4770.2000 MEDICAL CANNABIS LABORATORY APPROVAL; APPLICATION AND APPROVAL.

Subpart 1. **Application requirements.**

A. A laboratory must apply for the commissioner's approval on a form provided by the commissioner.

B. A laboratory must also submit the following items:

(1) a signed and notarized attestation:

(a) declaring any conflict of interest, actual or perceived, relating to its direct or indirect financial interests in any medical cannabis manufacturer form; and

(b) stating that the laboratory is independent from the medical cannabis manufacturers;

(2) the fields of testing it is applying for approval to test;

(3) its quality assurance manual;

(4) its standard operating procedures;

(5) sample handling, receipt, and acceptance procedures and policies;

(6) demonstration of laboratory capability and acceptable performance through a combination of:

(a) existing certificates and approvals;

(b) documented demonstrations of analytical capabilities; and

(c) documented and acceptable proficiency testing samples from an approved provider, where available;

(7) method validation procedures for testing methods; and

(8) 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.

C. A mobile laboratory is considered a separate laboratory and is subject to all requirements of parts 4770.1900 to 4770.2300. In addition to the requirements of subpart 1, a mobile laboratory must:

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

(2) designate which fields of testing, equipment, and personnel are associated with the mobile laboratory.

D. The following items are required and must be submitted to the commissioner before December 31, 2022:

(1) a copy of the lab's ISO/IEC 17025:2017 Certificate and Scope of Accreditation; and

(2) 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.

Subp. 2. **Application requirements; commissioner's evaluation.**

A. The commissioner must evaluate completed applications using the following criteria.

(1) A laboratory must operate formal management systems under the 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 which are incorporated by reference in part 4770.2800.

(2) A laboratory seeking initial or renewal medical cannabis laboratory approval after December 31, 2016, must be accredited to Standard ISO/IEC 17025:2005, which is incorporated by reference.

(3) A laboratory must specify one or more fields of testing for which it seeks approval. A laboratory must be approved for at least one field of testing to test medical cannabis for a medical cannabis manufacturer.

B. The commissioner must approve or deny the application within 60 days of receiving the completed application and any applicable information required under part 4770.2000, subpart 1, and subpart 2.

C. No board member, officer, employee, or other person with a financial interest in a medical cannabis manufacturer may have an interest or voting rights in the laboratory.

D. The commissioner's decision on a laboratory's application is a final agency decision.

Subp. 3. **Approval.**

A. When granting approval, the commissioner must notify the laboratory and include the following documentation:

(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 must issue a new document that specifies the revised scope of approval.

C. A laboratory's approval is valid for one year from the date of the commissioner's awarding approval or renewal of approval, unless the commissioner rescinds approval under part 4770.2100.

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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