9810.2102 MANUFACTURING.

Subpart 1. **Authorized activities.**

A. A cannabis business must have the office's approval before manufacturing regulated products. To obtain the office's approval to manufacture regulated products, a cannabis business must submit a manufacturing plan to the office for:

(1) an initial license application or an annual renewal application;

(2) an endorsement application, if applicable; or

(3) a notification of a change in business activity under item C.

B. A cannabis business may conduct only the manufacturing activities in the operator's manufacturing plan approved by the office.

C. A cannabis business must notify the office of any changes to the manufacturing plan at least ten business days before implementing the change. A cannabis business must describe the change to the manufacturing plan on forms approved by the office and pay all applicable fees pursuant to Minnesota Statutes, chapter 342. If the change to the manufacturing plan includes relocating the licensed manufacturing facility, a cannabis business must pay additional fees pursuant to Minnesota Statutes, section 342.12, at the time that the cannabis business submits the change to the office.

Subp. 2. **Manufacturing plan requirements.**

A. In addition to application and business plan requirements in Minnesota Statutes, sections 342.14 and 342.25, a manufacturing plan must include information describing:

(1) planned regulated product types and planned volumes of production;

(2) the proposed size and layout of the facility areas that the cannabis business will use exclusively for manufacturing, including a diagram indicating the placement of equipment;

(3) a diagram of the proposed ventilation and air filtration systems;

(4) plans for providing electricity, water, and other utilities necessary for manufacturing activities;

(5) plans for wastewater disposal and solid waste disposal for manufacturing activities;

(6) plans for recycling supplies, inputs, ingredients, and work-in-progress for manufacturing, including water and packaging materials;

(7) a pest management protocol to control or prevent the introduction of pests to the manufacturing site;

(8) the sources of all ingredients and inputs that the cannabis business intends to use in the manufacturing process;

(9) all processing steps that the cannabis business will take, including all potential product-related biological, chemical, and physical hazards that may occur during each step and the business's planned actions to control the identified hazards;

(10) standard operating procedures for sanitary handling of ingredients, in-process product, finished products, and packaging materials;

(11) a description of batch numbering and plant identifier control systems that the cannabis business will use;

(12) methods for securing inputs and ingredients regulated under Minnesota Statutes, chapter 342, and in-process products after the addition of the inputs and ingredients; and

(13) procedures for keeping records of each batch that accurately identify all inputs, processes, and waste that the cannabis business must enter into the statewide monitoring system and declare for laboratory testing, regulatory review, and inspection.

B. A cannabis business must:

(1) regularly update the manufacturing plan with any changes to reflect current practices; and

(2) provide the office with an updated manufacturing plan whenever the cannabis business makes a change to the plan.

Subp. 3. **Compliance-related activities and access.**

A. A cannabis business must provide the office access to:

(1) all areas where the cannabis business receives, handles, processes, stores, and ships regulated products;

(2) all land, buildings, and other structures that the cannabis business uses for manufacturing and storing regulated products;

(3) all technical specifications for products, processes, and equipment that the cannabis business uses in the production of regulated products; and

(4) all of the cannabis business's records related to the production of regulated products, including all analysis and testing requests and reports.

B. A cannabis business must allow the office to collect inputs, ingredients, in-process products, packaging, and finished products for laboratory analysis to establish whether the business is in compliance with this chapter and Minnesota Statutes, chapter 342. A cannabis business must provide items collected for this purpose to the office at no cost.

Subp. 4. **Restrictions.**

A. A cannabis business must not conduct manufacturing in an area that is not identified in the manufacturing plan or at a site that is not approved by the office to manufacture regulated products.

B. A cannabis business must not produce regulated products in excess of:

(1) the limit established in part 9810.2101; and

(2) the amount of products approved by the office.

C. A cannabis business may manufacture only products and product types approved under part 9810.2100. A cannabis business must ensure that all products comply with Minnesota Statutes, section 342.06.

Subp. 5. **Prohibited sales.** A cannabis business must not sell any cannabinoid product resulting from cannabis manufacturing to a buyer if the cannabis business knows or should reasonably know that the buyer would be engaging in prohibited activities under Minnesota Statutes, chapter 342, or applicable local or state law with the obtained cannabinoid plant product.

Subp. 6. **Cannabis manufacturing premises requirements.**

A. Manufacturing must take place in a facility that meets the applicable requirements of Minnesota Statutes, section 342.26. A manufacturing facility must:

(1) have adequate physical space for all manufacturing, including storage, in a fully enclosed and secured indoor facility according to part 9810.1104;

(2) be supplied with electrical service, water service, sewer service or treatment, and other utilities necessary for operations approved by the office;

(3) have ventilation and air-handling systems with temperature and humidity controls that are adequate for safe processing and sanitary operations;

(4) be supplied with lighting fixtures that are adequate to perform manufacturing and sanitation functions in a safe and sanitary manner;

(5) have floors, walls, and ceilings in the manufacturing area that are constructed with surfaces that can be easily cleaned and maintained in good repair to inhibit microbial growth; and

(6) have hand-washing facilities located in all manufacturing areas where unpackaged product is handled.

B. If a cannabis business sells regulated products to consumers on the premises where manufacturing is authorized by the office, the cannabis business must ensure that a fence or other adequate security measure is in place to separate customer areas of the premises from limited-access areas, including any area where samples for mandatory testing are collected, packaged, and sealed for transport to a cannabis testing facility.

C. A facility that manufactures dried cannabis flower must follow additional requirements under part 9810.2203.

D. A facility that manufactures ingestible and lower-potency hemp edibles must follow additional requirements under part 9810.2204.

E. A facility that manufactures cannabis concentrate must follow additional requirements under part 9810.2205.

Subp. 7. **Sources of ingredients from cannabis and hemp.**

A. All regulated products that are used in the manufacturing process must be purchased, acquired, or received from a cannabis business permitted to distribute regulated products or from a Minnesota Tribally licensed cannabis business.

B. Hemp-derived ingredients must:

(1) be sourced from compliant hemp grown under the authority of a federally compliant hemp program; or

(2) be purchased, acquired, and received from a cannabis business permitted to distribute hemp-derived products regulated by the office or from a Minnesota Tribally licensed cannabis business.

Subp. 8. **Batch identification and reporting.** Each plant used in manufacturing must be labeled with a batch number according to part 9810.1302.

Subp. 9. **Manufacturing inputs and ingredients.**

A. All products other than cannabis-derived ingredients and hemp-derived ingredients must be:

(1) safe for the intended purpose and use in the manufacturing process. Any solvent used in manufacturing must be safe for human consumption and approved for use in foods by the federal Food and Drug Administration;

(2) handled and used in a manner that prevents contamination with filth, residues, or other substances that would likely render products of the cannabis plant injurious to human health;

(3) in conformance with applicable sections of Minnesota Statutes, chapters 18B, 18C, and 18D, and other applicable laws; and

(4) stored in original containers with original labels intact or in working containers of diluted or prepared applications labeled with information required by Minnesota Statutes, chapters 18B, 18C, and 18D, and other applicable laws.

B. All manufacturing inputs, ingredients, and containers must be used, stored, and disposed of according to label instructions and in compliance with all other applicable laws and regulations.

Subp. 10. **Sanitary practices.**

A. A cannabis business must follow sanitary practices during all manufacturing, including receiving, storing, processing, handling, packaging, and labeling regulated products. At a minimum, a cannabis business's sanitary practices must:

(1) ensure that an individual who has a communicable disease or other illness does not perform any tasks that might contaminate regulated products;

(2) ensure that hand-washing facilities in manufacturing areas are supplied with:

(a) hot and cold running water;

(b) effective hand-cleaning and sanitizing solutions; and

(c) sanitary drying functions, such as electronic drying devices, single-use towels, or a sanitary towel service;

(3) ensure that a worker who comes into direct contact with regulated products uses hygienic practices, including maintaining the cleanliness of the worker's outer garments and washing hands thoroughly in a hand-washing area before starting work and at any other time when the worker's hands may have become soiled or contaminated;

(4) control environmental conditions and ensure that workers use sanitary handling practices to protect products against physical, chemical, and microbial contamination and store products in a manner to prevent the growth of microorganisms;

(5) control environmental conditions to prevent the deterioration of products or contents that are described on the products' labeling;

(6) ensure that tools, utensils, and equipment, including storage containers, that come into direct contact with ingredients, in-process products, and finished products are cleanable and constructed from materials that will not transfer to ingredients or finished products; and

(7) ensure that all product-contact surfaces, utensils, and equipment are cleaned before being used to manufacture products and are maintained in a condition that prevents contamination of ingredients or regulated products.

B. Packaging materials that come into direct contact with ingredients, in-process products, or finished products must be:

(1) safe for use with the intended products;

(2) stored and handled in a manner to prevent contamination of materials from the environment; and

(3) cleaned between uses if designed for cleaning and multiple uses or discarded after single use.

C. A cannabis business must make efforts to prevent pests by:

(1) using screening or other protection against the entry of pests; and

(2) promptly disposing of waste to minimize odors and the potential for waste to attract, harbor, or become a breeding place for pests.

D. A cannabis business must store toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals in a separate location away from regulated products and in accordance with applicable local, state, and federal workplace safety requirements.

Subp. 11. **Record keeping.**

A. A cannabis business must keep records of each batch of manufactured products. A cannabis business must enter manufacturing and batch information in the statewide monitoring system as required by parts 9810.1400 to 9810.1402.

B. At a minimum, manufacturing records must include the following information for all manufacturing that the cannabis business conducts:

(1) the date that a worker conducted manufacturing;

(2) the name of the worker conducting manufacturing or the name of the responsible worker when more than one worker conducts manufacturing;

(3) a description of manufacturing that was conducted;

(4) process control measurements; and

(5) the batch number of the products involved in manufacturing.

Subp. 12. **Medical cannabinoid product and adult-use cannabis product manufacturing.** A license holder that is endorsed or authorized by the office to manufacture both medical cannabinoid products and adult-use cannabis products must comply with this subpart to manufacture medical cannabis and adult-use cannabis products on the premises of the same facility.

A. A cannabis business's manufacturing facility may manufacture both medical cannabis and adult-use cannabis products on the premises of the same facility if:

(1) the cannabis business's manufacturing plan indicates that the cannabis business will manufacture both medical cannabis and adult-use cannabis products on the premises of the same facility;

(2) the office has approved the cannabis business's manufacturing plan; and

(3) the cannabis business has a valid endorsement under Minnesota Statutes, section 342.51, to process medical cannabinoid products.

B. If a cannabis business is manufacturing both medical cannabis and adult-use cannabis on the premises of the same facility, the facility must:

(1) track all medical cannabis separately from adult-use cannabis;

(2) store all medical cannabis separately from adult-use cannabis;

(3) ensure that medical cannabis is not manufactured simultaneously or contemporaneously with adult-use cannabis on the same piece of equipment; and

(4) update and maintain records for each piece of equipment that the facility uses to manufacture both medical cannabis and adult-use cannabis. A cannabis business must make the records available to the office upon request. The records must contain:

(a) the name of the individual who operated the equipment;

(b) tracking information for the cannabis or cannabis concentrate that was processed using the equipment;

(c) the date, time, and duration that the equipment was used; and

(d) tracking information for the resulting products.

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