingredients, and processing aids.

"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, equipment, and packaging.

"Department" means the State Department of Public Health.

"Edible cannabis product" means manufactured cannabis intended to be used, in whole or in part, for human consumption.

“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.

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

“Finished product” means a manufactured cannabis product in its final form to be sold at a dispensary.

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

“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.

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

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

“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.

“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.

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

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

“Lot” means a batch or a specifically identified portion of a batch.

“Lot number” means a distinctive group of numbers, letters, or symbols, or any combination thereof, that is unique to the lot of cannabis product, and from which the complete history of the manufacturing, packaging, labeling, and/or holding of a lot of cannabis product can be determined.

“Manufacturer licensee” or “licensee” means the holder of a manufacturer license issued pursuant to the Act associated with a specific manufacturing premises.

“Manufacture” means the production, preparation, propagation, or compounding of cannabis products. The term “manufacture” includes the following:

(a) Extraction processes

(b) Infusion processes

(c) Packaging or repackaging of manufactured medical cannabis or medical cannabis products.

(d) Labeling or relabeling the packages of manufactured medical cannabis or medical cannabis products.

The term “manufacture” does not include the following:

(a) The repacking of medical cannabis products from a bulk container by a distributor or dispensary where the product’s original packaging and labeling is not otherwise altered.

(b) The placing of medical cannabis products into exit packaging by a dispensary. For purposes of this section, “exit packaging” means any packaging required by the Bureau to hold a finished cannabis product after sale at a dispensary.

“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.

“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 manufactured cannabis to decomposition, that indicate that manufactured cannabis is

contaminated with filth, or that otherwise may cause manufactured cannabis to be adulterated.

"Monitor" means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

"Nonvolatile solvent" means any solvent used in the extraction process that is not a volatile solvent. For purposes of this chapter, a nonvolatile solvent includes carbon dioxide used for extraction.

"Package" or "packaging" means any container or wrapper that may be used for enclosing or containing any cannabis and cannabis products. The term "package" does not include any shipping container or outer wrapping used solely for the transportation of cannabis or cannabis products in bulk quantity to any licensed manufacturer or distributor.

"Pathogen" means a microorganism that can cause illness or injury.

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

"Pest" means undesired insect, rodent, nematode (small worm), fungus, bird, vertebrate, invertebrate, weed, virus, bacteria, or other microorganism (except microorganisms on or in humans or animals) declared to be injurious to health or the environment.

"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 (f) of section 19300.5 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.

"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 under the hazard analysis that are consistent with the

current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

“Primary panel” means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

“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. These 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.

“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.

“Qualified individual” means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture safe 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.

“Quality” means that the cannabis product consistently meets the established specifications for identity, cannabinoid concentration, composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration and misbranding.

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

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

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

"Quarantine" means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

“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.

“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.

“Sublet” means to lease or rent all or part of a leased or rented property.

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

“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.

“Track and trace system” means the universal identification certificate program for commercial medical cannabis activity authorized by this Chapter.

“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, propane, and ethanol.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Sections 19300.5, 19304, 19341, and 19347.2, Business and Professions Code.

§40101. [Reserved]

§40102. Owner.

(a) For publicly traded companies, “owner” means the chief executive officer or any person or entity with an aggregate ownership interest in the company of 5 percent or more.

(b) For all businesses other than publicly traded companies, an owner is:

(1) An individual that has an aggregate ownership interest, other than a security interest, lien, or encumbrance, in the business of 20 percent or more;

(2) The chief executive officer and all members of the board of directors of an entity when that entity has an aggregate ownership interest, other than a security interest, lien, or encumbrance, of 20 percent or more of the commercial cannabis business;

(3) An individual that will be participating in the direction, control, or management of the licensed commercial cannabis business. For purposes of this section, participating in the direction, control, or management of the licensed commercial cannabis business means that the individual has been delegated discretionary powers to organize, direct, carry on or control the operations of the licensed commercial cannabis business. Authority to control one or more of the following functions shall be prima facie evidence that such an individual is participating in the direction, control, or management of the licensed medical cannabis business:

(A) The hiring or firing of employees.

(B) Contracting for the purchase of furniture, equipment, or supplies.

(C) The making or participation in the making of policy decisions relative to operations of the licensed medical cannabis business.

(c) Individuals who have a community property interest under Family Code section 760 in the commercial cannabis business but who will not be participating in the direction, control, or management of the commercial cannabis business as defined under subsection (b)(3) of this section are not required to submit the information required of owners in the application for licensure under Section 40130. However, information regarding an individual with a community property interest shall be disclosed by the owner in the application for licensure pursuant to Section 40130. If a license in which an individual has a community property interest is revoked, the individual shall be

barred from holding an interest in the same license type as the license that was revoked for the same period of time as the owner is barred from obtaining a new license. If a license in which an individual has a community property interest in is denied, the individual shall be barred from holding an interest in the same license type as the license that was denied for the same period of time as an owner is barred from obtaining a new license.

(d) A bank or financial institution whose interest constitutes a loan is not considered to be an owner.

(e) The following individuals are considered to have a noncontrolling interest in the commercial cannabis business and are not required to submit the information required of owners in the application for licensure under Section 40130:

(1) Individuals that own an interest in a commercial cannabis business that is less than 5 percent for publicly traded companies or less than 20 percent for all other businesses;

(2) Individuals that own an interest of an entity owner under subsection (b)(2) that are not the chief executive officer nor a member of the board of directors; and

(3) Individuals that own an interest in an entity that owns an interest in a commercial cannabis business that is less than 20 percent.

Authority: Section 19302.1, subdivision (f); 19304; and 19300.5, subdivision (b), Business and Professions Code. Reference: Section 19300.5, subdivision (b), Business and Professions Code.

§§40103 – 40114. [Reserved]

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 medical cannabis products will be manufactured.

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

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19320, subdivisions (a) and (b); and 19341, Business and Professions Code.

§40116. [Reserved]

§40117. [Reserved]

§40118. Manufacturing License Classifications.

The following license types are available from the Department:

(a) “Type P,” for entities that only package or repackage medical cannabis products or label or relabel the cannabis product container. Entities that engage in packaging or labeling of their own product as part of the manufacturing process do not need to hold a separate Type P license. For purposes of section 19328 of the Business and Professions Code, a Type P license shall be subject to the same restrictions as a Type 6 license.

(b) “Type N,” for manufacturers that produce edible products or topical products using infusion processes, or other types of medical cannabis products other than extracts or concentrates, and that do not conduct extractions. For purposes of section 19328 of the Business and Professions Code, a Type N license shall be subject to the same restrictions as a Type 6 license.

(c) “Type 6,” for extractions using mechanical methods or nonvolatile solvents as defined by Section 40100. A Type 6 licensee may also conduct infusion operations, or packaging and labeling of its own cannabis products on the licensed premises, provided that the infusion method is noted on the application form and that the relevant information pursuant to subsection (b) of Section 40128 is provided to the Department.

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

(1) 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 is provided to the Department pursuant to subsection (b) of Section 40128.

(2) Conduct infusion operations on the licensed premises, provided that the infusion method is noted on the application form and that the relevant information is provided to the Department pursuant to subsection (b) of Section 40128.

(3) Conduct packaging and labeling of its own cannabis products.

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19300.7, subdivisions (k) and (l); and 19341, Business and Professions Code.

§40119. [Reserved]

§40120. [Reserved]

§40121. [Reserved]

§40122. [Reserved]

§40123. [Reserved]

§40124. [Reserved]

SUBCHAPTER 2 – MANUFACTURING LICENSES
Article 1. Applications for Licensure

§40125. New License Application.

An application for a new license shall be required under any of the following circumstances:

(a) The applicant or premises has not previously been licensed by the Department.

(b) The license expired and was not renewed in a timely manner.

(c) The applicant's license has been revoked by the local jurisdiction and/or the Department.

(d) The licensee holds a Type P license and wants to begin conducting infusions or extractions.

(e) The licensee holds a Type N license and wants to begin conducting extractions requiring a Type 6 or Type 7 license.

(f) The licensee holds a Type 6 license (nonvolatile solvent) and wants to begin conducting Type 7 extractions (volatile solvent).

(g) The applicant has changed.

(h) The licensee intends to relocate any portion of the manufacturing operation to new premises.

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); and 19341, Business and Professions Code.

§40126. [Reserved]

§40127. [Reserved]

§40128. Application Requirements.

To apply for a manufacturer license from the Department, an applicant shall submit the following:

(a) A completed application form as prescribed by the Department, or an online submission form as available, which includes the following information:

(1) Applicant information:

(A) Application type (new, renewal, change in operations, change in ownership);

(B) License type sought (Type N, Type P, Type 6, or Type 7);

(C) The legal business name of the applicant and the applicant's tax identification number;

(D) The name(s) under which the business will operate ("Doing Business As");

(E) If the applicant is a sole proprietor, the applicant's social security number and date of birth;

(F) The applicant's mailing address which will serve as the address of record;

(G) The name, title and phone number of the contact person for the applicant, and the applicant's contact email address;

(H) The seller's permit number issued by the Board of Equalization or evidence that the applicant has applied for a seller's permit from the Board of Equalization;

(I) The number, date of issuance and date of expiration of the local jurisdiction's license, permit or other authorization for the manufacture of medical cannabis products;

(J) The ownership structure of the applicant as filed with the California Secretary of State (e.g. limited liability company, joint partnership, S-Corporation). An applicant that is a foreign corporation shall include in its application the certificate of qualification issued by the Secretary of State of California under Corporations Code section 2105;

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

(L) Identification of other medical cannabis licenses the applicant holds or has applied for.

(2) Manufacturing Premises Information:

(A) The physical address of the manufacturing premises;

(B) The name, title and phone number of the person who manages the operation of the facility;

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

(D) The number of employees at the manufacturing site;

(E) The anticipated gross annual revenue from all sales of products manufactured at the manufacturing premises;

(F) 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, room, 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 indicating which part of the property is the proposed premises and will identify what the remaining property is used for.

(3) Disclosure of any of the following, including a description of the circumstances:

(A) Any criminal conviction substantially related to the qualifications of a manufacturer identified in Business and Professions Code section 19323(b)(4) or in Section 40162 of these regulations;

(B) Any violation of law that is substantially related to the qualifications of a manufacturer as identified in Section 40162;

(C) Any fines or penalties for cultivation or production of a controlled substance on public or private land;

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

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

(F) Any conviction of a crime related to fraud or embezzlement;

(G) Any conviction of a violent felony as specified in subdivision (c) of section 667.5 of the Penal Code;

(H) Any conviction of a serious felony as specified in subdivision (c) of section 1192.7 of the Penal Code;

(I) Whether the applicant is on parole or probation for a felony conviction;

(J) Whether the applicant has, as a licensed physician, ever made patient recommendations for medical cannabis pursuant to section 11362.7 of the Health and Safety Code;

(K) If the applicant is a natural person, the applicant shall also provide the information required by subdivision (a)(2) of this section.

(4) Licensed Activity:

(A) The type of activity conducted (extraction, infusion, packaging, labeling) including a description of extraction and infusion methods;

(B) The types of products that will be manufactured, packaged, or labeled.

(5) Attestations: The applicant shall attest to the following:

(A) The applicant is not licensed as a retailer of alcoholic beverages pursuant to Business and Professions Code, Division 9 (commencing with Section 23000).

(B) The applicant, if it has 20 or more employees, will enter into and abide by a labor peace agreement as required by Business and Professions Code section 19322(a)(6) .

(C) The applicant is in compliance with the licensing limitations specified in Business and Professions Code section 19328.

(D) The applicant understands that the requirements of operation pursuant to Subchapter 3 shall be met.

(6) The application shall be signed by the applicant under penalty of perjury, that the information provided is complete, true, and accurate.

(b) The applicant shall also submit the following documentation with the application:

(1) A description of inventory control procedures sufficient to demonstrate how the applicant will comply with the requirements of Section 40282;

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

(3) A description of the transportation process to be used by the applicant that is in compliance with state law;

(4) A description of security procedures sufficient to demonstrate how the applicant will comply with the requirements of Section 40200;

(5) In lieu of a description of the methods, processes and procedures to be used by the applicant, the applicant may submit a copy of such procedure with the application;

(6) 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 medical cannabis products on the property. The name, address and contact phone number for the owner or owner's agent shall be included;

(7) Documentation issued by the local jurisdiction certifying that the applicant is in compliance with all local ordinances and regulations, or that the applicant will be in compliance with all local ordinances and regulations by the time the Department issues a license;

(8) 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 medical cannabis product necessitated by a violation of the Act or the regulations adopted thereunder. All bonds required under this regulation must be in a form satisfactory to the State, issued by a corporate surety licensed to transact surety business in the State of California.

(c) The application shall be accompanied by a non-refundable application fee as specified in Section 40150.

(d) Any manufacturer submitting operating procedures and protocols to the Department pursuant to the Act and this division 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 otherwise exempt from public disclosure under the California Public Records Act in Government Code section 6250 et seq.

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); and 19341, Business and Professions Code.

§40129. [Reserved]

§40130. Owner Applications.

(a) Each owner shall submit the following information on a form prescribed by the Department or through online submission as available:

(1) Name;

(2) Title or position held;

(3) Social security number;

(4) Date of birth;

(5) Mailing address;

(6) Email address;

(7) Whether the owner has a financial interest in any license type other than manufacturing. For the purposes of this section, “financial interest” means an investment in a medical cannabis business, a loan provided to a medical cannabis business, or any other equity interest in a medical cannabis business.

(8) Whether the owner is a licensed physician making patient recommendations for medical cannabis;

(9) The date the owner’s fingerprints were submitted to the State Department of Justice;

(10) Disclosure of the information required by Section 40128(a)(3)(A)-(K).

(b) The following information regarding an individual with a community property interest in the commercial cannabis business under Family Code section 760 shall be provided by the owner:

(1) The full name of the individual.

(2) The individual’s date of birth.

(3) The individual’s social security number or individual taxpayer identification number.

(4) The individual’s mailing address.

(5) Whether the individual has a financial interest in any other licensee under the Act. For purposes of this section “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 owner form shall be signed by the owner under penalty of perjury that the information provided is complete, true, and accurate.

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); and 19341, Business and Professions Code.

§40131. [Reserved]

§40132. 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 bureau 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 Medical Cannabis Regulation and Safety Act and the Administrative Procedures Act;

(b) 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).

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

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19300.5(b), Business and Professions Code.

§40133. [Reserved]

§40134. [Reserved]

§40135. Incomplete Applications.

(a) Incomplete applications will not be processed. Applications will only be considered complete if all of the information requested under Section 40130 is included. The Department shall issue a 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 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); and 19341, Business and Professions Code.

§40136. [Reserved]

§40137. Application Withdrawal.

(a) An applicant may withdraw an application for 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.

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

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); and 19341, Business and Professions Code.

§40138. [Reserved]

§40139. [Reserved]

Article 2. Operations in Existence as of January 1, 2018

§40140. Applicants Operating Prior to January 1, 2018.

(a) An applicant that has been operating as a manufacturer on or before January 1, 2018 may continue to operate until the Department approves or denies its application, under the following conditions:

(1) The applicant submits a complete application prior to July 2, 2018;

(2) The applicant is operating pursuant to a license, permit, or other authorization from the local jurisdiction;

(3) The applicant continues to operate in compliance with all state and local requirements; and

(4) The applicant submits documentation of operation prior to January 1, 2018, including, but not limited to, any of the following:

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

(B) Collective or Cooperative Membership Agreement;

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

(D) Incorporation documents;

(E) Receipts evidencing business expenditures;

(F) Any other verifiable business record adequate to demonstrate the operation of the business prior to January 1, 2018.

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

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); and 19341, Business and Professions Code.

§40141. Priority of Review of Applications.

(a) Except as provided in subdivision (b), applications will be processed in the order in which they are received and determined to be complete.

(b) Priority shall be given to applicants that can demonstrate they were in operation and in good standing with the local jurisdiction by January 1, 2016, and whose ownership or premises are currently the same as they were on January 1, 2016. Priority applicants shall have their applications processed in the order in which they are received.

(c) For purposes of priority review under subdivision (b), the date the applicant began manufacturing operations shall be provided by the applicant. The applicant shall attest to the date and "good standing" with the local jurisdiction under penalty of perjury and shall provide a copy of any of the documentation specified in subdivision (a)(4) of Section 40140 to establish that operations began on or before January 1, 2016.

(d) For purposes of this section, "good standing" shall be evidenced by a document issued or signed by the local jurisdiction that contains the following:

(1) The name of the applicant;

(2) The address of premises to be licensed;

(3) The name of the office that issued the local license, permit, or other authorization;

(4) The name, contact information, and signature of the individual authorized to sign on behalf of the local jurisdiction;

(5) The statement: "The abovenamed party has been issued a license, permit, or other authorization from this jurisdiction to conduct commercial cannabis activity. The abovenamed party is currently in operation and is operating in good standing in this jurisdiction."

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); and 19341, Business and Professions Code.

§§ 40142 - 40149. [Reserved]

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 $2,000,000 (Tier III), the fee shall be $15,000.

(4) For a licensed premises with annual gross revenue of $2,000,001 to $5,000,000 (Tier IV), the fee shall be $35,000.

(5) For a licensed premises with annual gross revenue of over $5,000,000 (Tier V), the fee shall be $50,000.

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19321, subdivision (b); 19341; and 19350 Business and Professions Code.

§40151. [Reserved]

§40152. [Reserved]

§40153. [Reserved]

§40154. [Reserved]

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 within 30 calendars days of notification.

(c) The license shall become effective on the date the Department receives the applicable license fee.

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19304; 19320, subdivisions (a) and (b); and 19341, Business and Professions Code.

§40156. [Reserved]

§40157. [Reserved]

§40158. [Reserved]

§40159. Denial of License.

(a) The Department may deny an application for a new or renewal license for any reason specified in section 19323 of the Business and Professions Code. In addition, the Department may deny a license application for the following reasons:

(1) The applicant or owner has been convicted of any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself or herself or another, or to substantially injure another.

(2) The applicant or associated applicant made a material misrepresentation in the application for the license.

(3) The applicant or associated applicant 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.

(4) The applicant has been denied a license, permit, or other authorization to engage in commercial cannabis activity by a state or local licensing authority.

(5) The applicant has denied the Department access to the premises.

(b) The Department shall deny a license to an applicant if that applicant or an associated applicant holds additional licenses in violation of section 19328 of the Business and Professions Code.

(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.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Sections 19323, Business and Professions Code.

§40160. [Reserved]

§40161. [Reserved]

§40162. Substantially Related Acts.

(a) For the purpose of denial of a license, a conviction that is substantially related to the qualifications, functions, and duties of the business for which the application is made include:

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

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

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

(4) A felony conviction for hiring, employment 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; and

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

(6) A violation of sections 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).

(7) A violation of the California Food Sanitation Act, Health and Safety Code sections 111950-112130 that resulted in suspension or revocation of a license or any civil or criminal proceedings.

(8) Any violation of section 382 or 383 of the Penal Code.

(b) Except as provide in subparagraphs (4) and (5) of paragraph (a) and notwithstanding Chapter 2 (commencing with section 480) of Division 1.5 of the Business and Professions Code, a prior conviction, where the sentence, including any term of probation, incarceration, or supervised release, is completed, for possession of, possession for sale, sale, manufacture, transportation, or cultivation of a controlled substance is not considered substantially related, and shall not be the sole grounds for denial of a license. Conviction for any controlled substance felony subsequent to licensure shall be grounds for revocation of a license or denial of the renewal of a license.

Note: Authority: Sections 19302, 19304, and 19323(b)(4), Business and Professions Code. Reference: Sections 480 et seq. and 19323(b)(4), Business and Professions Code.

§40163. [Reserved]

§40164. [Reserved]

§40165. Criteria for Evidence of Rehabilitation.

(a) An applicant or associated applicant that has a prior criminal conviction for any offense specified in subparagraphs (A) – (D) of paragraph (4) of subdivision (b) of section 19323 of the Business and Professions Code, or Section 40162 of this chapter may request that the Department consider evidence of rehabilitation prior to denial of an application.

(b) 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 applicant'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 19323, subdivision (b)(4) of the Business and Professions Code.

(5) The extent to which the applicant or licensee 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.

(8) Other evidence of rehabilitation submitted by the applicant or licensee.

Note: Authority: Sections 19302, 19304, and 19323(b)(4), Business and Professions Code. Reference: Section 19323(b)(4), Business and Professions Code.

§40166. [Reserved]

§40167. Appeal of License Denial.

(a) Upon denial of an application for a license, the Department shall notify the applicant in writing that the application has been denied, will provide the reasons for the denial, and will inform the applicant of their right to a hearing.

(b) The applicant may appeal the license denial by filing a written petition with the Department within 30 calendar days of service of the notice of denial. The written petition must be postmarked within the 30-day period in order to satisfy the filing requirement. If a petition is not filed within the 30-day period, the applicant's right to a hearing is waived. The petition shall address the basis for denial identified by the Department, specify the reasons the applicant meets the requirements for licensure, and include evidence of rehabilitation, if applicable.

(c) Upon receipt of the petition, the Department shall set the petition for a hearing, which shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Section 19302.1(f), 19308, 19324, Business and Professions Code.

§40168. [Reserved]

§40169. Denial of Application – Reapplication.

An applicant whose license has been denied based on a substantially related offense or act may not reapply for licensure until after a period of one year has elapsed from the effective date of the denial.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Section 19324, Business and Professions Code.

§§40170 - 40174. [Reserved]

Article 5. Licensing

§40175. License Constraints.

(a) No applicant or associated applicant of any license issued by the Department to manufacture cannabis products shall hold a Type 8 or Type 11 license, as provided in section 19334 of the Business and Professions Code.

(b) A manufacturer licensee shall not manufacture, prepare, package or label any products other than cannabis products at the licensed premises.

(c) A manufacturer licensee shall not sublet any portion of the licensed premises of the manufacturing facility or plant.

Authority: Section 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19321, subdivision (a); and 19328, Business and Professions Code.

§40176. [Reserved]

§40177. [Reserved]

§40178. Material Change Request.

(a) A manufacturer licensee shall immediately notify the Department of any change in the information reported on the license application.

(b) A "Material Change Request" shall be submitted by a manufacturer licensee under the following circumstances:

(1) Change in ownership. When there is any change in ownership to the cannabis manufacturing operation, the licensee shall notify the Department. The new owner shall submit an owner application to the Department, and submit their fingerprints to the California Department of Justice. Consistent with Business and Professions Code section 19323, the Department shall review the qualifications of the owner and determine whether the change would constitute grounds for denial of the license. The Department may deny the change in ownership, or condition the license as appropriate.

(2) Change in Operations. If the licensee intends to conduct additional operations in accordance with section 19334 of the Business and Professions Code, the licensee shall submit a Material Change Request to the Department along with a description of each extraction or infusion method to be added, an updated product list, any applicable Standard Operating Procedures for the manufacturing operation, and an updated floor plan, if applicable. The licensee shall not conduct the additional extraction or infusion operations prior to receiving approval from the Department.

(c) The following changes cannot be provided to the Department through a Material Change Request and shall instead require a new license application:

(1) A change in the license applicant as defined in Section 40125.

(2) A relocation of the manufacturing premises.

Authority: Section 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f) and 19321, subdivision (a), Business and Professions Code.

§40179. [Reserved]

§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 the expiration date of the current license.

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

(d) A licensed manufacturer that does not submit a complete license renewal application to the Department within 30 days of the expiration of the current 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 (see Section 40128) on a form prescribed by the Director, or through online submission if available; the license fee as specified in Section 40150; and shall sign the form under penalty of perjury.

(f) All owners shall also complete the owner form 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: Section 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19321, subdivision (a); and 19350, Business and Professions Code.

§§40181 - 40199. [Reserved]

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 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 material 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 the integrity of the records is maintained.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: 19322, subdivision (b); 19327; and 19341, Business and Professions Code.

§40201. [Reserved]

§40202. [Reserved]

§40203. [Reserved]

§40204. [Reserved]

§40205. Video Surveillance.

(a) At a minimum, licensed premises shall have a complete digital video surveillance system with a minimum camera resolution of 1280 × 1024 pixels. The video surveillance system shall be capable of recording all pre-determined surveillance areas in any lighting conditions.

(b) The video surveillance system shall be capable of supporting 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, but are not limited to, the following:

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

(2) Areas where cannabis is destroyed;

(3) Limited-access areas;

(4) Security rooms;

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

(6) 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 of 20 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 30 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 Standards and Technology standards. The displayed date and time shall not significantly obstruct the view of recorded images.

Authority: Section 19304, Business and Professions Code. Reference: Section 19334, Business and Professions Code.

§§40206 – 40219. [Reserved]

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, such as screens or presses.

(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 CO_2 gas extraction system.

(4) Chemical extraction using a volatile solvent, as defined in Section 40100, subsection (bf).

(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) – (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 19304 and 19341, Business and Professions Code. Reference: Section 19341, subdivisions (a) and (b), Business and Professions Code.

§40221. [Reserved]

§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.

Authority: Section 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); and 19341, Business and Professions Code.

§40223. [Reserved]

§40224. [Reserved]

§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 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).

The certification document must contain the signature and stamp of a professional engineer and the serial number of the extraction unit being certified.

(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 meet any required fire, safety, and building code requirements specified in:

(1) National Fire Protection Association (NFPA) standards;

(2) International Building Code (IBC);

(3) International Fire Code (IFC); and

(4) Other applicable standards including all applicable fire, safety, and building codes related to the processing, handling and storage of the applicable solvent or gas.

Authority: Section 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19321, subdivision (a); and 19350, Business and Professions Code.

§§40226 - 40229. [Reserved]

Article 3. Good Manufacturing Practices

§40230. [Reserved]

§40231. [Reserved]

§40232. Requirements for Personnel.

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

(a) Disease control. Any person 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 persons 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) Where appropriate wearing hair nets, headbands, caps, beard covers, or other hair restraints in an effective manner.

(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 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40233. [Reserved]

§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 cannabis manufacturing plant grounds 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 plant in order to eliminate any pests, dirt, and/or filth that pose a source of cannabis product contamination.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40235. [Reserved]

§40236. Facility Construction and Design.

At minimum, a suitable 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 safe 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 ingredients 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.

(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, and toilet facilities, in 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 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40237. [Reserved]

§40238. Sanitary Operations.

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

(a) That 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) That 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) That 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 process or exposed:

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

(2) Those necessary for plant and equipment maintenance and operation; and

(3) Those necessary for use in the cannabis manufacturing facility's operations.

(d) That 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) That effective 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 plant 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) That 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) That 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) That, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into cannabis products during 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) That 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) That 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) That 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 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40239. [Reserved]

§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 at a suitable temperature, and under pressure as needed, 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. Toilet facilities shall be adequate, convenient, and furnish running water at of at least 100° F (30° C).

(f) Rubbish disposal. Rubbish 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 for 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 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40241. [Reserved]

§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.

(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 an appropriate 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, ingredients, or components shall be accurate and precise and 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 with prohibited additives.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§§40243 - 40249. [Reserved]

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 competent 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.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40251. [Reserved]

§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 contaminates. 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 shall not exceed generally acceptable limits set by the U.S. Food and Drug Administration for aflatoxins, other natural toxins, pest contamination, undesirable microorganisms, or extraneous materials for those materials or ingredients, 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 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40253. [Reserved]

§40254. Manufacturing Operations.

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

(a) That 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) That 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) That 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 section, “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) That work-in-process shall be handled in a manner that protects against allergen cross-contact, contamination, and growth of microorganisms.

(e) That effective measures shall be taken to protect finished cannabis products from allergen cross-contact and from contamination by raw materials, other ingredients, rejected components, or refuse. When raw materials, other ingredients, or refuse 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) That 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) That adequate measures shall be taken to protect against the inclusion of metal or other extraneous material in cannabis products.

(h) That adulterated cannabis products, raw materials, and other ingredients shall be disposed of in a manner that protects against the contamination of other cannabis products.

(i) That steps such as washing, peeling, trimming, cutting, sorting and 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) That, when required in the preparation of cannabis products capable of supporting microbial growth, heat blanching shall be effected by heating the cannabis product to the required temperature, holding that temperature for the required amount of time, 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) That batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time shall be treated or maintained in such a manner that they are protected against allergen cross-contact and contamination, and in a manner that minimizes the potential growth of undesirable organisms.

(l) That 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) That 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, intermediate moisture cannabis products, 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) That, when ice is used in contact with cannabis products, it shall be made from water that is safe and of adequate sanitary quality in accordance with Section 40240 subdivision (a), and shall be used only if it has been manufactured in accordance with current good manufacturing practices as outlined in this part.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40255. [Reserved]

§40256. Hazard Analysis.

The licensee shall conduct a hazard analysis to identify or 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, unapproved additives, 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 process;

(3) The design, function and condition of the manufacturing facility and its equipment;

(4) The ingredients and components used in a given cannabis product;

(5) The operation’s transportation and transfer practices;

(6) The facility’s manufacturing and processing procedures;

(7) The facility’s 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 19302.1(f), 19304, and 19341, Business and Professions Code.
Reference: Section 19302.1(f), 19303, 19316, and 19347.6, Business and Professions Code.

§40257. [Reserved]

§40258. Preventive Controls.

Upon completion of the hazard analysis, the licensee shall identify and implement 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 verification and records 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; that monitoring activities are being conducted as required; and that appropriate decisions about corrective actions are being made.

Authority: Sections 19302.1(f), 19304, and 19341, Business and Professions Code. Reference: Section 19302.1(f), 19303, 19316, and 19347.6, Business and Professions Code.

§40259. [Reserved]

§40260. Equipment and Machinery Qualification.

(a) The licensee shall establish and implement 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 and installed in compliance with design specification, not limited to: built as designed with proper materials, capacity, and functions, and properly 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 detailing and documenting the verification and re-verification of all equipment and machinery in operation on the licensed premises.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40261. [Reserved]

§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) An accurate statement of 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) Such specific actions shall include verifying the weight or measure of any component used in the finished cannabis product, and verifying the addition of any component; and

(E) For manual operations, such specific actions shall include:

(i) One person weighing or measuring a component and another person verifying the weight or measure; and

(ii) One person adding the component and another person verifying the addition.

(F) Special notations and precautions to be followed; and

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

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40263. [Reserved]

§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 batch number of the finished batch of cannabis product and the unique identifier number(s) of all cannabis products used in the batch.

(2) The lot number assigned for each of the following:

(A) Each lot of finished cannabis product from the batch;

(B) Each lot of cannabis product from the finished batch of cannabis product that is transferred to another licensed manufacturer for packaging or labeling;

(3) The identity of equipment and processing lines used in producing the batch;

(4) 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;

(5) 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;

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

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

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

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

(10) 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.

(11) 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.

(12) Documentation at the time of performance that quality control personnel have:

(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.

(13) 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;

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

(A) Include information adequate to identify the associated manufacturing plant or facility (e.g., the name, and when necessary, the location of the plant or facility);

(B) Include the date and, when appropriate, the time of the activity documented;

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

(D) Where appropriate, include the identity of the product and the lot number or batch identifier, if any.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40265. [Reserved]

§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, lot, or control number of the cannabis product, if available;

(3) The date the complaint was received and the name, address, 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 communication that contains any allegation, written, electronic, or oral, 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 a wrong ingredient, or any form of contaminant.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40267. [Reserved]

§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 a 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, and shall notify the Department of the quarantine. 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 as specified in Section 40290, and on video surveillance in accordance with subsection (e) of Section 40205. Except as provided in subparagraph (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 cannabis waste destruction.

(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, certain 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 product in an unsecured 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 40272, 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.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; and 19347.6, Business and Professions Code.

§40269. [Reserved]

Article 5. Record Keeping

§40270. 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;

(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; and

(8) Any other record or documentation required to be kept pursuant to this Division.

(b) The records required pursuant to subsection (a) shall be maintained in a manner immediately accessible on the premises to the Department and any enforcement agencies upon request for a period of two (2) years, except that outdated standard operating procedures shall not be accessible to onsite employees. After two (2) years, records may be maintained by the licensee in an alternate manner, provided that the records can be made available to the Department or enforcement agency no later than 48 hours following a request and that the records are retained for a period of 7 years in total.

(c) All documentation shall be maintained in English.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; and 19327, Business and Professions Code.

§40271. [Reserved]

§40272. Track-and-Trace Requirements for Manufacturers.

(a) A licensee shall enter the following events into the track-and-trace database:

(1) Receipt of cannabis material.

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

(3) Transfer of cannabis products to a distributor.

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

(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 transporter who transported the cannabis material or cannabis product.

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

(4) The weight of the cannabis material or cannabis product received or transferred.

(5) The date of receipt or transfer.

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

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

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19320; 19327; and 19335, Business and Professions Code.

§40273. [Reserved]

§40274. [Reserved]

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 to which personnel must adhere;

(b) Emergency response procedures including personnel training;

(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 Section 40272;

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

(g) Destruction procedures in compliance with Section 40290.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; 19320; 19327; and 19341, Business and Professions Code.

§40276. [Reserved]

§40277. [Reserved]

§40278. [Reserved]

§40279. [Reserved]

§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 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 food handler course 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 40140, applicable personnel shall complete the ANSI-accredited food handler course no later than 90 days after the effective date of the 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) An annual attestation by the licensee that he/she has received and understood all information and training provided in the training program.

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

(3) Documentation of training topics and dates of training completion for all personnel.

(4) Training topics and dates of refresher training completion for all personnel.

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

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

(c) The licensee may assign responsibility for ensuring compliance by individual personnel with the requirements of this section to supervisory personnel. Assigned supervisory personnel must have the education, training, or experience (or a combination thereof) necessary to ensure the production of clean and safe 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 understood all information and training provided in the training program. This documentation shall be maintained as part of the record requirements.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19316; 19327; and 19341, Business and Professions Code.

§40281. [Reserved]

§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 product at the licensed premises.

(b) A licensee shall reconcile the inventory of cannabis and cannabis products at the licensed premises with the records in the track-and-trace database at the close of business each day. 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 if an audit turns up a discrepancy that is not within five percent of the documented inventory.

(e) If a licensee finds evidence of theft or diversion, the licensee shall immediately report the theft or diversion to the Department.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19307; 19327; 19334, subdivision(c); 19335; and 19341, Business and Professions Code.

§40283. [Reserved]

§40284. [Reserved]

§40285. [Reserved]

§40286. [Reserved]

§40287. [Reserved]

§40288. [Reserved]

§40289. [Reserved]

§40290. Disposal of Cannabis Waste.

(a) In this division, “cannabis waste” is waste that is not hazardous waste as defined in Public Resources Code section 40141 and is solid waste, as defined in Public Resources Code section 40191, that contains cannabis and that has been made unusable and unrecognizable in the manner prescribed in subsection (e). A licensee may not sell cannabis waste.

(b) A licensee shall manage all waste that is hazardous waste, as defined in Public Resources Code section 40141, in compliance with all applicable hazardous-waste statutes and regulations.

(c) A licensee shall not dispose of medical cannabis products or cannabis waste in an unsecured waste receptacle, whether in the control of the licensee or not.

(d) Medical cannabis products that a licensee intends to render into cannabis waste shall be held in quarantine for a minimum of 72 hours. A licensee shall affix to each batch one or more documents with batch information and weight. At no time during the quarantine period may the cannabis be handled, moved, or rendered into cannabis waste. The cannabis is subject to inspection by the Department.

(e) A licensee shall make medical cannabis goods into cannabis waste by rendering the medical cannabis goods unusable and unrecognizable. The licensee shall render the cannabis goods into cannabis waste before removing the cannabis waste from the licensed premises. A licensee shall render the medical cannabis goods into cannabis waste by grinding and incorporating the cannabis with other ground material so that the resulting mixture is at least 50 percent non-cannabis material by volume. A licensee shall render medical cannabis goods into cannabis waste and track that waste one batch at a time and shall not comingle different batches into cannabis waste.

(f) The licensee shall render the medical cannabis goods into cannabis waste on camera in the manner required by Section 40205.

(g) Medical cannabis goods that a licensee wishes to deposit at a compostable materials handling operation or facility or at an in-vessel digestion operation or facility

may be rendered cannabis waste by incorporating any nonhazardous compostable material, as defined in Title 14, California Code of Regulations, Section 17852(a)(11), that a compostable materials handling operation or facility or in-vessel digestion operation or facility may lawfully accept.

(h) After a licensee renders the medical cannabis goods into cannabis waste, a licensee shall do one of the following with the cannabis waste:

(1) Dispose of the cannabis waste at a manned and fully permitted solid waste landfill;

(2) Deposit the cannabis waste at a manned compostable materials handling operation or a manned and fully permitted compostable materials handling facility; or

(3) Deposit the cannabis waste at a manned in-vessel digestion operation or and a manned and fully permitted in-vessel digestion facility.

(i) In addition to all other tracking requirements set forth in Section 40272, a licensee shall use the track-and-trace database and on-site documents to ensure the cannabis-waste materials are identified, weighed, and tracked while on the licensed premises and when disposed of or deposited in accordance with subsection (h).

(j) A licensee shall enter the date and time that the medical cannabis goods were rendered cannabis waste and the weight of the resulting cannabis waste into the track-and-trace database.

(k) A licensee shall maintain accurate and comprehensive records regarding cannabis waste material that account for, reconcile, and evidence all activity related to the generation and disposal or deposition of cannabis waste. A licensee shall obtain a record from the solid waste facility or operation evidencing the acceptance of the cannabis waste material at the facility or operation. The record must contain the name and address of the operation or facility, the date, the volume or weight of the cannabis waste accepted, and the name and signature of the person manning the facility or operation who accepts the cannabis waste. These documents are records subject to inspection by the Department and shall be kept in compliance with Section 40270.

(l) A licensee shall enter the date and time of the disposal or deposition of the cannabis waste at a solid waste facility into the track-and-trace database.

Authority: Sections 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19303; 19304; 19311, subdivision (d); 19332; and 19341; Business and Professions Code.

§40291. [Reserved]

§40292. Consent to Sample Collection.

A manufacturer licensee that transfers possession but not title of medical 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 19302.1, subdivision (f), 19304 and 19341, Business and Professions Code. Reference: Sections, 19302.1, subdivision (f); 19303; 19304; 19307; 19341; and 19343, Business and Professions Code.

§§40293 – 40299. [Reserved]

SUBCHAPTER 4. PRODUCTS
Article 1. Cannabis Product Standards

§40300. Prohibited Products.

(a) No licensee shall infuse alcoholic beverages, as defined in section 23004 of the Business and Professions Code, with cannabis.

(b) No cannabis product shall contain 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.

(c) No cannabis product shall be made of potentially hazardous food. Potentially hazardous food means any food capable of supporting the growth of infectious or toxigenic microorganisms when held at temperatures above 41 degrees Fahrenheit. This includes the following:

(1) Any cannabis product that must be held at or below 41 degrees Fahrenheit to keep it safe for human consumption;

(2) 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);

(3) Any canned cannabis product;

(4) Any juice. “Juice” means the liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree;

(5) Perishable bakery products that need to be held at temperatures below 41^0 Fahrenheit to prevent the growth of microorganisms, 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, eggs, or synthetic fillings; or meat-filled pies or pastries;

(6) Dairy products of any kind;

(7) Meat products of any kind; and

(8) Seafood products of any kind.

(d) Edible cannabis products produced for sale by the manufacturing licensee shall not include products set forth in Division 15 (commencing with § 32501) of the Food and Agriculture Code.

(e) No licensee shall manufacture cannabis products by applying cannabinoid concentrate or extract to commercially available candy or snack food items.

Authority: Section 19302.1(f), 19303, 19304, and 19341, Business and Professions Code. Reference: Section 19300.5(s) and 19347.6(a)(4), Business and Professions Code.

§40301. [Reserved]

§40302. Prohibited Ingredients and Components.

No product ingredients or components, other than cannabis extracts or concentrates, shall be used in the manufacture of an edible cannabis product unless such ingredients or components are approved by the United States Food and Drug Administration for use in food or food manufacturing.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f), 19316, and 19346.7, Business and Professions Code.

§40303. [Reserved]

§40304. [Reserved]

§40305. Edible Products – Serving Size.

(a) Edible cannabis products shall not contain more than ten (10) milligrams of THC per serving or more than one hundred (100) milligrams of THC per package of finished product.

(b) Edible products that constitute more than a single serving shall be scored, delineated, or otherwise similarly marked to indicate one serving.

Authority: Section 19302.1, subdivision (f); 19303; 19304; and 19341 Business and Professions Code. Reference: Section 19300.5 subdivision (s); and 19303, Business and Professions Code.

§40306. Finished Cannabis Products – Maximum THC Content.

For manufactured cannabis that is not an edible product, no package of finished cannabis product shall contain more than 1,000 mg of THC.

Authority: Section 19302.1, subdivision (f); 19303; 19304; and 19341 Business and Professions Code. Reference: Section 19300.5 subdivision (s); and 19303, Business and Professions Code.

§40307. Uniform Distribution.

Edible cannabis products shall be homogenized to ensure uniform disbursement of cannabinoids throughout the product.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f), 19316, 19344, and 19346.7, Business and Professions Code.

§40308. [Reserved]

§40309. [Reserved]

§40310. Contaminants.

(a) No cannabis product shall exceed the level of contaminants identified in Business and Professions Code section 19344 or set by the Bureau pursuant thereto.

(b) The mixing of a cannabis product containing defects at levels that render that the cannabis product adulterated with another lot of cannabis product is not permitted and renders the final cannabis product adulterated, regardless of the defect level of the final cannabis product.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f), 19316, 19344, and 19346.7, Business and Professions Code.

§§40311 – 40399. [Reserved]

SUBCHAPTER 5. LABELING AND PACKAGING REQUIREMENTS
Article 1. General Provisions

§40400. Applicability.

The requirements in this section 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.

Authority: Section 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19326, subdivision (b); 19341; 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 at a dispensary.

Authority: Section 19302.1, subdivision (f); 19303; 19304; and 19341, Business and Professions Code. Reference: Section 19326, subdivision (b); 19341; Business and Professions Code.

§40402. [Reserved]

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.

(c) All required label information shall be unobstructed and conspicuous.

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19300.5, subdivision (v); 19302.1, subdivision (f); 19347; 19347.5, Business and Professions Code.

§40404. [Reserved]

§40405. Primary Panel Labeling Requirements.

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

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

(2) 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;

(3) The cannabis product symbol as prescribed in Section 40412 ;

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

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

(6) The THC content and CBD content per serving, expressed in milligrams per serving; and

(7) The content of other cannabinoids or terpenes per serving if such information is verified by the certificate of analysis issued by a licensed testing laboratory pursuant to Business and Professions Code section 19344.

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

Authority: Sections 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19300.5, subdivision (v); 19302.1, subdivision (f); 19347; 19347.5, Business and Professions Code.

§40406. [Reserved]

§40407. [Reserved]

§40408. Informational Panel Labeling Requirements.

(a) The label for a medical 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 manufacture;

(3) Each of the following statements:

(A) “SCHEDULE I CONTROLLED SUBSTANCE.”

(B) “KEEP OUT OF REACH OF CHILDREN AND ANIMALS” in bold print.

(C) “FOR MEDICAL USE ONLY.”

(D) “IF PREGNANT OR BREASTFEEDING, CONSULT A PHYSICIAN PRIOR TO USE.”

(E) “THE INTOXICATING EFFECTS OF THIS PRODUCT MAY BE DELAYED BY UP TO TWO HOURS.”

(F) “THIS PRODUCT MAY IMPAIR THE ABILITY TO DRIVE OR OPERATE MACHINERY, PLEASE USE EXTREME CAUTION.”

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

(5) If an edible product that 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;

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

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

(8) The lot number;

(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; and

(11) The unique identifier.

(b) The informational panel text shall be in a type 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 type 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 type 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 19302.1, subdivision (f); 19304; and 19341, Business and Professions Code. Reference: Section 19300.5, subdivision (v); 19302.1, subdivision (f); 19347; 19347.5, Business and Professions Code.

§40409. [Reserved]

§40410. Labeling Restrictions.

The label shall not contain any of the following:

(a) Claims that the manufactured cannabis or cannabis product was grown in a California county when the cannabis was not grown there.

(b) The name of a California county unless the cannabis 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; or

(3) Any imitation of candy packaging or labeling.

(d) False labeling information. Labeling is false if it is false or misleading in any particular.

(e) Claims of health benefits or other physical benefits.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Sections 19341; and 19347, Business and Professions Code. Reference: Section 19300.5, subdivision (v); 19302.1, subdivision (f); 19332.5; 19347, 19347.5, Business and Professions Code.

§40411. [Reserved]

§40412. Cannabis Product Symbol.

The primary panel of a medical cannabis product shall be marked, stamped, or otherwise imprinted with the cannabis product symbol directly on the package.

(a) The symbol shall replicate the following in form and 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.

Authority: Sections 19304 and 19341, Business and Professions Code. Reference: Section 19300.5, subdivision (v), 19302.1, subdivision (f), 19347, 19347.5, Business and Professions Code.

§40413. [Reserved]

§40414. [Reserved]

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 a container within which a product is sealed so that the contents cannot be opened without obvious destruction of the seal.

(c) The package shall be child-resistant, which means the package shall be designed or constructed to be significantly difficult for children under five years of age to open or otherwise obtain access to the product contained therein within a reasonable time, and shall not be difficult for normal adults to open or obtain access to the product contained therein. 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)).

(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 19304 and 19341, Business and Professions Code. Reference: Section 19300.5, subdivision (v), 19302.1, subdivision (f), 19347, 19347.5, Business and Professions Code.

§§40416 - 40499. [Reserved]

SUBCHAPTER 6. INSPECTIONS AND ENFORCEMENT

§40500. 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 free 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 medical 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 medical cannabis product complies with the Act and these regulations.

(c) To the extent necessary for the enforcement of the Act and this Division the Department shall secure any sample or specimen of any medical 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.

(d) The Department shall be able to make analyses or examinations of 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.

(e) The Department shall be able to conduct investigations concerning the adulteration, misbranding or unlicensed production of any medical cannabis product including the ability to enter and inspect any place where any medical cannabis product is suspected of being manufactured or held in violation of the Act or these regulations.

Authority: Sections 19302.1, subdivision (f); 19304; 19307; and 19341, Business and Professions Code. Reference: Section 19302.1, subdivision (f); 19303; 19307; 19327; 19341; 19347.7; 19347.8 Business and Professions Code.

§§40501-41099. [Reserved]