

4770.0200 DEFINITIONS.

Subpart 1. **Scope.** The terms used in this chapter have the meanings given them in this part.

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 part 4770.2000 that are acceptable and allowed by the approved provider.

Subp. 3. **Approval.** "Approval" means acknowledgment by the commissioner that a laboratory has the policies, personnel, validation procedures, and practices to produce reliable data in the analysis of analytes and contaminants described in part 4770.1900.

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

- A. provides an adequate volume of samples to perform statistically valid analyses;
- B. calculates the number of standard deviations of the mean allowed using the results of all laboratories submitting test results after the exclusion of outlying values; and
- C. 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. 5a. **Audit sample.** "Audit sample" means a representative sample necessary to complete audit testing of plant material, a dried raw cannabis batch, or a dried raw cannabis finished good collected for audit testing under part 4770.3035.

Subp. 6. **Batch.**

A. "Batch" means a specific quantity of medical cannabis, including a set of plants of the same variety of medical cannabis that have been grown, harvested, and processed together and exposed to substantially similar conditions throughout cultivation and processing, that:

(1) is uniform and intended to meet specifications for identity, strength, purity, and composition; and

(2) is produced according to a single batch production record executed and documented during the same cycle of manufacture.

B. A batch of dried raw cannabis may not exceed 80 pounds.

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.

Subp. 7a. **Batch sample.** "Batch sample" means a representative sample taken from a batch of dried raw cannabis prior to laboratory testing.

Subp. 8. **Biosecurity.** "Biosecurity" means a set of preventative measures designed to reduce the risk of transmission of:

- A. infectious diseases in crops;
- B. quarantined pests;
- C. invasive alien species; and
- D. living modified organisms.

Subp. 8a. **CBD.** "CBD" means the compound cannabidiol, CAS number 13956-29-1.

Subp. 8b. **CBDA.** "CBDA" means cannabidiolic acid, CAS number 1244-58-2.

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

Subp. 9a. **Chemical composition.** "Chemical composition" means the distribution of individual components within a final formulation or finished good. This includes active ingredients, inactive ingredients, and other ingredients. Active ingredients include cannabinoids used to define a finished good in the registered products list. The concentration of each active ingredient may be given either in terms of milligram per milliliter (mg/mL) for liquids and milligram per gram (mg/g) for solids or in terms of mass fraction (weight percentage).

Subp. 10. **Commissioner.** "Commissioner" means the commissioner of the Department of Health or the commissioner's designee.

Subp. 10a. **Crop input.** "Crop input" means a substance other than water that is applied to or used in the cultivation of a cannabis plant for pest control, plant health, or growth management. Crop input includes pesticides, fungicides, plant regulators, fertilizers, and other agricultural chemicals regulated by the Minnesota Department of Agriculture.

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

Subp. 12. **Distribute or distribution.** "Distribute" or "distribution" means the delivery of medical cannabis to a patient, the patient's parent or legal guardian, or the patient's registered caregiver that is packaged in a suitable 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 and medical cannabis products are authorized.

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

Subp. 14a. **Dried raw cannabis.** "Dried raw cannabis" means the dried leaves and flowers of the mature cannabis plant. Dried raw cannabis includes pre-rolled cannabis as long as the pre-roll consists of only dried cannabis leaves and flowers, an unflavored rolling paper, and a filter or tip. Dried raw cannabis does not include the cannabis seeds, seedlings, stems, stalks, roots, or any part of the immature cannabis plant.

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 another person, either directly or indirectly, through business, investment, or spouse, parent, or child relationship. 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 or the person's spouse, parent, or child, in the aggregate, do not exceed one percent ownership in the medical cannabis manufacturer.

Subp. 16a. **Finished good.** "Finished good" means either an extract formulation that has been packaged and labeled for delivery to a medical cannabis distribution facility for distribution to patients or dried raw cannabis that has been packaged and labeled for delivery to a medical cannabis distribution facility.

Subp. 16b. **Flower.** "Flower" means the flower of the cannabis plant.

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

Subp. 17a. **Immature plant.** "Immature plant" means a nonflowering cannabis plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping, or seedling and is in a cultivation container.

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

Subp. 19. **International Standards Organization or ISO.** The "International Standards Organization" or "ISO" means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

Subp. 19a. **Labeling.** "Labeling" means all labels and other written, printed, or graphic matter on a packaged finished good or any container or wrapper accompanying the packaged finished good.

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 sufficient resources to comply with parts 4770.1900 to 4770.2400.

Subp. 21. **Laboratory.** "Laboratory" means a 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.

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 or practice and who is in a supervisory, lead worker, or similarly named position within an organization.

Subp. 24. **Manufacturing or manufacture.** "Manufacturing" or "manufacture" means the planting, cultivation, growing, and harvesting of cannabis and the process of converting harvested cannabis plant material into medical cannabis.

Subp. 25. **Manufacturing facility.** "Manufacturing facility" means any secured building, space, grounds, and physical structure of a medical cannabis manufacturer for the cultivation, harvesting, packaging, and processing of medical cannabis and where access is restricted to designated employees of a medical cannabis manufacturer and escorted visitors.

Subp. 26. **Medical cannabis.** "Medical cannabis" has the meaning given in Minnesota Statutes, section 152.22, subdivision 6.

Subp. 26a. **Medical cannabis brand name.** "Medical cannabis brand name" means the name under which a medical cannabis concentrate, a medical cannabis concentrate formulation, or a dried raw cannabis product is marketed and distributed.

Subp. 26b. **Medical cannabis concentrate.** "Medical cannabis concentrate" means a specific subset of medical cannabis that is produced by extracting cannabinoids from plant material. Categories of medical cannabis concentrate include products created using water-based, solvent-based, heat-based, or pressure-based extraction methods. Medical cannabis concentrate includes medical cannabis concentrate intended for use with a vaporizer delivery device or pressurized dose inhaler.

Subp. 26c. **Medical cannabis concentrate formulation.** "Medical cannabis concentrate formulation" means a liquid, including oil, a pill, or any other formulation type approved by the commissioner under Minnesota Statutes, sections 152.22, subdivision 6, paragraph (a), and 152.27, subdivision 2, paragraph (b), infused with medical cannabis and other ingredients that will be

packaged into a finished good without further change and is intended for use or consumption other than by smoking. Medical cannabis concentrate formulation includes oral suspensions, tinctures, lotions, ointments, and any other medical cannabis delivery method approved by the commissioner.

Subp. 27. **Medical cannabis manufacturer or manufacturer.** "Medical cannabis manufacturer" or "manufacturer" has the meaning given in Minnesota Statutes, section 152.22, subdivision 7.

Subp. 28. **Medical cannabis product.** "Medical cannabis product" has the meaning given in Minnesota Statutes, section 152.22, subdivision 8.

Subp. 29. **Medical cannabis waste.** "Medical cannabis waste" means medical cannabis that is returned, damaged, defective, expired, or contaminated.

Subp. 30. **Parent or legal guardian.** "Parent or legal guardian" has the meaning given in Minnesota Statutes, section 152.27, subdivision 5.

Subp. 31. **Patient.** "Patient" has the meaning given in Minnesota Statutes, section 152.22, subdivision 9.

Subp. 32. **Plant material.** "Plant material" means any cannabis plant, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots.

Subp. 33. **Plant material waste.** "Plant material waste" means plant material that is not used in the production of medical cannabis in a form allowable under Minnesota Statutes, section 152.22, subdivision 6.

Subp. 33a. **Plant regulator.** "Plant regulator" has the meaning given in Minnesota Statutes, section 18B.01, subdivision 20.

Subp. 33b. **Pre-roll.** "Pre-roll" means any combination of flower, shake, or leaf rolled in unflavored paper and intended to be smoked.

Subp. 34. **Production or produce.** "Production" or "produce" means:

- A. cultivating or harvesting plant material;
- B. processing or manufacturing; or
- C. packaging of medical cannabis.

Subp. 35. **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. 36. **Registered designated caregiver.** "Registered designated caregiver" has the meaning given in Minnesota Statutes, section 152.22, subdivision 11.

Subp. 36a. **Registered finished goods list.** "Registered finished goods list" means the official list maintained by the commissioner of finished goods permitted to be dispensed within the registry.

The manufacturer must provide the commissioner the finished good's chemical composition, the total volume or weight of each active ingredient, storage instructions, and estimated expiration date. If a finished good will be dispensed in an amount larger than one unit or dose, the manufacturer must specify the volume or weight and chemical composition that constitutes a single dose.

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

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

Subp. 38a. **Remediation.** "Remediation" means any process that removes or reduces the level of contaminants in a batch of dried raw cannabis flower and trim, either through extraction of oils or other means.

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

Subp. 39a. **Rinsate.** "Rinsate" means a dilute mixture of a crop input or crop inputs with water, solvents, oils, commercial rinsing agents, or other substances that is produced by or results from the cleaning of crop input application equipment or containers.

Subp. 39b. **Shake.** "Shake" means pieces of a cannabis flower that were once part of larger buds.

Subp. 40. **Sufficient cause to believe.** "Sufficient cause to believe" means grounds asserted in good faith that are not arbitrary, irrational, unreasonable, or irrelevant and that 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.

Subp. 41. **THC.** "THC" means tetrahydrocannabinol, CAS number 1972-08-3.

Subp. 42. **THCA.** "THCA" means tetrahydrocannabinolic acid, CAS number 23978-85-0.

Subp. 43. **Total cannabinoid content.** "Total cannabinoid content" means the combined target values by weight of all cannabinoids defining a finished good in the registered finished goods list, not including cannabinoids present only in trace amounts.

Subp. 44. **Total CBD content.** "Total CBD content" means the sum of the amount of CBD and 87.7 percent of the detectable amount of CBDA present in the product or plant material.

Subp. 45. **Total THC content.** "Total THC content" means the sum of the amount of THC and 87.7 percent of the detectable amount of THCA present in the product or plant material.

Subp. 46. **Water activity.** "Water activity" or " a_w " means a measure of the free moisture in usable cannabis and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Statutory Authority: *MS s 14.389; 152.25; 152.26; 152.261*

History: *39 SR 1080; 40 SR 1599; 46 SR 1011*

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