

641—154.33(124E) Production requirements.**154.33(1) Cultivation and processing.**

a. All phases of production shall take place in designated, restricted access areas in accordance with rule 641—154.21(124E).

b. The production process shall be designed to limit contamination.

c. Each production area shall allow for access, observation, and inventory of each plant group.

154.33(2) Crop inputs and plant batches.

a. The manufacturer shall use the secure sales and inventory tracking system to maintain an electronic record of all crop inputs. The record shall include the following:

(1) The date of input application;

(2) The name of the employee applying the crop input;

(3) The crop input that was applied;

(4) The plants that received the application; and

(5) A copy of or electronic link to the safety data sheet for the crop input applied.

b. At the time of harvesting, all plants shall be tracked in a batch process with a unique batch number that shall remain with the batch through final processing into medical cannabidiol.

c. Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the secure sales and inventory tracking system or other manifest system.

154.33(3) Production of medical cannabidiol.

a. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process.

b. Medical cannabidiol shall be prepared, handled, and stored in compliance with the sanitation requirements in this rule.

c. A manufacturer shall produce shelf-stable, nonperishable forms of medical cannabidiol.

d. A manufacturer shall ensure that the cannabinoid content of the medical cannabidiol it produces is homogenous.

e. Each lot of medical cannabidiol shall be assigned a unique lot number and recorded in the secure sales and inventory tracking system or other manifest system.

154.33(4) General sanitation requirements. A manufacturer shall take all reasonable measures and precautions to ensure that:

a. Any employee who has a communicable disease does not perform any tasks that might contaminate plant material or medical cannabidiol;

b. Hand-washing facilities are:

(1) Convenient and furnished with running water at a suitable temperature;

(2) Located in all production areas; and

(3) Equipped with effective hand-cleaning and -sanitizing preparations and sanitary towel service or electronic drying devices;

c. All employees working in direct contact with plant material and medical cannabidiol use hygienic practices while on duty, including:

(1) Maintaining personal cleanliness; and

(2) Washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated;

d. Litter and waste are routinely removed and the operating systems for waste disposal are routinely inspected;

e. Floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair to inhibit microbial growth;

f. Lighting is adequate in all areas where plant material and medical cannabidiol are processed, stored, or sold;

g. Screening or other protection against the entry of pests is provided, including that rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests;

h. Any buildings, fixtures, and other facilities are maintained in a sanitary condition;

- i.* Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant material and medical cannabidiol and in accordance with applicable local, state, or federal law;
- j.* All contact surfaces, utensils, and equipment used in the production of plant material and medical cannabidiol are maintained in a clean and sanitary condition;
- k.* The manufacturing facility water supply is sufficient for necessary operations;
- l.* Employees have accessible toilet facilities that are sanitary and in good repair; and
- m.* Plant material and medical cannabidiol that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

154.33(5) Storage.

a. A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing, ensuring that:

(1) Plant material and medical cannabidiol are returned to a secure location immediately after completion; and

(2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area.

b. A manufacturer shall store all plant material and medical cannabidiol during production, transport, and testing, and all saleable medical cannabidiol:

(1) In areas that are maintained in a clean, orderly, and well-ventilated condition; and

(2) In storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind.

c. To prevent degradation, at all times, a manufacturer shall store all plant material and medical cannabidiol under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

d. A manufacturer shall maintain a separate secure storage area for medical cannabidiol that is returned from a dispensary.

154.33(6) Scales. All scales used to weigh usable plant material for purposes of these rules shall be certified in accordance with ISO/IEC 17025 dated 2017, which is incorporated herein by reference.

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