

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. 6. **Batch.** "Batch" means a specific quantity of medical cannabis 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.

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. 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 the Department of Health or the commissioner's designee.

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

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

- (1) cultivating or harvesting plant material;
- (2) processing or manufacturing; or
- (3) 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. 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. 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. 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.

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

History: *39 SR 1080; 40 SR 1599*

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