

Section proposed for repeal:

Chapter 73. Laboratories

~~§73.25. Environmental Laboratory Certification and Accreditation.~~

~~(a) Purpose. This section establishes a two-tiered program for the certification and accreditation of environmental laboratories. The first tier of this program is established to certify laboratories performing microbiological and chemical analysis of drinking water for compliance with EPA regulations issued pursuant to the Safe Drinking Water Act (SDWA). The second tier of this program is established to accredit laboratories performing analysis for compliance with the SDWA and the Clean Water Act (CWA) federal programs that voluntarily comply with the consensus standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC).~~

~~(b) Definitions. The following words and terms when used in this section shall have the following meanings unless the context clearly indicates otherwise.~~

~~–(1) Accreditation—The recognition of a laboratory as having met the requirements of subsection (f) of this section.~~

~~–(2) Accrediting Authority—The territorial, state or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.~~

~~–(3) Certification—The recognition of a laboratory as having met the requirements of subsection (e) of this section.~~

~~–(4) CWA—The Clean Water Act also known as the Federal Water Pollution Control Act.~~

~~–(5) Deficiency—A noncompliance with one or more of the requirements of this section.~~

~~–(6) Environmental laboratory—a scientific laboratory that performs analyses to determine the chemical, molecular, or pathogenic components of drinking water, wastewater, hazardous wastes, soil, or air.~~

~~–(7) EPA—The United States Environmental Protection Agency.~~

~~–(8) Federal Water Pollution Control Act (Clean Water Act)—The enabling legislation under 33 United States Code §§1251 et seq., Public Law 92-50086, Stat. 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance.~~

~~–(9) Fields of Testing—NELAC's approach to accrediting laboratories by program, method and analyte or component.~~

~~–(10) Interim accreditation—The temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment, which has been delayed for reasons beyond the control of the laboratory.~~

~~–(11) Interim certification—The temporary certification status for a laboratory that has met all certification criteria except for a pending on-site assessment, which has been delayed for reasons beyond the control of the laboratory.~~

~~–(12) NELAC—The National Environmental Laboratory Accreditation Conference.~~

~~–(13) NELAC Standards—Standards that include procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the National Environmental Laboratory Accreditation Conference.~~

- ~~–(14) NELAP—The National Environmental Laboratory Accreditation Program.~~
- ~~–(15) NELAP Approved Accrediting Authority—An accrediting authority that has received recognition from NELAP.~~
- ~~–(16) NELAP Primary Accrediting Authority—The agency or department designated at the Territory, State or Federal level as the recognized authority with the responsibility and accountability for granting NELAC accreditation for a specified field of testing.~~
- ~~–(17) NELAP Secondary Accrediting Authority—The territorial, state or federal agency that grants NELAC accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accrediting Authority.~~
- ~~–(18) Proficiency testing program—The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.~~
- ~~–(19) Proficiency testing study provider—Any person, private party, or government entity that meets stringent criteria to produce and distribute NELAC proficiency testing samples, evaluate study results against published performance criteria and report the results.~~
- ~~–(20) Revoke—To remove a laboratory's certification or accreditation or the approval for a certified or accredited laboratory to perform one or more specified methods.~~
- ~~–(21) Safe Drinking Water Act (SDWA)—The enabling legislation, 42 United States Code §§300f *et seq.* (1974), (Public Law 93-523), that requires the EPA to protect the quality of drinking water in the United States by setting maximum allowable contaminant levels, monitoring, and enforcing violations.~~
- ~~–(22) SDWA—The Safe Drinking Water Act.~~
- ~~–(23) Suspension—The temporary removal of a laboratory's accreditation or certification for a defined period of time, which shall not exceed 6 months, to allow the laboratory time to correct deficiencies or areas of non-compliance with this rule.~~
- ~~–(24) TNRCC—The Texas Natural Resource Conservation Commission.~~
- ~~(e) Administration by department. The department shall administer the environmental laboratory certification and accreditation program established by the Health and Safety Code, Chapter 421 and this section.~~
- ~~(d) Implementation.~~
 - ~~–(1) Laboratories currently certified by the department have two years from promulgation of this rule to comply with all requirements of this rule.~~
 - ~~–(2) The department shall not implement subsection (f) of this section until it is recognized as an accrediting authority by NELAP.~~
- ~~(e) Certification.~~
 - ~~–(1) Standard for certification. A laboratory certified by the department pursuant to this rule shall comply with the standards outlined in the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-B-97-001, March 1997, and is adopted by reference into this rule. This document is available for review during normal business hours at the department's Bureau of Laboratories, 1100 West 49th Street, Austin Texas.~~
 - ~~–(2) Certification requirements. To become certified, to renew certification, or to become recertified under this rule, a laboratory must:~~
 - ~~—(A) submit a completed application to the department, on forms provided by the department that shall include:~~

- (i) the legal name of the laboratory;
 - (ii) the mailing address;
 - (iii) the billing address;
 - (iv) the name of the laboratory owner;
 - (v) the mailing address of the owner;
 - (vi) the physical address of the laboratory;
 - (vii) the name and phone number of technical director(s), however named, and the lead technical director (if applicable);
 - (viii) the name and daytime phone number of the laboratory quality assurance officer;
 - (ix) the name and daytime phone number of a laboratory contact person;
 - (x) the laboratory hours of operation;
 - (xi) fields of testing for which the laboratory is requesting certification;
 - (xii) methods employed including components;
 - (xiii) description of laboratory type (for example):
 - (I) commercial;
 - (II) federal;
 - (III) hospital or health care facility;
 - (IV) state;
 - (V) academic institutes;
 - (VI) public water system;
 - (VII) public waste water system;
 - (VIII) industrial (an industry with a discharge permit);
 - (IX) mobile; or
 - (X) other (describe).
 - (xiv) fee enclosed (if applicable);
 - (xv) description of geographical location;
 - (xvi) fax number;
 - (xvii) lab identification number; and
 - (xviii) quality manual;
 - (B) be enrolled in a proficiency testing program and meet all requirements of paragraph (4) of this subsection;
 - (C) pay all fees under §73.22 of this title prior to the issuance of a certificate:
 - (i) out-of-state laboratories that meet requirements through reciprocity are exempt from category fees;
 - (ii) laboratories that use third party assessors to meet the on-site assessment requirements are exempt from category fees.
 - (D) pass an on-site assessment by meeting all requirements of paragraphs (5)–(7) of this subsection.
- (3) Certification of laboratories outside the State of Texas.
- (A) The department shall certify an out-of-state laboratory to perform environmental sample analysis provided:
 - (i) the laboratory is certified by the EPA or a State Certification Authority for those fields of testing in which the laboratory is requesting certification pursuant to this rule;
 - (ii) the laboratory submits to the department a completed application, copies of the laboratory's two most recent proficiency test results, and its written quality assurance manual;

~~—(iii) the laboratory submits to the department a copy of its most recent (less than two years old) on-site assessment report from the EPA or State Certification Authority together with a current copy of the laboratory's certification listing the categories, analytes or components, and approved methods; and~~

~~—(iv) the department determines that the out-of-state certification program is equivalent to the requirements of this rule.~~

~~—(B) If upon review of the required documents, the department determines that the out-of-state certification program is equivalent to the requirements of this rule, the department will not require an on-site assessment by its assessors and certification shall be granted after the assessed fees are paid.~~

~~—(C) If upon review of the required documents, the department determines that the out-of-state certification program is not equivalent or cannot determine if the out-of-state certification is equivalent to the requirements of this rule, the department will notify, in writing, the applicable certification authority and the laboratory. However, the laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated.~~

~~—(D) If the laboratory's status is changed from certified to provisionally certified or not certified by the laboratory's primary certification authority, the laboratory shall notify the department within 30 days of receipt of notification of the intent to downgrade by the primary certification authority.~~

~~—(4) Proficiency testing requirements for certification. For a laboratory to become certified or to maintain certification for a component by a specific method, the laboratory shall, at its own expense meet the proficiency testing requirements of this subsection.~~

~~—(A) The laboratory shall enroll and participate in a proficiency testing program for each component for which it seeks certification. For each of these components for which proficiency testing is not available, the laboratory shall establish, maintain, and document the accuracy and reliability of its procedures through a system of internal quality management.~~

~~—(B) The laboratory shall participate in more than one proficiency testing program if necessary to be evaluated to obtain or maintain approval to analyze a component.~~

~~—(C) The laboratory shall use a proficiency test provider that is accredited by the National Institute of Standards and Technology.~~

~~—(D) The laboratory shall follow the proficiency testing provider's instructions for preparing the proficiency testing sample and shall analyze the proficiency testing sample as if it were a client sample.~~

~~—(E) The laboratory shall direct the proficiency testing provider to send, either in hard copy or electronically, a copy of each evaluation of the laboratory's proficiency testing study results to the department. The laboratory shall allow the proficiency testing provider to release all information necessary for the department to assess the laboratory's compliance with this rule.~~

~~—(F) Proficiency testing providers shall evaluate results from all proficiency testing studies using NELAC mandated acceptance criteria described in Chapter 2, Appendix A, of the NELAC standards.~~

~~—(G) In each calendar year, the laboratory shall complete at least two separate proficiency testing studies for each component. The department may determine the months of participation in the proficiency testing program.~~

~~—(H) The laboratory shall be successful in at least one of the most recent two proficiency testing studies for each field of testing, subgroup, or component for which it is certified.~~

~~—(I) The laboratory shall be successful in at least one proficiency testing study annually for each SDWA method for which it is certified.~~

~~—(J) The certified laboratory shall not:~~

~~—(i) discuss the results of a proficiency testing study with any other laboratory until after the deadline for receipt of results by the proficiency testing provider; (ii) if the laboratory has multiple testing sites or separate location, discuss the results of a proficiency testing study across sites or locations until after the deadline for receipt of results by the proficiency testing provider;~~

~~—(iii) send proficiency testing samples or portions of samples to another laboratory to be tested; or~~

~~—(iv) knowingly receive proficiency testing samples from another laboratory for analysis and fail to notify the department of the receipt of the other laboratory's sample within five business days of discovery.~~

~~—(K) The following are strictly prohibited:~~

~~—(i) performing multiple analyses (replicates, duplicates) which are not normally performed in the course of analysis of routine samples;~~

~~—(ii) averaging the results of multiple analyses for reporting when not specifically required by the method; or~~

~~—(iii) permitting anyone other than bona fide laboratory employees who perform the analyses on a day-to-day basis for the laboratory to participate in the generation of data or reporting of results.~~

~~—(L) The laboratory shall maintain a copy of all proficiency testing records, including analytical worksheets and proficiency testing provider report of results.~~

~~—(5) On-site assessments for certification.~~

~~—(A) The department is authorized to conduct on-site assessments of the laboratory at any time during normal business hours.~~

~~—(B) An on-site assessment shall be conducted prior to the issuance of a certificate. Thereafter, an on-site assessment shall be conducted every two years. If the laboratory completes all of the requirements for continued certification except that of an on-site assessment because the department is unable to schedule the assessment, the department may issue interim certification for a period not to exceed six months.~~

~~—(C) The laboratory shall ensure that its documented Quality System, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and other records needed to verify compliance with this rule are available for review during the on-site laboratory assessment. The laboratory shall allow the department's authorized personnel to examine records; observe the laboratory's procedures, facilities, and equipment; and interview staff as necessary to determine such compliance.~~

~~—(D) The department shall issue an assessment report to the laboratory documenting any deficiencies found by the assessor within 30 calendar days of the on-site assessment.~~

~~—(E) The department shall adopt procedures specifying the application criteria for acceptance and approval of approved third-party laboratory accreditation organizations.~~

~~—(6) Corrective action reports in response to on-site assessment for certification.~~

~~—(A) A corrective action report must be submitted by the laboratory to the department in response to any assessment report received by the laboratory after an on-site assessment. The corrective action report shall include the action that the laboratory shall implement to correct each deficiency and the time period required to accomplish the corrective action.~~

~~—(B) After being notified of deficiencies, the laboratory shall have 30 calendar days from the date of receipt of the assessment report to provide a corrective action report to the department.~~

~~—(C) The department shall evaluate the corrective action report and respond to the laboratory within 30 calendar days of receipt of the report.~~

~~—(D) If the corrective action report (or a portion) is deemed unacceptable to remediate a deficiency, the laboratory shall have an additional 30 calendar days to submit a revised corrective action report.~~

~~—(E) If the corrective action report is not acceptable to the department after the second submittal, certification shall be revoked for all or any portion of its scope of certification for all or any of a field of testing, method, or component within a field of testing.~~

~~—(F) All information included and documented in an assessment report and the corrective action report are considered to be public information with the exception of proprietary data such as: confidential business information and classified national security information which will be excluded from all public records.~~

~~—(G) If the laboratory fails to implement the corrective actions as stated in their corrective action report, certification for fields of testing, specific methods, or components within those fields of testing shall be revoked.~~

~~—(7) Method approval for certification.~~

~~—(A) A laboratory must request approval to analyze for a component as part of its application for certification or renewal of certification. The laboratory must specify the method by which the analysis shall be performed. Approval to analyze for a component by the specific method shall be granted only after an on-site assessment. The laboratory shall:~~

~~—(i) provide documentation that it has the necessary equipment and trained technical employees to perform the test;~~

~~—(ii) provide documentation that the laboratory has passed two proficiency testing studies for the component(s) in question;~~

~~—(iii) provide its standard operating procedure for the method used for the component(s) in question;~~

~~—(iv) provide documentation of its initial demonstration of analytical capability; and~~

~~—(v) provide documentation establishing the laboratory's method detection limit for the component.~~

~~—(B) At any time a laboratory may request approval to analyze for additional components or to analyze by additional methods by submitting a written request together with the documentation required in subparagraph (A) of this paragraph. The department may require an on-site assessment prior to the granting of approval.~~

~~—(C) SDWA methods of analysis shall be as specified in 40 Code of Federal Regulations Chapter 141 of the National Primary Drinking Water Regulation, or by any alternative analytical technique as specified by the department and approved by the Administrator of the EPA under 40 Code of Federal Regulations §141.27.~~

~~—(D) The department adopts by reference the federal regulations referred to in subparagraph (C) of this paragraph. These documents are available for review during normal business hours at the department's Bureau of Laboratories, 1100 West 49th Street, Austin Texas.~~

~~—(8) Period of certification.~~

~~—(A) The period of certification shall be 24 months from the date of issuance of the certificate.~~

~~—(B) To renew certification, a laboratory shall reapply to the department and meet all the requirements for certification prior to the termination of their certification.~~

~~—(9) Display of certificate. A current certificate shall be displayed at all times in a prominent place in each certified laboratory where it may be viewed by the public.~~

~~—(10) Denial and revocations of certification.~~

~~—(A) The department is authorized to deny, suspend, limit, or revoke the certification of any laboratory that does not comply with the requirements in the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-B-97-001, March 1997, and this rule.~~

~~—(B) In determining the denial, revocation, suspension, or limitation, the department shall consider such factors as the gravity of the offense, the danger the offense poses to the public, the intent of the violation, the extent of the violation, and the proposed correction of the problem.~~

~~—(C) The department is authorized to immediately suspend the certification of a laboratory when the department determines that any condition in the laboratory presents a clear and present danger to public health and safety.~~

~~—(D) Any laboratory, which has its certification revoked, denied, suspended, or limited shall be allowed to apply for a fair hearing conducted by the department. The technical director or quality assurance officer shall submit a written request to the department within 30 days of receipt of notice. The hearing will be conducted using the department's fair hearing procedures in 25 Texas Administrative Code, Chapter 1, Subchapter C (relating to Fair Hearing Procedures).~~

~~—(11) Changes of name or ownership. A certified laboratory must notify the department in writing within 30 days of major changes in personnel, equipment or laboratory location. A major change in personnel is defined as the loss or replacement of the laboratory supervisor or a situation in which a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted.~~

~~(f) Accreditation.~~

~~—(1) Standard for accreditation. A laboratory accredited by the department pursuant to this rule shall comply with the consensus standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC). The NELAC Constitution, Bylaws, and Standards, EPA 600/R-99/068, revised as of June 29, 2000, are adopted by reference into this rule. These specifications are available for review during normal business hours at the department's Bureau of Laboratories, 1100 West 49th Street, Austin Texas.~~

~~—(2) Fields of Testing. The department will offer accreditation for analysis performed for compliance purposes with the Safe Drinking Water Act and the Clean Water Act.~~

~~—(3) Accreditation requirements. To become accredited, to renew accreditation, or to become reaccredited under this rule, a laboratory must meet all the requirements of the NELAC standard and:~~

~~—(A) submit a completed application to the department, on forms provided by the department that shall include the information required by §§4.1.7.1 and 4.1.7.2 of the NELAC standards;~~

~~—(B) be enrolled in a proficiency testing program and meet all requirements of subsection (5) of this section;~~

~~—(C) pay all fees under §73.22 of this title (relating to Fees) prior to the issuance of accreditation. Out of state laboratories that meet the requirements through reciprocity are exempt from category fees;~~

~~—(D) pass an on-site assessment to determine competence in the areas listed in §3.6.1 of the NELAC Standard and meet all requirements of paragraph (6) of this subsection.~~

~~—(4) Reciprocity. An out-of-state laboratory shall be eligible for reciprocal accreditation to perform environmental sample analysis provided the laboratory is accredited by an agency recognized as a NELAP approved accrediting authority for those fields of testing in which the laboratory is requesting accreditation pursuant to this rule.~~

~~—(A) To apply for reciprocal accreditation the laboratory shall submit to the department:~~

~~—(i) a completed application;~~

~~—(ii) copies of the laboratory's three most recent proficiency test results;~~

~~—(iii) its written quality assurance manual; and~~

~~—(iv) a copy of its most recent (less than two years old) on-site assessment report from the accrediting authority or from the accrediting authority's delegated assessor body, together with a current copy of the laboratory's accreditation that lists the categories, analytes, or components, and methods accredited.~~

~~—(B) The department shall review the documentation submitted by the laboratory and grant reciprocal accreditation in compliance with §6.2.1 of the NELAC standard.~~

~~—(5) Proficiency testing requirements for accreditation.~~

~~—(A) To be accredited initially and to maintain accreditation a laboratory must comply with the proficiency testing requirements of §§2.4, 2.5 and 2.7 of the NELAC standard.~~

~~—(B) The laboratory shall direct the proficiency testing provider to send, either in hard copy or electronically, a copy of each evaluation of the laboratory's proficiency testing study results to the department. The laboratory shall allow the proficiency testing provider to release all information necessary for the department to assess the laboratory's compliance with this rule.~~

~~—(C) Proficiency testing providers shall evaluate results from all proficiency testing studies using NELAC mandated acceptance criteria described in Chapter 2, Appendix, C the NELAC standards.~~

~~—(D) The laboratory shall maintain a copy of all proficiency testing records, including analytical worksheets and proficiency testing provider report of results.~~

~~—(6) On-site assessments for accreditation.~~

~~—(A) On-site assessments will be conducted by the department in accordance with the requirements outlined in Chapter 3 the NELAC standard.~~

~~—(i) The department is authorized to conduct on-site assessments of the laboratory at any time during normal business hours.~~

~~—(ii) An on-site assessment shall be conducted prior to granting accreditation. Thereafter, an on-site assessment must be completed at least every two years. If the laboratory completes all of the requirements for continued accreditation except that of an on-site assessment because the department is unable to schedule the assessment, the department may issue interim accreditation for a period not to exceed six months. Assessments for cause may be conducted at any time. (iii) The department shall adopt procedures specifying the application criteria for acceptance and approval of third-party laboratory accreditation organizations to perform the onsite assessment.~~

~~—(iv) The department shall issue an assessment report to the laboratory documenting any deficiencies found by the assessor within 30 calendar days of the on-site assessment.~~

~~—(B) Preparation and evaluation of corrective action reports in response to on-site assessment shall be in compliance with §4.1.3 of the NELAC standard.~~

~~—(i) The laboratory must submit a plan of corrective action to the department within 30 days of receipt of any assessment report. The corrective action plan shall include the action that the laboratory shall implement to correct each deficiency and the time period required to accomplish the corrective action.~~

~~—(ii) The department shall respond to the action noted in the corrective action report within 30 calendar days of receipt.~~

~~—(iii) If the corrective action report (or a portion) is deemed unacceptable to remediate a deficiency, the laboratory shall have an additional 30 calendar days to submit a revised corrective action report.~~

~~—(iv) If the corrective action report is not acceptable to the department after the second submittal, the laboratory shall have accreditation revoked pursuant to §4.4.3 of the NELAC standard for all or any portion of its scope of accreditation for any or all of a field of testing, method, or component within a field of testing.~~

~~—(v) All information included and documented in an assessment report and the corrective action report are considered to be public information and are to be released.~~

~~—(vi) If the laboratory fails to implement the corrective actions as stated in their corrective action report, accreditation for fields of testing, specific methods, or analytes within those fields of testing shall be revoked.~~

~~—(vii) Proprietary data, confidential business information and classified national security information will be excluded from all public records.~~

~~—(7) Awarding of accreditation. The department shall award accreditation in compliance with §4.6 of the NELAC standard. When the laboratory has met the requirements specified for receiving accreditation, the laboratory shall receive a certificate awarded on behalf of the department as the accrediting authority. The certificate shall be signed by a member of the department and shall be considered an official document. It will be transmitted as a sealed and dated (effective date and expiration date) document containing the NELAP insignia. The certificate shall comply with §4.6 of the NELAC standard and include:~~

~~—(A) name of laboratory;~~

~~—(B) address of laboratory;~~

~~—(C) fields of testing (program, method, analyte or component); and~~

~~—(D) addenda or attachments (these shall be considered to be official documents.~~

~~—(8) Period of accreditation.~~

~~—(A) The period of accreditation shall be 12 months from the date of issuance.~~

~~—(B) To renew accreditation, a laboratory shall reapply to the department and meet all requirements for accreditation prior to the termination of their accreditation.~~

~~—(9) Display of accreditation. A current accreditation document shall be displayed at all time in a prominent place in each accredited laboratory where it may be viewed by the public.~~

~~—(10) Denial and revocations of accreditation.~~

~~—(A) Pursuant to §4.4 of the NELAC standard, the department is authorized to deny, suspend, limit, or revoke the accreditation of any laboratory that does not comply with the requirements in the NELAC Standards and this rule.~~

~~—(B) Any laboratory, which has its accreditation, revoked, denied, suspended, or limited shall be allowed to apply for a fair hearing conducted by the department. The technical director or quality assurance officer shall submit a written request to the department within 30 days of receipt of the notice. The hearing will be conducted using the department's fair hearing procedures in 25 Texas Administrative Code, Chapter 1, Subchapter C (relating to Fair Hearing Procedures).~~

~~—(11) Notification and reporting requirements. The accredited laboratory shall notify the department of any changes in key accreditation criteria within 30 calendar days of the change. This written notification includes but is not limited to changes in the laboratory ownership, location, key personnel and major instrumentation. All such updates are public record and any or all of the information contained therein may be placed in the national database.~~

~~—(12) Technical Committee.~~

~~—(A) The department shall establish one or more technical committees for the assistance in interpretation of requirements and for advising the department on the technical matters relating to the operation of its environmental laboratory accreditation program.~~

~~—(B) Appointments to the committee shall be made from lists of nominees solicited by the department, and shall provide adequate representation of interested parties and environmental laboratories subject to this rule.~~

~~—(C) The department shall determine the terms of office of appointees. All committee members shall serve without compensation and shall pay their own expenses incurred as a result of attending meetings or engaging in any other activity pursuant to this section.~~