

EFFECTIVE DATE
DECEMBER 17, 2006

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

179 NAC 20

TITLE 179 PUBLIC WATER SYSTEMS

CHAPTER 20 LABORATORY CERTIFICATION AND AGREEMENT REQUIREMENTS FOR TESTING DRINKING WATER

20-001 SCOPE AND 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. These regulations also establish requirements for agreements between the Department and laboratories to test drinking water. The authority is found in Neb. Rev. Stat. §§71-5303, 71-5306, and 71-2619 to 71-2621.

20-002 DEFINITIONS:

Agreement means a binding contract between the Department and a laboratory.

Certificate means 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.

Compliance samples mean those water samples required under the Nebraska Safe Drinking Water Act and Title 179 Nebraska Administrative Code to determine whether a public water system meets current drinking water standards.

Deficiency means a failure to meet the established minimum standards.

Department means the Department of Health and Human Services Regulation and Licensure.

Director means the Director of Regulation and Licensure or his or her authorized representative.

EPA means the United States Environmental Protection Agency.

NELAC means National Environmental Laboratory Accreditation Conference.

NELAP means National Environmental Laboratory Accreditation Program.

PT means proficiency testing.

20-003 CERTIFICATION FOR LABORATORIES IN NEBRASKA

20-003.01 Application: The director of a laboratory must make a formal request for certification in writing. The application must be submitted to the Department and may be:

1. A request for first-time certification for microbiology, chemistry, or radiochemistry;
2. A request for certification to analyze additional or newly regulated contaminants;
3. A request to reapply for certification after correction of deficiencies which resulted in the downgrading/revocation of certification status.

20-003.02 Types of Certification: After reviewing PT sample results and an on-site visit, the Department will classify the laboratory for each contaminant or group of contaminants according to the following rating scheme:

1. Certified: A laboratory that meets the regulatory performance criteria as explained in the *Manual for the Certification of Laboratories Analyzing Drinking Water*, fifth edition, January 2005 and all other applicable regulatory requirements. The manual, EPA 815-R-05-004, is incorporated herein by reference. It is available for viewing at the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, Lincoln, NE 68509. Copies may be obtained from the Office of Ground Water and Drinking Water, Technical Support Center, Cincinnati, OH 45268, EPA 815-R-05-004, or the manual may be obtained on-line at <http://www.epa.gov/safewater/certlab/labindex.html>.
2. Provisionally Certified: A laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in Title 179. 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.
3. Not Certified: A laboratory that possesses deficiencies and, in the opinion of the Department, cannot consistently produce valid data.
4. Interim Certification may be granted in certain circumstances when 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 PT 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. An example of a situation where this type of certification is warranted would be a laboratory that has requested certification for the analysis of additional analytes that involve a method for which it already has certification. The Department will review the laboratory's quality control data before granting this type of certification.

20-003.03 Certification Requirements: To be certified by the Department a laboratory must meet the following requirements:

1. Use the methods specified in the U.S. Environmental Protection Agency Drinking Water Regulations, 40 CFR part 141.21 to 141.25; 141.27; 141.30; 141.74, 141.89; 141.131, 143.3, and 143.4 (July 1, 2004 which are incorporated herein by this reference. These documents are available online at http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr141_04.html or from the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, Lincoln, NE 68509.
2. Meet all laboratory requirements, including a current laboratory Quality Assurance (QA) Plan, as specified in the *EPA Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition*, January 2005.
3. 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*, Nov. 1995, (EPA 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 Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, Lincoln, NE 68509 or it may be obtained on-line at <http://www.epa.gov/quality/qs-docs/g6-final.pdf>.
4. Employ both a laboratory director/manager and a QA officer having the following qualifications:
 - a. The laboratory director/manager must be a qualified professional with the technical education and experience, and managerial capability commensurate with the size/type of the laboratory. The laboratory director/manager 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 QA criteria and regulatory requirements.

- b. The QA officer must be independent from the laboratory management, if possible, and have direct access to the highest level of management. The QA 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 QA 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.
5. Document the laboratory has analyzed a PT sample with acceptable results for each test method for which certification is requested within the past 60 calendar days. PT samples must be purchased from a PT provider approved by EPA. The approved PT provider must send results of the PT samples directly to the Department.
6. Submit the following:
 - a. A completed application – Attachment 1 which is incorporated herein by reference;
 - b. A signed Attestation of Compliance form – Attachment 2 which is incorporated herein by reference;
 - c. A completed Checklist for Certification of Drinking Water Laboratories for Nebraska – Attachment 3 which is incorporated herein by reference;
 - d. A completed Personnel for Certification form – Attachment 4 which is incorporated herein by reference, and a copy of certification of their academic training [diploma(s) or transcript(s)];
 - e. A completed list of Matrix, Method and Analyte form – Attachment 5 which is incorporated herein by reference – indicating what certification is being requested;
 - f. A signed copy of the laboratory's current analytical and administrative standard operating procedures (SOPs), in the proper EPA format, for each method/analyte/matrix for which the laboratory is requesting certification;
 - g. A copy of the laboratory's current signed Quality Assurance Manual in the proper EPA format;
 - h. A copy of the completed chemistry and/or microbiology checklist from the Fifth edition of the *Manual for Certification of Laboratories Analyzing Drinking Water* (January 2005) depending on the methods/analytes being requested and/or any checklist supplied

by the Department in the certification packet. A completed chemistry checklist is required when chemistry method certification is being requested and a completed microbiology checklist is required when microbiological methods are being requested; and

- i. The PT provider must send the most current PT results for each method/analyte, to the Department. If the laboratory is applying for a new certification for an analyte/method it must have a PT provider send a copy of PT results performed within the last 60 days for each analyte/method. If the laboratory is applying for recertification, at least one acceptable PT result must be received for each method/analyte in every 12-month period.
7. Perform all analyses for which the laboratory is certified in accordance with the standards required for certification.
 8. Be able to provide documentation to the Department that the person(s) analyzing any PT sample(s) is a laboratory employee who routinely analyzes drinking water compliance samples.
 9. Analyze the PT samples by each method for which the laboratory wishes to be certified.
 10. Analyze PT samples in the same manner (including the same number of times) that the laboratory tests compliance samples.
 11. Agree to test all drinking water samples for which the laboratory is certified to perform tests by a certified method and in the same manner (including the same number of times) the laboratory would perform compliance testing.
 12. 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.

20-003.04 Inspections of Laboratories Located in the State of Nebraska

20-003.04A The Department will conduct an inspection at least once every three years to determine if the laboratory is meeting the required standards for certification based on the requirements of these regulations, or the Department may recognize an on-site inspection conducted by EPA or NELAP, provided their standards are at least as stringent as those required by these regulations.

20-003.04B The Department may conduct an inspection of a certified laboratory or a laboratory applying for certification at any time during standard working hours.

20-003.04C The Department will document any deficiencies from the standards within 60 calendar days of the inspection and will issue a draft report to the laboratory.

20-003.04D The inspected laboratory must respond in writing to each deficiency noted in the on-site inspection report with an acceptable plan of correction and completion date within 30 calendar days.

20-003.04E Once a response is received by the Department, any changes needed will be made and a final on-site inspection report will be sent to the laboratory.

20-003.05 Continued Certification: To maintain certification by the Department a laboratory must:

1. Notify the Department in writing within 30 days of any change to the following:
 - a. The name and street address (not PO Box) of the laboratory;
 - b. The name of the laboratory director/manager;
 - c. The name of the laboratory QA officer;
 - d. Test methods used;
 - e. QA plan;
 - f. Standard operating procedures; or
 - g. The name of the primary analyst for certified methods.
2. Document that the laboratory has successfully analyzed a PT sample every 12 months for each test method for which certification is requested.
 - a. PT samples must be purchased from an EPA approved PT provider.
 - b. Results of the PT samples must be sent to the Department directly from the PT provider.

- c. If the results of a PT sample are unacceptable, the laboratory has 30 calendar days to perform another test and obtain satisfactory results.
- d. PT samples must be analyzed in the same manner (including the same number of times) as routine samples.

20-003.06 Downgrading Certification Status

20-003.06A A laboratory will be downgraded to provisionally certified status for a contaminant or group of contaminants for any of the following reasons:

1. Failure to analyze a PT sample at least every 12 months within the acceptance limits specified by the PT provider.
2. Failure of a certified laboratory to notify the Department within 30 days of major changes (e.g., in personnel, equipment, or laboratory location);
3. Failure to satisfy the Department that the laboratory is maintaining the required standard of quality, based upon an on-site evaluation;
4. Failure to report compliance data to the public water system or the Department drinking water program in a timely manner, thereby preventing compliance with federal or state regulations and endangering public health. Data which may cause the system to exceed a maximum contaminant level must be reported as soon as possible.

20-003.06B Procedures for Downgrading to Provisionally Certified Status

1. If a laboratory is subject to downgrading on the basis of the criteria in 179 NAC 20-003.06A, the Department will notify the laboratory director or owner by certified mail of its intent to downgrade within 14 days from becoming aware of the situation warranting downgrading. The laboratory director will review the problems cited, and within 30 days of receipt of the letter, send a letter to the Department specifying what immediate corrective actions are being taken and any proposed actions that need the concurrence of the Department. The Department will consider the adequacy of the response and will notify the laboratory in writing by certified mail of its certification status within 14 days of receipt of the response. The Department will follow up to ensure that corrective actions have been taken.
2. If a laboratory fails to analyze a PT or other unknown sample within the acceptance limits, the Department will not downgrade certification if the laboratory identifies and corrects the problem within 30 days of being notified of the failure. If, after review of the submitted information, the Department determines that the laboratory need not be downgraded, then within 30 days of this decision, the Department will notify the

laboratory that it is required to analyze another PT sample. If the laboratory analyzes this second unknown sample within the acceptance limits established by the PT provider or the Department, the laboratory will not be downgraded. If the laboratory fails to analyze this second unknown sample within the established limits, the Department will downgrade the laboratory to provisionally certified status and will notify the laboratory within 14 days by certified mail. Laboratories will be downgraded only for the analyte failed, except where the Department or EPA certifies a group of related analytes based on a limited number of analytes in the group.

3. During any phase of this procedure, a laboratory may request that EPA or the Department provide technical assistance to help identify and resolve any problem.
4. Once the Department notifies a laboratory in writing that it has been downgraded to provisionally certified status for procedural, administrative, equipment or personnel deficiency, the laboratory must correct its problem within three months. If the laboratory was downgraded to provisionally certified status because of a failure to analyze a PT sample (or other unknown test sample) within the acceptance limits specified in Title 179, the laboratory must correct its problems and satisfactorily analyze another PT sample (or other unknown sample) within one month of receipt of the second PT sample. A provisionally certified laboratory may continue to analyze samples for compliance purposes, but must notify its clients of its downgraded status and provide that information, in writing, on any report.

20-003.07 Upgrading Certification: 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 or revocation have been corrected.

20-004 CERTIFICATION THROUGH RECIPROCITY: A laboratory located outside the State of Nebraska may be certified by submitting:

1. A completed application – Attachment 1.
2. Signed Attestation of Compliance form – Attachment 2.
3. A copy of the laboratory's EPA or NELAC Certification Certificate, clearly showing the name of the laboratory, the certification entity, the methods/analytes the certification covers, the beginning date and the expiration date of the certificate.
4. A copy of the laboratory's current signed Quality Assurance Manual.

5. The most recent PT results for the analyte(s)/method(s) for which certification is requested.
6. A copy of the laboratory's latest on-site audit report.

20-005 AGREEMENTS: The Department may enter into agreements with laboratories to perform drinking water analyses for public water systems. To be considered, the laboratory must submit the following to the Department:

1. A completed application – Attachment 1 – or a copy of the current laboratory certificate from the Department, the state of the laboratory's location, from NELAP, or EPA, clearly showing the name of the laboratory, the certification entity, the methods/analytes the certification covers, the beginning date and the expiration date of the certificate;
2. Proof of the ability to submit the results in an electronic format acceptable to the Department.

20-006 RENEWAL: The Department will notify all certified laboratories and all laboratories that have entered into an agreement with the Department 90 days prior to the expiration date of the current certification or agreement that renewal is required and explain the process for renewal.

20-006.01 All laboratory certifications will be valid for a period of time not to exceed 36 months, expiring on December 31 of the third year.

20-006.02 All laboratory agreements expire each year on December 31.

20-007 DISCIPLINARY ACTIONS

20-007.01 A laboratory certification or agreement may be denied, revoked, suspended or refused renewal for any of the following reasons:

1. Failure to comply with the provisions of 179 NAC 20;
2. Falsification of data or other deceptive practices;
3. Failure to maintain required staff;
4. Failure to comply with the reporting requirements;
5. Any breach of the requirements in the statute or regulations;
6. Failure to use the analytical methodology for which the laboratory is certified;
7. Refusal to participate in an on-site evaluation conducted by the Department;
8. Failure to successfully analyze a PT sample or any other unknown test sample for a particular contaminant with the acceptance limits specified;
9. Failure to demonstrate to the Department that the laboratory has corrected deviations identified during an on-site evaluation; or

10. Persistent failure to report compliance data to the public water system or the Department drinking water program in a timely manner, thereby preventing compliance with federal and/or state regulations and endangering public health. Data which may cause the system to exceed a maximum contaminant level must be reported as soon as possible.

20-007.02 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/manager or other designated representative of the laboratory, within such period, gives written notice to the Department of a desire for hearing. The director/manager or other designated representative of the laboratory will then be given an opportunity for formal hearing before the Department and will have the right to present evidence on the laboratory's behalf. On the basis of the evidence presented, the denial will be affirmed or set aside, and a copy of the decision setting forth the findings of fact and the specific reasons upon which the decision is based will be sent by either certified or registered mail to the applicant. The decision becomes final 30 days after the copy is mailed unless the applicant, within such period, appeals the decision pursuant to Chapter 84, Article 9. Hearings before the Department will be conducted in accordance with Chapter 84, Article 9 and 184 NAC 1, the Rules of Practice and Procedure of the Department.

20-008 RECORD KEEPING: The certification program manager 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/correspondence used to determine compliance with the requirements in 179 NAC 20. Records may include checklists, corrective action reports, final reports, certificates, PT study results and related documents.

20-009 FEES: The fees for inspection of a laboratory are as follows:

- | | | |
|----|-----------------------------|--------|
| 1. | Bacteriological examination | \$150 |
| 2. | Inorganic chemical analysis | \$100 |
| 3. | Heavy metal analyses | \$200 |
| 4. | Organic chemical analyses | \$200- |
| 5. | Radiochemical analyses | \$200 |

179 NAC 20 Attachment 1



STATE OF NEBRASKA

HEALTH AND HUMAN SERVICES REGULATION
AND LICENSURE LABORATORY
3701 South 14th Street, Lincoln, Nebraska 68502
402-471-8426

**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: <input type="checkbox"/> Initial Certification Request <input type="checkbox"/> Re-certification Request <input type="checkbox"/> Certification through Reciprocity Request <input type="checkbox"/> Additional Method/Analyte Certification Request <input type="checkbox"/> 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): <input type="checkbox"/> County Health Department <input type="checkbox"/> Utility Laboratory <input type="checkbox"/> University/Academic Department <input type="checkbox"/> Commercial Laboratory <input type="checkbox"/> Other (please describe) _____			
3. Location of Laboratory (physical address):		Street/PO/Route:	
		City:	State: Zip:
4. Mailing Address (if different from above):		Street/PO/Route:	
		City:	State: Zip:
5. Name of Lead Technical Director (e.g., Laboratory Director):		6. Telephone Number:	
7. Name of QA Officer:		8. Telephone Number:	
9. Hours of Operation:	10. E-mail Address:	11. Fax Number:	
12. Certification Number (if already certified):		13. EPA ID (required for PT acceptance):	
14. Primary Accrediting Authority (if requesting reciprocal certification):			
15. <input type="checkbox"/> Check here if requesting a laboratory agreement to perform Drinking Water Coliform Testing for public water systems in Nebraska.		<input type="checkbox"/> Check here if you can prove you can meet the electronic data submittal requirement.	
16. <input type="checkbox"/> Check here if additional method(s) and/or analyte(s) certification is being requested at this time. (If this application is for additional analytes and/or test methods, do not include methods or analytes you are currently certified to perform by the State of Nebraska.)			

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ATTESTATION OF COMPLIANCE

I, _____ of _____
(Laboratory Director or QA Officer) (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 applicant/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 QA Officer)

(Printed Name of QA Officer)

(Printed Legal Name of Laboratory)

(Current Date)

(Signature of Technical Director(s))

(Printed Name of Technical Director(s))

179 NAC 20 Attachment 3

INSTRUCTIONS AND CHECKLIST FOR CERTIFICATION OF DRINKING WATER LABORATORIES FOR NEBRASKA

- _____ Fill out and submit the Application for Certification of Drinking Water Testing Laboratories for Nebraska.
- _____ Fill out, sign and submit the Attestation of Compliance Form.
- _____ Submit one copy of the Instructions and Checklist for Certification of Drinking Water Laboratories for Nebraska. Initial each item on the list that you have authorized or included in your application package.
- _____ Fill out and submit the attached Personnel Form along with Certification of Academic Training. (A photocopy of diploma is sufficient.)
- _____ Request the desired sample Matrix, Test Methods, and Analytes for certification by:
 1. Filling out the Certification Request Form, being sure to indicate each matrix-method-analyte combination in which certification is desired.
 2. If requesting reciprocal certification (secondary accreditation or recognition), be sure that the 2-letter state abbreviation of the corresponding primary Accrediting Authority for each matrix-method-analyte combination is indicated in the proper area. DO NOT indicate any secondary Accrediting Authority. (The primary analyst is not required on reciprocal certification requests.)
- _____ Arrange through your proficiency provider for results from the latest PT testing round attempted, for each applicable sample matrix, method and analyte to be sent directly to our office, if this has not already been completed.
 1. An acceptable result performed within the last 12 months MUST be available for each analyte and method on your certification.
 2. For new applications or additional analyte or method requests, all PT testing results must have been submitted directly to the Nebraska Drinking Water Certification office by your PT provider within the last 60 days.
 3. **All** PT testing results must be sent directly to our laboratory from your PT provider.
- _____ Submit one current signed copy of the Laboratory's QA Plan. (Desirable but not required if requesting reciprocity certification.)
- _____ Submit the completed QA Manual Checklist. (Not required if requesting reciprocal certification.)
- _____ Submit one copy of each matrix-method-analyte combination SOP(s) or any appropriate administrative SOP(s). (Not required if requesting reciprocal certification.)
- _____ If you are requesting reciprocal certification, submit a current copy of your Certification Certificate, include a current list of Fields of Accreditation issued by the specified EPA or NELAC primary Accrediting Authority(ies). Each Certificate must clearly include the expiration date.
- _____ Applicants requesting certification or agreements with the Department may at any time be requested to complete a checklist which follows the EPA *Manual for Certification of Laboratories Analyzing Drinking Water*, Fifth Edition January 2005 or submit to an on-site laboratory inspection during business hours. (Not required for reciprocity requests.) If a checklist has been submitted to your laboratory with your application, please complete the checklist and return it with your application.
- _____ Applicants within the State of Nebraska, requesting certification or certification and agreements with the Department, will have an on-site inspection within the next three years. The inspection will be conducted during regular business hours. An inspection fee will be assessed at the rate stated in Title 179 NAC 20. (The fee will be billed at the time of inspection.)

179 NAC 20 Attachment 4

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 5

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	
8b. Data validation process	
8c. Reporting, including procedures and format	
8d. Data verification process	

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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 person 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	

