

CHAPTER 33.1-23-02 ENVIRONMENTAL LABORATORY CERTIFICATION PROGRAM

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33.1-23-02-01. Applicability and scope.

This chapter applies to all laboratories required to be certified under North Dakota Century Code section 23.1-01-14. A laboratory that performs tests and analyses, the results of which must be reported to the department to meet permit conditions or other department program or regulatory requirements, must be certified for the parameters and methods required by the permit or department program, unless the permit or department program specifically exempts the parameters or methods from certification requirements. Certification requirements are equal to those required by federal programs for regulated parameters by promulgated methods unless otherwise specified or required by a department program.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-02. Definitions.

In this article, unless the context otherwise requires, the following definitions apply:

1. "Analyte" means the chemical substance, physical property, or organism determined in a sample.
2. "Analyte group" means a set of analytes that can be determined using the same method or technology.
3. "Biosolids" means sewage sludge or a solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Biosolids includes domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.
4. "Certified laboratory" means a laboratory that has a valid certification issued by the department.
5. "Client" means an entity that has arranged with a laboratory to perform tests and analyses to meet the requirements of a department issued permit or another department program or regulatory requirement.
6. "Coal Combustion Residual Rule" means the sampling and analysis requirements under title 40 Code of Federal Regulations, part 257 and appendices III and IV to part 257.
7. "Department" means the North Dakota department of environmental quality.
8. "Department program" means a program or rule administered by the department which requires submission of data for compliance reporting purposes that must come from a certified laboratory.
9. "Field of testing" means the combination of analyte, method, matrix, and program for which a laboratory may hold accreditation or certification.
10. "Initial application" means an application submitted by a laboratory that either has never had certification or has not met the requirements and qualifications for either a renewal or revised application.
11. "Laboratory" means a facility that performs analyses on potable water, nonpotable water, a hazardous liquid, or solid matrix.
12. "Manual for the Certification of Laboratories Analyzing Drinking Water" means the environmental protection agency publication "Manual for the Certification of Laboratories Analyzing Drinking Water", 5th edition and including supplement 1 to the 5th edition of the "Manual for the Certification of Laboratories Analyzing Drinking Water" and supplement 2 to the 5th edition of the "Manual for the Certification of Laboratories Analyzing Drinking Water".
13. "Method" means an environmental protection agency promulgated or environmental protection agency accepted published scientific technique for performing a specific measurement. Method includes instructions for sample preparation, sample preservation, and sample analysis.
14. "Method defined parameter" means parameters that are physical or chemical properties of materials determined with specific methods used to evaluate whether the materials comply with certain Resource Conservation and Recovery Act of 1976, 42 U.S.C. section 6901 et seq., subtitle C regulations.
15. "National Primary Drinking Water Regulations" means the federal program authorized under title 40 Code of Federal Regulations, part 141, section 141.1 et seq.

16. "National pollutant discharge elimination system" means the federal program authorized under title 40 Code of Federal Regulations, part 136, section 136.1 et seq.
17. "Nonpotable water" means water not suitable for drinking. It is a matrix in the Clean Water Act Program, the Resource Conservation and Recovery Act program and the Coal Combustion Residuals Rule program.
18. "North Dakota Environmental Laboratory Certification Program Manual" means the manual used by the environmental laboratory certification program for chemistry parameters. It is available on the department's website and is the Rev. November 2019 edition.
19. "Parameter" means the chemical substance, physical property, or organism being determined.
20. "Point value" means the numerical increments which represent the amount necessary to cover costs of reviewing applications, issuing certifications, conducting laboratory evaluations, training, collecting fees, and providing compliance assistance and other anticipated costs of administering the environmental laboratory certification program.
21. "Potable water" means water suitable for drinking. It is the matrix in the Safe Drinking Water Act program.
22. "Proficiency test" means the process of testing and reporting of test results performed by a laboratory for a specific analyte or analyte group to determine the ability of a laboratory to employ applicable analytical methods and to produce an accurate measurement of the concentration of the analyte or analyte group in the sample.
23. "Reciprocal certification" means a reciprocal or secondary certification that is based on a primary certification.
24. "Renewal application" means an application submitted by a laboratory to renew an existing certification.
25. "Reporting limit" means the lowest level of an analyte that can be accurately recovered from the matrix of interest. This limit is equivalent to a level of quantitation.
26. "Resource Conservation and Recovery Act" means the federal law found under 42 U.S.C. section 6901 et seq. (1976) and its corresponding regulations found under title 40, Code of Federal Regulations, parts 239 through 282.
27. "Revised application" means an application that is submitted to make changes to an existing certification.
28. "SW-846" means the environmental protection agency guidance for using the "Test Methods for Evaluation Solid Waste: Physical/Chemical Methods", Publication SW-846, United States environmental protection department (2019). This guidance consists of three main parts: chapters, methods, and supporting documents and is the environmental protection agency SW-846 compendium.
29. "Test methods for evaluating solid waste: physical/chemical methods" means the environmental protection agency publication also known as SW-846.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-03. General requirements for required methods.

The analytical methods, sample collection, and preservation procedures used to analyze samples for programs required by a federal agency must meet the requirements specified in the relevant parts of the Code of Federal Regulations as stated herein. The laboratory's analytical methods, sample collection, and preservation procedures also must meet the requirements specified by the department program. Certification requirements are based on the analysis of regulated parameters by promulgated methods unless otherwise specified or required by a department program.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-04. Biosolids program methods.

For analysis of sewage sludge samples required by state and federal rules, laboratories shall use the methods and test procedures in title 40, Code of Federal Regulations, part 503, and publication SW-846.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-05. Clean Water Act program methods.

For analysis of water or wastewater samples required by state and federal clean water rules, laboratories shall use the methods and test procedures in title 40, Code of Federal Regulations, part 136.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-06. Coal Combustion Residuals Rule program methods.

For analysis of water or wastewater samples required by state and federal coal combustion residuals in landfills and surface impoundments rules and regulations as amended, laboratories shall use methods appropriate for groundwater sampling and that accurately measure hazardous constituents and other monitoring parameters in groundwater samples. Metals analysis must be for "total recoverable" concentrations. Parameters are found at appendix III to part 257 and appendix IV to part 257.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-07. Nonpotable water program methods.

For analysis of water or wastewater samples as requested by the department or to support studies of specific industries or for use in broad national surveys, laboratories shall use validated methods and test procedures. Environmental protection agency methods are preferred but other state approved and validated methods may be acceptable.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-08. Potable water program methods.

For analysis of suitable drinking water samples as requested by the department or to support studies of specific industries or for use in broad national surveys, laboratories shall use validated methods and test procedures. Environmental protection agency methods are preferred, but other state approved and validated methods may be acceptable.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-09. Resource Conservation and Recovery Act program methods.

For analysis of wastewater, waste, and solid and hazardous waste samples, laboratories shall use the methods and test procedures found in the SW-846 or as deemed by the division of waste management within the department. Modifications may be used with the approval of the department or accrediting body except for method-defined parameters. Method-defined parameters can only be determined by the methods prescribed in Resource Conservation and Recovery Act of 1976 regulations because the methods are part of the regulations. These methods must be followed exactly as written, or the resulting data cannot be used to ensure regulatory compliance. A list of method-defined parameters found under title 40 Code of Federal Regulations, part 260, section 260.11.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-10. Safe Drinking Water Act program methods.

For analysis of drinking water samples required by state and federal Safe Drinking Water Act rules, laboratories shall use the methods and test procedures in title 40 Code of Federal Regulations, part 141. Laboratories also shall comply with the "Manual for the Certification of Laboratories Analyzing Drinking Water" requirements.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-11. Alternate methods.

Provisions for the use of alternate methods to be used in the Safe Drinking Water Act program and the Clean Water Act program are found within the corresponding federal laws and regulations. A laboratory may request approval for alternate methods by following the instructions provided in the appropriate sections of the federal laws and regulations for the Clean Water Act program and the Safe Drinking Water Act program.

History: Effective July 1, 2020; amended effective January 1, 2022.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-12. Solids and chemicals program methods.

For analysis of solids and chemical samples as requested by the department or to support studies of specific industries or for use in broad national surveys, laboratories shall use validated methods and test procedures. Environmental protection agency methods are preferred but other state approved and validated methods may be acceptable.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-13. Personnel and contact information.

A laboratory shall have adequate staff with the education, training, or experience to meet the requirements of certification. At least one staff person must be identified as the laboratory administrator and that person's contact information must be provided with the certification application. The laboratory administrator shall notify the department when there are changes in contact information for the laboratory administrator, change of address, owner, or legally responsible party no later than thirty days after the change occurs.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-14. Quality system.

The laboratory shall have a quality assurance and quality control program that meets the criteria specified in the "North Dakota Environmental Laboratory Certification Program Manual" that includes:

1. A quality assurance manual or plan;
2. Standard operating procedures; and
3. Traceability, documentation, recordkeeping, and reporting.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-15. Access to premises.

The laboratory shall allow the department and its agents reasonable access to the laboratory for inspection and evaluation purposes and shall produce such information and records as the department requests to determine compliance with this article.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-16. Access to records.

The laboratory shall maintain all records used to demonstrate the laboratory's compliance with certification requirements. If a laboratory analyzes samples from a client, then upon request, the laboratory shall provide to the client the records that support the client's test results. The laboratory also shall make records available to the department upon its request.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-17. Subcontracting.

A laboratory that has samples analyzed by another laboratory shall use laboratories that have valid department certification if the data is to be reported to the department.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-18. Certification status.

1. A laboratory may not alter or misrepresent its certification status and attending documents issued by the department in any brochures, promotional literature, or advertising materials. A laboratory may not describe its certification status in a manner that implies certification in areas that are outside the actual scope of certification. General statements, such as "A North Dakota Certified Laboratory" or "Certified in North Dakota" are not specific enough and can be misleading. The department may require appropriate corrective action, including publication of a retraction of the misleading information.
2. A laboratory may not represent analytical results as certified after its certification has expired or been discontinued, suspended, or revoked.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-19. Response.

A laboratory shall timely respond in writing to any written communication from the department.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-20. Application contents for primary certification.

1. A laboratory shall submit an initial application if:
 - a. It has never received primary or reciprocal certification under this article;
 - b. It has had its primary certification or department reciprocal certification revoked in total;
 - c. Its certification has expired for more than one year; or
 - d. It has submitted an application that has remained incomplete for more than one year.
2. To apply for initial or renewal of certification, a laboratory shall submit an application on forms provided by the department. The required information includes:
 - a. Identifying information;
 - b. At least one field of testing for which the laboratory seeks certification;
 - c. The laboratory's most recent quality assurance manual or plan meeting the standards of the "North Dakota Environmental Laboratory Certification Program Manual";
 - d. The laboratory's most recent standard operating procedures for each field of testing that meets the standards of the "Environmental Laboratory Certification Program Manual";
 - e. If the application is an initial request for certification, the most recent proficiency test result for each field of testing for which the laboratory is requesting certification. The proficiency test must have been completed no more than twelve months prior to the date that the renewal application is received by the department, no more than six months prior

to the date the initial application is received and must meet the proficiency test requirements;

- f. A list of the laboratory's detection limits and reporting limits for each field of testing for which the laboratory is requesting certification; and
 - g. Any other additional information requested by the department as necessary to determine compliance in this article.
3. The owner of laboratory facilities with multiple locations shall submit a separate application for each laboratory location.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-21. Application period.

Initial applications and revised applications may be submitted to the department at any time.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-22. Certification renewal.

When a laboratory's certification has expired, the laboratory shall apply for a renewed certification.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-23. Modified application.

A laboratory with a valid certification shall submit a modified application, including the information required for primary certifications or reciprocal certifications, to the department to:

- 1. Add a program for which the laboratory does not currently have certification;
- 2. Add a test method in a program for which the laboratory is already certified;
- 3. Add a parameter or analyte to a test method for which the laboratory is already certified; or
- 4. To change the name of the certified laboratory on the certification documents.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-24. Conditions for reapplication.

A laboratory notified of or involved in a corrective action or with a suspended certification is not eligible to apply for a certification renewal for the affected field of testing until the laboratory receives confirmation from the department that the corrective action is complete, or the laboratory has been reinstated after suspension. If the department revoked the laboratory's certification, the laboratory shall apply for initial certification, in accordance with this article, as if it were a new laboratory.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-25. Term of primary certification.

1. Primary certification is granted following the procedure as outlined in the "North Dakota Environmental Laboratory Certification Program Manual".
2. Certification becomes effective the date of issuance and is valid for three years unless suspended, revoked, or voluntarily discontinued. Any request for an extension must be in writing. The certification period may be extended for good cause as determined by the department.
3. Standards of quality in the "Manual for Laboratories Analyzing Drinking Water" must be met in order to qualify for certification.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-26. Limit of certification.

Certification of a laboratory is not an endorsement by the department of the quality or validity of the data generated by a laboratory. Certification does not guarantee the usability of data generated by a laboratory for an intended purpose. The users of laboratory results are responsible for determining whether to accept or reject analytical data from a certified laboratory.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-27. Term of reciprocal certification and application contests.

1. Reciprocal certification is granted following the procedure as outlined in the "North Dakota Environmental Laboratory Certification Program Manual".
2. A laboratory holding a primary accreditation or certification from another accrediting body may apply for reciprocal certification in North Dakota.
3. The department may approve other certifying authorities of federal agencies and agencies of other states for reciprocal recognition of laboratory certification programs or portions of programs that are substantially equivalent.
4. A certification program is considered substantially equivalent if a review of the certification authority's rules are substantially equivalent to the rules and guidelines of the department's laboratory certification program and including:
 - a. Inspections of certified laboratories are performed at intervals not exceeding three years;
 - b. The certifying authority requires an acceptable corrective action response associated with enforcement action, suspension, or revocation from the laboratory; and
 - c. The certifying authority is the primary authority for necessary enforcement actions, such as suspension or revocation of the laboratory's certification.
5. The department may give reciprocal certification for a laboratory that:
 - a. Submits an application meeting the certification requirements of section 33.1-23-02-23;

- b. Submits the appropriate fees with its application;
 - c. Provides a copy of current certification documents ,including certificate, letter, and list of certified parameters, from the primary certifying state or private or federal authority; and
 - d. Provides a copy of the primary certifying authority's most recent audit report and including any corrective action that was taken.
6. A laboratory certified under this section shall notify the department within thirty days after any enforcement action is taken by the reciprocal certifying authority.
 7. Laboratories certified under reciprocity agreements are subject to this article unless specifically stated as a unique requirement for primary certification.
 8. Certification becomes effective the date of issuance and is valid for up to three hundred sixty-five days unless suspended, revoked, or voluntarily discontinued. The certification period may be extended for good cause as determined by the department. The certification period on the North Dakota certificate shall not exceed the certification period on the primary certificate.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-28. Department notification - Voluntary withdrawal or discontinuation of certification.

1. If a laboratory chooses to withdraw its application for certification or discontinue its current certification, in total or in part, the laboratory shall notify the department in writing and specify the effective date of withdrawal or discontinuation and the field of testing for which certification is being withdrawn or discontinued. The laboratory shall submit notification at least thirty days before the effective date of withdrawal or discontinuation.
2. After the effective date of voluntary withdrawal or discontinuation of certification, the laboratory may not provide analytical results for compliance reporting or any department program for the field of testing for which certification has been withdrawn or discontinued.
3. A laboratory shall apply for revised reciprocal certification within thirty days of the issuance of a primary revised certification.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-29. Client notification required.

1. When the laboratory is discontinuing certification voluntarily, at least thirty days before the effective date of the laboratory's discontinuation of certification, the laboratory shall notify clients and affected regulatory agencies in writing of the discontinuation date and which fields of testing will be affected. The laboratory shall submit a copy of each client notification to the department at the same time the notification is sent under section 33.1-23-02-40.
2. The laboratory shall notify clients immediately if:
 - a. The primary certification authority downgrades the status for a parameter or field of testing to "not certified"; or
 - b. Certification is revoked, suspended, or terminated by the primary certification authority.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-30. Recertification.

To be recertified after voluntary withdrawal or discontinuation of certification, a laboratory shall submit an application meeting the requirements for:

1. A revised application, if reapplying within one year of the date that certification was discontinued; or
2. An initial application, if certification has been discontinued for more than one year.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14

33.1-23-02-31. Certification modification, suspension, revocation, or denial.

The department may modify, suspend, revoke, or deny a certification for reasons pertaining to: circumstances that do not meet the purpose and provisions of this article, the provisions of the certification, or the materials submitted as part of the application for certification; or, violations of any applicable laws or rules. The department shall provide written notice to the laboratory specifying the basis for the modification, suspension, revocation, or denial. The laboratory may request a hearing in accordance with North Dakota Century Code chapter 28-32 on the issue of modification, suspension, revocation, or denial of the laboratory's certification. The laboratory's hearing request must be made in writing and received by the department within thirty days after the laboratory's receipt of the notice.

History: Effective July 1, 2020.

General Authority: NDCC 23.1-01-14

Law Implemented: NDCC 23.1-01-14