641—154.25(124E) Production requirements.

154.25(1) *Cultivation and processing.*

a. Only a licensed manufacturer is authorized to produce and manufacture medical cannabidiol.

b. All phases of production shall take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with rule 641—154.18(124E).

c. The production process shall be designed to limit contamination. Examples of contamination include mold, fungus, bacterial diseases, rot, pests, nonorganic pesticides, and mildew.

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

e. Biosecurity measures shall be in effect as described in the operating documents pursuant to subrule 154.17(1).

154.25(2) *Crop inputs and plant batches.*

a. All crop inputs used by a manufacturer must be approved by the department prior to the first application of the input. A manufacturer shall email a request for approval of a crop input to the department. The subject line of the email shall read, "RESPONSE REQUIRED – Crop input approval request." The department shall have up to 48 hours to respond with an approval or denial. A manufacturer may proceed with the application if the department does not reply within 48 hours of receiving the request. A crop input will remain approved unless or until the department withdraws the approval because of newly discovered product safety concerns. The department shall give a manufacturer written notification 48 hours before withdrawing an approval of a crop input.

b. The manufacturer shall use the department's 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;

(5) The amount of crop input that was applied; and

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

c. At the time of planting, 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.

d. A manufacturer shall record any removal of plants from the batch, including the reason for removal, on a record maintained at the manufacturing facility for at least five years.

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

154.25(3) *Production of medical cannabidiol.*

a. A manufacturer shall comply with all state and local building and fire code requirements.

b. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.

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

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

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

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

154.25(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. Plumbing size and design meets operational needs and all applicable state and local laws;

m. Employees have accessible toilet facilities that are sanitary and in good repair; and

n. Plant material and medical cannabidiol that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

154.25(5) *Storage.*

a. A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing to prevent diversion, theft, or loss, including ensuring that:

(1) Plant material and medical cannabidiol are returned to a secure location immediately after completion of the process or at the end of the scheduled business day; and

(2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area if a process is not completed at the end of a business day.

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, a manufacturer shall store all plant material and medical cannabidiol in production, transport, and testing, and all saleable 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, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the returned medical cannabidiol is destroyed. For purposes of this rule, a separate secure storage area includes a container, closet, or room that can be locked or secured.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter]