### MANUFACTURED CANNABIS SAFETY BRANCH



This checklist is designed to assist you in reviewing the conditions of your cannabis manufacturing facility in preparation for or between inspections by the Manufactured Cannabis Safety Branch. The items listed below represent the major areas evaluated during a routine inspection, however it may not include all items evaluated and is not intended to substitute reading the regulations.

### Security Plan/Video Surveillance (§40200, 40205)

A written security plan is in use to prevent unauthorized access and theft. It includes, at a minimum, an alarm system, sign in/out procedures, perimeter security, and limited access areas.

Video surveillance is not obstructed and includes all areas where cannabis or cannabis products are stored, processed or moved within the premises, including limited access areas such as walk-in refrigerators and extraction rooms.

Video surveillance system continuously records 24 hours per day.

Video surveillance recordings are timestamped and kept for a minimum of 90 days.

### Inventory Management & Track-and-Trace (§40282, 40510-40517)

A written inventory control plan is in use; the business can identify where cannabis items are located within the facility at any given time.

All cannabis, cannabis products and in-process items containing cannabis are recorded in track-and-trace and tagged with Package Tags.

Changes to cannabis inventory are recorded in track-and-trace within 24 hours.

On-site inventory is reconciled with track-and-trace records every 30 days.

Transfers of cannabis products onto or off the manufacturing premises is conducted by a licensed distributor and recorded in track-and-trace using a transfer manifest; product does not move back and forth between manufacturing and distribution premises without a transfer manifest.

# Premises Diagram (§40105)

The premises diagram on file (uploaded in the Manufactured Cannabis Licensing System) accurately reflects the current layout of the premises

# Closed-Loop Extractions, If Applicable (§40222, 40225)

N/F

A California-licensed engineer has verified the equipment as it is installed and has certified it is safe for use with the intended solvent. The certification document contains the signature and stamp of the engineer and serial number of the extraction unit.

The local fire official has approved the extraction system, solvents and operation.

Any hydrocarbon-based solvents used are at least 99% purity.

A serial number is visible and affixed to extraction unit.

A written procedure is in use for training operators of closed-loop extraction system.

A written procedure is in use for maintaining the closed-loop system according to manufacturer specifications. Maintenance is documented using schedules/logs.

The extraction area is ventilated and operated in accordance with Cal/OSHA regulations.

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www.cdph.ca.gov/mcsb

mcsb@cdph.ca.gov

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## Non-Volatile Solvent Extractions, If Applicable (§40220, 40223)

N/A

Any non-hydrocarbon solvents used (ethanol, CO2, vegetable oil, glycerin, etc.) are food grade.

All solvents used for extraction or post-processing are included on the license application and have been approved by the Department. No blended or denatured solvents are being used, unless approved by the Department.

Ethanol extraction operations have been approved by the local fire code official and are operated in accordance with Cal/OSHA and any other state and local requirements.

N/A

### Master Manufacturing Protocols (§40255)

There is a written Master Manufacturing Protocol for each unique formulation of cannabis product manufactured at the premises

Each Master Manufacturing Protocol includes, at a minimum, written instructions for performing each step in the manufacturing process, identities and weights of ingredients, intended cannabinoid concentration, and references to packaging and labeling to be used.

# Batch Production Records (§40258)

A written Batch Production Record is prepared every time a batch of a cannabis product is manufactured, and the record follows the appropriate Master Manufacturing Protocol

Each batch production record includes, at a minimum, documentation of each steps in the production process including initials of the person who completed the step, the batch/lot number of the finished product, UIDs of the finished product and all cannabis ingredients, and any batch/lot IDs for ingredients used.

# Product Quality Plan (§40253)

Written Product Quality Plan is used for each type of product manufactured at premises

Each Product Quality Plan evaluates potential risks to cannabis product quality from biological, chemical and physical hazards, identifies preventative measures to mitigate risks, and identifies methods to evaluate and monitor risk prevention effectiveness

# Good Manufacturing Practices (§40230-40248)

**Grounds, Building and Premises**: The facility and fixtures are maintained to be clean, sanitary, and in good repair. Precautions are taken to minimize the potential for pest entry

**Equipment and Utensils**: Cleaning, sanitizing and maintenance procedures are documented using written procedures and logs. Equipment and utensils are used in accordance with their design

**Cannabis Product Components**: Raw materials and ingredients are stored properly and held at appropriate temperature to prevent contamination and adulteration. Ingredients that contain major food allergens are identified and stored to prevent cross-contact with other items

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## Personnel (§40246)

A written Disease Control Plan is in use which prevents employees with illness or open lesions from contact with manufacturing areas. Personnel report illnesses or open lesions to supervisors

Employees wear clean outer clothing and personal protective equipment (PPE), when needed, to protect against allergen cross-contact/contamination of products, surfaces, and materials.

Employees practice thorough hand washing before and after each absence from their workstation and any time hands become soiled or contaminated.

Eating food, drinking beverages, and storage of personal belongings are confined to areas separate from where cannabis products may be exposed and where utensils are washed.

Employees receive training on the health and safety hazards present at the premises.

### Weights and Measures (§40277)

Weighing devices are approved, tested, and sealed by the county sealer.

A licensed weighmaster performs the weighing, measuring or counting of cannabis or cannabis products, using sealed weighing devices, when that amount is for commercial transactions.

## Packaging & Labeling: Finished Goods, If Applicable (§40403-40417)

N/A

Packaging is, at a minimum, child-resistant, tamper evident and opaque (if an edible).

Primary panels of labels include, at a minimum, the product identity and universal symbol.

Informational panels of labels include, at a minimum, the UID and batch/lot number, the name and contact information of the licensed manufacturer, a complete ingredient list, and an allergen warning statement (if applicable).

Innermost product containers are labeled with, at a minimum, the universal symbol.

Labeling does not make any health claims (i.e., claims of therapeutic effect) and is not designed to be attractive to children.

## Waste Management (§40290)

Cannabis waste is made unrecognizable and unusable on the manufacturing premises

Cannabis waste is held in a secured area until pickup or self-hauling occurs

For hauled waste: Waste hauler documentation and contact information is maintained N/A

For self-hauled cannabis waste: A weight ticket/receipt is obtained from the waste facility N/A

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# **QUICK REFERENCE: Required Documents**

The documents below must be available onsite (either printed or electronic) and 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 §40255

Batch Production Records §40258

Product Quality Plans §40253

### **Quality Control Program**

Equipment and Utensil Maintenance Procedures, Schedule and Logs §40243

Personnel Disease Control Procedures §40246

Cannabis Product Component Quality Procedures §40248

### **Standard Operating Procedures**

Security Procedures §40200

Emergency Response Procedures and Safety Data Sheets (SDS) §40275

Inventory Control Procedures §40235-40258, 40282

Waste Management Procedures §40290

Track-and-Trace Procedures §40510-40512

Product Complaint Procedures §40295

Recall Procedures §40297

#### **Personnel Training Program**

Training Procedures and Documentation of Employee Completion §40280

Cal/OSHA 30-hour general industry outreach course certificate, if applicable N/A

Food Handler Certificates, if applicable §40280 N/A

#### **Quality Control Program**

Premises Diagram §40105

Shipping Manifests, Sales Invoices, & Receipts §40500

Closed-loop System Certification, if applicable §40225 N/A

HACCP Plan, if applicable §40270 N/A

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