Checklist

Cannabis Manufacturer: Self-Inspection Checklist

This checklist is designed to help you review the conditions of your cannabis manufacturing facility in preparation for an inspection by Department of Cannabis Control (Department) staff. The items listed below represent the major areas evaluated during a routine compliance inspection.

The requirements come from division 10 of the California Business and Professions Code (BPC) and California Code of Regulations, title 4 (4 CCR), which are available at the Department's website: https://cannabis.ca.gov/cannabis-laws/laws-and-regulations/. Please be aware that this checklist is not an exhaustive list or substitution for ensuring compliance with all applicable statutory and regulatory requirements to your license type.

Inventory Management & Track and Trace Requirements
4 CCR §§ 15000.1, 15000.7, 15047.1-15052.1, 17218

- ☐ A written inventory control plan is in use and the business can identify where all cannabis and cannabis products in their track and trace account are located within the licensed premises.
- ☐ The following activities have been entered in the track and trace system within 24 hours of each occurrence: receipt of cannabis or cannabis products, rejection of cannabis or cannabis products, manufacturing of cannabis or cannabis products, use of cannabis or cannabis product for internal quality control testing or product research and development, destruction or disposal of cannabis or cannabis products, packaging or repackaging of cannabis or cannabis products, and sale or donation of cannabis or cannabis products.
- ☐ On-site cannabis and cannabis product inventory is reconciled with the track and trace system at least once every 30 days and the results are documented and available to the Department upon request.
- ☐ All cannabis and cannabis products are assigned a package tag that is recorded in the track and trace system. Package tags are affixed to the container holding the cannabis. If a single batch of cannabis or cannabis product is held in multiple containers, the package tag is affixed to one of the containers and the remaining

containers (and units within each container) are labeled with the UID number and placed contiguous to one another.

- ☐ All transfers of cannabis or cannabis product onto or off the manufacturing premises are conducted by a licensed distributor, and transfer manifests are created in the track and trace system before the transfer occurs.

Note: Cannabis or cannabis product that has passed regulatory compliance testing and is moved from a distribution premises to a manufacturing premises must be resubmitted for regulatory compliance testing. Cannabis or cannabis product that has failed regulatory compliance testing may not be moved from a distribution premises to a manufacturing premises unless approved for remediation by the Department.

Security Measures
4 CCR §§ 15042, 15042.1, 15044, 15046, 15047

- ☐ Security measures include an alarm system, commercial-grade locks, sign-in/sign-out procedures, perimeter security, and if necessary, designated limited-access areas.
- ☐ Video surveillance system clearly captures all areas where cannabis or cannabis products are weighed, packed, stored, loaded, and unloaded for transportation, prepared, or moved within the licensed premises. This includes areas such as walk-in refrigerators and extraction rooms. Limited access areas, security rooms, areas storing a surveillance-system storage device, and entrances and exits to the licensed premises shall also be recorded.
- ☐ Video surveillance system continuously records 24 hours per day, at a minimum of 15 frames per second, and video surveillance recordings clearly and accurately display the time and date and are kept for a minimum of 90 days. Must demonstrate the ability to easily retrieve and playback video surveillance footage up to 90 days prior to the inspection.

Premises Diagram
4 CCR §15006

- ☐ The premises diagram on file with the Department is a complete and detailed diagram of the premises and accurately reflects the current layout of the premises. Use the How To: Make a Premises Diagram Checklist to make sure your premises diagram includes all required information.

Master Manufacturing Protocols
4 CCR §17215

- ☐ There is a written Master Manufacturing Protocol for each unique formulation of cannabisproduct manufactured, and for each batch size. Use the Master Manufacturing Protocol Checklist to make sure your protocols include all required information.

Batch Production Records

4 CCR §17216

- ☐ A written batch production record is prepared every time a batch of a cannabis product is manufactured, or a batch of cannabis or cannabis product is remediated.
- ☐ The batch production record documents complete information relating to the production and control of each batch. Use the Batch Production Records Checklist to make sure you include allrequired information.

Product Quality Plan

4 CCR §17214

- ☐ A written Product Quality Plan is developed and used for each type of cannabis productmanufactured at premises.
- ☐ Each Product Quality Plan evaluates potential risks that may cause the product to be adulterated or misbranded, or may cause the product to fail laboratory testing or quality assurance review. The Product Quality Plan shall evaluate biological, chemical, and physical hazards associated with the premises and the manufacturing process; identify preventative measures to mitigate these risks; and identify methods to evaluate and monitor risk prevention effectiveness.

Good Manufacturing Practices

4 CCR §§ 17207-17210, 17212, 17214

- ☐ Walls, ceilings, and floors in manufacturing areas are constructed of material that is smooth,nonporous, easily cleanable, corrosion-resistant, and suitable to the activities that will be conducted in those areas.
- ☐ Openings into the building are screened, sealed, or protected to minimize the potential for peststo enter the building. Take special note of windows, door gaps, ventilation ducts, and rollup doors.
- ☐ Handwashing stations are available for employees. They contain warm water and are adequately stocked with soap and paper towels or air hand dryers.
- ☐ Interior lighting is shatter resistant in all areas where cannabis or cannabis products are exposed, or where breakage may result in contamination of cannabis components or packaging materials.
- ☐ Equipment and utensils are cleaned, sanitized, and kept in good repair. There are written procedures for cleaning, sanitizing, and maintaining equipment and utensils, as well as schedules and logs to document cleaning, sanitizing, and maintenance.
- ☐ Cannabis product components are properly stored to protect against allergen cross-contact, contamination, and to minimize deterioration. Raw materials and ingredients that require refrigeration are kept below 41° Fahrenheit.
- ☐ An allergen control program is in place to prevent mislabeling of allergens in finished cannabis products, and to prevent allergen cross-contact.

- □ Major food allergens, and ingredients that contain allergens, are identified, and stored in a manner that prevents allergen cross-contact with other raw materials or ingredients.

Manufacturing Personnel and Training Program

4 CCR §§ 17211, 17211.1, 15002, 15020

- □ A written disease control plan is in place to exclude personnel with illness or open lesions (e.g., boil, sore, cut, rash, or infected wound) from any manufacturing operations until their health condition is corrected.
- □ Personnel maintain personal cleanliness by wearing clean outer clothing, and using personal protective equipment (PPE), including hair restraints, when required to protect against contamination and allergen cross-contact of cannabis products.
- □ Personnel practice thorough hand washing before and after each absence from their workstation and any time hands become soiled or contaminated.
- □ Personal belongings (e.g., cell phones, clothing, jewelry) are stored in areas separate from wherecannabis products are exposed or where equipment or utensils are washed.
- □ Eating food, drinking beverages, chewing gum, and using tobacco are confined to areas separate from where cannabis products may be exposed and where utensils are washed.
- □ Manufacturing personnel who prepare, handle, or package edible cannabis products have completed a California food handler certificate course from an entity accredited by the American National Standards Institute.
- □ All employees receive training on health and safety hazards present at the premises, emergency response procedures, security procedures, record keeping requirements, and training requirements. Training is documented.
- □ Manufacturing personnel receive specific training on cannabis manufacturing processes including standard operating procedures, quality control procedures, product quality plans,proper and safe usage of equipment and machinery, safe work practices, cleaning and maintenance, and emergency operations. Training is documented.
- □ If the cannabis business employs two or more people, evidence that one supervisor and one employee have completed a Cal-OSHA 30-hour general industry outreach course are available for Department review.

Weighing Devices and Weighmasters

4 CCR §17221

- □ Weighing devices are approved, tested, sealed, and are currently registered with a county sealer.
- □ A valid and current weighmaster license can be provided to the Department.
- □ All individuals who weigh, measure, or count cannabis or cannabis products when

conducting commercial transactions or for entry into the track and trace system are included on the valid weighmaster license.

- □ Weighmaster certificates are obtained when payment is dependent on the quantity or weight of cannabis or cannabis product.

Packaging & Labeling Cannabis and Cannabis Products
4 CCR §§ 17398-17412

- □ Cannabis goods packaged for retail sale meet all packaging requirements.
- □ All cannabis goods packaged for retail sale meet child-resistant packaging requirements.
- □ Manufactured cannabis products packaged for retail sale meet all labeling requirements.
- □ Non-manufactured cannabis goods packaged for retail sale meet all labeling requirements.

Waste Management
4 CCR §17223

- □ Cannabis or cannabis product batches that are disposed of because they fail internal quality testing, quality assurance review by a distributor, or regulatory compliance testing, are rendered unusable prior to disposal.
- □ Cannabis waste is held in a secured receptacle or secured area on the licensed premises until it is picked up by a third-party waste hauler or self-hauled to a permitted waste facility.
- □ *If using a third-party waste hauler*: documentation is maintained evidencing subscription to awaste hauling service and contact information for the waste hauler.
- □ *For self-hauled cannabis waste*: a weight ticket or receipt from the waste facility is obtained foreach delivery of cannabis waste.

Extraction and Solvent Requirements, If Applicable
4 CCR §§ 17202.1, 17203, 17204, 17205

- □ Hydrocarbon-based solvents used for extraction or post-extraction processing are at least 99%purity. Documentation evidencing solvent purity must be made available to employees and to the Department upon request.
- □ Nonhydrocarbon-based solvents used for extraction or post-extraction processing (e.g., ethanol, CO_2, vegetable oil, glycerin, dry ice, etc.) are food-grade. Documentation evidencing solvent purity must be made available to employees and to the Department upon request.
    - □ Ethanol based solutions used for extraction or post-extraction processing may be used provided the ethanol component is food grade and the non-ethanol component is:
        - □ Food-grade, or

- □ A hydrocarbon that is a least 99% purity and is less than 5% of the total ethanol-based solution volume, and
    - □ Documentation evidencing purity and composition must be made available to the Department upon request.
    - □ Ethanol extraction operations have been approved by the local fire code official, if required bylocal ordinance, and are operated in accordance with Cal/OSHA requirements and any other applicable state and local requirements.

Closed-Loop Extraction System Requirements, If Applicable

4 CCR §§ 17202.1, 17203, 17204, 17206, 17206.1

- □ Chemical extractions using CO2, a volatile solvent (i.e., hydrocarbon such as propane or butane), or chlorofluorocarbon, or other fluorinated gas are conducted in a commercially manufactured closed-loop system that bears a permanently affixed serial number and is designed to recover the solvents.
- □ Closed-loop extraction systems are certified by a California-licensed engineer after installation, and before use.The certification document contains the following:
- □ Name, signature, and stamp of the engineer,
- □ Serial numbers of all extraction units certified,
- □ List of solvents deemed safe for use with each system,
- □ The address of the premises where the systems were certified.
- □ Closed-loop extraction systems are recertified by a California-licensed engineer if any of the following:
- □ 5 years have elapsed since the date of the last certification,
- □ Modified beyond the original equipment specifications, or
- □ Moved to a different premises.
- □ The closed-loop extraction systems, the extraction operations, the required gas detection systems, and the facilities and other equipment used, have been approved by the local fire code official, as required by local ordinance, and are operated in accordance with Cal/OSHA requirements and any other applicable state and local requirements.
- □ Prior to operating the extraction system, staff have completed training on how to use thesystem, including how to safely handle and store solvents, and training is documented.
- □ A written procedure is in use for maintaining the closed-loop extraction system according tomanufacturer specifications, and maintenance is documented using logs.

A written procedure is in use for verifying the closed-loop extraction system is operatingaccording to manufacturer specifications, and verification is documented using logs.

QUICK REFERENCE: Required Documentation

The documents below must be available onsite (either printed or in electronic form) and provided at the Department's request. For reference, we have included the section numbers for the regulations which detail what is required to be included in each document.

Manufacturing Procedures

- ☐ Master Manufacturing Protocols §17215
- ☐ Batch Production Records §17216
- ☐ Product Quality Plans §17214

Quality Control Program

- ☐ Equipment and Utensil Cleaning and Maintenance Procedures, Schedules, and Logs §17210
- ☐ Manufacturing Personnel Procedures §17211
- ☐ Cannabis Product Component Quality Control Procedures §17212

Standard Operating Procedures

- ☐ Security Plan for Licensed Manufacturers §15042.1
- ☐ Emergency Response Procedures and Safety Data Sheets (SDS) §17217
- ☐ Inventory Control Procedures §17218
- ☐ Waste Management Procedures §17223
- ☐ Track and Trace Procedures §§15047.1-15052.1
- ☐ Voluntary Recall Procedures §17226
- ☐ Training Procedures and Documentation of Employee Completion §17211.1

Other Required Documentation

- ☐ Product Complaint Records §17225
- ☐ Premises Diagram §15006
- ☐ Sales Invoices and Receipts §15037
- ☐ Contracts Regarding Commercial Cannabis Activity §15037
- ☐ Closed-loop System Certification, if applicable §17206.1
- ☐ Documentation evidencing solvent purity, if applicable §17204
- ☐ California Food Handler Certificates, if applicable §17211.1
- ☐ Juice or Beverage Manufacturing HACCP, if applicable §17219
- ☐ Cal-OSHA 30-hour general industry outreach course certificate, if applicable §15002
- ☐ Weighmaster Certificate §17221

The Department of Cannabis Control (DCC) licenses and regulates commercial cannabis activity within California. To learn more about the California cannabis market, state licenses or laws, visit cannabis.ca.gov. Email questions to info@cannabis.ca.gov or call 1-844-61-CA-DCC (1-844-612-2322).