



Summary slide

All **personnel** must have a clear understanding of the importance of their jobs and how they can affect the safety/quality of the product.



Not enough to '**train**' them to do their jobs, they need to understand why they do it and why it's important to do it correctly.



Standard Operating Procedures

- Written procedures
- Record is generated

Inspection

What will you look for?

How will you evaluate each observation?

Article 3. Good Manufacturing Practices

40230 Manufacturing Practices Definitions

40235 Quality Control Program

40240 Grounds, Building and Manufacturing Premises

40243 Equipment and Utensils

40246 Personnel *Licensees shall implement written procedures...*

40248 Cannabis Product Components

40250 Manufacturing Processes and Procedures

40253 Product Quality Plan

40255 Master Manufacturing Protocol

40258 Batch Production Record

Article 6. Other Responsibilities

§40275. Standard Operating Procedures

(a) Establish and maintain written SOPs, easily accessible to onsite personnel. Shall include:

- 1) Policies or procedures developed in accordance with the **security plan** required by Section 40200 (*security of facility, records*)
- 2) Emergency response procedures, including SDS for chemicals on-site
- 3) Policies and procedures developed in accordance with Section 40225 (*Closed Loop Extraction System requirements*)
- 4) Policies and procedures developed in accordance with Article 3 (GMPs) Subchapter 3**
- 5) Procedures for Track and Trace Requirements (Article 2 of Subchapter 6)
- 6) Inventory control procedures in compliance with Section 40282 and
- 7) Cannabis waste management procedures in compliance with Section 40290

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

Standard Operating Procedures



1. Purpose/Objective
2. Frequency
3. Who
4. Procedure
5. Monitoring
6. Corrections
7. Verification
8. Records
9. Other special considerations

May also include:

- A standard
- Record review procedures
- References

What to look for:

- Written in 'simple' language
- Easy to follow format
- Appropriate for their operation
- Everyone has access

WHY ARE SOPs IMPORTANT?

- Consistency in performance
- Critical for 'training'
- Records provide proof that task was done → verification

Records

- Document everything that is done to show who did it, when and how
 - Assure compliance with plan
 - If there is ever a problem, may refer back to a record to identify a potential source

Records must be meaningful



- Avoid checkmarks – become very routine
- Look for meaningful data (volumes, time, etc.) to track what was actually done, by whom and when

§40246. Personnel



(a) **Disease Control**

- Any individual who (by medical examination or supervisory observation) has an **illness** specified in H&SC 113949.2(a) or an
- **Open lesion** (boil, sores, cut, rash or infected wound) – *unless covered* in accordance with the requirements of H&SC 113949.2(b)
- Shall be excluded from **any manufacturing operations** until their health is corrected
- Personnel shall be instructed to **report** such health conditions to their supervisors



Personnel

- Disease Control
 - Infectious illness
 - Injuries or skin conditions
 - Cut, boil, rash, infected wound



What does 'covered' mean?
Band-aid? Finger cot?
Single use glove

Other symptoms:

- Coughing
- Sneezing
- Yellow eyes/skin



§40246. Personnel

Intent

- Infectious illnesses can be transmitted to the edible product or to each other
- Protect product, contact surfaces and packaging materials

Issues

- Employees may hide symptoms in order to continue working
- Supervisors may not be well-versed in identifying conditions that may be transmitted OR they may be more concerned with getting product out

Everybody must understand the importance of the policy

§ 40246. Personnel

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

ALLERGEN CROSS-CONTACT

- The unintentional incorporation of a food allergen into a cannabis product

- ‘Allergen’ means



- A major food allergen including Big 8
- A food ingredient that contains protein derived from a major food allergen.
- Does not include a highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

Potential areas for cross-contact

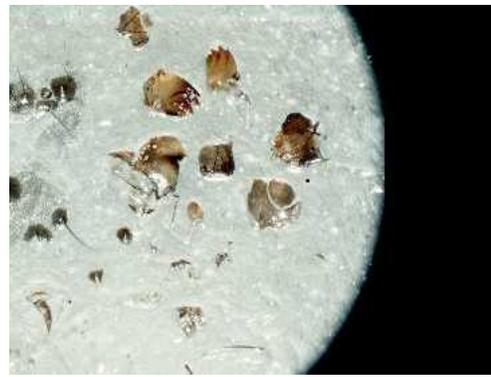
- Employee practices
- Physical separation of raw materials
- Equipment, tools, etc. not properly designated or cleaned

Things to look for

- Proper plant design
- Plant lay-out, flow
- Crowded processing conditions
- Employee awareness

Contamination

- Pest residuals
 - Insects/fragments, droppings
 - Rodent hair, droppings
 - Bird feathers, droppings
- Personnel residuals
 - Hair, fingernails, jewelry, trash, etc.
- Building/Equipment residuals
 - Condensate, paint, rust, glass, metal
- Others
 - Rotten fruit/vegetables
 - Spoiled ingredients
 - Mold



§40246. Personnel, (b) Cleanliness

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



Why is it important?

What is the company policy?

Are employees 'trained' on the subject?

Are employees following procedures?

If smocks are provided, who launders them?

§40246. Personnel, (b) Cleanliness

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

§40246. Personnel, (b) Cleanliness

→ §40240(E) hand-washing facilities → meet H&SC 113953 (a) through (d)

- (a) Shall be provided **within or adjacent to toilet facilities**. The number of handwashing facilities required shall be in accordance with local building and plumbing codes.
- (b) (1) Except as otherwise provided in **Section 114358**, food facilities constructed or extensively remodeled after January 1, 1996, that handle **non-prepackaged food**, shall provide facilities exclusively for handwashing in food preparation areas and in warewashing areas that are not located within or immediately adjacent to food preparation areas. Handwashing facilities shall be **sufficient in number and conveniently located** so as to be accessible at all times for use by food employees.
- (2) The handwashing facility shall be separated from the warewashing sink by a metal splashguard with a height of at least 6 inches, that extends from the back edge of the drainboard to the front edge of the drainboard, the corners of the barrier to be rounded. No splashguard is required if the distance between the handwashing sink and the warewashing sink drainboards is 24 inches or more.
- (c) Handwashing facilities shall be equipped to provide warm water **under pressure for a minimum of 15 seconds** through a mixing valve or combination faucet. If the temperature of water provided to a handwashing sink is not readily adjustable at the faucet, **the temperature of the water shall be at least 100°F, but not greater than 108°F**.
- (d) An automatic handwashing facility may be installed and used in accordance with the manufacturer's instructions.

§114358

- (a) Notwithstanding [Section 113953](#) (*previous slide*), handwashing facilities for **temporary food facilities that operate for three days or less** may include a container capable of providing a continuous stream of water from an approved source that **leaves both hands free to allow vigorous rubbing with soap and warm water for 10 to 15 seconds, inclusive.**
- (b) **Temporary food facilities** that handle only prepackaged food and comply with [Section 113952](#) (*next slide*) shall not be required to provide a handwashing facility, except as required in [Section 114359](#) (*next slide*) .
- (c) A catch basin shall be provided to collect wastewater, and the wastewater shall be properly disposed of according to [Section 114197](#) (*next slide*).
- (d) **Handwashing facilities shall be equipped with handwashing cleanser and single-use sanitary towels.**
- (e) **A separate receptacle shall be available for towel waste.**

HAND WASHING FACILITIES

- Location
 - Within or adjacent to toilet facilities
 - Easily accessible
 - Appropriate number
 - Separate from warewashing sink?
- Maintenance
 - Supply of warm water under pressure
 - *Supply soap and paper towels*
 - *Facilities cleaned and in good repair*



§40246. Personnel, (b) Cleanliness

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

How can this be monitored?

Covered in training?

Observe people?

Reminders?

NOTICE

EMPLOYEES MUST

WASH HANDS

--- BEFORE ---

RESUMING WORK

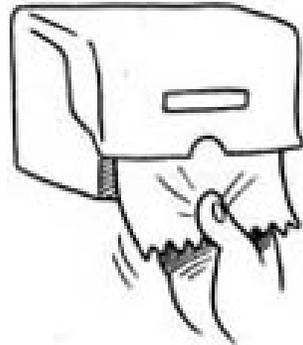
START →



1. Wet hands



6. Turn off
taps with
towel



5. Towel dry

HAND WASHING STEPS



2. Soap
(20 seconds)



3. Scrub backs
of hands, wrists,
between fingers,
under fingernails.



4. Rinse

§40246. Personnel, (b) Cleanliness

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



Hair clips?

Pens in top pocket?

Buttons? Glitter?

Piercings?

- What's acceptable?

- What isn't?

What kind of material is ok as a covering?

To whom does this apply?

- Everyone?

- Visitors?

- Inspectors??

§40246. Personnel, (b) Cleanliness

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

Gloves

- Purpose?
- Type
 - Disposable
 - Powder free
 - Nitrile vs Latex
- Proper care



§40246. Personnel, (b) Cleanliness

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



**What's
acceptable?**

Policy?

Enforcement?

§40246. Personnel, (b) Cleanliness

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



Look for storage sites

- Secure
- Not flat on top
- Open underneath to allow for cleaning, inspection
- Clean-out schedule

Personal belongings include jackets, caps, lunch boxes, cell phones, water bottles, etc.

They can transport contaminants (microorganisms, allergens, pet hair, dust, insects, etc.) to the work station.

§40246. Personnel, (b) Cleanliness

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

Can fall into the product, may contain allergens, trash, etc.

What about drinking water, especially where it's hot?

Look for a designated location, make sure it's being used, and that people wash their hands before going back to production areas.

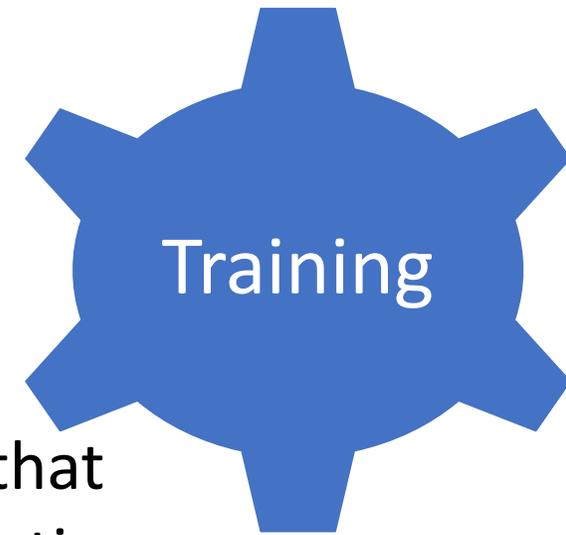
§40246. Personnel, (b) Cleanliness

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

Additional considerations ...
Allows each facility to evaluate and consider other potential sources of contamination

Article 6. Other Responsibilities

§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 safety data sheet for each solvent or chemical
 - (C) Emergency response procedures
 - (D) Security procedures
 - (E) Record keeping requirements
 - (F) Training requirements

Article 6. Other Responsibilities

§40280. Training Program (continued)

- (2) **Manufacturing and production personnel**, prior to independently engaging in any cannabis manufacturing process:
 - (A) An overview of the cannabis manufacturing process and standard operating procedure(s)
 - (B) Quality control procedures
 - (C) The product quality plans developed in accordance with Section 40253
 - (D) Proper and safe usage of equipment or machinery
 - (E) Safe work practices applicable to an employee's job tasks, including appropriate use of any necessary safety or sanitary equipment
 - (F) Cleaning and maintenance requirements
 - (G) Emergency operations, including shutdown
 - (H) **Any additional information reasonably related to an employee's job duties**

Article 6. Other Responsibilities

§40280. Training Program (continued)

- (3) Additionally, a licensee that produces edible cannabis products shall ensure that **all personnel who prepare, handle, or package edible products** successfully complete a *California food handler certificate course* from an entity accredited by the American National Standards Institute (ANSI) within 90 days of commencing employment at the premises and again every three years during employment. The licensee shall obtain documentation evidencing the fulfillment of this requirement;
- (4) The licensee shall ensure that **all personnel** receive **annual refresher training** to cover, at minimum, the topics listed in this subsection. This annual refresher training must be completed within 12 months of the previous training completion date.

Article 6. Other Responsibilities

§40280. Training Program (continued)

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

- (1) A **list of all personnel at the premises**, including at minimum, name and job duties of each individual
- (2) Documentation of **training topics and dates of training completion**, including refresher training, for all personnel
- (3) The signature of each individual personnel and the licensee **verifying receipt and understanding** of each training or refresher training completed by the individual
- (4) Any official **documentation attesting to the successful completion** of required training by personnel

Article 6. Other Responsibilities

§40280. Training Program (continued)

- (c) The licensee may assign responsibility for the training of individual personnel to supervisory personnel. Assigned **supervisory personnel** must have the education, training, or experience (or a combination thereof) necessary to ensure the production of quality cannabis products by all personnel. The **assigned training personnel** shall sign and date a document on an annual basis attesting that he or she *has received and understands* all information that will be provided to individual personnel in the training program. This documentation shall be maintained as part of the record requirements.
- (d) For licensees in operation pursuant to Section 40126 (Temporary Licenses), applicable personnel shall receive required training no later than 90 days after the effective date of the annual license.

Training / Education – what to look for

- All the topics are covered and taught by an appropriate individual
- Pertinent personnel are given the training at the required time frames (and refresher training)
 - Certificates are accurate and current

- Procedures and **why** they are important are explained
- Procedures are **demonstrated**
- Is there a way to make sure they **understood** what was being taught
- Is there supervision or oversight of how procedures are followed?

Training / Education – what to look for

- Is everyone aware of the policies and procedures?
- Is everyone following them?



Any questions?