

4770.2100 MEDICAL CANNABIS LABORATORY APPROVAL; INSPECTION AND COMPLIANCE.**Subpart 1. Laboratory inspection and reports.**

A. The commissioner may inspect a lab without prior notice at any time during normal business hours to verify compliance with parts 4770.1900 to 4770.2200. The commissioner may inspect:

- (1) approved laboratories; and
- (2) laboratories requesting approval.

B. If the commissioner has sufficient cause to believe that a laboratory's proficiency, execution, or validation of analytical methodologies are deficient, the commissioner may require and a laboratory must obtain third-party validation and ongoing monitoring of the laboratory. The laboratory must pay for all costs associated with the commissioner-ordered third-party validation.

C. An approved laboratory must provide reports to the commissioner regarding chemical compositions, microbial compositions, dosages, and noncannabis drug interactions under Minnesota Statutes, section 152.25, as requested by the commissioner.

D. An approved laboratory must provide reports to the medical cannabis manufacturer on forms provided by the commissioner.

Subp. 2. Laboratory approval requirements.

A. An approved laboratory may not misrepresent its approval on any document or marketing material.

B. A laboratory must make its current approval documentation and corresponding scope of approval available upon the request of:

- (1) a client;
- (2) the commissioner; or
- (3) a regulatory agency.

Subp. 3. Rescinding approval.

A. The commissioner may rescind an approved cannabis laboratory's approval if the commissioner determines the laboratory has failed to:

- (1) submit accurate application materials to the commissioner under part 4770.2000;
- (2) comply with application requirements under part 4770.2000;

- (3) comply with all applicable laws, rules, standards, policies, and procedures;
- (4) allow the commissioner or designee to perform physical inspection of facilities;
- (5) submit copies of inspection and corrective reports issued by the approved ISO/IEC 17025 accreditation body, as requested by the commissioner;
- (6) provide the medical cannabis manufacturer with timely reports; or
- (7) provide the medical cannabis manufacturer with reports compliant with the commissioner's designated test report format.

B. A laboratory must return its approval letter to the commissioner immediately if the commissioner rescinds the laboratory's approval.

C. The commissioner's decision to rescind approval of an approved medical cannabis laboratory is a final agency decision.

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

History: *39 SR 1080*

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