TITLE 179 PUBLIC WATER SYSTEMS

CHAPTER 20 LABORATORY CERTIFICATION AND AGREEMENT REQUIREMENTS FOR TESTING DRINKING WATER

001. AUTHORITY. These regulations establish requirements for laboratories to be certified to test drinking water compliance samples. The certification is specific to contaminants and methods used to test drinking water. The authority is found in Neb. Rev. Stat. §§ 71-5303, 71-5306, and 71-2619 to 71-2621.

002. DEFINITIONS. For purposes of these regulations, definitions in the Nebraska Safe Drinking Water Act and the following definitions are hereby adopted.

002.01 AGREEMENT. A binding contract between the Department and a laboratory.

002.02 CERTIFICATE. The document issued by the Department indicating that the laboratory has fulfilled the requirements for certification and is authorized to perform analyses for water intended for human consumption.

002.03 COMPLIANCE SAMPLES. Those water samples required under the Nebraska Safe Drinking Water Act and Title 179 Nebraska Administrative Code (NAC) to determine whether a public water system meets current drinking water standards.

002.04 DEFICIENCY. A failure to meet the established minimum standards.

002.05 DEPARTMENT. The Division of Public Health of the Department of Health and Human Services.

003. CERTIFICATION FOR LABORATORIES IN NEBRASKA.

003.01 APPLICATION. The owner of a laboratory must make an application for certification in writing. The application must be submitted to the Department and may be:

003.1(A) A request for first-time certification for microbiology, chemistry, or radiochemistry;

003.01(B) A request for certification to analyze additional or newly regulated contaminants;

003.01(C) A request to reapply for certification after correction of deficiencies which resulted in the revocation of certification status; or

003.01(D) A request for certification for microbiology, chemistry, or radiochemistry based on certification or accreditation from a nationally recognized accreditation program, or another state with a certification program approved by the Environmental Protection Agency.

003.02 FIRST-TIME CERTIFICATION. An applicant for first-time certification for microbiology, chemistry, or radiochemistry must submit the following information:

003.02(A) A completed Application (Attachment 1) which is incorporated herein by reference;

003.02(B) A signed Attestation of Compliance form (Attachment 2) which is incorporated herein by reference;

003.02(C) A completed Personnel for Certification form (Attachment 3) which is incorporated herein by reference, and a copy of certification of their academic training (diploma(s) or transcript(s));

003.02(D) A completed Quality Assurance Manual Checklist (Attachment 4) which is incorporated herein by reference;

003.02(E) A completed List of Matrix, Method and Analyte form (Attachment 5) which is incorporated herein by reference, indicating what certification is being requested;

003.02(F) A signed copy of the laboratory's current analytical and administrative standard operating procedures, in the proper Environmental Protection Agency format, for each method, analyte, and matrix for which the laboratory is requesting certification;

00302(G) A copy of the laboratory's current signed quality assurance manual in the proper Environmental Protection Agency format;

003.02(H) A checklist from the Environmental Protection Agency *Manual for Certification of Laboratories Analyzing Drinking Water*, Fifth Edition (January 2005) including Supplement 1 (June 2008) and Supplement 2 (November 2012) depending on the methods and analytes being requested. A completed chemistry checklist form is required when chemistry methods certification is being requested, a completed microbiology checklist form is required when microbiological methods certification is being requested, and a completed radiochemistry checklist form is required when radiochemistry methods certification is being requested; and

003.02(I) The proficiency testing provider must send the most current proficiency testing results for each method and analyte, to the Department. If the laboratory is applying for a new certification for a method and analyte it must have a proficiency testing provider send a copy of proficiency testing results performed within the last 60 days for each method and analyte. If the laboratory is applying for recertification, at least one acceptable proficiency testing result must be received for each method and analyte in every 12-month period.

003.03 ADDITIONAL OR NEWLY REGULATED CONTAMINANTS. An applicant wishing to analyze additional or newly regulated contaminants in microbiology, chemistry, or radiochemistry must submit the following information:

003.03(A) A completed Application (Attachment 1) which is incorporated herein by reference;

003.03(B) A signed Attestation of Compliance form (Attachment 2) which is incorporated herein by reference;

003.03(C) A completed Personnel for Certification form (Attachment 3) which is incorporated herein by reference, and a copy of certification of their academic training (diploma(s) or transcript(s));

003.03(D) A completed Quality Assurance Manual Checklist (Attachment 4) which is incorporated herein by reference;

003.03(E) A completed List of Matrix, Method and Analyte form (Attachment 5) which is incorporated herein by reference, indicating what certification is being requested;

003.03(F) A signed copy of the laboratory's current analytical and administrative standard operating procedures, in the proper Environmental Protection Agency format, for each method, analyte, and matrix for which the laboratory is requesting certification;

003.03(G) A copy of the laboratory's current signed quality assurance manual in the proper Environmental Protection Agency format;

003.03(H) A checklist from the Environmental Protection Agency *Manual for Certification of Laboratories Analyzing Drinking Water,* Fifth Edition (January 2005) including Supplement 1 (June 2008) and Supplement 2 (November 2012) depending on the methods and analytes being requested. A completed chemistry checklist form is required when chemistry methods certification is being requested, a completed microbiology checklist form is required when microbiological methods certification is being requested, and a completed radiochemistry checklist form is required when radiochemistry methods certification is being requested; and

003.03(I) The proficiency testing provider must send the most current proficiency testing results for each method and analyte, to the Department. If the laboratory is applying for a new certification for a method and analyte it must have a proficiency testing provider send a copy of proficiency testing results performed within the last 60 days for each method and analyte. If the laboratory is applying for recertification, at least one acceptable proficiency testing result must be received for each method and analyte in every 12-month period.

003.04 UPGRADING CERTIFICATION. An applicant requesting to reapply for certification after a downgrading of certification status. Through a written request, a laboratory may seek upgrading of certification, when and if the laboratory can demonstrate to the Department that the deficiencies that produced provisionally certified status have been corrected.

003.05 CERTIFICATION. After reviewing each application for certification, proficiency testing sample results, on-site visit results for applicable laboratories, and on-site visit reports for reciprocity applicants, the Department will classify the laboratory for each contaminant or group of contaminants according to the following rating scheme:

003.05(A) CERTIFIED. A laboratory that meets the requirements set out in 179 NAC 20-005.

003.05(B) PROVISIONALLY CERTIFIED. A laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in Title 179 NAC. A provisionally certified laboratory may analyze drinking water samples for compliance purposes, if its clients are notified of its downgraded status in writing, on any report. Provisional certification will not be given if the Department believes that the laboratory cannot perform an analysis within the acceptance limits specified in Title 179 NAC.

003.05(C) NOT CERTIFIED. A laboratory that possesses deficiencies and, in the opinion of the Department, cannot consistently produce valid data.

003.05(D) INTERIM CERTIFICATION. A laboratory may be granted interim certification in certain circumstances when a certified laboratory wants to add an analyte or analytes to their certification involving a method for which it already has certification and it is impossible or unnecessary to perform an on-site audit. Interim certification status may be granted if, for example, the Department determines that the laboratory has the appropriate instrumentation, is using the approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed proficiency testing samples, if available, for the contaminants in question. The Department will perform an on-site audit as soon as possible but no later than three years after the application is received. The Department will review the laboratory's quality control data and proficiency testing data before granting this type of certification.

003.05(E) RECIPROCITY. Certified by reciprocity as set out in 179 NAC 20-003.06.

003.06 CERTIFICATION BY RECIPROCITY.

003.06(A) A laboratory requesting Nebraska certification because they hold accreditation from a national accrediting body, another state that is Environmental Protection Agency certified, or Environmental Protection Agency or state certified laboratory located outside the State of Nebraska may be certified by:

(i) Submitting a completed Application (Attachment 1);
(ii) Submitting a signed Attestation of Compliance form (Attachment 2);
(iii) Submitting a copy of the laboratory's certification and accreditation certificate, clearly showing the name of the laboratory, the certification or accreditation entity, the methods and analytes the certification covers, the beginning date and the expiration date of the certificate;
(iv) Submitting a copy of the laboratory's current signed quality assurance manual;

(v) Having a proficiency testing provider send the most recent proficiency testing results for the method(s) and analyte(s) for which certification is requested directly to the Department; and

(vi) Submitting a copy of the laboratory's latest on-site audit report.

004. APPROVED CERTIFICATION BODIES AND ACCREDITATION BODIES. The Department will accept certification or accreditation from the following organizations for the purposes of certification in Nebraska:

(i) An Environmental Protection Agency Certified Laboratory.

(ii) A state laboratory certified by the Environmental Protection Agency.

(iii) A laboratory certified by a state certification program.

(iv) A laboratory accredited by the National Environmental Laboratory Accreditation Program.

005. CERTIFICATION STANDARDS FOR LABORATORIES IN NEBRASKA. To be certified by the Department, a laboratory must meet the following requirements:

005.01 The regulatory performance criteria as explained in the Environmental Protection Agency *Manual for the Certification of Laboratories Analyzing Drinking Water*, F~~f~~ifth E~~e~~dition, (January 2005) including Supplement 1 (June 2008) and Supplement 2 (November 2012) and all other applicable regulatory requirements. The manual, Environmental Protection Agency 815-R-05-004, is incorporated herein by reference. It is available for viewing at the Department of Health and Human Services Division of Public Health, 301 Centennial Mall South, Lincoln, NE 68509. The manual may be obtained on-line at http://dhhs.ne.gov/publichealth/Pages/lab_certification.aspx.

005.02 Use the methods specified in Title 179 NAC incorporated herein by this reference. These documents are available for viewing at the Department of Health and Human Services Division of Public Health, 301 Centennial Mall South, Lincoln, NE 6850, or on-line at http://dhhs.ne.gov/publichealth/Pages/lab_certification.aspx.

005.03 Comply with a current laboratory quality assurance plan, as specified in the Environmental Protection Agency *Manual for the Certification of Laboratories Analyzing Drinking Water,* Fifth Edition, (January 2005) including Supplement 1 (June 2008) and Supplement 2 (November 2012).

005.04 Maintain current administrative and analytical standard operating procedures that follow the format set out in *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality Related Documents, April* 2007, (Environmental Protection Agency QA/G-6), published by the United States Environmental Protection Agency Quality Assurance Division, Washington, DC 20460, which is incorporated herein by this reference. This document may be viewed at the Office of the Department of Health and Human Services, Division of Public Health, 301 Centennial Mall South, Lincoln, NE 68509 or it may be obtained on-line at http://dhhs.ne.gov/publichealth/Pages/lab_certification.aspx.

005.05 Employ both a laboratory director and a quality assurance manager having the following qualifications:

005.05(A) The laboratory director must be a qualified professional with the technical education and experience, and managerial capability commensurate with the size and type of the laboratory. The laboratory director is ultimately responsible for ensuring that all laboratory personnel have demonstrated proficiency for their assigned functions and that all data reported by the laboratory meet the required quality assurance criteria and regulatory requirements.

005.05(B) The quality assurance manager must be independent from the laboratory management, if possible, and have direct access to the highest level of management. The quality assurance manager must have a bachelor's degree in science or the equivalent work experience, training in quality assurance principles commensurate with the size and sophistication of the laboratory, and at least one year of experience in quality assurance.

The quality assurance manager must have at least a working knowledge of the statistics involved in quality control of laboratory analysis; and a basic understanding of the methods which the laboratory employs.

005.06 Document the laboratory has analyzed a proficiency testing sample with acceptable results for each test method for which certification is requested within the past 60 calendar days. Proficiency testing samples must be purchased from a proficiency testing provider approved by National Environmental Laboratory Accreditation Program. The approved proficiency testing provider must send results of the proficiency testing samples directly to the Department.

005.07 Be able to provide documentation to the Department that the person(s) analyzing any proficiency testing sample(s) is a laboratory employee who routinely analyzes drinking water compliance samples.

005.08 Analyze the proficiency testing samples by each method for which the laboratory wishes to be certified.

005.09 Analyze proficiency testing samples in the same manner (including the same number of times) that the laboratory tests compliance samples.

005.10 For those laboratories that do compliance testing for a system(s) in which they may have a vested interest or by which they may be owned, agree to have a minimum of 10% of the minimum number of samples per month required in 179 NAC 3-004.01B, or a minimum of one sample per week of drinking water compliance testing, whichever is more, analyzed by the Department Laboratory or a certified laboratory which maintains an agreement with the Department for the specific compliance testing and which is not owned by and does not have a vested interest in the testing results. Compliance samples must be collected and analyzed at regular time intervals throughout the month.

005.11 The ability to submit results in an electronic format acceptable to the Department.

005.12 To maintain continued certification by the Department a laboratory must:

005.12(A) Notify the Department in writing within 30 days of any change to the following:

(i) The name and street address (not PO Box) of the laboratory;
(ii) The name of the laboratory director;
(iii) The name of the laboratory quality assurance manager;
(iv) Test methods used;
(v) Quality assurance plan;
(vi) Standard operating procedures; or
(vii) The name of the primary analyst for certified methods.

005.12(B) Document that the laboratory has successfully analyzed a proficiency testing sample every 12 months for each test method for which certification is maintained.

(i) Proficiency testing samples must be purchased from a National Environmental Laboratory Accreditation Program approved proficiency testing provider.

(ii) Results of the proficiency testing samples must be sent to the Department directly from the proficiency testing provider.

(iii) If the results of a proficiency testing sample are unacceptable, the laboratory has 30 calendar days to perform another test and obtain satisfactory results.

(iv) Proficiency testing samples must be analyzed in the same manner (including the same number of times) as routine samples.

005.13 All laboratory certifications will be valid for no more than 36 months, expiring on December 31 of the third year. Certifications based upon reciprocity will be valid based on the expiration date of the certifying body's certificate. In no instance will the reciprocity certification exceed 36 months.

006. DISCIPLINARY ACTIONS.

006.01 A laboratory will be downgraded to provisionally certified status for a contaminant or group of contaminants for any of the following reasons:

006.01(A) Failure to analyze a proficiency testing sample at least every 12 months within the acceptance limits specified by the proficiency testing provider.

006.01(B) Failure of a certified laboratory to notify the Department within 30 days of major changes (e.g., in personnel, equipment, or laboratory location).

006.01(C) Failure to satisfy the Department that the laboratory is maintaining the required standard of quality, based upon an on-site evaluation.

006.01(D) Failure to report compliance data to the public water system or the Department drinking water program in a timely manner as set out in Title 179 NAC. Data which may cause the system to exceed a maximum contaminant level must be reported as soon as possible as set out in Title 179 NAC.

006.02 A laboratory certification or agreement may be denied, revoked, suspended, or refused renewal for any of the following reasons:

006.02(A) Violation of Neb. Rev. Stats. §§ 71-2619 to 2621, the Nebraska Safe Drinking Water Act, or these regulations;

006.02(B) Falsification of data or other deceptive practices;

006.02(C) Failure to maintain required staff;

006.02(D) Failure to comply with the reporting requirements;

006.02(E) Failure to use the analytical methodology for which the laboratory is certified;

006.02(F) Refusal or failure to participate in an on-site evaluation conducted by the Department or to provide information or documents requested by the Department;

006.02(G) Failure to successfully analyze a proficiency testing sample or any other unknown test sample for a particular contaminant within the acceptance limits specified;

006.02(H) Failure to demonstrate to the Department that the laboratory has corrected deviations identified during an on-site evaluation; or

006.02(I) Persistent failure to report compliance data to the public water system or the Department drinking water program in a timely manner as set out in Title 179 NAC. Data which may cause the system to exceed a maximum contaminant level must be reported as soon as possible as set out in Title 179 NAC.

006.03 In the event of any disciplinary action, the decision of the Department will be final 30 days after the mailing of the notice unless the director or other designated representative of the laboratory, within such period, gives written notice to the Department of a desire for hearing. Hearings before the Department will be conducted in accordance with Chapter 84, Article 9 and 184 NAC 1.

007. RECORD KEEPING. The laboratory must ensure that records for on-site laboratory assessments and certification program reviews are maintained in an easily accessible central location for a period of six years to include the last two on-site audits. This includes records and correspondence used to determine compliance with the requirements in 179 NAC 20 and checklists, corrective action reports, final reports, certificates, proficiency testing study results, and related documents.

008. FEES. The fees for inspection of a laboratory are as follows:

008.01 Bacteriological examination $150.

008.02 Inorganic chemical analyses $100.

008.03 Heavy metal analyses $200.

008.04 Organic chemical analyses $200.

008.05 Radiochemical analyses $200.

179 NAC 20 Attachment 1

DEPARTMENT HEALTH AND HUMAN SERVICES
PUBLIC HEALTH ENVIRONMENTAL LABORATORY
3701 South 14th Street
Lincoln, Nebraska 68502
402-471-8407

APPLICATION FOR CERTIFICATION OF DRINKING WATER TESTING LABORATORIES FOR NEBRASKA

Please complete all applicable parts of this form using a typewriter or computer or print in ink.
When completed, return to the above address to the attention of the QA Manager.

Date of Request:	Date Request Received:
Check all that apply: ☐ Initial Certification Request ☐ Re-certification Request ☐ Certification through Reciprocity Request ☐ Additional Method/Analyte Certification Request ☐ Nebraska Coliform Testing Agreement Request	

1. Name of Laboratory or Facility (as it should appear on the Certificate or Agreement):			
2. Description of Laboratory (check one): ☐ County Health Department ☐ Utility Laboratory ☐ University/Academic Department ☐ Commercial Laboratory ☐ Other (please describe) _____			
3. Location of Laboratory (physical address):	Street/Route:		
	City:	State:	Zip:
4. Mailing Address (if different from above):	Street/PO/Route:		
	City:	State:	Zip:
5. Name of Owner		6. Telephone Number:	
7. Name of Laboratory Director:		8. Telephone Number:	
9. Name of QA Manager:		10. Telephone Number:	
11. Hours of Operation:	12. E-mail Address:		13. Fax Number:
14. Certification Number (if already certified):		15. EPA ID (required for PT acceptance):	
16. Primary Accrediting Authority (if requesting reciprocal certification):			
		☐ Check here if you can prove you can meet the electronic data submittal requirement.	

ATTESTATION OF COMPLIANCE

I, _____ of _____
(Laboratory Director or Quality Assurance Manager) (Laboratory Name)

understand and acknowledge that the laboratory is required to be continually in compliance with all of the provisions and standards set forth in the State of Nebraska Title 179 Chapter 20 Laboratory Certification Requirements for Testing Drinking Water Regulations, which has been determined to be equivalent to or more stringent than requirements for the Environmental Protection Agency for Drinking Water Testing. I also understand that the laboratory will be subject to suspension, revocation, and denial of accreditation as specified therein and that the laboratory is subject to the enforcement and penalty provision as stated in the current Nebraska statutes and/or regulations and of any secondary accrediting authorities from whom I have obtained accreditation.

I further attest that all certified environmental analyses performed are done in accordance with the provisions and standards set forth in the State of Nebraska Title 179 Chapter 20 Laboratory Certification Requirements for Testing Drinking Water Regulations, which has been determined to be equivalent to or more stringent than the standards of the Environmental Protection Agency for Drinking Water Testing.

I hereby certify that I am authorized to sign this application on behalf of the owner and that there are no misrepresentations in my answers to the questions on this application. The information, statements, facts, and representations given and made are true and correct, and I am aware that any misrepresentations or falsifications constitute grounds for the imposition of penalties by law.

_____ _____
(Signature of Quality Assurance Manager) (Printed Name of Quality Assurance Manager)

_____ _____
(Printed Legal Name of Laboratory) (Current Date)

_____ _____
(Signature of Laboratory Director(s)) (Printed Name of Laboratory Director(s))

179 NAC 20 Attachment 3

Personnel for Certification Form

Position/Title	Name	Academic Training (e.g., H.S., BS, Chemistry, 20 sem-hr Micro)	Area of Lab Responsibility	Experience Years/Area	Phone Number	E-Mail Address

179 NAC 20 Attachment 4

Quality Assurance Manual Checklist

Please indicate, by section number and/or page number, where the following elements are found in the submitted Laboratory Quality Assurance Manual. See the *Manual for the Certification of Laboratories Analyzing Drinking Water*, section labeled Laboratory Quality Assurance Plan starting on page III-4 for more information. If a particular item is not relevant, the QA plan should state this and provide a brief explanation.

MANDATORY ELEMENTS	**QUALITY MANUAL REFERENCE**
Title page signed and dated	
1a. Chart or table showing laboratory organization and responsibility and relationship between management and the quality system	
1b. List of key individuals responsible for production of valid results and routine assessment of the quality systems	
1c. Reference to job descriptions of staff, training provided, and documentation of staff proficiency	
2. Process used to identify clients Data Quality Objectives	
3a. List of SOP's with dates of last revisions	
3b. Where current copies of SOP's are stored	
3c. SOP's are reviewed annually and revised as changes are made	
3d. SOP's have signature pages and revisions dated	
4a. Sampling, preserving, shipping, receiving, and storage procedures	
4b. How forms are filled out and availability of hard copies of electronic data	
4c. How samples are checked on arrival	
4d. Sample instructions are available	
5. Laboratory sample handling procedures	
5a. Sample login procedure	
5b. Storage of samples	
5c. Sample tracking process	
5d. Sample chain of custody	
5e. Sample rejection	
6. Calibration procedures for chemistry	
6a. Specify type of calibration used for each method and frequency of use	
6b. Standards source, age, storage, labeling	
6c. Perform data comparability checks	
6d. Use of control charts	
7. Analytical procedures (may reference SOP)	
7a. Cite complete method manual	
7b. Quality control procedures required by the methods that must be followed	
8. Data reduction, validation, reporting, and verification	
8a. Data reduction process	

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8b. Data validation process	
8c. Reporting, including procedures and format	
8d. Data verification process	
8e. Procedure for data corrections	
9. Type of quality control checks and the frequency of use	
9a. Instrument performance check standards	
9b. Frequency and acceptability of method detection limit calculations	
9c. Calibration, internal, and surrogate standards	
9d. Laboratory reagent blank, field reagent blank, and trip blank	
9e. Field and laboratory matrix replicates	
9f. Quality control and performance evaluation samples	
9g. Laboratory fortified blank and laboratory fortified sample matrix replicates	
9h. Initial demonstration of method capability and use of control charts	
9i. Qualitative identification/confirmation of contaminants	
9j. Parameters for microbiology should include or reference:	
aa. Positive and negative controls used	
bb. Confirmation, verification of presumptive total coliform positive samples	
cc. Sterility controls	
dd. Performance evaluation and quality control samples	
10. List schedules of internal and external system and data quality audits and inter-laboratory comparisons (may reference SOP)	
11. Preventative maintenance procedures and schedules	
11a. Location of instrument manuals and schedules and documentation of routine equipment maintenance	
11b. Availability of instrument spare parts in the laboratory	
11c. List any maintenance contracts in place	
12. Corrective action contingencies	
12a. Response to obtaining unacceptable results from analysis of PT samples and from internal QC checks	
12b. Name of person(s) responsible for various corrective actions	
12c. How corrective actions taken are documented	
13. Record keeping procedures	
13a. Procedures and documentation of those procedures	
13b. Length of storage, media type (electronic or hard copy)	
13c. Security policy of electronic databases	

179 NAC 20 Attachment 5

LIST OF MATRIX, METHOD, AND ANALYTE CERTIFICATION REQUESTED

Matrix	Analyte	Method Number	Primary Analyst