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[4770.0100 APPLICABILITY AND PURPOSE.](#)

Parts 4770.0200 to 4770.2700 establish the criteria and procedures to be used by the commissioner for the registration and oversight of a medical cannabis manufacturer.

[4770.0200 DEFINITIONS.](#)

Subpart 1. Applicability. The terms used in this chapter have the meaning given them in this part and in Minnesota Statutes, sections 152.22 through 152.37.

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Subp. 2. Acceptable performance or acceptable results. “Acceptable performance or “acceptable results” means analytical test results generated by a laboratory using methods as specified in parts 4770.XXXX that acceptable and allowed by the approved provider.

Subp. 3. Approval. “Approval” means acknowledgment by the commissioner that a laboratory has the policies, personnel, validated procedures and practices to produce reliable data in the analysis of analytes and contaminants described in part 4770.XXXX.

Subp. 4. Approved provider. “Approved provider” means a provider of performance testing samples that the commissioner has determined:

1. provides an adequate volume of samples to perform statistically valid analyses;
2. calculates the number of standard deviations of the mean allowed using the results of all labs submitting test results after the exclusion of outlying values;
and
3. allows a range of standard deviations of the mean no less stringent than the range allowed by the General Requirements for the competency of reference material producers in ISO Guide 34.

Subp. 5. Audit. “Audit” means a financial review by an independent certified public accountant that includes select scope engagement or other methods of review that analyze operational or compliance issues.

Subp. 6. Batch. “Batch” means a specific quantity that is uniform and intended to meet specifications for identity, strength, purity and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling batch record.

Subp. 7. Batch number. “Batch number” means a unique numeric or alphanumeric identifier assigned to a batch by a manufacturing facility when the batch is first planted. The batch number must contain the manufacturing facility number and a sequence to allow for inventory and traceability.

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Subp. 8. Biosecurity. "Biosecurity" means a set of preventative measures designed to reduce the risk of transmission of infectious diseases in crops, quarantined pests, invasive alien species, and living modified organisms.

Subp. 9. Certified financial audit. "Certified financial audit" means the annual financial audit required under Minnesota Statutes, section 152.37, subdivision 2.

Subp. 10. Commissioner. "Commissioner" means the commissioner of health or the commissioner's designee.

Subp. 11. Disqualifying felony offense . "Disqualifying felony offense" has the meaning given in Minnesota section 152.22, subdivision 3.

Subp. 12. "Distribute" or "distribution". "Distribute" or "distribution" means the delivery of medical cannabis to a patient, parent or legal guardian, or registered caregiver that is packaged in a container appropriately labeled for subsequent administration to or use by a patient who is participating in the registry program and who is authorized to receive medical cannabis.

Subp. 13. Distribution facility. "Distribution facility" means any building or grounds of a medical cannabis manufacturer where the sale and distribution of medical cannabis are authorized and the production of medical cannabis is prohibited at the distribution facility. A distribution facility may be part of a manufacturing facility and any distribution facility not on the same property as a manufacturing facility is prohibited from performing any production activities.

Subp. 14. Diversion. "Diversion" means the intentional transfer of medical cannabis to a person other than a patient, designated registered caregiver or a parent or legal guardian of a patient if the parent or legal guardian of a patient is listed on the registry verification."

Subp. 15. Field of Testing. "Field of Testing" means the combination of product type and analyte for which a laboratory has applied or received approval by the commissioner.

Subp. 16. Financial interest. "Financial interest" means any actual or future right to ownership, investment or compensation arrangement in a medical cannabis manufacturer with

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another person, either directly or indirectly, through business, investment or spouse, parent or child. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by the person, the person's spouse, parent or child, in the aggregate, do not exceed one per cent ownership in the medical cannabis manufacturer.

Subp. 17. Health care practitioner. “Health care practitioner” has the meaning given in Minnesota Statutes, section 152.22, subdivision 4.

Subp. 18. Inspection. “Inspection” an on-site evaluation of laboratory facilities, records, personnel, equipment, methodology, and quality assurance practices by the commissioner for compliance with the applicable provisions of this chapter.

Subp. 19. International Standards Organization or ISO. The “International Standards Organization” is an independent, non-governmental membership organization and the world's largest developer of voluntary International Standards.

Subp. 20. Laboratory managing agent. “Laboratory managing agent” means a person, as defined in Minnesota Statutes, section 326.71, subdivision 8, who is legally authorized to direct the activities of the laboratory and commit the appropriate resources to comply with parts 4770.XXXX to XXXX.

Subp. 21. Laboratory. “Laboratory” means fixed-based or mobile structure, a person, corporation, or other entity, including a government or tribal entity, that examines, analyzes or tests samples.

Subp. 22. Laboratory owner. “Laboratory owner means” a person who:

- A. is a sole proprietor of a laboratory;
- B. holds a partnership interest in a laboratory; or
- C. owns five percent or more of the shares in a corporation that owns a laboratory

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Subp. 23. Laboratory technical manager. “Laboratory Technical Manager” means a person who is scientifically responsible to ensure the achievement and maintenance of quality and analytical standards of practice and who is in a supervisory, lead worker, or similarly named positions within an organization.

Subp. 24. Manufacturing facility. “Manufacturing facility” means any secured building, space, grounds, and physical structure of a medical cannabis manufacturer for the production, cultivation, harvesting, manufacturing, packaging, and distribution of medical cannabis and where access is restricted to designated employees of a medical cannabis manufacturer.

Subp. 25. Medical cannabis. “Medical cannabis” has the meaning given in Minnesota section 152.22, subdivision 6.

Subp. 26. Medical cannabis waste. “Medical cannabis waste” means medical cannabis that is returned, damaged, defective, expired, or contaminated.

Subp. 27. Medical cannabis manufacturer or manufacturer. “Medical cannabis manufacturer” or “manufacturer” has the meaning given in Minnesota section 152.22, subdivision 7.

Subp. 28. Medical cannabis product. “Medical cannabis product” has the meaning given in Minnesota section 152.22, subdivision 8.”

Subp. 29. Parent or legal guardian. “Parent or legal guardian” has the meaning given in Minnesota Statutes, section 152.27, subd. 5.

Subp. 30. Patient. “Patient” has the meaning given in Minnesota Statutes, section 152.22, subdivision 9.”

Subp. 31. Plant material. “Plant material” means any cannabis plant, seeds, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots.

Subp. 32. Plant material waste. “Plant material waste” means plant material that is not used in the production of medical cannabis in a form allowable under MS 152.22, subdivision 6.

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Subp. 33. Production or produce. "Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion, or natural processing or manufacturing of cannabis, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

Subp. 34. Proficiency Testing Sample or PT Sample. "Proficiency Testing Sample or PT Sample" means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis.

Subp. 35. Manufacturing or manufacture. "Manufacturing" or "manufacture" means the process of converting harvested cannabis plant material into a finished product by manual labor or machinery designed to meet a specific need or customer expectation, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

Subp. 36. Registered designated caregiver. "Registered designated caregiver" has the meaning given in Minnesota section 152.22, subdivision 11."

Subp. 37. Registry program. "Registry program" has the meaning given in Minnesota section 152.22, subdivision 12."

Subp. 38. Registry verification. "Registry verification" has the meaning given in Minnesota section 152.22, subdivision 13."

Subp. 39. Restricted access area. "Restricted access area" means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested,

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stored, packaged, sold, or processed for sale, under control of the medical cannabis manufacturer, and where no one under the age of 21 is permitted.

Subp. 40. Sufficient cause to believe. "Sufficient cause to believe" means grounds put forth in good faith which are not arbitrary, irrational, unreasonable, or irrelevant and which make the proposition asserted more likely than not, provided the grounds are based on at least one of the following sources:

- A. facts or statements supplied by a patient, the patient's parent or legal guardian, the patient's designated registered caregiver, or an employee or agent of a medical cannabis manufacturer;
- B. reports from an approved laboratory that indicate concerns with the chemical or bacterial composition of the medical cannabis;
- C. financial records of a medical cannabis manufacturer;
- D. police records;
- E. court documents; or
- F. facts of which the commissioner or the commissioner's employees have personal knowledge.

4770.0300 DUTIES OF THE COMMISSIONER.

Subpart 1. Interagency agreements. The commissioner is authorized to enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulatory or inspection duties of a medical cannabis manufacturer and the registry program.

Subp. 2. Notice to public safety. If the commissioner has sufficient cause to believe that there is a threat to public safety, then the commissioner must notify local law enforcement agencies of any conditions that pose a threat to public safety, including:

- A. Loss or theft of medical cannabis or plant material;
- B. Diversion or potential diversion of medical cannabis or plant material;

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C. Unauthorized access of the patient registry.

Subp. 3. Inspection of medical cannabis manufacturer. A medical cannabis manufacturer is subject to reasonable inspection by the commissioner under Minnesota Statutes, section 152.29, subdivision 1. For purposes of this part, reasonable inspection means unannounced inspections by the commissioner of all:

- A. aspects of the business operations, including the requirements under part 4770.0400, subpart 1;
- B. physical locations of medical cannabis manufacturer, its manufacturing facility, and distribution facilities;
- C. financial information and inventory documentation; and
- D. physical and electronic security systems.

Subp. 4. Fees. Any fees collected by the commissioner under Minnesota Statutes, section 152.35 are not refundable.

Subp. 5. Patient costs; pricing.

- A. A medical cannabis manufacturer must follow the requirements under Minnesota Statutes, section 152.35, paragraph (d) in establishing a reasonable fee.
- B. The commissioner must annually review price costing by a medical cannabis manufacturer.

4770.0400 MEDICAL CANNABIS MANUFACTURER; OPERATIONS.

Subpart 1. Operating documents. Under Minnesota Statutes, section 152.29, subdivision 1, the operating documents of a medical cannabis manufacturer must describe operational and management practices, including:

- A. Record keeping;

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- B. Security measures to deter and prevent theft of medical cannabis;
- C. Unauthorized entrance into areas containing medical cannabis;
- D. Types and quantities of medical cannabis products that are produced at the manufacturing facility;
- E. Methods of planting, harvesting, drying, and storage of medical cannabis;
- F. Estimated quantity of all crop inputs used in cannabis plant cultivation;
- G. Estimated quantity of waste material to be generated;
- H. Disposal methods for all waste material;
- I. Employee training methods for the specific phases of production;
- J. Biosecurity measures used in cannabis plant production and in medical cannabis production;
- K. Response strategies to reconcile discrepancies in accounting of product inventories;
- L. Sampling strategy and quality testing for labeling purposes;
- M. Medical cannabis packaging and labeling procedures;
- N. Procedures for the mandatory and voluntary recall of medical cannabis;
- O. Response plans for measures to be taken in the event of a security breach at a manufacturing or distribution facility, or while medical cannabis is in route to a manufacturing or distribution facility;
- P. Business continuity plan;
- Q. Records relating to all transport activities; and
- R. Other information deemed necessary and requested by the commissioner.

Subp. 2. Prohibited activities.

- A. No person must own and operate a manufacturing facility unless the person is registered as a medical cannabis manufacturer by the commissioner under Minnesota Statutes, section 152.25.

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B. A medical cannabis manufacturer and its employees, agents, or owners, must not:

1. produce or manufacture cannabis in any location except in those areas designated in the registration agreement.
2. sell, deliver, transport or distribute medical cannabis or medical cannabis products from any location except its manufacturing facility or its distribution facility;
3. produce or manufacture medical cannabis or for use outside of Minnesota;
4. sell or distribute medical cannabis to any person other than a:
 - (a) patient;
 - (b) parent or legal guardian; or
 - (c) designated registered caregiver .
5. deliver or transport medical cannabis to any location except its distribution facilities and a laboratory approved by the commissioner.
6. sell cannabis that is not packaged and labeled in accordance with part 4770.XXXX; and
7. permit the consumption in or on the grounds of the medical cannabis manufacturer, its manufacturing facility and its distribution facility.

Subp. 3. Criminal background checks. A medical cannabis manufacturer is prohibited from employing any person who has a disqualifying felony offense following a Minnesota criminal history background check and a federal criminal history background check performed by the Bureau of Criminal Apprehension under Minnesota Statutes, section 152.29, subdivision 1.

Subp. 4. Conflict of interest; Health care practitioner activity restrictions. A medical cannabis manufacturer must not permit a health care practitioner who certifies qualifying conditions for patients:

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- A. to hold a direct or indirect economic interest in a medical cannabis manufacturer;
- B. to serve on the board of directors or as an employee of a medical cannabis manufacturer;
- C. to advertise with a medical cannabis manufacturer in any capacity; and
- D. a medical cannabis manufacturer may not accept, solicit, or offer any form of remuneration from a health care practitioner who certifies qualifying conditions for patients.

4770.0500 MEDICAL CANNABIS MANUFACTURER; QUALITY CONTROL AND ASSURANCE PROGRAM.

Subpart 1. Quality Control Program. A medical cannabis manufacturer must develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabis. Assessment includes a profile of the active ingredients, including shelf-life, and the presence of inactive ingredients, and contaminants. A medical cannabis manufacturer must use these testing results to determine appropriate storage conditions and expiration dates.

Subp. 2. Sampling protocols. A medical cannabis manufacturer must develop and follow written procedures for sampling medical cannabis that require that the manufacturer:

- A. conducts sample collection in a manner that provides analytically sound and representative samples;
- B. documents every sampling event and provide this documentation to the commissioner upon request;
- C. describes all sampling and testing plans in written procedures that include the sampling method and the number of units per batch to be tested; and

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- D. ensures that random samples from each batch are:
- 1 taken in an amount necessary to conduct the applicable test;
 - 2 are labeled with the batch unique identifier;
 - 3 submitted for testing; and
 - 4 the results are retained for at least five years.

Subp. 3. Sampling; testing levels.

- A. A medical cannabis manufacturer must develop acceptance criteria for all potential contaminants based on the levels of metals, microbes or other contaminants that the manufacturer uses in cultivating and producing medical cannabis. The testing levels are subject to approval by the commissioner.
- B. A medical cannabis manufacturer must conduct sampling and testing using acceptance criteria that are protective of patient health. The sampling and testing results must assure that batches of medical cannabis meet allowable health risk limits for contaminants.
- C. A medical cannabis manufacturer must reject a medical cannabis batch that fails to meet established standards, specifications, and any other relevant quality-control criteria.
- D. A medical cannabis manufacturer must develop and follow a written procedure for responding to results indicating contamination. The procedure must include destroying contaminated medical cannabis and determine the source of contamination.
- E. A medical cannabis manufacturer must retain documentation of test results, assessment, and destruction of medical cannabis for at least five years.

Subp. 4. Quality assurance program; Stability Testing.

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- A. The quality assurance program must include procedures for performing stability testing of each product type produced to determine product shelf-life that addresses:
1. Sample size and test intervals based on statistical criteria for each attribute examined to assure valid stability estimates;
 2. Storage conditions for samples retained for testing; and
 3. Reliable and specific test methods.
- B. Stability studies must include:
1. Medical cannabis testing at appropriate intervals;
 2. Medical cannabis testing in the same container-closure system in which the drug product is marketed; and
 3. Testing medical cannabis for reconstitution at the time of dispensing, as directed in the labeling, and after the samples are reconstituted.
- C. If shelf-life studies have not been completed before July 1, 2015, a medical cannabis manufacturer may assign a tentative expiration date, based on any available stability information. The manufacturer must concurrently conduct stability studies to determine the actual product expiration date.
- E. After the manufacturer verifies the tentative expiration date, or determines the appropriate expiration date, the medical cannabis manufacturer must include that expiration date on each batch of medical cannabis.
- F. Stability testing must be repeated if the manufacturing process or the product's chemical composition is changed.

Subp. 5. Reserve samples.

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- A. A medical cannabis manufacturer must retain a uniquely labeled reserve sample that represents each batch of medical cannabis and store it under conditions consistent with product labeling. The reserve sample must be stored in the same immediate container-closure system in which the medical cannabis is marketed, or in one that has similar characteristics. The reserve sample must consist of at least twice the quantity necessary to perform all the required tests.

- B. A medical cannabis manufacturer must retain the reserve for at least one year following the batch's expiration date.

Subp. 6. Retesting. When the commissioner deems that public health may be at risk, he or she may require the manufacturer to retest any sample of plant material or medical cannabis.

4770.0600 LOCATION; DISTANCE FROM A SCHOOL.

To comply with Minnesota Statutes, section 152.29 (j), a medical cannabis manufacturer must measure the distance of a manufacturing facility or a distribution facility from a public or private school as the shortest distance between the closest point of the property lines. For purposes of this part, "public or private school" means any property owned, leased, or controlled by a school district, charter school, or accredited nonpublic school where an elementary, middle, secondary school, secondary vocation center, or other school providing educational services in kindergarten through grade 12 is located, or used for educational purposes and "accredited nonpublic school" means any nonpublic school accredited by an accrediting agency recognized by the Minnesota nonpublic education council under section 123B.445, excluding home schools.

4770.0700 HOURS OF OPERATION; ACCESS.

Subpart 1. Hours of operation. The commissioner must limit the hours of operation of a distribution facility if there is sufficient cause to believe that limiting the hours of operation protects public safety.

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Subp. 2. Restricted access areas. A medical cannabis manufacturer must use an electronic controlled access system to limit entrance to all restricted access areas of manufacturing facilities and distribution facilities.

A. Controlled access systems must:

- (1) Limit access to authorized individuals;
- (2) Track personnel entry and exit times;
- (3) Lock-down the facility in the event of a security threat;
- (4) Store data for retrieval;
- (5) Remain operable in the event of power failure; and
- (6) Enable remote administration.

B. The medical cannabis manufacturer must immediately submit stored controlled access system data to the commissioner upon the commissioner's request.

C. Restricted access areas must be identified by with a sign that states: "Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only".

4770.0800 ADVERTISING AND MARKETING.

Subpart 1. Permitted marketing and advertising activities. A medical cannabis manufacturer may:

A. Display a business name and logo on medical cannabis labels, signs, a website and informational material provided to patients. The name or logo must not include:

- (1) medical symbols;
- (2) images of cannabis or cannabis smoking paraphernalia;
- (3) colloquial references to cannabis; or
- (4) names of cannabis plant strains.

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B. Display signs on the medical cannabis manufacturing facility and distribution facility.

C. Maintain a business website, with contains the following information:

1. medical cannabis manufacturer name;
2. distribution facility location;
3. contact information;
4. hours of operation;
5. medical cannabis products provided;
6. product pricing; and
7. other information as approved by the commissioner.

Subp. 2. Marketing and advertising activities; commissioner approval required.

- A. A medical cannabis manufacturer must request and receive the commissioner's written approval before beginning marketing or advertising activities that are not specified in subpart 1.
- B. The commissioner has 60 calendar days to approve marketing and advertising activities submitted under this subpart unless additional information is needed for the commissioner's review.

Subp. 3. Inconspicuous display. A medical cannabis manufacturer must arrange displays of merchandise, interior signs, and other exhibits so as to prevent public viewing from outside the manufacturing facility and distribution facility.

4770.0850. PACKAGING AND LABELING

Subpart 1. Medical cannabis packaging. The medical cannabis manufacturer must package all medical cannabis intended for distribution according to the following standards:

- A. Medical cannabis containers must be:
 - (1) Plain;
 - (2) Chosen to maximize shelf-life of contained medical cannabis;

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(3) Tamper-evident; and

(4) Child-resistant.

B. Medical cannabis packaging must not bear a reasonable resemblance to any commercially available product.

C. Medical cannabis must be packaged in a manner that is not attractive to children, including:

1. Packaging must not depict the product, cartoons, or images other than the medical cannabis manufacturer's business name logo.

2. Any name that might be customarily associated with persons under the age of 18 is prohibited;

Subp. 2 Medical cannabis trade names. The medical cannabis manufacturer's medical cannabis trade names must comply with the following standards:

A. Names are limited to those that clearly reflect the product's medical cannabis nature;

B. Any name that is identical to, or confusingly similar to, the name of an existing non-cannabis product is prohibited;

C. Any name that is identical to, or confusingly similar to, the name of an unlawful product or substance is prohibited; and

D. Any name that contains language that suggests using medical cannabis for recreational purposes or for a condition other than a qualifying medical condition is prohibited.

Subp. 3. Labeling.

A. A medical cannabis manufacturer must ensure that all medical cannabis dispensed is labeled with the following information:

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1. The qualifying patient’s registry identification number, name, and date of birth;
2. the name and date of birth of the designated registered caregiver, if applicable;
3. the name of the qualifying patient’s parent or legal guardian, if listed on the registry verification, if applicable;
4. the qualifying patient’s address;
5. the name and address of the medical cannabis manufacturer where the medical cannabis was manufactured;
6. the medical cannabis’s chemical composition;
7. the dosage;
8. directions for use of the product, if relevant;
9. all ingredients of the product, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight shown with common or usual names;
10. date of manufacture;
11. this statement, including capitalization: “This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Do not drive or operate heavy machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.”; and
12. this statement: “This medical cannabis is for therapeutic use only. Diversion of this product is a felony and may result in the revocation of your registration.”

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B. Labeling text must not include any false or misleading statements regarding health or physical benefits to the consumer.

C. A package may contain multiple labels. The labels, however, must be unobstructed and conspicuous so that no information required by these rules is obstructed.

4770.0900. MONITORING AND SURVEILLANCE REQUIREMENTS.

Subpart 1. 24-hour closed-circuit television. A medical cannabis manufacturer must operate and maintain in good working order 24-hours, seven days per week, closed-circuit television (CCTV) surveillance system on all of its premises that visually records:

- A. all phases of the cultivation of cannabis, including propagation, vegetation, and flowering, harvesting, and processing, and production;
- B. all areas that might contain cannabis, including all safes and vaults;
- C. at all points of entry and exit, including sales areas;
- D. the entrance to the video surveillance room; and
- E. any parking lot, which must have appropriate lighting for the normal conditions of the area under surveillance.

Subp. 2. Camera specifications. Cameras must do the following:

- A. capture clear and certain identification of any person entering or exiting the manufacturing facility or distribution facility.
- B. have ability to immediately produce a clear, color, still photo either live or from a recording;
- C. Embed a date and time stamp on all recordings that must be synchronized, set correctly, and not obscure the picture;

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D. remain operational during a power outage

Subp. 3. Video recording specifications. A video recording must export still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video must be archived in a proprietary format that ensures authentication and guarantees that the recorded image has not been altered. Exported video must also be saved in an industry-standard file format that can be played on a standard computer operating system. All recordings must be erased or destroyed before disposal.

Subp. 4 Additional requirements.

- A. Each manufacturer must have a backup alarm system that detects unauthorized entry when the facility is closed.
- B. The manufacturer must maintain security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

Subp. 5. Retention. The manufacturer must ensure that 24-hour recordings from all video cameras are:

- A. available for immediate viewing by the commissioner upon request;
- B. retained for at least 90 calendar days;
- C. maintained free of alteration or corruption; and
- D. retained longer as needed if the manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

4770.1000. ALARM SYSTEM REQUIREMENTS.

- A. A medical cannabis manufacturer must install and maintain a professionally monitored security alarm system that provides intrusion detection and fire detection

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of all facility entrances and exits, rooms with exterior windows, rooms with exterior walls, roof hatches, skylights, and storage rooms.

B. For purposes of this part, a security alarm system means a device or series of devices intended to summon law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

1. hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transit a remote or local audible, visual, or electronic signal;
2. motion detectors;
3. pressure switches;
4. duress alarm;
5. panic alarm;
6. holdup alarm;
7. automatic voice dialer;
8. a failure notification system that provides an audible, text or visual notification of any failure in the surveillance system; and
9. must remain operational during a power outage.

B. The commissioner must have the ability to access a medical cannabis manufacturer's security alarm system.

C. The security alarm system must be inspected and all devices tested annually by a qualified alarm vendor.

[4770.1100. TRANSPORTATION OF MEDICAL CANNABIS.](#)

Subpart 1. Transportation of medical cannabis and plant material; when authorized.

A. A medical cannabis manufacturer is authorized to transport medical cannabis:

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- (1) From its manufacturing facility to its distribution facilities;
- (2) From its manufacturing facility to a laboratory for testing; and
- (3) From its manufacturing facility or distribution facility to a Waste to Energy facility.

B. A medical cannabis manufacturer is authorized to transport plant material:

- (1) From its manufacturing facility to a waste disposal site; and
- (2) When a specific request from the manufacturer is approved by the commissioner.

Subp. 2. Transport manifest required.

A. Before transporting medical cannabis, a medical cannabis manufacturer must:

- 1. Complete a transport manifest on a form prescribed by the commissioner;
- 2. Transmit a copy of the transport to the manufacturer's distribution facility before transport; and.
- 3. Maintain all transport manifests [for how long?] and make them available upon request of the commissioner.

B. The transport manifest must be signed by an authorized medical cannabis manufacturer employee upon departure from the manufacturing facility and by an authorized medical cannabis manufacturer employee upon receipt at a distribution facility.

C. An authorized employee of the manufacturer at a distribution facility must:

- 1. verify and document the type and quantity of the transported product against the transport manifest;
- 2. return a copy of the signed transport manifest to the manufacturing facility

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3. track the medical cannabis that is received as inventory according to part 4770.XXXX

Subp. 3. Transportation of medical cannabis; vehicle requirements.

- A. All medical cannabis that is transported on public roadways must be:
 1. packaged in tamper-evident containers;
 2. transported so as not to be visible or recognizable from outside the vehicle.
 3. In a vehicle that must not bear any markings to indicate that the vehicle is transporting cannabis or bear the name or logo of the manufacturer.

- B. Any motor vehicle transporting medical cannabis on public roadways must:
 1. Travel directly to the distribution facility; and
 2. Document all stops in transit, including refueling, as follows:
 - (a) Reason for the stop;
 - (b) Duration of the stop;
 - (c) Location of the stop; and
 - (d) Activities of employees exiting the vehicle

 3. In the event of an emergency requiring the vehicle to stop, the driver must notify 911 and complete an incident report form as prescribed by the commissioner.

- C. A medical cannabis manufacturer must staff all transport motor vehicles with a minimum of two employees. At least one employee must remain with the motor vehicle at all times that the motor vehicle contains medical cannabis.

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- D. Each employee must have communication access with personnel at the manufacturer and the ability to contact law enforcement through the 911 emergency system at all times that the motor vehicle contains medical cannabis.
- E. An employee must carry his or her employee identification card at all times when transporting medical cannabis and, upon request, must produce the identification card to the commissioner or to a law enforcement officer who is acting in the course of official duties.
- F. A medical cannabis manufacturer is prohibited from leaving a vehicle that transporting medical cannabis unattended overnight

4770.1200. DISPOSAL OF MEDICAL CANNABIS AND PLANT MATERIAL.

Subpart 1. Medical cannabis take-back. The medical cannabis manufacturer must accept at no charge unused, excess, or contaminated medical cannabis from a patient or registered designated caregiver. The manufacturer must:

- A. Dispose of the returned medical cannabis as provided in subpart 2; and,
- B. Maintain a written record of disposal that includes:
 - (1) the name of the patient or registered designated caregiver that returned the medical cannabis;
 - (2) the date the medical cannabis was returned;
 - (3) the quantity of medical cannabis returned; and
 - (4) the type of cannabis returned.

Subp. 2. Medical cannabis and plant material waste. The medical cannabis manufacturer must store, secure, and manage medical cannabis waste and plant material waste in accordance with all applicable federal, state and local regulations.

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A. The manufacturer must dispose of medical cannabis waste by incineration at an Waste to Energy facility according to [applicable regulations].

B. The manufacturer must dispose of plant material waste by composting as follows:

(1) at the manufacturing facility, according to applicable law; or

(2) at an approved composting facility according to applicable law.

(3) Before transport, plant material waste must be rendered unusable and unrecognizable by grinding and incorporating the waste with a greater quantity of non-consumable, solid wastes including:

(a) paper waste;

(b) cardboard waste;

(c) food waste;

(d) grease or other compostable oil waste;

(e) compost activators;

(f) soil; or,

(g) other waste approved by the commissioner.

Subp. 3. Liquid waste. The medical cannabis manufacturer must dispose of all liquid waste generated in the process of cultivating, manufacturing and distributing medical cannabis in accordance with all applicable federal, state and local regulations.

Subp. 4. Chemical waste. The medical cannabis manufacturer must dispose of all chemical product waste generated in the process of cultivating, manufacturing and distributing medical cannabis in accordance with all applicable federal, state and local regulations.

Subp. 5. Waste-tracking requirements. The medical cannabis manufacturer must use forms prescribed by the commissioner to maintain accurate and comprehensive records regarding

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waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of medical cannabis waste and plant material waste.

4770.1300. MANDATORY SIGNAGE.

- A. A medical cannabis manufacturer must post a sign in a conspicuous location at each entrance of the manufacturing facility that reads, "PERSONS UNDER TWENTY-ONE YEARS OF AGE NOT PERMITTED ON THESE PREMISES."
- B. A medical cannabis manufacturer must post a sign in a conspicuous location at each entrance of the premises that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."
- C. An employee of a medical cannabis manufacturer must keep his or her employee identification card visible at all times when on the property of a cultivation center and during the transportation of medical cannabis to a distribution facility.
- D. A visitor must wear a visitor pass issued by the medical cannabis manufacturer visible at all times.

4770.1400 PERSONNEL IDENTIFICATION SYSTEM. A medical cannabis manufacturer must use a personnel identification system that controls and monitors individual employee access to restricted access areas within the manufacturing facility and distribution facility and meets the requirements of this part and part 4770.0700.

Subpart 1. Employee identification card requirement. An employee identification card must contain:

- A. The name of the cardholder;
- B. The date of issuance and expiration;
- C. An alphanumeric identification number that is unique to the card holder; and

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D. A photographic image of the cardholder.

Subp. 2 Employee identification card on person and visible at all times. A medical cannabis manufacturer employee must keep his or her identification card visible at all times when on the premises of the medical cannabis manufacturer and when transporting medical cannabis to a distribution facility.

Subp. 3. Termination of employment. Upon termination of an employee, a medical cannabis manufacturer must obtain and destroy and the terminated employee's identification card.

4770.1500. CLOSURE OF OPERATIONS; DEREGISTRATION.

Subpart 1. Notice. A medical cannabis manufacturer must notify the commissioner at least six months before closing the manufacturing facility and its distribution facilities.

Subp. 2. Destruction of plant material and medical cannabis. The commissioner must verify the remaining inventory of the manufacturer and seize all plant material, plant material waste, and medical cannabis if a medical cannabis manufacturer ceases operations. The commissioner must ensure that any plant material, plant material waste, and medical cannabis are destroyed by incineration at a Waste to Energy facility.

[PLACEHOLDER: Procedures for facility shutdown]

4770.1600. RECORD KEEPING; REQUIREMENTS.

- A. A medical cannabis manufacturer must maintain for at least five years complete, legible, and current records, including:
1. The date of each sale or distribution to a distribution facility;
 2. The name, address, and registration number of a distribution facility;

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3. The item number, product name, and quantity of cannabis sold or otherwise distributed;
 4. Records of sale prices of for the medical cannabis from patients;
 5. The quantity and form of medical cannabis maintained by the medical cannabis manufacturer at the manufacturing facility on a daily basis; and
 6. The amount of plants being grown at the manufacturing facility on a daily basis.
- B. A medical cannabis manufacturer must maintain records that reflect all financial transactions and the financial condition of the business. The following records must be maintained for at least five years and, upon request of the commissioner, must be available for inspection:
1. Purchase invoices, bills of lading, transport manifests, sales records, copies of bills of sale and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;
 2. Bank statements and canceled checks for all business accounts;
 3. Accounting and tax records;
 4. Records of all financial transactions, including contracts and agreements for services performed or services received;
 5. All personnel records.
 6. Soil amendment, fertilizers, crop inputs applied to the growing medium, plants, or plant material used in the process of growing plant material;

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7. Production records, including planting, harvest and curing, weighing, destruction of plant material, creating batches of medical cannabis; disposal of waste materials associated with production.
8. Transportation records;
9. Inventory records;
10. Records of all samples sent to a testing lab and the quality assurance test results; and
11. Records of any theft, loss, or other unaccountability of any medical cannabis or plant material.

4770.1700 MEDICAL CANNABIS MANUFACTURER; PRODUCTION REQUIREMENTS

Subpart 1. Cultivation and General Processing.

- A. Only a medical cannabis manufacturer is permitted to cultivate plant material.
- B. Each manufacturer must develop and maintain an Operations and Management Practices Plan for each production area. The commissioner must approve the Operations and Management Practices Plan.
- C. All phases of the cultivation of plant material must take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with part 4770.0900.
- D. All areas in the cultivation area must be compartmentalized based on function.

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and access must be restricted between compartments.

E. The cultivation process must be designed to limit contamination, including, but not limited to, mold, fungus, bacterial diseases, rot, pests, non-organic pesticides, mildew, and any other harmful contaminant identified by the commissioner.

F. Each production area must have an open aisle on all sides of each plant group to allow for unobstructed travel, observation and inventory of each plant group.

G. Each production area must be maintained free of debris.

H. Biosecurity measures must be implemented and maintained at all times.

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

(1) The date of application;

(2) The name of the individual making the application;

(3) The product that was applied;

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

(5) The amount of product that was applied; and

(6) A copy of the label of the product applied.

J. At the time of planting, all plants must be accounted for as a batch with a unique batch number that must remain with the batch through final packaging.

K. A manufacturer must record any removal of plants from the batch on a record maintained at the manufacturing facility for at least 5 years.

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L. The batch number must be displayed on the approved label of the product designated for distribution.

Subp. 2. Production of medical cannabis.

A. A manufacturer must produce medical cannabis in specifically designated and restricted-access areas.

B. All areas in the manufacturing facility must be compartmentalized based on function, and access must be restricted between compartments.

C. The commissioner must approve the manufacturer's use of any hydrocarbon-based extraction process before the manufacturer uses such an extraction process to produce medical cannabis.

D. Medical cannabis, in all allowable forms, must be prepared, handled, and stored in compliance with the sanitation requirements in this part.

E. A manufacturer must adequately refrigerate perishable forms of medical cannabis.

F. 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 person who has:

(1)an infectious illness;

(2)open lesions, including boils, sores, or infected wounds; or

(3)any other abnormal source of microbial contamination

is excluded from contact with plant material or medical cannabis operations until the condition is corrected.

B. Hand-washing facilities are:

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- (1) Adequate, convenient, and furnished with running water at a suitable temperature;
- (2) Located in the manufacturing facility where good sanitary practices require employees to wash or sanitize their hands, including all production areas; and
- (3) Equipped with effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

C. All persons working in direct contact with plant material and medical cannabis must conform to hygienic practices while on duty, including:

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

D. Litter and waste are properly removed and the operating systems for waste disposal are maintained in a manner so that they do not constitute a source of contamination in areas where plant material and medical cannabis are exposed;

E. Floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and that each is kept clean and in good repair;

G. There is adequate lighting in all areas where plant material and medical cannabis are processed, stored or sold, and where equipment or utensils are cleaned;

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

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

J. Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified, held, and stored in a manner that protects against contamination of plant material

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medical cannabis and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation, or ordinance;

K. All contact surfaces, utensils, and equipment used in the production of plant material and medical cannabis are maintained in a clean and sanitary condition, including that such surfaces, utensils, and equipment are cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the U.S. Environmental Protection Agency (EPA), in accordance with labeled instructions;

L. The manufacturing facility water supply is sufficient for necessary operations;

M. Plumbing is of adequate size and design, and adequately installed and maintained, to carry sufficient quantities of water to required locations throughout the manufacturing facility and remove waste without cross-contamination;

N. Employees have adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and

O. Plant material and medical cannabis that can support the rapid growth of undesirable microorganisms are held in a manner that prevents the growth of these microorganisms.

Subp. 4. Storage.

A. A manufacturer must keep and store medical cannabis, plant material and medical cannabis in the process of cultivation, processing, transport, and testing in such a manner as to prevent diversion, theft, or loss, including that:

(1)Plant material and medical cannabis is accessible only to the minimum number of specifically authorized manufacturer's agents essential for efficient operation;

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

(3) If a process is not completed at the end of a business day, the tanks, vessels, bins, or bulk containers containing plant material or medical cannabis must be locked inside a secure area.

B. A manufacturer must keep and store all plant material and medical cannabis in the process of cultivation, processing, transport, and testing and all saleable medical cannabis as follows:

(1) Under conditions that will protect it against physical, chemical, and microbial contamination as well as against deterioration of the product and its container;

(2) In areas that must be maintained in a clean, orderly and well ventilated condition; and

(3) In storage areas that must be free from infestation by insects, rodents, birds, and pests of any kind.

C. A manufacturer must maintain a separate secure storage area for medical cannabis that is returned, outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until such products are destroyed.

4770.1800. INVENTORY.

Subpart 1. Controls and procedures. A medical cannabis manufacturer must establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of plant material and medical cannabis to prevent and detect any diversion, theft, or loss in a timely manner.

Subp. 2. Reliable and ongoing supply. A medical cannabis manufacturer must provide a reliable and ongoing supply of medical cannabis as required by Minnesota Statutes, section 152.29, subdivision 2.

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Subp. 3. Initial inventory. A medical cannabis manufacturer must:

- A. conduct an initial comprehensive inventory on the date it first cultivates plant material and distributes medical cannabis; and
- B. maintain a real-time record of its inventory of plant material and medical cannabis to include:

- 1. Date and time of the inventory;
- 2. Summary of inventory findings;
- 3. Names of the employee(s) conducting the inventory; and
- 4. Other information deemed necessary and requested by the commissioner.

Subp. 4. Waste inventory. The medical cannabis manufacturer must maintain a real-time record of its inventory of all medical cannabis waste and plant material waste for disposal.

Subp. 5. Reconciliation. At the close of business each day, a medical cannabis manufacturer must reconcile all:

- A. Plant material at the manufacturing facility and in-transit; and
- B. Medical cannabis at the manufacturing facility, distribution facility, and in-transit.

Subp. 6. Scales. All scales used to weigh usable cannabis for purposes of assessing inventory must be certified in accordance with applicable standards.

4770.1900 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM.

Subpart 1. Scope. The commissioner approves the medical cannabis laboratory approval program under Minnesota Statutes, section 152.29, and approves a laboratory independent of a medical cannabis manufacturer.

Subp. 2 Available products types and analytes.

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- A. The commissioner must maintain and publish a list of all analytes available for approval. The category of analytes include:
1. Cannabinoid profile;
 2. Metals;
 3. Pesticide residues and plant growth regulators;
 4. Microbiological contaminants and mycotoxins; and
 5. Residual solvents;
- B. The list of analytes must be reviewed at least every six months and any updates published in the State Register and posted on the program's website. The commissioner must publish the notification of changes and review comments on the changes no less than 30 days from the date the list is published.

4770.2000 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM; APPLICATION.

Subpart 1. Application Requirements.

- A. A laboratory may request to be approved by the commissioner for the use of procedures to test the product types and analytes eligible for approval according to part 4770.1900, subpart 2..
- B. A laboratory is encouraged to operate formal management systems in accordance to International Organization for Standardization (ISO). The ISO/IEC 17025, *General Requirements for the Competency of Testing and Calibration Laboratories*, includes technical and management system requirements.
- C. A laboratory seeking initial or renewal medical cannabis laboratory approval after December 31, 2016, must be accredited to Standard ISO/IEC 17025:2005, *General*

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Requirements for the Competency of Testing and Calibration Laboratories, of the International Organization for Standardization.

- D. A laboratory must specify the field of testing for which it seeks approval. No laboratory approval shall be awarded for any field of testing without the laboratory meeting the approval requirements. No laboratory may receive approval without approval of at least one field of testing.
- E. A laboratory must apply on a form provided by the commissioner. The laboratory must supply the following information:
1. the legal name and legal status of the laboratory;
 2. the physical location, postal mailing address of the laboratory;
 3. the owner of the laboratory;
 4. the names and telephone numbers and electronic mail address of a designated contact person;
 5. the names and telephone number and electronic mailing address of laboratory director;
 6. the name of at least one managing agent; and
 7. the name of at least one technical manager.
- F. A laboratory must submit with the completed application form the following items:
- (1) a signed and notarized attestation form stating the laboratory is independent from the medical cannabis manufacturers. The laboratory must declare any conflict of interest, actual or perceived, relating to the direct or indirect financial interests in medical cannabis manufacturer;
 - (2) a quality assurance manual;
 - (3) standard operating procedures ;

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- (4) sample handling, receipt and acceptance procedures and policies;
- (5) demonstration of laboratory capability and acceptable performance through a combination of:
 - i. existing certificates/approvals;
 - ii. documented demonstrations of analytical capabilities;
 - iii. documented and acceptable proficiency testing samples from an approved provider, where available
- (6) method validation procedures for testing methods;
- (7) the name and educational qualifications of at least one technical manager responsible for the laboratory achieving and maintaining the quality and analytical standards of practice;
- (8) a copy of the lab's ISO/IEC 17025:2005 Certificate and Scope of Accreditation, on or before December 31, 2016.
- (9) a copy of the lab's most recent assessment report including the scope of the assessment to ensure the evaluation of the medical cannabis fields of testing, on or before December 31, 2016.

Subp. 2. Additional Application Requirements for Mobile Laboratories. A mobile laboratory is considered a separate laboratory and is subject to all requirements of parts 4770.1900 to 4770.2500. In addition to the requirements of subpart 1, a mobile laboratory must:

A. submit a vehicle identification number, license plate number, or other uniquely identifying information to the commissioner when applying for approval; and

B. Designate which fields of testing, equipment and personnel are associated with the mobile laboratory.

Subp. 3. Application Review. Within 30 days of receiving the application form and the information required in subpart 1 and subpart 2, the commissioner shall:

- A. notify the laboratory in writing of any omission or error in the application;

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- B. deny approval according to part 4770.2100, subpart 2 for an initial application or revoke approval for a renewal application if the laboratory does not submit to the commissioner the required information within 15 days after receiving an error notice under item A;
- C. award approval according to part 4770.2100, subpart 1 if the laboratory's application meets the applicable standards of parts 4770.1900 to 4770.2500.
- D. notify the laboratory that its current approval for fields of testing shall be continued until the commissioner fully reviews all documentation for compliance with parts 4770.1900 to 4770.2500.

Subp. 4. Laboratory Inspection and Reports.

- A. The commissioner may conduct inspections of a laboratory requesting approval or approved laboratories. A laboratory meeting the application requirements may perform analyses and report results with the same approved status, the interim approval status shall not exceed 6 months.
- B. The commissioner may notify a laboratory before arrival at the facility or may conduct an inspection without prior notice at any time during normal business hours to verify compliance with parts 4770.1900 to 4770.2500. When the commissioner provides notification, the notification may be written or oral.
- C. The commissioner may require third party validation and on-going monitoring of the laboratory to ensure proficiency, execution and validation of analytical methodologies. The laboratory must pay for all costs associated with the commissioner ordered third party validation.

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- D. The commissioner may consult and request reports from the approved laboratory regarding chemical compositions, dosages and noncannabis drug interactions under Minnesota Statutes, section 152.24.
- E. The commissioner maintains the right to request reports and procedures from an applicant or approved laboratory in regards to compliance with this rule.

4770.2100 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM; COMMISSIONER APPROVAL OR DENIAL.

Subpart 1. Awarding Approval

- A. The commissioner's documentation of laboratory approval must include:
 - (1) a letter acknowledging compliance with approval requirements by the laboratory;
 - (2) the scope of approval for the laboratory;
 - (3) the logo of the Minnesota Department of Health;
 - (4) the name of the laboratory;
 - (5) the address of the laboratory; and
 - (6) the expiration date of the approval.
- B. If a laboratory's scope of approval changes, the commissioner shall issue a new document with the scope of approval;
- C. A laboratory's approval is valid for one year from the date of awarding approval or renewal of approval, unless conditions warrant denial or rescinding approval by the commissioner under subpart 2.
- D. A laboratory must return its approval letter to the commissioner upon rescinding approval of the laboratory.

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- E. An approved laboratory must not misrepresent its approval on any document, including laboratory reports, catalogs, advertising, business solicitations, proposals, quotations, or other materials.

- F. A laboratory must make available its current approval documentation and corresponding scope of approval upon the request of a client, approval authority, or regulatory agency. The laboratory must not supply a copy of its current approval without the accompanying copy of its scope of approval.

Subp. 2. Denial of laboratory approval. The denial or approval for the approved medical cannabis laboratory list is considered a final decision of the commissioner.

4770.2200 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM; LIST OF APPROVED LABS.

Subpart 1. Commissioner list of approved cannabis labs (a) the commissioner shall publish a list of approved cannabis laboratories, the primary laboratory contact, phone numbers, location and lab's scope of approval.

Subp. 2. Approval rescinded. The commissioner shall rescind approval for an approved cannabis laboratory if the commissioner determines one or more of the following reasons exist:

- (1) Failure to comply with or misrepresentation of application materials required by part 4770.2000;
- (2) Nonconformance with the applicable laws, rules, standards, policies and procedures;
- (3) History of repeated nonconformance or complaints regarding the analysis of medical cannabis;

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- (4) Failure to allow the commission or designee to perform physical inspection of facilities or failure to provide copies of inspection and corrective report(s) issued by the approved ISO/IEC 17025 accreditation body; and
- (5) Failure to provide the medical cannabis manufacturer (s) with timely reports compliant with the commissioner's designated test report format.

Subp. 3. Decision of the commissioner is final. Rescinding approval from the approved medical cannabis laboratory list is considered a final decision of the commissioner.

4770.2300 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM; VARIANCES.

The commissioner may grant a variance from parts 4770.1900 to 4770.2500. To request a variance, a laboratory must indicate in writing:

- (1) The rule part and language for which the variance is sought;
- (2) Reasons for the request;
- (3) Alternate measures that will be taken if the request for variance is granted;
- (4) The length of time of the variance; and
- (5) Data to ensure analytical results of equal or better reliability, if applicable.

4770.2400 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM; VOLUNTARY WITHDRAWAL OF APPROVAL.

A. If a laboratory chooses to withdraw its application for approval or its current approval in total or in part, then the laboratory must notify the commissioner in writing and specify the effective date of withdrawal.

B. By the effective date of the withdrawal of approval, in total or in part, the laboratory must notify current clients, manufacturers and regulatory agencies of its intent to withdraw its approval and must indicate the effective date of the withdrawal. The notifications from the laboratory must be in writing. The laboratory must submit a copy of each notification to the commissioner at the that the notification is sent to clients, manufacturers or regulatory agencies.

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4770.2500 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM; DUTY TO NOTIFY.

A. A laboratory must notify the commissioner in writing within 30 days of a change in:

- (1) the name of the laboratory;
- (2) the physical location, postal mailing address, and electronic mailing address of the laboratory;
- (3) the owner of the laboratory;
- (4) the names, telephone numbers or email address of the designated contact person;
- (5) the name of at least one managing agent with signatures attested by notarial officers;
- (6) the names of at least one technical manager;
- (7) major analytical equipment; or
- (8) test methods.

B. With the notification, a laboratory must provide results of proficiency testing samples or demonstrations or capability, analyzed in the new laboratory location or analyzed under the change in laboratory owner, instrumentation or methods.

4770.2600 MEDICAL CANNABIS LABORATORY APPROVAL PROGRAM; APPEAL OF ADMINISTRATIVE DECISION.

A. The commissioner must notify a laboratory in writing the reason(s) for the decision to deny or rescind laboratory approval.

B. A laboratory has 30 days from the date of received the decision to appeal the decision. A request to appeal the decision must:

- (1) be in writing;
- (2) indicate the facts the laboratory disputes;
- (3) be signed by the laboratory managing agent; and
- (4) be sent to the commissioner.

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- 2) Upon receipt of an appeal request, the commissioner has 60 days to decide the appeal and the commissioner's decision is considered a final decision of the commissioner.

4770.2700 MEDICAL CANNABIS MANUFACTURER; FINANCIAL EXAMINATIONS; PRICING REVIEWS.

- A. A medical cannabis manufacturer must maintain financial records in accordance with generally accepted accounting principles and, upon request, must provide any financial records to the commissioner.
- B. The commissioner must request an additional audit of the medical cannabis manufacturer, of the same time period, if the commissioner finds one or more of the following:
1. credible evidence or allegations of financial reporting irregularities not revealed in the annual certified financial audit; or
 2. reasonable cause to believe there are operational or compliance irregularities involving financing, budgeting, revenues, sales or pricing.