

CHAPTER 33.1-23-03

ENVIRONMENTAL LABORATORY CERTIFICATION PROFICIENCY TESTING

Section

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33.1-23-03-01. Proficiency testing requirements.

1. A laboratory shall complete at least one proficiency test successfully for each field of testing for which it applies for certification. The laboratory must complete the proficiency test no more than six months prior to submitting the application. If no proficiency test sample is available for an analyte, the laboratory is exempt from the requirements of this section only for that analyte.
2. Proficiency tests results must be included with the initial or revised certification application required for a primary certification or for reciprocal certification. Proficiency test results also may be reported to the department by the proficiency test provider upon completion of the study.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-03-02. Laboratory testing of proficiency test study samples.

To ensure valid proficiency test results, the laboratory shall:

1. Obtain all proficiency test study samples as unknowns from a nationally recognized accreditation program approved vendor;
2. Manage, analyze, report, and otherwise handle all proficiency test samples in the same manner as routine samples, including the same staff, procedures, equipment, and facilities used for routine analysis for the field of testing;
3. Employ the same calibration, quality control, acceptance criteria, sequence of analytical steps, number of replicates, and other standard operating procedures for proficiency test samples as used when analyzing routine samples; and
4. Follow sample preparation steps for the proficiency test sample as instructed by the proficiency test sample provider.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-03-03. Reporting results.

1. A laboratory shall submit the results of all proficiency tests to the department no later than thirty days after the laboratory receives the results from the proficiency test sample provider.
2. A laboratory conducting proficiency testing as part of an initial or revised application shall submit the results of proficiency tests as part of the application.

3. A laboratory either shall provide a copy of the original results to the department or authorize the proficiency test sample provider to provide all results directly to the department.
4. Proficiency test samples analyzed or reported to the proficiency test sample provider after the provider's study closing date are not valid for compliance with the proficiency testing requirements under this section.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-03-04. Restrictions on exchanging information.

Prior to the time the results of the proficiency test are submitted to the proficiency test sample provider, a laboratory may not:

1. Communicate proficiency test results to another laboratory, including intercompany communication; or
2. Attempt to obtain the assigned value of any proficiency test sample from a proficiency test sample provider or another laboratory.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-03-05. Evaluation on results.

1. A laboratory must demonstrate passing performance to the department, as determined by the proficiency test sample provider, for each parameter and method or field of testing reported.
2. A laboratory may use one proficiency test sample for multiple methods.
3. A laboratory may not request a revised report from the proficiency test sample provider when the requested revisions are the result of error on the part of the laboratory.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-03-06. Repeat proficiency tests.

1. A laboratory with primary certification may repeat proficiency tests after obtaining unacceptable results as follows:
 - a. If the first proficiency test result is unacceptable, the laboratory shall resolve the suspected cause, document the corrective action, and complete a second proficiency test within thirty days of receiving the unacceptable result;
 - b. If the second proficiency test result is unacceptable, the laboratory shall:
 - (1) Resolve the suspected cause and submit a corrective action report to the department within thirty days of receiving the second unacceptable result; and
 - (2) Order and complete a third proficiency test within thirty days of receiving the unacceptable result of the second proficiency test;

- c. If the third proficiency test result is unacceptable, the laboratory may not provide analytical results for compliance reporting or any department program for the field of testing for which the laboratory failed to demonstrate acceptable proficiency test results. The laboratory may resume providing analytical results when the laboratory passes two consecutive proficiency tests conducted at least fifteen days apart. The laboratory shall submit a corrective action report to the department within thirty days of passing the second of the two proficiency tests.
2. The "North Dakota Environmental Laboratory Certification Program Manual" governs when a portion of a multiple analyte group proficiency test is unacceptable.
3. The department may request additional information necessary to validate sample results generated during the testing period covered under this section.
4. A laboratory with reciprocal certification must follow the repeat proficiency test guidelines established by its primary certification agency.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14