9810.3000 TESTING FACILITY STANDARDS.

Subpart 1. **Incorporation by reference.**

A. ISO/IEC Standard 17025: General Requirements for the Competence of Testing and Calibration Laboratories (Edition 3 2017) is incorporated by reference. The standard is published by the International Organization for Standardization (ISO), is subject to frequent change, and is available through the Minitex interlibrary loan system.

B. ISO/IEC Standard 17043, Conformity Assessment - General Requirements for the Competence of Proficiency Testing Providers (Edition 2 2023) is incorporated by reference. The standard is published by the ISO, is subject to frequent change, and is available through the Minitex interlibrary loan system.

C. Official Methods of Analysis of AOAC International (22nd edition 2023) is incorporated by reference. The methods of analysis are published by AOAC International, are subject to frequent change, and are available through the Minitex interlibrary loan system.

Subp. 2. **Testing facility inspection.** A testing facility that tests regulated products must submit to an inspection by the office upon request. A testing facility must ensure that all protocols and records that the facility must maintain under Minnesota Statutes, section 342.38, are readily available to the office upon request.

Subp. 3. **Testing facility reports.** A testing facility regulated under Minnesota Statutes, chapter 342, must provide all information requested by the office regarding sample handling, testing facility practices, copies of relevant analytical records, and all other information required by the office relevant to determining the testing facility's compliance with this chapter and Minnesota Statutes, chapter 342.

Subp. 4. **General operations.**

A. A testing facility must operate formal management systems under the International Organization for Standardization (ISO) and obtain and maintain ISO/IEC Standard 17025 accreditation through a laboratory-accrediting organization.

B. A testing facility may demonstrate the facility's analytical capability and performance to the office through a combination of:

(1) existing certificates and approvals;

(2) documented demonstrations of analytical capabilities; or

(3) annual participation and passing performance in a proficiency testing program accredited under ISO/IEC Standard 17043.

C. A testing facility must maintain written standard operating procedures describing the actions to receive, prepare, and test all representative samples under Minnesota Statutes, chapter 342, for each regulated product that the testing facility handles. A testing facility's standard operating procedures must include:

(1) the procedure for receiving samples;

(2) the procedure for handling samples;

(3) the procedure for representative subsampling when the whole sample is not used for analysis;

(4) sample testing procedures; and

(5) sample testing acceptance criteria.

D. A testing facility must maintain the identity and integrity of all samples handled from the time that the testing facility receives the samples. A testing facility must report to the office all analytical results from received samples and must report how any untested samples were disposed of.

E. A testing facility must notify the office in writing of any planned operational change at least 30 days before the change occurs.

Subp. 5. **Prohibited activities.** A testing facility must not:

A. misrepresent approval from the office of any document or marketing material;

B. refuse inspection of the premises of the testing facility and related records by authorized representatives of the office; or

C. falsify, misreport, or misrepresent any testing data or test results to the office or to another cannabis business.

Subp. 6. **Approvals by the office.** A testing facility may seek the office's approval to use specific procedures to test the allowable product types and analytes. To maintain an active license under Minnesota Statutes, chapter 342, a testing facility must have office approval for at least one field of testing. A testing facility is not required to seek approval for all fields of testing to maintain licensure. To receive approval from the office, a testing facility must:

A. specify one or more fields of testing for which the facility seeks office approval;

B. use analytical testing methods for the safety tests required by part 9810.3100, subpart 4, and Minnesota Statutes, section 342.61, subdivision 2, that are based upon published peer-reviewed methods, have been validated for cannabis testing by an independent third party, and have been internally verified by the testing facility according to Appendix J or K of the Official Methods of Analysis, which are incorporated by reference in subpart 1;

C. ensure that the facility's method validation procedures for testing methods meet the validation guidelines of the Official Methods of Analysis; and

D. ensure that method verification results have sufficient specificity and sensitivity to meet the reporting limit requirements for each analyte for which the testing facility is requesting approval.

Subp. 7. **Revocation conditions.** The office must revoke a testing facility's approval for any and all analytical testing methods when the testing facility has failed to:

A. submit accurate application materials to the office as required in Minnesota Statutes, chapter 342;

B. comply with application requirements under Minnesota Statutes, chapter 342;

C. comply with all applicable law;

D. allow the office to physically inspect the testing facility; or

E. submit copies of inspection and corrective reports issued by the approved ISO/IEC 17025 accreditation body or proficiency testing program when requested by the office.

Subp. 8. **Personnel; training; oversight.** A testing facility must operate under the direction of at least one technical manager responsible for the testing facility's ability to achieve and maintain the quality and analytical standards of practice.

Subp. 9. **Record keeping.**

A. In addition to other record-keeping requirements under this chapter and Minnesota Statutes, chapter 342, a testing facility must record all testing facility data packages in the statewide monitoring system. A testing facility must maintain a record of a data package for at least three years.

B. A record of a data package must include:

(1) a case narrative written on cannabis testing facility letterhead that:

(a) describes any sample receipt, preparation, or analytical issues that the facility encounters and any method nonconformances or exceedance of quality assurance or quality control criteria used by the cannabis testing facility; and

(b) identifies the preparation and analytical methods used by the testing facility;

(2) a signed statement by a testing facility authorized representative verifying the accuracy, completeness, and compliance with the analytical testing methods of the results presented;

(3) a summary of analytical results with sufficient data to evaluate the testing results, including a summary of laboratory quality assurance or quality control results; and

(4) a copy of the sample result report required under subpart 10.

C. When reporting a testing facility's results, the testing facility report must include:

(1) chain-of-custody information or other information indicating requested analyses; and

(2) documentation of sample collection and receipt.

Subp. 10. **Sample result reporting.**

A. All samples received and processed by the testing facility must have a completed sample result report that is recorded in the statewide monitoring system.

B. A sample result report must state whether:

(1) the complete sample was homogenized and tested as received; or

(2) a portion was sampled by the testing facility for analysis.

C. A testing facility must report measurement uncertainty and limits of detection or limits of quantitation with the results of testing representative samples of products.

D. For each sample submitted for analysis, a testing facility must provide to the submitting entity a certificate of analysis that includes:

(1) the testing facility's name and license number issued by the office;

(2) the submitting entity's name and license number issued by the office;

(3) the product category, product type, and name of the product being sampled;

(4) the product batch number represented by the sample;

(5) a summary of the analytical results, including the sample identifier, the methods that the facility performed, the target compounds, the sample result, the reporting limit, the proper qualifier according to laboratory standard procedures, the units of measure used, the preparation date, if applicable, and the analysis date; and

(6) for homogeneity and contaminant analysis, a determination of whether the analytical results meet the acceptance criteria established by the office.

Subp. 11. **Disposal.** A testing facility must dispose of unanalyzed portions of a sample according to part 9810.1200 unless the facility is holding the samples at the office's request or for stability testing.

Subp. 12. **Variance.**

A. A testing facility licensed by the office may seek a variance from this chapter.

B. A request for a variance must contain:

(1) the rule part and language for which the variance is sought;

(2) the reasons for the request;

(3) alternate measures that the testing facility will take if the office grants the facility's request for a variance;

(4) the proposed length of time of the variance; and

(5) data that the testing facility will provide to the office to ensure that analytical results have equal or better reliability, if applicable.

C. The office must evaluate a testing facility's request for a variance and approve the request if:

(1) the variance request contains the information required in item B;

(2) granting the variance would have no potential adverse effect on public health, safety, or the environment;

(3) the alternative measures that the testing facility would take if the variance is granted are equivalent to or better than the measures required by this chapter;

(4) strict compliance with this chapter would impose an undue burden on the applicant or on the industry as a whole;

(5) the variance does not deviate from a statutory standard or violate federal laws or regulations; and

(6) the variance has only a future effect.

D. If the office grants a variance:

(1) any alternative measures or conditions of a variance approved by the office are enforceable according to Minnesota Statutes, section 14.055; and

(2) a violation of the alternative measures or conditions of a variance approved by the office subjects the testing facility to the enforcement actions and penalties provided in law or rule.

E. The office must deny, revoke, or refuse to renew a variance when the applicant has not met the criteria in item C or does not comply with the additional measures or conditions according to item D.

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