4770.1700 MEDICAL CANNABIS MANUFACTURER; PRODUCTION REQUIREMENTS.

Subpart 1. **Cultivation and processing.**

A. Only a registered medical cannabis manufacturer is authorized to produce and manufacture medical cannabis.

B. All phases of production must take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with part 4770.0900.

C. All areas must be compartmentalized based on function, and employee access must be restricted between compartments.

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

E. Each production area must have an open aisle for unobstructed access, observation, and inventory of each plant group.

F. Biosecurity measures must be in effect and documented according to part 4770.0400, subpart 1.

G. The manufacturer must maintain a record at the facility of all crop inputs for at least five years. The record must include the following:

(1) the date of application;

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

(3) the crop input that was applied;

(4) the section, including the square footage, that received the application by batch number;

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

(6) a copy of the label of the crop input applied.

H. At the time of planting, all plants must be tracked in a batch process with a unique batch number that must remain with the batch through final packaging.

I. A manufacturer must record any removal of plants from the batch on a record maintained at the manufacturing facility for at least five years.

J. The batch number must be displayed on the label of the medical cannabis.

Subp. 2. **Production of medical cannabis.**

A. The commissioner must approve the manufacturer's use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.

B. Medical cannabis must be prepared, handled, and stored in compliance with the sanitation requirements in this part.

C. A manufacturer must refrigerate perishable forms of medical cannabis.

D. A manufacturer must ensure that the cannabinoid content of the medical cannabis it produces is homogenous.

Subp. 3. **General sanitation requirements.** A manufacturer must 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 cannabis;

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 cannabis must 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 cannabis 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 cannabis 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 cannabis are maintained in a clean and sanitary condition are cleaned and sanitized as frequently as necessary to protect against contamination;

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 cannabis that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

Subp. 4. **Storage.**

A. A manufacturer must store plant material and medical cannabis during production, transport, and testing to prevent diversion, theft, or loss, including ensuring:

(1) plant material and medical cannabis 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 cannabis are locked inside a secure area if a process is not completed at the end of a business day.

B. A manufacturer must store all plant material and medical cannabis production, transport, and testing, and all saleable medical cannabis:

(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 must store all plant material and medical cannabis in production, transport, and testing, and all saleable medical cannabis under conditions that will protect it against physical, chemical, and microbial contamination and deterioration of the product and its container.

D. A manufacturer must maintain a separate secure storage area for medical cannabis that is returned, including medical cannabis that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until the returned medical cannabis is destroyed. For purposes of this part, a separate, secure storage area includes a container, closet, or room that can be locked or secured.

Statutory Authority: *MS s 14.389; 152.25; 152.26*

History: *39 SR 1080*

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