

The Texas Natural Resource Conservation Commission (commission) proposes new Chapter 25, Accreditation of Environmental Testing Laboratories, Subchapter A, Environmental Testing Laboratory Accreditation and Certification, §§25.1, 25.2, 25.4, 25.6, and 25.8; Subchapter B, Environmental Testing Laboratory Accreditation, §§25.9, 25.10, 25.12, 25.14, 25.16, 25.18, 25.20, 25.22, 25.24, 25.26, 25.30, 25.32, 25.34, 25.36, and 25.38; and Subchapter C, Environmental Testing Laboratory Certification, §§25.50, 25.52, 25.54, 25.56, 25.58, 25.60, 25.62, 25.64, 25.66, 25.68, 25.70, 25.74, 25.76, and 25.78.

#### BACKGROUND AND SUMMARY OF THE FACTUAL BASIS FOR THE PROPOSED RULES

Commercial, governmental, industrial, and other environmental testing laboratories located inside and outside of Texas analyze thousands of environmental samples each year. The results of these analyses are used by the commission to make permitting, compliance, enforcement, cleanup, and other decisions.

The environmental testing laboratory accreditation program was transferred from the Texas Department of Health (TDH) to the commission as part of House Bill (HB) 2912, 77th Legislature, 2001.

Oversight of environmental testing laboratories has been limited to the TDH's formal certification of laboratories analyzing drinking water samples, inspections by the executive director that may have occurred as part of a larger permit compliance inspection, and inspections performed as part of the commission's limited laboratory inspection program. TDH had also developed rules for a voluntary laboratory accreditation program for laboratories analyzing wastewater samples, but had not yet implemented the program.

The Sunset Advisory Commission noted the commission's reliance on environmental data in its decision-making, the limited oversight of environmental laboratories producing the data, and other issues in its staff report concerning the commission. Highlighted as Issue 5, the report included the following key findings: "1) Oversight of environmental labs providing data to the State is inconsistent and divided between agencies; 2) Unregulated, unaccredited labs are more likely to produce inaccurate data for agency decision making, resulting in increased risk to public health and the environment, and increased agency costs; and 3) Uniform standards provided by a national accreditation program would allow Texas labs to effectively compete with accredited labs in other states." (Sunset Advisory Commission Staff Report, Texas Natural Resource Conservation Commission, 2000, page 49.)

The report went on to make several recommendations, including that: 1) the commission be required to implement a voluntary environmental laboratory accreditation program consistent with national standards; 2) the Drinking Water Laboratory Certification Program be transferred from TDH to the commission; 3) the commission be required to accept only data or analyses from accredited laboratories for all decisions affecting permitting, compliance, enforcement, and corrective action; and 4) on-site or in-house labs be exempt from accreditation. With these recommendations, the Sunset Advisory Commission stated in its report that, "This should increase the confidence in agency decision making, provide greater assurance of protecting public health, and minimize unnecessary costs for the agency." (Sunset Advisory Commission Staff Report, Texas Natural Resource Conservation Commission, 2000, page 54.)

In 2001, the 77th Texas Legislature passed HB 2912, §1.12, which amended Texas Water Code (TWC) by adding new §5.127. This section requires that all data used by the commission for commission decisions regarding permits or other authorizations, compliance matters, enforcement actions, or corrective actions be from an accredited environmental testing laboratory, unless the environmental testing laboratory is: an in-house or on-site environmental testing laboratory periodically inspected by the commission; accredited under federal law; or providing data and analysis for emergency response activities and required data and analysis are not available from an accredited environmental testing laboratory. New §5.127 also allows the commission to require that data used in other commission decisions be obtained from an accredited environmental testing laboratory and requires the commission to periodically inspect unaccredited in-house or on-site environmental testing laboratories providing data for commission decisions.

The Legislature also passed HB 2912, Article 6, which transferred Texas Health and Safety Code (THSC), Chapter 421, to TWC, Chapter 5, redesignating Chapter 421 as Subchapter R, §§5.801 - 5.807 and amending it to revise the definitions and numbering. Subchapter R transferred authority for environmental laboratory accreditation and drinking water certification from TDH to the commission and requires that the state's environmental testing laboratory accreditation program be consistent with the National Environmental Laboratory Accreditation Conference (NELAC). Subchapter R also created a special account for accreditation and certification fees.

TWC, §5.802 requires that the environmental testing laboratory accreditation program be consistent with NELAC standards. The commission is adopting by reference the NELAC standards approved by NELAC in May 2001. This document is available on-line at [www.epa.gov/ttnnela1/2001standards.html](http://www.epa.gov/ttnnela1/2001standards.html) or may be viewed in the library at the commission's central office at 12100 Park 35 Circle in Austin. Accredited environmental testing laboratories as well as those seeking accreditation must comply with all NELAC standards; however, for clarity and usability the commission has included only portions of the standards in the proposed rules.

Additionally, HB 2912, §18.02 transferred the Safe Drinking Water Certification Program from the TDH to the commission, effective September 1, 2001. The commission is currently operating the drinking water laboratory certification program according to the rules adopted by the TDH.

Finally, HB 2912, §18.03 transferred the Environmental Testing Laboratory Certification Program, including existing authority, accreditation, appropriations, rules, equipment, and personnel involved in lab accreditation from TDH to the commission, effective September 1, 2001. As required by HB 2912, §18.03(d), accreditation requirements relating to data provided for commission decisions take effect three years after the commission publishes notice in the *Texas Register* that the agency's accreditation program has met NELAC standards. Until that date, environmental testing laboratories that analyze samples for compliance with the Safe Drinking Water Act (SDWA) must continue to be certified according to Chapter 25. After that date, laboratories that analyze samples for compliance with the SDWA must be accredited according to Chapter 25, and the executive director, as authorized by the commission's rules, will no longer grant certifications. To ease the transition from the environmental

testing laboratory certification program to the environmental testing laboratory accreditation program, Subchapter C is as similar to Subchapter B as possible.

The proposed rules are necessary for the implementation and administration of HB 2912, §§1.12, 6.01, 18.02, and 18.03. Proposed new Chapter 25 will establish an accreditation program for environmental testing laboratories providing data for commission decisions for all media and continue the existing environmental laboratory certification program for laboratories providing data to the commission for decisions relating to compliance with the SDWA. The proposed accreditation and certification programs include analyses and tests performed by environmental testing laboratories but do not include field measurements, source air emission measurements, or the use of continuous analysis devices outside of a laboratory. The commission will monitor NELAC's development of field activity standards, and may include accreditation standards for field measurements at a later date.

#### SECTION BY SECTION DISCUSSION

The title of this chapter is Environmental Testing Laboratory Accreditation and Certification.

##### *Subchapter A, General Provisions*

Proposed new §25.1, Purpose, describes the purpose of Chapter 25 and states that while accreditation of an environmental laboratory is voluntary, the commission will only accept data for a commission decision from an accredited laboratory, except as provided in new §25.6. This subsection also states the accreditation program will become effective three years after notice is published that the program has met NELAC requirements. During the three-year period, laboratories that supply data for

commission decisions relating to the SDWA must be certified. After the three-year period, all data and analyses referenced in new §25.4(b) and (c) must be provided by accredited laboratories.

Proposed new §25.2, Definitions, defines words and terms as used in this chapter.

Accreditation is defined as an authorization granted by the executive director to an environmental testing laboratory that meets requirements of Subchapters A and B. The definition clarifies one of the two authorizations granted by the executive director according to Chapter 25.

Accrediting authority is defined as an agency recognized by the National Environmental Laboratory Accreditation Program that grants accreditation on behalf of a state, territory, or federal agency. The definition, with changes to simplify the language of the definition, is from NELAC, §1A, Glossary, and is incorporated in this rule.

Analyte is defined as a constituent for which an environmental sample is analyzed. The definition clarifies one element of the fields of accreditation and fields of certification.

Certification is defined as an authorization granted by the executive director to an environmental testing laboratory which analyzes drinking water and meets requirements of Subchapters A and C. The definition clarifies one of the two authorizations granted by the executive director according to Chapter 25.

Environmental testing laboratory is defined as a scientific laboratory that performs analyses to determine the chemical, molecular, or pathogenic components of environmental media for regulatory compliance. The definition is from TWC, §5.801, and is incorporated in the rule.

Environmental testing laboratory assessment is defined as the process used by an accrediting or certifying authority to measure the performance, effectiveness, and conformity of an environmental testing laboratory to the accreditation or certification standards and this chapter. An environmental testing laboratory assessment may include a physical inspection of a laboratory and its operations. The definition clarifies the components of an environmental testing laboratory inspection.

Fields of accreditation is defined as the matrix, technology, method, and analyte or analyte group for which an environmental testing laboratory may be accredited. The definition clarifies the types of accreditations the executive director will offer.

Fields of certification is defined as the methods and analytes for which an environmental testing laboratory may be certified. The methods and analytes are used in a commission decision relating to compliance with the SDWA. The definition clarifies the types of certifications the executive director will offer.

In-house environmental testing laboratory is defined as an environmental testing laboratory that provides analytical data to its operator for a commission decision relating to permits or other authorizations issued to the laboratory's operator; compliance matters and enforcement actions taken

concerning the laboratory's operator; or corrective actions taken by the laboratory's operator to satisfy statutes, rules, or commission orders. This definition, which clarifies that an in-house environmental testing laboratory is a specific type of environmental testing laboratory, implements TWC, §5.127(b).

Laboratory personnel is defined as individuals who manage, perform, maintain, or verify the work or the quality of the work at the environmental testing laboratory. The definition clarifies who must perform certain activities prescribed in Chapter 25.

Matrix is defined as sample type, including drinking water; nonpotable water; solid and chemical materials; air and emissions; and biological tissue. The definition clarifies one element of the fields of accreditation.

Mobile environmental testing laboratory is defined as an environmental testing laboratory capable of being moved from one site to another site. The definition clarifies a type of laboratory that may be accredited according to Chapter 25.

National Environmental Laboratory Accreditation Conference (NELAC) is defined as the voluntary organization of state, territorial, and federal environmental officials and interest groups whose primary purpose is to establish mutually acceptable national standards for accrediting environmental testing laboratories. The definition, with changes to simplify the language of the definition, is from NELAC, §1A, Glossary, and is incorporated in this rule.

National Environmental Laboratory Accreditation Program (NELAP) is defined as the environmental testing laboratory accreditation program including NELAC. The definition, with changes to simplify the language of the definition, is from NELAC, §1A, Glossary, and is incorporated in this rule.

On-site environmental testing laboratory is defined as an in-house environmental testing laboratory that is located at a regulated entity. This definition, which clarifies a type of environmental testing laboratory, implements TWC, §5.127(b).

Operator is defined as an individual authorized to act on behalf of the environmental testing laboratory. This definition clarifies who is responsible for acting on behalf of an environmental testing laboratory.

Primary accreditation is defined as accreditation of an environmental testing laboratory according to NELAC standards and the requirements of this chapter. This definition distinguishes a primary accreditation from a secondary accreditation.

Proficiency test sample is defined as a sample, the composition of which is unknown by an environmental testing laboratory or the individual performing the analysis. The sample is used to evaluate whether the laboratory and analyst can produce results within specified acceptance criteria. This definition, with changes to simplify the language of the definition, is from NELAC, §1A, Glossary, and is incorporated into this rule.

Quality system is defined as a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring the quality of its work processes, products, and services. The quality system provides the framework for planning, implementing, and assessing work performed by the environmental testing laboratory for quality assurance and quality control. This definition is from NELAC, §1A, Glossary, and is incorporated in this rule.

Secondary accreditation is defined as accreditation granted by the executive director to an environmental testing laboratory that has been granted primary accreditation by another NELAP accrediting authority. This definition distinguishes secondary accreditation from primary accreditation.

In proposed new §25.4, Applicability, subsections (a) - (d) allow an environmental testing laboratory to apply for accreditation after the commission publishes notice in the *Texas Register* that the accreditation program has met NELAC standards. These subsections require that an environmental testing laboratory that provides data used by the commission to make a decision relating to a permit, authorization, compliance action, enforcement action, corrective action, characterization of an environmental process or condition, or an assessment of an environmental process or condition become accredited no later than three years after the commission publishes notice in the *Texas Register* that the accreditation program has met NELAC standards except as provided in new §25.6. Further, these subsections require that an in-house environmental testing laboratory be accredited if it provides analytical data to a third party and the data are used by the commission to make a decision relating to a permit, authorization, compliance action, enforcement action, corrective action, characterization of an environmental process or condition,

or an assessment of an environmental process or condition. These subsections implement TWC, §5.127(a) - (c) and §5.802, and HB 2912, §18.03.

Subsection (e) requires an environmental testing laboratory that provides data relating to the SDWA be accredited or certified by the agency or certified by the United States Environmental Protection Agency (EPA) until the commission publishes notice in the *Texas Register* that the accreditation program has met NELAC standards. This subsection continues existing requirements contained in 30 TAC Chapter 290.

Subsection (f) provides that three years after the commission publishes notice in the *Texas Register* that the accreditation program has met NELAC standards, the agency's drinking water certification program will be eliminated and all environmental testing laboratories that provide data relating to the SDWA will have to be accredited by the agency or certified by EPA. The commission has determined that once the environmental testing laboratory accreditation program is implemented it will be easier and more cost-effective to have only one environmental testing laboratory program. An environmental testing laboratory may obtain accreditation for each field of certification it has under the environmental testing laboratory certification program. This subsection implements HB 2912, §18.03(d).

Proposed new §25.6, Conditions Under Which the Commission May Accept Analytical Data, states the commission may accept data from: 1) an unaccredited on-site or in-house environmental laboratory that is regulated according to the terms of a permit, registration, or other authorization issued by the commission to the operator of the laboratory and that is inspected at least every three years by the

executive director; 2) an environmental testing laboratory accredited under federal law; 3) a laboratory that provides analytical data necessary for emergency response activities and the required analytical data are not otherwise available from a laboratory accredited according to Chapter 25; or 4) a laboratory that provides a type of analytical data for which the agency does not offer accreditation. This section implements TWC, §5.127.

Proposed new §25.8, Contracting, provides the executive director with the authority to contract for services related to Chapter 25, and allows the executive director to authorize contractors to collect fees for these services. The commission determined this section is necessary to efficiently implement this chapter.

*Subchapter B, Environmental Testing Laboratory Accreditation*

Proposed new §25.9, Standards for Environmental Testing Laboratory Accreditation, provides that accreditation will be based on the environmental testing laboratory's conformance to NELAC standards and the requirements of this chapter. This section implements TWC, §5.802.

In proposed new §25.10, Fields of Accreditation, subsection (a) requires the executive director to identify fields of accreditation offered by the agency and make a list of this information available to the public through the commission's website and Compliance Support Division and Agency Communications. The website address is <http://www.tnrcc.state.tx.us/enforcement/csd/qa>. The phone number for the Compliance Support Division is (512) 239-6300. The phone number for Agency Communications is (512) 239-0028. This information will be available after the commission receives

approval as a NELAC accrediting authority. This subsection follows NELAC's structure of accrediting an environmental testing laboratory by matrix, technology, method, and analyte or analyte group, and thus is included in this rule to make this rule consistent with NELAC, which is required by TWC, §5.802. Additionally, this section informs the public and environmental testing laboratories where a current list of the fields of accreditation available to environmental testing laboratories can be found. Subsection (b) allows the executive director to change fields of accreditation offered by the agency after 30 days' notice on the agency website. This provision allows the executive director to modify the fields of accreditation as technology changes and as the law changes without requiring a rule change. It would take substantially longer than 30 days to amend the rule each time a new field of accreditation was offered, or the analyte list changed on one of the multi-analyte lists, and it is important that the executive director be able to make changes to the fields of accreditation quickly to account for changes in analytical capabilities, as well as changes in the law. Additionally, this section provides a way to inform environmental testing laboratories of changes to fields of accreditation in a timely manner.

In proposed new §25.12, Initial Application for Accreditation, subsection (a) requires that an application for accreditation be filed using a form provided by the executive director. The proposed rule also requires an applicant to submit any required or requested documents and records and the fee provided in new §25.30 with the application. This subsection implements TWC, §5.803. Subsection (b) allows an operator of an environmental laboratory to request that noncontiguous facilities and mobile laboratories be accredited as a single entity if they operate under the same ownership, day-to-day management, day-to-day technical direction, and quality system, including document management, records management, and test reporting. The commission determined it is appropriate to accredit

noncontiguous facilities and mobile laboratories as a single entity if the environmental testing laboratory meets the listed requirements because the goal of NELAC is to promote uniform standards of quality. This objective will be met by allowing environmental testing laboratories with more than one location, whether fixed or mobile, to obtain a single accreditation. Subsection (c) allows an operator of an environmental laboratory to submit an application for accreditation or an application to increase the laboratory's fields of accreditation at any time. The commission anticipates that environmental testing laboratories will continuously evaluate the fields of accreditation that they want to pursue. The executive director determined it is appropriate to allow environmental testing laboratories to modify their fields of accreditation at any time so that the environmental testing laboratories can pursue various types of analytical work.

Proposed new §25.14, Term of Accreditation, establishes a one-year term of accreditation.

Additionally, this section authorizes the executive director to grant interim accreditation for up to one year in order to schedule an environmental testing laboratory assessment. This section implements NELAC, §4.2, Period of Accreditation, and §4.5.1, Interim Accreditation.

In proposed new §25.16, Renewal Application for Accreditation, subsection (a) provides that the executive director must receive an environmental testing laboratory's renewal application and applicable fees no later than the expiration date of a laboratory's accreditation. The commission has determined that it is important to provide environmental testing laboratories with a definite deadline for renewal applications. Subsection (b) provides that, if a renewal application is received after the expiration date of the laboratory's accreditation, the laboratory must apply for and meet all requirements for a new

accreditation, including an environmental testing laboratory assessment. The commission has determined that it is important to provide environmental testing laboratories with a definite deadline for renewal applications. Finally, subsection (c) requires that modifications made during the term of an accreditation to increase a laboratory's fields of accreditation be renewed on the accreditation renewal date, regardless of the date of the modifications. The commission has determined that it is appropriate to have all of an environmental testing laboratory's fields of accreditation expire on the same date because it will simplify the recordkeeping requirements for both the environmental testing laboratory and the executive director, thus, reducing the risk that an environmental testing laboratory will fail to renew a specific field of accreditation in a timely manner.

In proposed new §25.18, Environmental Testing Laboratory Assessments, subsection (a) requires an environmental testing laboratory assessment before the executive director grants an environmental testing laboratory's initial accreditation and at least every two years after accreditation is granted. This provision implements NELAC, §3.3.1, Frequency and Types of On-Site Assessments. Subsection (b) authorizes the executive director to perform either announced or unannounced assessments. This provision implements NELAC, §3.3.4, Announced and Unannounced Visits.

In proposed new §25.20, Proficiency Test Sample Analysis, subsection (a) requires environmental testing laboratory personnel to periodically analyze proficiency test samples before accreditation is granted. For initial accreditation, the proposed rule requires the operator of an environmental testing laboratory to ensure that two proficiency test samples are successfully analyzed according to NELAC standards. This section implements NELAC, §2.4.1, Required Level of Participation; §2.7.2, Initial or

Continuing PT Studies; and §4.14, Proficiency Test Samples. For environmental testing laboratories seeking ongoing accreditation, subsection (b) requires the operator of an environmental testing laboratory to ensure that two proficiency test samples per year for each field of accreditation are analyzed according to NELAC standards. If a laboratory does not meet requirements for ongoing analyses of proficiency test samples, the proposed rule allows a laboratory to participate in supplemental proficiency test studies according to NELAC standards. This subsection implements NELAC, §2.4.1, Required Level of Participation; §2.7.3.1, Supplemental PT Studies for Demonstrating Corrective Action; §2.7.2, Initial or Continuing PT Studies; and §2.7.3, Supplemental PT Studies. Additionally, this subsection would require the executive director to determine a laboratory's accreditation status within 60 days if the laboratory does not successfully analyze proficiency test samples as required. This subsection implements NELAC, §2.7.5, Second Failed Study. Finally, subsection (c) requires laboratories to purchase proficiency test samples, if available, from NELAP-designated vendors. This subsection implements NELAC, §2.4.1, Required Levels of Participation and §4.1.4, Proficiency Testing Samples.

In proposed new §25.22, Secondary Accreditation of Out-of-State Environmental Testing Laboratories, subsection (a) requires the executive director to grant or renew the accreditation of an environmental testing laboratory that is located in another state and that is accredited by a NELAP-approved accrediting authority, other than Texas, within 30 days after receiving the laboratory's completed application and fee, if the laboratory is accredited for the requested fields of accreditation. This subsection implements TWC, §5.804. Subsection (b) requires the executive director to notify the laboratory in writing within 30 days of the executive director's decision to grant or deny the

accreditation. This subsection implements TWC, §5.804 and NELAC, §1.5.3. The commission has determined that subsection (b) should be included in the rule to specify how much time the executive director has to evaluate an out-of-state environmental testing laboratory's accreditation. This subsection also assures out-of-state laboratories that the executive director will act on their applications in a timely manner.

Proposed new §25.24, Duties and Responsibilities of Accredited Laboratories, establishes duties and responsibilities of an environmental testing laboratory accepting accreditation. The duties and responsibilities include providing reasonable access to the executive director to the laboratory and its facilities, personnel, documents, records, data, analyses, and operations; using and displaying the accreditation certificate according to the NELAC standards; and operating the laboratory and maintaining the laboratory's accreditation according to NELAC standards and the proposed rules. This section implements TWC, §5.805 and NELAC, §3.5, Assessment Procedures; §4.3, Maintaining Accreditation; §4.6, Awarding of Accreditation; and §4.6.1, Use of NELAC Accreditation by Accredited Laboratories.

Proposed new §25.26, Withdrawal from Accreditation Program, allows an environmental testing laboratory to withdraw from the accreditation program in whole or in part at any time by notifying the executive director in writing. This section implements NELAC, §4.4.4, Voluntary Withdrawal. The NELAC standard requires written notification no later than 30 days before the expiration of an environmental testing laboratory's accreditation. The proposed rule is less restrictive because the commission intends to allow an environmental testing laboratory to withdraw from the accreditation

program in whole or in part at any time.

Proposed new §25.30, Accreditation Fees, requires accreditation fees to cover program costs and establishes a new fee structure for the program. Subsection (b) requires an environmental testing laboratory applying for accreditation to pay an annual administrative fee of \$500 for primary accreditation and annual category fees. Subsection (c) requires an environmental testing laboratory applying for secondary accreditation to pay an annual administrative fee of \$250 and annual category fees. Category fees are based on the types of analyses a laboratory performs for which the environmental testing laboratory is seeking accreditation. Subsections (d) - (h) include 51 categories of analysis, including categories related to drinking water; non-potable water; biologic tissue; solid and chemical materials; and air. Subsection (i) requires the operator of an environmental testing laboratory located in another state and applying for primary accreditation to pay a fee equal to the reasonable travel costs associated with conducting an assessment at the laboratory. Subsection (j) allows fees for accreditation modifications, replacement of accreditation certificates, and reinstatement of a suspended accreditation. All fees will be nonrefundable.

The proposed accreditation fees were developed to produce enough revenue to recover the cost of the accreditation program, as required by TWC, §5.803(b). Annual program costs were estimated using standard employee salary rates and estimates of staffing requirements, training, travel, supply, and other costs. Annual program revenues were calculated using estimates of the number of laboratories that will become accredited and the types of analyses these laboratories will perform.

The number of laboratories that will become accredited is not known. Staff estimates 200 in-state laboratories will receive accreditation. This number is based on staff's experience inspecting commercial laboratories over the past several years.

The fields of accreditation for which these laboratories will seek accreditation is also not known. Therefore, staff estimates the types of analyses and proportion of the estimated 200 laboratories performing these types of analyses. The estimates are also based on staff's experience inspecting commercial laboratories over the past several years.

The proposed fees include categories based on sample matrix and types of analyses. The matrices correspond to the matrices used by NELAC for fields of accreditation. The types of analyses reflect groups of analytical techniques and technology staff have encountered inspecting commercial laboratories over the past several years.

The categories are weighted to reflect their relative complexity, difficulty and time required for environmental testing laboratory inspection, and numbers of analyses. The relative complexity, difficulty and time required for the inspection, and numbers of analyses were based on the agency's regulatory programs and staff's experience inspecting commercial laboratories over the past several years. Each category weight was multiplied by a constant dollar amount to arrive at the annual category fee. The constant dollar amount was assigned to produce enough revenue to recover the cost of the accreditation program, as required by TWC, §5.803(b).

In addition to category fees, the proposed accreditation fees include an annual administrative fee. The administrative fee was assigned to produce, with the category fees, enough revenue to recover the cost of the accreditation program. A lower annual administrative fee was assigned for laboratories seeking secondary accreditation. The lower fee reflects the commission's judgment that secondary accreditation costs should be somewhat lower than costs for awarding primary accreditations, because the executive director's staff will not be required to conduct an environmental testing laboratory assessment.

The proposed accreditation fees include a fee equal to the reasonable travel costs (including transportation, lodging, per diem, and any telephone charges) associated with conducting an assessment at an out-of-state laboratory. The fee ensures the agency will recover out-of-state travel costs that arise from inspections of laboratories located in other states.

The proposed accreditation fees also include fees for adding one or more fields of accreditation; replacing an accreditation certificate; recording an ownership change; processing a late renewal; and reinstating a suspended accreditation. These fees were assigned to ensure the agency receives revenue from activities outside of the routine accreditation process.

In proposed new §25.32, Denial of Accreditation Application, subsection (a) allows the executive director to deny an initial or renewal application for insufficiency. An application may be determined to be insufficient if laboratory personnel fail to submit a completed application; fail to submit the required fees; fail to successfully analyze and report proficiency test samples; fail to implement a quality system; fail to document that laboratory personnel meet education, training, and experience

requirements; fail to allow entry during normal business hours for an assessment; fail to pass required environmental testing laboratory assessments; fail to submit a report identifying action the environmental testing laboratory will take to correct deficiencies in the assessment report within 30 days of receiving an assessment report; or fail to implement actions to correct the deficiencies identified in the assessment report as identified by the executive director. This subsection provides consistency with other program areas. Subsection (b) allows the commission to deny an applicant's initial or renewal application for accreditation for cause after notice and an opportunity for a hearing if the laboratory personnel misrepresent any fact pertinent to receiving or maintaining accreditation or the laboratory or its operator is indebted to the state for a fee, penalty, or tax imposed by the statute or any other reason which causes the executive director to determine that quality of the data being produced by the laboratory's personnel is unreliable or inaccurate, based on the facts of the case. This subsection provides consistency with other program areas. Finally, subsection (c) requires an environmental testing laboratory to wait at least six months before reapplying for accreditation if the laboratory was unsuccessful in correcting deficiencies and the laboratory's application is denied. If an application is denied for cause, the environmental testing laboratory must wait six months from the date of the commission's final decision to reapply. The purpose of the six-month period is to allow an environmental testing laboratory sufficient time to correct deficiencies and prepare a new application for accreditation. This section implements NELAC, §4.4.1, Denial.

In proposed new §25.34, Suspension of Accreditation, subsection (a) allows the commission to suspend an environmental laboratory's accreditation in whole or in part for up to six months after notice and opportunity for hearing according to 30 TAC Chapter 80. Reasons for suspension include: failure to

maintain a quality system; failure to comply with minimum performance and quality assurance standards; failure to maintain records of the laboratory's personnel, operations, data, or analyses; failure to successfully complete required proficiency tests; failure to employ staff that meet required personnel qualifications for education, training, and experience; and failure to notify the executive director of changes in accreditation criteria. Subsection (b) requires the executive director to reinstate an environmental testing laboratory's accreditation if the laboratory effectively corrects and takes steps to prevent a recurrence of the deficiencies that led to a suspension; complies with requirements imposed by the executive director or the commission; and submits an acceptable application for reinstatement.

In proposed new §25.36, Revocation of Accreditation, subsection (a) allows the commission to revoke an environmental testing laboratory's accreditation after notice and opportunity for hearing according to Chapter 80. This section implements TWC, §5.807. Subsection (b) requires the commission to revoke applicable parts of a laboratory's accreditation for certain deficiencies related to unsuccessful analyses of proficiency test samples. This section implements TWC, §5.807 and NELAC, §4.4.3, Revocation. Subsection (c) requires an environmental testing laboratory to wait at least one year after revocation before reapplying for accreditation and requires an environmental testing laboratory whose accreditation was revoked to meet all requirements for a new accreditation, including an environmental testing laboratory assessment.

In proposed new §25.38, Accreditation Advisory Committee, subsection (a) requires the executive director to establish an advisory committee to help interpret NELAC standards and to advise the executive director and the commission on technical matters relating to the operation of the accreditation

program. Subsection (b) requires that the committee abide by TWC, §5.107 and 30 TAC Chapter 5. This section provides the executive director with the ability to consult with outside groups to improve the environmental testing laboratory accreditation program. This section implements NELAC, §6.2(g).

*Subchapter C, Environmental Testing Laboratory Certification*

Proposed new §25.50, Standards for Environmental Testing Laboratory Certification, requires conformity with the *Manual for the Certification of Laboratories Analyzing Drinking Water*, Fourth Edition, EPA 815-B-97-001, March 1997; and the *Lab Cert Manual Errata*, Labcert Bulletin, EPA-815-N-99-002a, April 1999, published by the EPA, and requirements contained in Chapter 25, as the basis for certifying an environmental testing laboratory's capability to analyze samples for compliance with the SDWA. This section continues the Safe Drinking Water Certification Program as it was administered by TDH.

In proposed new §25.52, Fields of Certification, subsection (a) requires the executive director to identify fields of certification that are offered by the agency and make a list of this information available to the public through the agency's website and Compliance Support Division and Agency Communications. The website address is <http://www.tnrcc.state.tx.us/enforcement/csd/qa>. The phone number for the Compliance Support Division is (512) 239-6300 and the phone number for Agency Communications is (512) 239-0028. This information will be available upon the effective date of these rules. Subsection (b) allows the executive director to change fields of certification offered by the agency after 30 days' notice on the agency website. This provision allows the executive director to modify the fields of certification if the commission changes the requirements for the Safe Drinking

#### Water Certification Program.

In proposed new §25.54, Initial Application for Certification, subsection (a) requires that an application for certification be filed using a form provided by the executive director. The proposed rule also requires an applicant to submit any required or requested documents and records and the fee provided in §25.70 with the application. This section implements TWC, §5.803 and provides consistency with §25.12. Subsection (b) allows an operator of an environmental laboratory to request that noncontiguous facilities be certified as a single entity if they operate under the same ownership, day-to-day management, day-to-day technical direction, and quality system, including document management, records management, and test reporting. The commission determined it is appropriate to accredit noncontiguous facilities as a single entity if the environmental testing laboratory meets the listed requirements to promote uniform standards of quality. This objective will be met by allowing environmental testing laboratories with more than one location to obtain a single accreditation. Subsection (c) allows an operator of an environmental laboratory to submit an application for certification or an application to increase the laboratory's fields of certification at any time. The commission anticipates that environmental testing laboratories will continuously evaluate the fields of certification that they want to pursue. The commission has determined that it is appropriate to allow environmental testing laboratories to modify their fields of certification at anytime so that the environmental testing laboratories can pursue various types of analytical work.

Proposed new §25.56, Term of Certification, establishes a one-year term of certification if the environmental testing laboratory application meets the standards for certification of this chapter. Subsection (b) allows the executive director to grant interim certification for up to one year in order to schedule an environmental testing laboratory inspection. This section continues the Safe Drinking Water Certification Program as it was administered by TDH.

In proposed new §25.58, Renewal Application for Certification, subsection (a) provides that the executive director must receive an environmental testing laboratory's renewal application and applicable fees no later than the expiration date of a laboratory's certification. The executive director has determined that it is important to provide environmental testing laboratories with a definite deadline for renewal applications. Subsection (b) provides that, if a renewal application is received after the expiration date of the laboratory's certification, the laboratory must apply for and meet all requirements for a new certification, including an environmental testing laboratory assessment. Subsection (c) requires that modifications made during the term of a certification to increase a laboratory's fields of certification be renewed on the certification renewal date, regardless of the date of the modifications. This section is consistent with §25.16 of Subchapter B.

Proposed new §25.60, Environmental Testing Laboratory Certification Assessments, requires environmental testing laboratory assessments of environmental testing laboratories before certification is granted initially and at least every three years after certification is granted. Subsection (b) allows these environmental testing laboratory assessments to be announced or unannounced. This section implements the environmental testing laboratory assessment program required by the SDWA.

Proposed new §25.62, Proficiency Test Sample Analyses, requires an environmental testing laboratory to periodically analyze certain proficiency test samples before and after certification is granted.

Subsection (a) requires, for initial certification, the successful analysis of one proficiency test sample for each field of certification during the previous 12 months. For ongoing certification, subsection (b) requires analysis of two proficiency test samples per year approximately six months apart for each field of certification and successful analysis of one proficiency test sample each year for each field of accreditation. If a laboratory does not meet requirements for ongoing analysis of proficiency test samples, the proposed rule allows a laboratory to participate in supplemental proficiency test studies.

This section also requires the executive director to determine a laboratory's certification status within 60 days if the laboratory does not successfully analyze proficiency test samples as required. Subsection (c) requires laboratories to purchase proficiency test samples from vendors approved by the National Institute for Standards and Technology. This section continues the Safe Drinking Water Program as it was administered by TDH.

Proposed new §25.64, Secondary Certification of Out-of-State Environmental Testing Laboratories, requires the executive director to grant or renew the certification of an environmental testing laboratory that is in another state and certified by the EPA or another state within 30 days if the laboratory submitted the required application, was already certified for the applicable fields of certification by the EPA or other state, and paid required fees. Subsection (b) requires that the executive director notify the laboratory in writing within 30 days of granting or denying certification. This section is consistent with §25.16 of Subchapter B.

Proposed new §25.66, Duties and Responsibilities of Certified Laboratories, establishes duties and responsibilities of a laboratory applying for and accepting certification. The duties and responsibilities include providing reasonable access to the executive director to the laboratory and its facilities, personnel, documents, records, data, analyses, and operations and operating the laboratory and maintaining the laboratory's certification according to the standards for certification included in Chapter 25. This section continues the Safe Drinking Water Certification Program as it was administered by TDH.

Proposed new §25.68, Withdrawal From Certification Program, allows an environmental testing laboratory to withdraw from the certification program in whole or in part at any time by notifying the executive director in writing. This section is consistent with §25.26 of Subchapter B.

Proposed new §25.70, Certification Fees, requires certification fees to cover program costs and establishes a fee structure for the program. Environmental testing laboratories applying for primary certification will be required to pay an annual administrative fee of \$500 and annual category fees, while environmental testing laboratories applying for secondary certification will pay an annual administrative fee of \$250 and category fees. Category fees would be based on the types of analyses a laboratory performs and for which the laboratory chooses to seek certification. The proposed rule contains 11 drinking water categories, including microbiology, radiochemistry, metals, general chemistry, disinfection by-products, volatile organic compounds by gas chromatograph mass spectrometry, semivolatile organic compounds by gas chromatograph mass spectrometry, organic compounds by gas chromatography using detection other than mass spectrometry, organic compounds

by high performance liquid chromatography, polychlorinated dibenzo-p-dioxins and dibenzofurans, and asbestos. Subsection (e) requires the operator of an environmental testing laboratory located in another state and applying for primary certification to pay a fee including costs equal to the reasonable travel costs associated with conducting an assessment at the laboratory. Subsection (f) also allows fees for certification modifications, replacement of certification certificates, and reinstatement of suspended certifications. All fees are nonrefundable.

The proposed certification fees were developed to produce enough revenue to recover the cost of the certification program. Annual program costs were estimated using standard employee salary rates and existing staffing, training, travel, supplies, and other costs. Annual program revenues were calculated using current drinking water laboratory certifications, the types of analyses these laboratories perform, and current appropriations.

The proposed fees use categories based on a drinking water matrix and drinking water analyses. The matrix and types of analyses and category fees are consistent with Subchapter B as it relates to the analysis of drinking water samples.

In addition to category fees, the proposed certification fees include annual administrative fees. The proposed certification fees include a fee equal to the reasonable travel costs (including transportation, lodging, per diem, and any telephone charges) associated with conducting an assessment at an out-of-state laboratory. The proposed certification fees also include fees for adding one or more fields of certification; replacing a certification certificate; and reinstating a suspended certification. These fees

are consistent with Subchapter B.

Proposed new §25.74, Denial of Certification Application, allows the executive director to deny an application for certification for insufficiency or cause after notice and opportunity to file a motion to overturn according to 30 TAC §50.139. Subsection (a) allows the executive director to deny an initial or renewal application for insufficiency. An application may be determined to be insufficient if laboratory personnel fail to submit a completed application; fail to submit the required fees; fail to successfully analyze and report proficiency test samples; fail to implement a quality system; fail to document that laboratory personnel meet education, training, and experience requirements; fail to allow entry during normal business hours for an assessment; fail to pass required environmental testing laboratory assessments; fail to submit a report identifying action the environmental testing laboratory will take to correct deficiencies in the assessment report within 30 days of receiving an assessment report; or fail to implement actions to correct the deficiencies identified in the assessment report by the executive director. Subsection (b) allows the commission to deny an applicant's initial or renewal application for cause after notice and an opportunity for a hearing if the laboratory personnel misrepresent any fact pertinent to receiving or maintaining accreditation or the laboratory or its operator is indebted to the state for a fee, penalty, or tax imposed by the statute within the commission's jurisdiction or any other reason which causes the executive director to determine that quality of the data being produced by the laboratory's personnel is unreliable or inaccurate, based on the facts of the case. This section is consistent with Subchapter B.

Proposed new §25.76, Suspension of Certification, allows the commission to suspend an environmental testing laboratory's certification in whole or in part for up to six months after notice and opportunity for hearing according to Chapter 80. Reasons for suspension include failure to maintain a quality system; failure to comply with minimum performance and quality assurance standards; failure to maintain records of the laboratory's personnel, operations, data, or analysis; failure to successfully complete required proficiency tests; failure to employ staff that meet required personnel qualifications for education, training, and experience; or failure to notify the executive director of changes in certification criteria. Subsection (b) requires the executive director to reinstate an environmental testing laboratory's certification if the laboratory effectively corrected and took steps to prevent a recurrence of the deficiencies that led to a suspension, complied with requirements imposed by the executive director and the commission, and submitted an acceptable application for reinstatement.

Proposed new §25.78, Revocation of Certification, allows the commission to revoke an environmental testing laboratory's certification after notice and opportunity for hearing according to Chapter 80. Reasons for revocation include: failure to correct deficiencies that led to a suspension of certification within six months of the notice of suspension; failure to submit an acceptable report identifying actions the environmental testing laboratory will take to correct deficiencies identified in the environmental testing laboratory assessment; failure to implement actions to correct deficiencies identified during an environmental testing laboratory assessment; failure to complete required proficiency test studies; submission of proficiency test sample results generated by another laboratory as its own; misrepresentation of any fact pertinent to receiving and maintaining certification; failure to allow entry during normal business hours for an environmental testing laboratory assessment; conviction of charges

relating to the falsification of any report relating to a laboratory analysis; failure to remit fees within the time limit established by the executive director; or indebtedness to the state for a fee, penalty, or tax imposed by a statute within the commission's jurisdiction or a rule adopted under such a statute.

Subsection (b) requires the commission to revoke applicable parts of a laboratory's certification for certain deficiencies related to unsuccessful analysis of proficiency test samples. Finally, subsection (c) requires an environmental testing laboratory whose certification was revoked to meet all requirements for a new certification, including an environmental testing laboratory assessment. This section is consistent with Subchapter B with the exception of proficiency testing requirements because of differences between the programs.

#### FISCAL NOTE: COST TO STATE AND LOCAL GOVERNMENT

John Davis, Technical Specialist with Strategic Planning and Appropriations, has determined that for each year of the first five-year period the proposed rules are in effect, there will be significant fiscal implications for the agency due to administration and enforcement of the proposed rules. There will also be fiscal implications for units of state and local government operating environmental testing laboratories that provide certain compliance data to the commission. Units of government that do not operate environmental testing laboratories would not be affected by the proposed rules.

Commercial, governmental, industrial, and other environmental testing laboratories located inside and outside of Texas analyze thousands of environmental samples each year. The results of these analyses are used by the commission to make permitting, compliance, enforcement, cleanup, and other decisions.

Oversight of environmental testing laboratories has been limited to TDH's formal certification of laboratories analyzing drinking water samples, inspections by the executive director that may have occurred as part of a larger permit compliance inspection, and inspections performed as part of the commission's limited laboratory inspection program. TDH had also developed rules for a voluntary laboratory accreditation program for laboratories analyzing wastewater samples, but had not yet implemented the program.

In 2001, the 77th Texas Legislature passed HB 2912, §1.12, which amended TWC by adding new §5.127. This section requires that all data used by the commission for commission decisions regarding permits or other authorizations, compliance matters, enforcement actions, or corrective actions be from an accredited environmental testing laboratory, unless the environmental testing laboratory is: an in-house or on-site environmental testing laboratory periodically inspected by the commission; accredited under federal law; or providing data and analysis for emergency response activities and required data and analysis are not available from an accredited environmental testing laboratory. New §5.127 also allows the commission to require that data used in other commission decisions be obtained from an accredited environmental testing laboratory and requires the commission to periodically inspect unaccredited in-house or on-site environmental testing laboratories providing data for commission decisions.

The Legislature also passed HB 2912, Article 6, which transferred THSC, Chapter 421, to TWC, Chapter 5, redesignating Chapter 421 as Subchapter R, §§5.801 - 5.807 and amending it to revise the definitions and numbering. Along with the transfer, Article 6 was amended to include new Subchapter

R. Subchapter R transferred authority for environmental laboratory accreditation and drinking water certification from TDH to the commission and requires that the state's environmental testing laboratory accreditation program be consistent with the NELAC. Subchapter R also created a special account for accreditation and certification fees.

TWC, §5.802 requires that the environmental testing laboratory accreditation program be consistent with NELAC standards. The commission is adopting by reference the NELAC standards approved by NELAC in May 2001.

Additionally, §18.02 of HB 2912 transferred the Safe Drinking Water Certification Program from the TDH to the commission, effective September 1, 2001. The commission is currently operating the drinking water laboratory certification program according to the rules adopted by the TDH.

Finally, §18.03 of HB 2912 transferred the Environmental Testing Laboratory Certification Program, including existing authority, accreditation, appropriations, rules, equipment, and personnel involved in lab accreditation from the TDH to the commission, effective September 1, 2001. As required by HB 2912, §18.03(d), accreditation requirements relating to data provided for commission decisions take effect three years after the commission publishes notice in the *Texas Register* that the agency's accreditation program has met NELAC standards. Until that date, environmental testing laboratories that analyze samples for compliance with the SDWA must continue to be certified according to Chapter 25. After that date, laboratories that analyze samples for compliance with the SDWA must be accredited according to Chapter 25, and the executive director, as authorized by the commission's

rules, will no longer grant certifications.

The proposed rules would implement portions of HB 2912 relating to two types of authorizations to be issued by the commission. Accreditations would be issued to environmental testing laboratories providing data for commission decisions relating to all media. Certifications would be issued to environmental testing laboratories providing data for commission decisions relating to compliance with the SDWA only. The commission anticipates no significant fiscal implications for any one laboratory that seeks either accreditation or drinking water certification under the proposed rules. For the purposes of this fiscal note, it is assumed approximately 200 environmental testing laboratories will pursue accreditation and the 113 environmental testing laboratories that currently have drinking water certifications will renew their certifications. It is assumed that none of the laboratories likely to seek accreditation is a unit of state or local government.

The proposed rules would establish fees for environmental testing laboratory accreditations and certifications. For accreditations, the commission is proposing an administrative fee and category fees that applicants will be required to remit annually. Additionally, affected laboratories would be required to purchase and analyze two proficiency test samples annually. The cost of a proficiency test sample is anticipated to range from \$150 to \$4,750 per sample, depending on the range of analyses a laboratory performs and for which it chooses to seek accreditation. The administrative fee is \$500, unless the laboratory is located in another state and is already accredited. In this case, the laboratory is seeking secondary accreditation from the agency, and the annual administrative fee would be \$250. Each testing category will be assigned a fee from \$75 to \$300. According to the proposed rules, in-house

environmental testing laboratories operated by units of government would be required to become accredited if they provide data to third parties for commission decisions. In-house environmental testing laboratories operated by units of government that provide data to their respective units of government would not be required to become accredited but may choose to do so. The commission has not determined the number of governmental laboratories that will likely apply for and receive accreditation. The costs presented in the small and micro-business assessment section of this fiscal note would apply to units of government with in-house environmental testing laboratories that seek accreditation.

For drinking water certifications, the commission is proposing an administrative fee and category fees that applicants will be required to remit annually. Additionally, affected laboratories would continue to be required to purchase and analyze two proficiency test samples annually. The annual cost for a proficiency test sample for drinking water analysis is anticipated to range from \$40 to approximately \$1,500 per sample, depending on the range of analyses for which a laboratory chooses to seek certification. The administrative fee is \$500, unless the laboratory is located in another state and is already certified. In this case, the laboratory is seeking secondary certification from the agency, and the annual administrative fee would be \$250. Each testing category will be assigned a fee from \$75 to \$300. The commission has assigned fees to 11 testing categories for drinking water analyses. The categories are microbiology, radiochemistry, metals, general chemistry, disinfection by-products, volatile organic compounds by gas chromatograph mass spectrometry, semivolatile organic compounds by gas chromatograph mass spectrometry, organic compounds by gas chromatography using detection other than mass spectrometry, organic compounds by high performance liquid chromatography,

polychlorinated dibenzo-p-dioxins and dibenzofurans, and asbestos. The total category fee for each laboratory will depend on the number of tests for which it seeks certification. The commission anticipates the total cost per laboratory will range from \$325 (\$250 out-of-state, secondary certification, administrative fee, and one \$75 category fee) to \$2,600 (\$500 administrative fee and 11 category fees totaling \$2,100). The commission anticipates no significant fiscal implications for the modifications proposed to the existing drinking water certification program. The commission has identified 113 laboratories that are currently certified to conduct drinking water analysis. Of this total, 71 are owned and operated by units of state or local government. The fees for the majority of these laboratories will not change according to the proposed rules. The fees for three of these laboratories would increase by an average of \$1,050, while fees for one of the laboratories would decrease by \$280. Fees for the remaining 67 laboratories owned and operated by units of state or local government would not be affected due to implementation of the proposed rules. The commission anticipates the total annual increased fees from environmental testing laboratories owned and operated by units of state and local government receiving certifications according to the proposed rules will be approximately \$2,870.

The commission will also incur costs administering the environmental testing laboratory accreditation and certification programs. The 77th Legislature appropriated additional funding to the commission for the accreditation program in the amount of \$412,633 in Fiscal Year (FY) 2002 and \$444,760 in FY 2003.

The legislature authorized two additional full-time employees (FTEs) in FY 2002 and three additional FTEs in 2003. The 77th Legislature also appropriated additional funding to the commission for the

drinking water certification program in the amount of \$308,941 in FY 2002 and \$271,796 in FY 2003.

Two FTEs transferred to the commission to administer the drinking water certification program.

#### PUBLIC BENEFIT AND COSTS

Mr. Davis has also determined that for each of the first five years the proposed rules are in effect, the public benefit anticipated as a result of implementing the proposed rules will be anticipated improvements in laboratory data used by the agency to make permitting, compliance, enforcement, cleanup, and other decisions.

The proposed rules would implement portions of HB 2912 relating to two types of authorizations to be issued by the commission. Accreditations would be issued to environmental testing laboratories providing data for commission decisions relating to all media. Certifications would be issued to environmental testing laboratories providing data for commission decisions relating to compliance with the SDWA only. The commission anticipates no significant fiscal implications for any one laboratory that seeks either accreditation or drinking water certification under the proposed rules. For the purposes of this fiscal note, it is assumed approximately 200 environmental testing laboratories will pursue accreditation and the 113 environmental testing laboratories that currently have drinking water certifications will renew their certifications.

The proposed rules would establish fees for environmental testing laboratory accreditations and certifications. For accreditations, the commission is proposing an administrative fee and category fees that applicants will be required to remit annually. Additionally, affected laboratories would be required

to purchase and analyze two proficiency test samples annually. The cost of a proficiency test sample is anticipated to range from \$150 to \$4,750 per sample, depending on the range of analyses a laboratory performs and for which it chooses to seek accreditation. The administrative fee is \$500, unless the laboratory is located in another state and is already accredited. In this case, the laboratory is seeking secondary accreditation from the agency, and the annual administrative fee would be \$250. Each testing category will be assigned a fee from \$75 to \$300. All of the laboratories the commission estimates will seek accreditation are anticipated to be small or micro-businesses. The costs presented in the small and micro-business assessment section of this fiscal note would apply to individuals and larger businesses that seek accreditation.

The commission anticipates no significant fiscal implications for the modifications proposed to the existing drinking water certification program. The commission has identified 38 existing privately-owned and operated laboratories that are currently certified to conduct drinking water analysis. All of the businesses are believed to be small or micro-businesses; therefore, the fiscal implications for these sites will be discussed in the small and micro-business assessment section of this fiscal note.

#### SMALL AND MICRO-BUSINESS ASSESSMENT

There will be adverse fiscal implications, which are not anticipated to be significant, for small and micro-businesses due to implementation of the proposed rules. The proposed rules would implement portions of HB 2912 relating to two types of authorizations to be issued by the commission.

Accreditations would be issued to environmental testing laboratories providing data for commission decisions relating to all media. Certifications would be issued to environmental testing laboratories

providing data for commission decisions relating to compliance with the SDWA only. The commission anticipates no significant fiscal implications for any one laboratory that seeks either accreditation or drinking water certification under the proposed rules. For the purposes of this fiscal note, it is assumed approximately 200 environmental testing laboratories will pursue accreditation and the 113 environmental testing laboratories that currently have drinking water certifications will renew their certifications.

The proposed rules would establish fees for environmental testing laboratory accreditations and certifications. For accreditations, the commission is proposing an administrative fee and category fees that applicants will be required to remit annually. Additionally, affected laboratories would be required to purchase and analyze two proficiency test samples annually. The cost of a proficiency test sample is anticipated to range from \$150 to \$4,750 per sample, depending on the range of analyses a laboratory performs and for which it chooses to seek accreditation. The administrative fee is \$500, unless the laboratory is located in another state and is already accredited. In this case, the laboratory is seeking secondary accreditation from the agency, and the annual administrative fee would be \$250. The commission has assigned fees to 51 testing categories, based on five matrices and 14 types of analyses. The matrices are drinking water, nonpotable water, solid and chemical material, biological tissue, and air emissions. The types of analyses are microbiology, aquatic toxicity, radiochemistry, particulate matter, metals, waste characteristics, general chemistry, disinfection by-products, volatile organic compounds by gas chromatograph mass spectrometry, semivolatile organic compounds by gas chromatograph mass spectrometry, organic compounds by gas chromatograph, organic compounds by high performance liquid chromatography, polychlorinated dibenzo-p-dioxins and dibenzofurans, and

asbestos and airborne fibers. The total category fee for each laboratory will depend on the number of different tests for which it seeks accreditation. Each testing category will be assigned a fee from \$75 to \$300. The total category fee for each laboratory will depend on the number of different tests for which it seeks accreditation. The commission anticipates the total annual cost per laboratory will range from \$325 (\$250 out-of-state, secondary accreditation, administrative fee, and one \$75 category fee) to \$10,025 (\$500 administrative fee, and 51 category fees totaling \$9,525). Assuming that 100 of the 200 laboratories expected to pursue accreditation perform relatively few types of analyses, 70 perform a moderate number of types of analyses, and 30 perform a large number of types of analyses, the commission anticipates the total annual fees from environmental testing laboratories receiving accreditations according to the proposed rules will be approximately \$645,000. All of the affected laboratories are estimated to be small and micro-businesses.

For drinking water certifications, the commission is proposing an administrative fee and category fees that applicants will be required to remit annually. Additionally, affected laboratories would continue to be required to purchase and analyze two proficiency test samples annually. The annual cost for a proficiency test sample for drinking water analysis is anticipated to range from \$40 to approximately \$1,500 per sample, depending on the range of analyses a laboratory performs and for which it chooses to seek certification. The administrative fee is \$500, unless the laboratory is located in another state and is already certified. In this case, the laboratory is seeking secondary certification from the agency, and the annual administrative fee would be \$250. Each testing category will be assigned a fee from \$75 to \$300. The commission has assigned fees to 11 testing categories for drinking water analyses. The total category fee for each laboratory will depend on the number of tests for which it seeks certification.

The commission anticipates the total cost per laboratory will range from \$325 (\$250 out-of-state, secondary certification, administrative fee, and one \$75 category fee) to \$2,600 (\$500 administrative fee and 11 category fees totaling \$2,100). The commission anticipates no significant fiscal implications for the modifications proposed to the existing drinking water certification program. The commission has identified 42 privately-owned and operated laboratories that are currently certified to conduct drinking water analyses. All of the businesses are believed to be small or micro-businesses. The fees for five of these laboratories would not change, and the fees for three of the laboratories would be reduced by \$60. The fees for the remaining 34 laboratories would be increased by an average of approximately \$740 per year. The commission anticipates the total annual increased fees from environmental testing laboratories owned and operated by small and micro-businesses receiving certifications according to the proposed rules will be approximately \$25,000 per year.

The following is an analysis of the costs per employee for small and micro-businesses required to pay accreditation or certification fees. Small and micro-businesses are defined as having fewer than 100 or 20 employees, respectively. The commission estimates 40 of the 200 environmental testing laboratories estimated to become accredited are small businesses and 160 are micro-businesses. The commission estimates 31 of the 113 laboratories currently certified for drinking water analyses are small businesses and 11 are micro-businesses. The 40 small businesses estimated to become accredited would pay an average of \$92 per employee per year to obtain an accreditation according to the proposed rules. The 160 micro-businesses estimated to become accredited would pay an average of \$400 per employee per year to obtain an accreditation. The 31 small businesses that currently have drinking water certifications would pay an average of \$8.00 more per employee per year to renew their certifications

according to the proposed rules. The 11 micro-businesses that currently have drinking water certifications would pay an average of \$37 more per employee per year to renew their certifications.

#### LOCAL EMPLOYMENT IMPACT

The commission has reviewed these proposed rules and determined that a local employment impact statement is not required because the proposed rules do not adversely affect a local economy in a material way for the first five years that the proposed rules are in effect.

#### DRAFT REGULATORY IMPACT ANALYSIS DETERMINATION

The commission has reviewed the proposed rulemaking in light of the regulatory analysis requirements of Texas Government Code, §2001.0225, and has determined that the rulemaking is not subject to §2001.0225 because it does not meet the definition of a "major environmental rule" as defined in that statute. A rule is a major environmental rule if it meets the two requirements set out in 2001.0225.

The first requirement of a major environmental rule is that the specific intent of the rule is to protect the environment or reduce risks to human health from environmental exposure. The second requirement is that the rule may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. This rulemaking has two major purposes. First, it will provide a mechanism for the commission to accredit scientific laboratories that analyze environmental samples. Second, the proposed rules continue the certification program for scientific laboratories that analyze samples under the SDWA until the laboratory accreditation program is in place. Protection of the environment and human health may be a result of this rulemaking, but that result is not the specific intent of the rules.

Thus, these rules do not meet the definition of a major environmental rule.

Additionally, these proposed rules are not a major environmental rule in that they do not meet any of the four applicability requirements of the second part of the definition of a major environmental rule. A rule is considered a major environmental rule if as a result of the rule: a federal standard is exceeded (unless the rule is specifically required by state law); an express requirement of state law is exceeded (unless the rule is specifically required by federal law); a requirement of a delegation agreement or contract between the state and the federal government is exceeded; or the rule is adopted solely under the general powers of the agency. First, these proposed rules do not exceed a standard set by federal law. These proposed rules will implement a laboratory accreditation program. NELAP encourages each state to participate; however, participation is not mandated at the federal level. The SDWA requires environmental testing laboratories that analyze samples for compliance with the SDWA be certified. These rules incorporate that requirement, which is a federal requirement, but they do not exceed the federal requirement. Second, these rules do not exceed an express requirement of state law, rather they implement state law, specifically TWC, Chapter 5, Subchapter R, and TWC, §5.127. Third, these rules do not exceed a delegation agreement or contract, because there is no federal authority regarding laboratory accreditation. Fourth, these rules do not adopt a rule solely under the general powers of the commission and do not exceed an express requirement of state law. The requirements that would be implemented through these rules are expressly defined under TWC, Chapter 5, Subchapter R, which requires the commission to enact rules governing the accreditation of environmental laboratories. Thus, these rules do not meet any of the requirements for them to be considered a major environmental rule.

#### TAKINGS IMPACT STATEMENT ASSESSMENT

The commission has prepared a takings impact assessment for these proposed rules under Texas Government Code, §2007.43. This rulemaking has two major purposes. First, it will provide a mechanism for the commission to accredit scientific laboratories that analyze environmental samples. Second, the proposed rules continue the certification program for scientific laboratories that analyze samples under the SDWA until the laboratory accreditation program is in place.

These rules are proposed in an effort to reasonably fulfill an obligation mandated by state law to implement a voluntary environmental testing laboratory accreditation program and to continue the drinking water laboratory certification program, previously managed by the TDH. The proposed rules will substantially advance the implementation of the requirements under TWC Chapter 5, Subchapter R. Promulgation and enforcement of these proposed rules will not affect private real property. Therefore, the commission has determined that these proposed new rules will not result in a takings.

#### CONSISTENCY WITH THE COASTAL MANAGEMENT PROGRAM

The executive director reviewed the proposed rulemaking and found that the proposed rules are neither identified in Coastal Coordination Act Implementation Rules, 31 TAC §505.11, relating to Actions and Rules Subject to the Texas Coastal Management Program (CMP), nor will they affect any action or authorization identified in 31 TAC §505.11. Therefore, the proposed rules are not subject to the CMP.

#### ANNOUNCEMENT OF HEARING

The commission will hold public hearings on this proposal in Fort Worth, on May 29, 2002 at 7:00 p.m., in the Fort Worth Regional Office located in at 2315 Gravel Drive, as well as in Austin on June 4, 2002 at 2:00 p.m., Texas Natural Resource Conservation Commission, 12100 Park 35 Circle, Building F, Room 2210, and in Houston, on June 5, 2002 at 7:00 p.m., at the City of Houston Pollution Control Building Auditorium, located at 7411 Park Place Boulevard. The hearings will be structured for the receipt of oral or written comments by interested persons. Individuals may present oral statements when called upon in order of registration. Open discussion will not occur during the hearings; however, an agency staff member will be available to discuss the proposal 30 minutes prior to the hearings and answer questions before and after the hearings.

Persons with disabilities who have special communication or other accommodation needs, who are planning to attend the hearing, should contact the Office of Environmental Policy, Analysis, and Assessment at (512) 239-4900. Requests should be made as far in advance as possible.

#### SUBMITTAL OF COMMENTS

Comments may be submitted to Angela Slupe, Office of Environmental Policy, Analysis, and Assessment, MC 205, P.O. Box 13087, Austin, Texas 78711-3087, or faxed to (512) 239-4808. All comments should reference Rule Log Number 2001-078-025-AD. Comments must be received by 5:00 p.m., June 10, 2002. For further information, contact Kathy Ramirez, Policy and Regulations Division, at (512) 239-6757.

**SUBCHAPTER A: GENERAL PROVISIONS**

**§§25.1, 25.2, 25.4, 25.6, 25.8**

STATUTORY AUTHORITY

The new sections are proposed under the authority granted to the commission by the Texas Legislature in HB 2912, §1.12, Use of Environmental Testing Laboratory Data and Analysis; Article 6, Accreditation of Environmental Testing Laboratories; §18.02, Transfer of Safe Drinking Water Laboratory Certification Program; and §18.03, Transfer of Environmental Testing Laboratory Certification Program. The new sections will be implemented in accordance with TWC, §5.802, which requires the commission to adopt rules for the administration of an environmental testing laboratory accreditation program; §5.803, which requires the commission to establish a schedule of reasonable accreditation fees; §5.804, which authorizes the commission to adopt rules governing accreditation of an environmental laboratory accredited in another state; and §5.805, which requires the commission to adopt rules to implement TWC, Chapter 5, Subchapter R; and §5.127, which allows the commission to accept environmental testing laboratory data and analyses for use in commission decisions regarding any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions only if the data and analyses are prepared by an environmental testing laboratory accredited by the commission under Subchapter R or an environmental testing laboratory described in subsection (b). Additionally, the commission may accept for use in its decisions data and analyses prepared by an on-site or in-house environmental testing laboratory if the laboratory is periodically inspected by the commission; an environmental testing laboratory that is accredited under federal law; or, if the data and analyses are necessary for emergency response

activities and the required data and analyses are not otherwise available, an environmental testing laboratory that is not accredited by the commission under Subchapter R or under federal law. Further, the commission by rule may require that data and analyses used in other commission decisions be obtained from an environmental testing laboratory accredited by the commission under Subchapter R. Finally, the commission is required to periodically inspect on-site or in-house environmental testing laboratories described in Subchapter R. These new sections are also proposed under the general authority granted in TWC, §5.102, which authorizes the commission to perform any acts necessary and convenient to the exercise of its jurisdiction and powers; §5.013, which establishes the general jurisdiction of the commission over other areas of responsibility as assigned to the commission under TWC and other laws of the state; TWC, §5.103 and §5.105, which authorize the commission to adopt rules and policies necessary to carry out its responsibilities and duties under TWC, §5.013(15); §5.107, which authorizes the commission to establish Advisory Committees; and §5.122, which authorizes the commission to delegate uncontested matters to the executive director.

The proposed new sections implement HB 2912, §1.12, Article 6, §18.02, and §18.03. Additionally, the new sections implement TWC, Chapter 5, Subchapter R, §§5.802 - 5.805, 5.127, 5.102, 5.013, 5.103, 5.105, 5.013(15), 5.107, and 5.122.

**§25.1. Purpose.**

This chapter describes requirements for accreditation and certification of environmental testing laboratories. Accreditation is voluntary; however, the commission may accept environmental testing

laboratory data and analyses for use in commission decisions regarding any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions only if the data and analyses are prepared by an environmental testing laboratory accredited by the commission under this chapter, except as provided in §25.6 of this title (relating to Conditions Under Which the Commission May Accept Analytical Data). The agency's accreditation program will become effective three years after the date notice is published in the *Texas Register* that the commission's laboratory accreditation program has met National Environmental Laboratory Accreditation Conference standards. At that time all data and analyses referenced in §25.4(b) and (c) of this title (relating to Applicability) must be provided by accredited laboratories. In the interim all environmental testing laboratories that supply data for commission decisions relating to the Safe Drinking Water Act must be certified.

**§25.2. Definitions.**

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) **Accreditation** - An authorization granted by the executive director to an environmental testing laboratory that meets requirements of this subchapter and Subchapter B of this chapter (relating to Environmental Testing Laboratory Accreditation).

(2) **Accrediting authority** - An agency recognized by the National Environmental Laboratory Accreditation Program (NELAP) that grants accreditation on behalf of a state, territory, or federal agency.

(3) **Analyte** - A constituent for which an environmental sample is analyzed.

(4) **Certification** - An authorization granted by the executive director to an environmental testing laboratory which analyzes drinking water and which meets requirements of this subchapter and Subchapter C of this chapter (relating to Environmental Testing Laboratory Certification).

(5) **Environmental testing laboratory** - A scientific laboratory that performs analyses to determine the chemical, molecular, or pathogenic components of environmental media for regulatory compliance.

(6) **Environmental testing laboratory assessment** - The process used by an accrediting or certifying authority to measure the performance, effectiveness, and conformity of an environmental testing laboratory to the National Environmental Laboratory Accreditation Conference (NELAC) accreditation or EPA certification standards and this chapter. An environmental testing laboratory assessment may include a physical inspection of a laboratory and its operations.

(7) **Fields of accreditation** - The matrix, technology, method, and analyte or analyte group for which an environmental testing laboratory may be accredited.

(8) **Fields of certification** - The methods and analytes for which an environmental testing laboratory may be certified. The methods and analytes are used in a commission decision relating to compliance with the Safe Drinking Water Act.

(9) **In-house environmental testing laboratory** - An environmental testing laboratory that provides analytical data to its operator for a commission decision relating to:

(A) permits or other authorizations issued to the laboratory's operator;

(B) compliance matters and enforcement actions taken concerning the laboratory's operator; or

(C) corrective actions taken by the laboratory's operator to satisfy statutes, rules, or commission orders.

(10) **Laboratory personnel** - Individuals who manage, perform, maintain, or verify the work or the quality of the work at the environmental testing laboratory.

(11) **Matrix** - Sample type, including drinking water; nonpotable water; solid and chemical materials; air and emissions; and biological tissue.

(12) **Mobile environmental testing laboratory** - An environmental testing laboratory capable of being moved from one site to another site.

(13) **National Environmental Laboratory Accreditation Conference (NELAC)** - The voluntary organization of state, territorial, and federal environmental officials and interest groups whose primary purpose is to establish mutually acceptable national standards for accrediting environmental testing laboratories.

(14) **National Environmental Laboratory Accreditation Program (NELAP)** - The environmental testing laboratory accreditation program including NELAC.

(15) **On-site environmental testing laboratory** - An in-house environmental testing laboratory located at a regulated entity.

(16) **Operator** - An individual authorized to act on behalf of the environmental testing laboratory.

(17) **Primary accreditation** - Accreditation of an environmental testing laboratory according to NELAC standards and the requirements of this chapter.

(18) **Proficiency test sample** - A sample, the composition of which is unknown by an environmental testing laboratory or the individual performing the analysis. The sample is used to evaluate whether the laboratory and analyst can produce results within the specified acceptance criteria.

(19) **Quality system** - A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring the quality of its work processes, products, and services. The quality system provides the framework for planning, implementing, and assessing work performed by the environmental testing laboratory for quality assurance and quality control.

(20) **Secondary accreditation** - Accreditation granted by the executive director to an environmental testing laboratory that has been granted primary accreditation by another NELAP accrediting authority.

**§25.4. Applicability.**

(a) An environmental testing laboratory may apply for accreditation after the commission publishes notice in the *Texas Register* that the environmental testing laboratory accreditation program has met National Environmental Laboratory Accreditation Conference (NELAC) standards.

(b) An environmental testing laboratory must be accredited according to this chapter, except as provided in §25.6 of this title (relating to Conditions Under Which the Commission May Accept Analytical Data), if the laboratory provides analytical data which is used for a commission decision relating to a:

(1) permit;

(2) authorization;

(3) compliance action;

(4) enforcement action;

(5) corrective action;

(6) characterization of an environmental process or condition; or

(7) assessment of an environmental process or condition.

(c) An in-house environmental testing laboratory is to be accredited if it provides analytical data to a third party and the data is used for a commission decision relating to a:

(1) permit;

(2) authorization;

(3) compliance action;

(4) enforcement action;

(5) corrective action;

(6) characterization of an environmental process or condition; or

(7) assessment of an environmental process or condition.

(d) Subsections (b) and (c) of this section apply only to environmental testing laboratory results submitted to the commission on or after the third anniversary of the date on which the commission publishes notice in the *Texas Register* that the commission's environmental laboratory testing program established under this chapter has met NELAC standards.

(e) Until subsection (d) of this section is effective, an environmental testing laboratory that provides analytical data used for a commission decision relating to the Safe Drinking Water Act (SDWA) must be:

(1) accredited according to this subchapter and Subchapter B of this chapter (relating to Environmental Testing Laboratory Accreditation);

(2) certified according to this subchapter and Subchapter C of this chapter (relating to Environmental Testing Laboratory Certification); or

(3) certified by EPA.

(f) After subsection (d) of this section is effective, an environmental testing laboratory that provides analytical data used for a commission decision relating to the SDWA will no longer be certified and must be accredited according to this subchapter and Subchapter B of this chapter, unless the laboratory is certified by the EPA.

**§25.6. Conditions Under Which the Commission May Accept Analytical Data.**

The commission may accept analytical data provided by an environmental testing laboratory that is not accredited according to this chapter if the laboratory:

(1) is an on-site or in-house environmental testing laboratory that is:

(A) inspected at least every three years by the executive director; and

(B) regulated according to the terms of a permit, registration, or other authorization, and the permit, registration, or other authorization was issued by the commission to the operator of the laboratory;

(2) is accredited under federal law, including certification by the EPA to provide analytical data for decisions relating to compliance with the Safe Drinking Water Act;

(3) provides analytical data necessary for emergency response activities and the required analytical data are not otherwise available from an environmental testing laboratory accredited according to this chapter or federal law; or

(4) provides analytical data for which the commission does not offer accreditation.

**§25.8. Contracting.**

The executive director may contract with persons to provide services required by this chapter.  
The executive director may authorize contractors to collect reasonable fees for the services provided.

**SUBCHAPTER B: ENVIRONMENTAL TESTING LABORATORY ACCREDITATION**

**§§25.9, 25.10, 25.12, 25.14, 25.16, 25.18, 25.20, 25.22, 25.24, 25.26, 25.30, 25.32, 25.34, 25.36,**

**25.38**

STATUTORY AUTHORITY

The new sections are proposed under the authority granted to the commission by the Texas Legislature in HB 2912, §1.12, Use of Environmental Testing Laboratory Data and Analysis; Article 6, Accreditation of Environmental Testing Laboratories; §18.02, Transfer of Safe Drinking Water Laboratory Certification Program; and §18.03, Transfer of Environmental Testing Laboratory Certification Program. The new sections will be implemented in accordance with TWC, §5.802, which requires the commission to adopt rules for the administration of an environmental testing laboratory accreditation program; §5.803, which requires the commission to establish a schedule of reasonable accreditation fees; §5.804, which authorizes the commission to adopt rules governing accreditation of an environmental laboratory accredited in another state; and §5.805, which requires the commission to adopt rules to implement TWC, Chapter 5, Subchapter R; and §5.127, which allows the commission to accept environmental testing laboratory data and analyses for use in commission decisions regarding any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions only if the data and analyses are prepared by an environmental testing laboratory accredited by the commission under Subchapter R or an environmental testing laboratory described in subsection (b). Additionally, the commission may accept for use in its decisions data and analyses prepared by an on-site or in-house environmental testing laboratory if the laboratory is: periodically inspected by the commission; an environmental testing laboratory that is

accredited under federal law; or, if the data and analyses are necessary for emergency response activities and the required data and analyses are not otherwise available, not accredited by the commission under Subchapter R or under federal law. Further, the commission by rule may require that data and analyses used in other commission decisions be obtained from an environmental testing laboratory accredited by the commission under Subchapter R. Finally, the commission is required to periodically inspect on-site or in-house environmental testing laboratories described in Subchapter R. These new sections are also proposed under the general authority granted in TWC, §5.102, which authorizes the commission to perform any acts necessary and convenient to the exercise of its jurisdiction and powers; §5.013, which establishes the general jurisdiction of the commission over other areas of responsibility as assigned to the commission under TWC and other laws of the state; TWC, §5.103 and §5.105, which authorize the commission to adopt rules and policies necessary to carry out its responsibilities and duties under TWC, §5.013(15); §5.107, which authorizes the commission to establish Advisory Committees; and §5.122, which authorizes the commission to delegate uncontested matters to the executive director.

The proposed new sections implement HB 2912, §1.12, Article 6, §18.02, and §18.03. Additionally, the new sections implement TWC, Chapter 5, Subchapter R, §§5.802 - 5.805, 5.127, 5.102, 5.013, 5.103, 5.105, 5.013(15), 5.107, and 5.122.

**§25.9. Standards for Environmental Testing Laboratory Accreditation.**

Accreditation shall be based on an environmental testing laboratory's conformance to National Environmental Laboratory Accreditation Conference standards approved May 2001 and the requirements of this chapter.

**§25.10. Fields of Accreditation.**

(a) The executive director shall identify and make available to the public a list of the fields of accreditation offered under this chapter. A list of the fields of accreditation shall be made available on the commission's website and upon request from the Compliance Support Division and Agency Communications.

(b) The executive director may modify the fields of accreditation offered under this chapter after providing 30 days' notice on the commission's website.

**§25.12. Initial Application for Accreditation.**

(a) An application for accreditation shall be made on a form provided by the executive director. The application must be submitted to the executive director with any documents and records required in the application or requested by the executive director and the fee provided in §25.30 of this title (relating to Accreditation Fees).

(b) The operator of an environmental testing laboratory may request that noncontiguous facilities and mobile laboratories be accredited as a single entity, if the facilities and mobile laboratories operate as a single laboratory under the same:

(1) ownership;

(2) day-to-day management;

(3) day-to-day technical direction; and

(4) quality system, including document management, records management, and test reporting.

(c) The operator of an environmental testing laboratory may submit an application for initial accreditation or an application to increase its fields of accreditation at any time.

**§25.14. Term of Accreditation.**

(a) The executive director shall award accreditation for a period of one year if an environmental testing laboratory's application and operations conform to the National Environmental Laboratory Accreditation Conference (NELAC) standards and this chapter.

(b) The executive director may issue an interim accreditation for up to 12 months to an environmental testing laboratory that meets the NELAC standards and requirements of this chapter except when an environmental testing laboratory assessment has not been completed because the executive director has been unable to schedule an assessment within six months of receiving a complete application for accreditation.

**§25.16. Renewal Application for Accreditation.**

(a) The executive director must receive an environmental testing laboratory's application to renew the laboratory's accreditation along with the applicable fees no later than the date on which the accreditation expires.

(b) The operator of an environmental testing laboratory that fails to submit an application to renew accreditation before the date on which the accreditation expires must apply for and meet all requirements for a new accreditation, including an environmental testing laboratory assessment.

(c) Modifications made during the term of an accreditation to increase the number of an environmental testing laboratory's fields of accreditation shall be renewed on the accreditation renewal date, regardless of the date of the modification.

**§25.18. Environmental Testing Laboratory Assessments.**

(a) Environmental testing laboratory assessments shall be conducted:

(1) before accreditation is granted, except as provided in §25.14 of this title (relating to Term of Accreditation); and

(2) at least every two years after an environmental testing laboratory receives accreditation.

(b) Assessments may be announced or unannounced.

**§25.20. Proficiency Test Sample Analyses.**

(a) The operator of an environmental testing laboratory applying for initial accreditation shall ensure that two proficiency test samples are successfully analyzed, according to National Environmental Laboratory Accreditation Conference (NELAC) standards, for each requested field of accreditation.

(b) The operator of an accredited environmental testing laboratory shall ensure at least two proficiency test samples are analyzed each year for each field of accreditation according to NELAC standards. An environmental testing laboratory that does not meet the requirements of the subsection may participate in a supplemental proficiency test study according to the NELAC standards.

(c) The executive director shall determine the environmental testing laboratory's accreditation status for all affected fields of accreditation within 60 days of determining that laboratory personnel failed to analyze proficiency test samples successfully according to NELAC standards.

(d) Proficiency test samples, if available, shall be purchased from a National Environmental Laboratory Accreditation Program designated provider.

**§25.22. Secondary Accreditation of Out-of-State Environmental Testing Laboratories.**

(a) The executive director shall grant or renew the secondary accreditation of an environmental testing laboratory located in another state and accredited by another National Environmental Laboratory Accreditation Program accrediting authority within 30 days after receiving a complete application along with the appropriate fee according to §25.30 of this title (relating to Accreditation Fees) if the laboratory's existing accreditation includes the fields of accreditation for which the laboratory has applied to the executive director.

(b) The executive director shall notify an environmental testing laboratory in writing within 30 days of granting or denying accreditation.

**§25.24. Duties and Responsibilities of Accredited Environmental Testing Laboratories.**

By applying for or accepting accreditation, the operator of the laboratory certifies the information contained in the application is true and correct and agrees to:

(1) provide reasonable access to the executive director to facilities, personnel, documents, records, data, analyses, and operations which the executive director determines are necessary for accreditation;

(2) use and display the accreditation certificate according to the National Environmental Laboratory Accreditation Conference (NELAC) standards; and

(3) operate the environmental testing laboratory and maintain its accreditation according to the NELAC standards and this chapter.

**§25.26. Withdrawal from Accreditation Program.**

The operator of an environmental testing laboratory may surrender the laboratory's accreditation, in whole or in part, by notifying the executive director in writing at any time.

**§25.30. Accreditation Fees.**

(a) The executive director shall establish accreditation fees that cover program costs, including costs associated with application review; initial, routine, and follow-up inspections; and preparation of reports.

(b) The operator of an environmental testing laboratory seeking primary accreditation shall pay the following fees:

(1) an annual administrative fee of \$500; and

(2) an annual accreditation fee based on the categories for which the laboratory is accredited.

(c) The operator of an environmental testing laboratory seeking secondary accreditation shall pay the following fees:

(1) an annual administrative fee of \$250; and

(2) an annual accreditation fee based on the categories for which the laboratory is accredited.

(d) For accreditation relating to drinking water, the categories and annual fees are:

(1) microbiology - \$75;

(2) radiochemistry - \$225;

(3) metals - \$225;

(4) general chemistry - \$225;

(5) disinfection by-products - \$150;

(6) volatile organic compounds by gas chromatograph mass spectrometry - \$150;

(7) semivolatile organic compounds by gas chromatograph mass spectrometry - \$150;

(8) organic compounds by gas chromatography using detection other than mass spectrometry - \$300;

(9) organic compounds by high performance liquid chromatography - \$300;

(10) polychlorinated dibenzo-p-dioxins and dibenzofurans - \$150; and

(11) asbestos - \$150.

(e) For accreditation relating to non-potable water, the categories and annual fees are:

(1) microbiology - \$75;

(2) aquatic toxicity - \$150;

(3) radiochemistry - \$150;

(4) metals - \$225;

(5) general chemistry - \$225;

(6) volatile organic compounds by gas chromatograph mass spectrometry - \$150;

(7) semivolatile organic compounds by gas chromatograph mass spectrometry - \$150;

(8) organic compounds by gas chromatography:

(A) total petroleum hydrocarbons by agency methods 1005 only - \$150; and

(B) all compounds - \$300;

(9) organic compounds by high performance liquid chromatography - \$300;

(10) polychlorinated dibenzo-p-dioxins and dibenzofurans - \$150; and

(11) asbestos - \$150.

(f) For accreditation relating to biologic tissue, the categories and annual fees are:

(1) radiochemistry - \$150;

(2) metals - \$225;

(3) general chemistry - \$225;

(4) volatile organic compounds by gas chromatograph mass spectrometry - \$150;

(5) semivolatile organic compounds by gas chromatograph mass spectrometry - \$150;

(6) organic compounds by gas chromatography - \$300;

(7) organic compounds by high performance liquid chromatography - \$300; and

(8) polychlorinated dibenzo-p-dioxins and dibenzofurans - \$150.

(g) For accreditation relating to solid and chemical materials, the categories and annual fees are:

(1) microbiology - \$75;

(2) radiochemistry - \$150;

(3) metals - \$225;

(4) waste characteristics - \$150;

(5) general chemistry - \$225;

(6) volatile organic compounds by gas chromatograph mass spectrometry - \$150;

(7) semivolatile organic compounds by gas chromatograph mass spectrometry - \$150;

(8) organic compounds by gas chromatography:

(A) total petroleum hydrocarbons by agency method 1005 only - \$150; and

(B) all compounds - \$300;

(9) organic compounds by high performance liquid chromatography - \$300;

(10) polychlorinated dibenzo-p-dioxins and dibenzofurans - \$150; and

(11) asbestos - \$150.

(h) For accreditation relating to air, the categories and annual fees are:

(1) radiochemistry - \$150;

(2) particulate matter - \$75;

(3) metals - \$225;

(4) general chemistry - \$150;

(5) volatile organic compounds by gas chromatograph mass spectrometry - \$150;

(6) semivolatile organic compounds by gas chromatograph mass spectrometry - \$150;

(7) organic compounds by gas chromatography - \$300;

(8) organic compounds by high performance liquid chromatography - \$300;

(9) polychlorinated dibenzo-p-dioxins and dibenzofurans - \$150; and

(10) asbestos and airborne fibers by microscopy - \$150.

(i) The operator of an environmental testing laboratory located in another state and applying for primary accreditation shall also pay a fee equal to the reasonable travel costs (including transportation, lodging, per diem, and any telephone charges) associated with conducting an assessment at the laboratory.

(j) The following fees shall be assessed, as applicable, in addition to the annual administrative and category fees and travel costs:

(1) to modify an existing accreditation and add one or more fields of accreditation - \$250;

(2) to replace an accreditation certificate - \$50; and

(3) to reinstate a suspended accreditation - \$250.

(k) All fees are nonrefundable.

**§25.32. Denial of Accreditation Application.**

(a) Insufficiency. The executive director may deny an initial or renewal application for environmental testing laboratory accreditation for insufficiency. The executive director shall notify the laboratory of the intent to deny the application and advise the applicant of the opportunity to file a motion to overturn under §50.139 of this title (relating to Motion to Overturn Executive Director's Decision). The executive director may determine an application is insufficient if laboratory personnel fail to:

(1) submit a completed application;

(2) submit the required fees;

(3) successfully analyze and report proficiency test samples;

(4) implement a quality system;

(5) document that laboratory personnel meet personnel qualifications of education,

training, and experience;

(6) allow the executive director entry during normal business hours for an environmental testing laboratory assessment;

(7) pass required environmental testing laboratory assessments;

(8) submit a report identifying actions the environmental testing laboratory will take to correct the deficiencies identified in the environmental testing laboratory assessment report within 30 days of receiving an assessment report; or

(9) implement actions to correct the deficiencies identified in the environmental testing laboratory assessment report within the time approved by the executive director.

(b) Cause. After notice and opportunity for hearing, the commission may deny an environmental testing laboratory's initial or renewal application for accreditation if:

(1) laboratory personnel misrepresent any fact pertinent to receiving or maintaining accreditation; or

(2) the laboratory or its operator is indebted to the state for a fee, penalty, or tax imposed by a statute within the commission's jurisdiction or a rule adopted under such a statute; or

(3) any other reason which causes the executive director to determine that quality of the data being produced by the laboratory's personnel is unreliable or inaccurate, based on the facts of the case.

(c) Waiting period. If the operator of an environmental testing laboratory is not successful in correcting deficiencies as required by the National Environmental Laboratory Accreditation Conference standards and this chapter and the laboratory's application is denied, the laboratory's operator must wait a minimum of six months before reapplying for accreditation.

**§25.34. Suspension of Accreditation.**

(a) After notice and opportunity for hearing according to Chapter 80 of this title (relating to Contested Case Hearings), the commission may suspend an environmental testing laboratory's accreditation, in whole or in part, for up to six months. Reasons to suspend an environmental testing laboratory's accreditation include failing to:

(1) maintain a quality system;

(2) comply with minimum performance and quality assurance standards;

(3) maintain records of the laboratory's personnel, operations, data, or analysis;

(4) successfully complete required proficiency tests;

(5) employ staff that meet required personnel qualifications for education, training, and experience; or

(6) notify the executive director of changes in accreditation criteria.

(b) Accreditation shall be reinstated if the executive director determines that the environmental testing laboratory personnel have:

(1) effectively corrected and taken steps to prevent a recurrence of the deficiencies that led to the suspension of accreditation;

(2) complied with all requirements imposed by the executive director or the commission; and

(3) submitted an application for reinstatement that conforms to National Environmental Laboratory Accreditation Conference standards and the requirements of this chapter.

**§25.36. Revocation of Accreditation.**

(a) After notice and opportunity for hearing according to Chapter 80 of this title (relating to Contested Case Hearings), the commission may revoke an environmental testing laboratory's accreditation, in whole or in part, if the laboratory:

(1) fails to correct deficiencies that led to a suspension of accreditation within six months of the notice of suspension;

(2) fails to submit an acceptable corrective action report in response to an assessment;

(3) fails to implement a corrective action related to any deficiencies noted in the environmental laboratory testing assessment report;

(4) fails to provide required proficiency test sample results;

(5) submits proficiency test sample results generated by another laboratory as its own;

(6) misrepresents any fact pertinent to receiving or maintaining accreditation;

(7) fails to allow the executive director entry during normal business hours for an environmental testing laboratory assessment;

(8) is convicted of charges relating to the falsification of any report relating to a laboratory analysis;

(9) fails to remit fees within the time limit established by the executive director; or

(10) is indebted to the state for a fee, penalty, or tax imposed by a statute within the commission's jurisdiction or a rule adopted under such a statute.

(b) The commission shall revoke an environmental testing laboratory's accreditation for each applicable field of accreditation if, after being suspended due to failure of proficiency test samples, an environmental testing laboratory's analysis of the next proficiency test sample results in three consecutively failed proficiency test samples.

(c) An environmental testing laboratory whose accreditation is revoked shall wait a minimum of one year before reapplying for accreditation, and the laboratory shall meet all requirements for a new accreditation, including an environmental testing laboratory assessment.

**§25.38. Accreditation Advisory Committee.**

(a) The executive director shall establish a technical advisory committee to assist in interpreting National Environmental Laboratory Accreditation Conference standards and to advise the executive director and the commission on technical matters relating to the accreditation program.

(b) The technical advisory committee shall function according to Texas Water Code, §5.107 and Chapter 5 of this title (relating to Advisory Committees).

**SUBCHAPTER C: ENVIRONMENTAL TESTING LABORATORY CERTIFICATION**

**§§25.50, 25.52, 25.54, 25.56, 25.58, 25.60, 25.62, 25.64, 25.66,**

**25.68, 25.70, 25.74, 25.76, 25.78**

STATUTORY AUTHORITY

The new sections are proposed under the authority granted to the commission by the Texas Legislature in HB 2912, §1.12, Use of Environmental Testing Laboratory Data and Analysis; Article 6, Accreditation of Environmental Testing Laboratories; §18.02, Transfer of Safe Drinking Water Laboratory Certification Program; and §18.03, Transfer of Environmental Testing Laboratory Certification Program. The new sections will be implemented in accordance with TWC, §5.802, which requires the commission to adopt rules for the administration of an environmental testing laboratory accreditation program; §5.803, which requires the commission to establish a schedule of reasonable accreditation fees; §5.804, which authorizes the commission to adopt rules governing accreditation of an environmental laboratory accredited in another state; §5.805, which requires the commission to adopt rules to implement TWC, Chapter 5, Subchapter R; and §5.127, which allows the commission to accept environmental testing laboratory data and analyses for use in commission decisions regarding any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions only if the data and analyses are prepared by an environmental testing laboratory accredited by the commission under Subchapter R or an environmental testing laboratory described in subsection (b). Additionally, the commission may accept for use in its decisions data and analyses prepared by an on-site or in-house environmental testing laboratory if the laboratory is periodically inspected by the commission; an environmental testing laboratory that is

accredited under federal law; or, if the data and analyses are necessary for emergency response activities and the required data and analyses are not otherwise available, an environmental testing laboratory that is not accredited by the commission under Subchapter R or under federal law. Further, the commission by rule may require that data and analyses used in other commission decisions be obtained from an environmental testing laboratory accredited by the commission under Subchapter R. Finally, the commission is required to periodically inspect on-site or in-house environmental testing laboratories described in Subchapter R. These new sections are also proposed under the general authority granted in TWC, §5.102, which authorizes the commission to perform any acts necessary and convenient to the exercise of its jurisdiction and powers; §5.013, which establishes the general jurisdiction of the commission over other areas of responsibility as assigned to the commission under TWC and other laws of the state; TWC, §5.103 and §5.105, which authorize the commission to adopt rules and policies necessary to carry out its responsibilities and duties under TWC, §5.013(15); §5.107, which authorizes the commission to establish Advisory Committees; and §5.122, which authorizes the commission to delegate uncontested matters to the executive director.

The proposed new sections implement HB 2912, §1.12, Article 6, §18.02, and §18.03. Additionally, the new sections implement TWC, Chapter 5, Subchapter R, §§5.802 - 5.805, 5.127, 5.102, 5.013, 5.103, 5.105, 5.013(15), 5.107, and 5.122.

**§25.50. Standards for Environmental Testing Laboratory Certification.**

Certification of an environmental testing laboratory that analyzes samples for compliance with the Safe Drinking Water Act shall be based on a laboratory's conformance to standards contained in the *Manual for the Certification of Laboratories Analyzing Drinking Water*, Fourth Edition, EPA 815-B-97-001, March 1997; and the *Lab Cert Manual Errata*, Labcert Bulletin, EPA-815-N-99-002a, April 1999, published by the EPA, and the requirements of this chapter.

**§25.52. Fields of Certification.**

(a) The executive director shall identify and make available to the public the fields of certification offered under this chapter. A list of fields of certification shall be made available on the commission's website and upon request from the Compliance Support Division and Agency Communications.

(b) The executive director may modify the fields of certification offered under this chapter with 30 days' notice on the commission's website.

**§25.54. Initial Application for Certification.**

(a) An application for certification must be made on a form provided by the executive director. The application must be submitted to the executive director with any documents and records required in

the application or requested by the executive director and the fee provided in §25.70 of this title (relating to Certification Fees).

(b) The operator of an environmental testing laboratory may request that noncontiguous facilities be certified as a single entity if the facilities operate as a single laboratory under the same:

(1) ownership;

(2) day-to-day management;

(3) day-to-day technical direction; and

(4) quality system, including document management, records management, and test reporting.

(c) The operator of an environmental testing laboratory may submit an application for initial certification or an application to increase its fields of certification at any time.

**§25.56. Term of Certification.**

(a) The executive director shall award certification for a period of one year if an environmental testing laboratory's application and operations conform to standards for certification and this chapter.

(b) The executive director may issue an interim certification for up to 12 months to an environmental testing laboratory that meets standards for certification and requirements of this chapter except when an environmental testing laboratory assessment has not been completed because the executive director has been unable to schedule the assessment within six months of receiving a complete application for accreditation.

**§25.58. Renewal Applications for Certification.**

(a) The executive director must receive an environmental testing laboratory's application to renew the laboratory's certification along with the applicable fees no later than the date on which the certification expires.

(b) The operator of an environmental testing laboratory that fails to submit an application to its renew certification before the date on which the certification expires must apply for and meet all requirements for a new certification, including an environmental testing laboratory assessment.

(c) Modifications made during the term of a certification to increase the number of an

environmental testing laboratory's fields of certification shall be renewed on the certification renewal date, regardless of the date of the modification.

**§25.60. Environmental Testing Laboratory Certification Assessments.**

(a) Environmental testing laboratory assessments shall be conducted:

(1) before certification is granted, except as provided in §25.56 of this title (relating to Term of Certification); and

(2) at least every three years after an environmental testing laboratory receives certification.

(b) Assessments may be announced or unannounced.

**§25.62. Proficiency Test Sample Analyses.**

(a) The operator of an environmental testing laboratory applying for initial certification shall ensure that laboratory personnel successfully analyze one proficiency test sample for each requested field of certification. The proficiency test samples shall be analyzed no more than 12 months prior to submitting the application.

(b) The operator of a certified environmental testing laboratory shall ensure that laboratory personnel analyze at least two proficiency test samples each year approximately six months apart. The operator of a certified environmental testing laboratory shall ensure that laboratory personnel successfully analyze one proficiency test sample for each field of certification each year. An environmental testing laboratory that does not meet the requirements of this subsection may participate in a supplemental proficiency test study.

(c) The executive director shall determine the environmental testing laboratory's certification status for all affected fields of certification within 60 days of determining that laboratory personnel failed to analyze proficiency test samples successfully according to this subsection.

(d) Proficiency test samples shall be purchased from a provider approved by the National Institute for Standards and Technology, if available.

**§25.64. Secondary Certification of Out-of-State Environmental Testing Laboratories.**

(a) The executive director shall grant or renew within 30 days of receipt of the application the secondary certification of an environmental testing laboratory located in another state that is certified by the EPA or a state other than Texas if the:

(1) laboratory submits an application to the executive director that conforms to the standards for certification and this chapter;

(2) laboratory's existing certification includes the fields of certification for which the laboratory has applied to the executive director; and

(3) laboratory pays fees assessed under this chapter.

(b) The executive director shall notify an environmental testing laboratory in writing within 30 days of granting or denying certification.

**§25.66. Duties and Responsibilities of Certified Laboratories.**

By applying for or accepting certification, the operator of an environmental testing laboratory certifies that information contained in the application is true and correct and agrees to:

(1) provide reasonable access to the executive director to facilities, personnel, documents, records, data, analyses, and operations which the executive director determines are necessary for certification; and

(2) operate the environmental testing laboratory and maintain its certification according to the standards for certification and this chapter.

**§25.68. Withdrawal from Certification Program.**

The operator of an environmental testing laboratory may surrender the laboratory's certification, in whole or in part, by notifying the executive director in writing at any time.

**§25.70. Certification Fees.**

(a) The executive director shall establish certification fees that cover program costs, including costs associated with application review; initial, routine, and follow-up inspections; and preparation of reports.

(b) The operator of a laboratory seeking primary certification shall pay the following fees:

(1) an administrative fee of \$500 per year; and

(2) an annual certification fee based on the categories for which the laboratory is certified.

(c) The operator of a laboratory seeking secondary certification shall pay the following fees:

(1) an administrative fee of \$250 per year; and

(2) an annual certification fee based on the categories for which the laboratory is certified.

(d) The categories and annual fees are:

(1) microbiology - \$75;

(2) radiochemistry - \$225;

(3) metals - \$225;

(4) general chemistry - \$225;

(5) disinfection by-products - \$150;

(6) volatile organic compounds by gas chromatograph mass spectrometry - \$150;

(7) semivolatile organic compounds by gas chromatograph mass spectrometry - \$150;

(8) organic compounds by gas chromatography using detection other than mass spectrometry - \$300;

(9) organic compounds by high performance liquid chromatography - \$300;

(10) polychlorinated dibenzo-p-dioxins and dibenzofurans - \$150; and

(11) asbestos - \$150.

(e) The operator of an environmental testing laboratory located in another state and applying for primary certification shall also pay a fee equal to the reasonable travel costs (including transportation, lodging, per diem, and telephone and duplication charges) associated with conducting an assessment at the laboratory.

(f) The following fees shall be assessed, as applicable, in addition to the annual administrative and category fees and travel costs:

(1) to modify an existing certification and add one or more fields of certification - \$250;

(2) to replace a certification certificate - \$50; and

(3) to reinstate a suspended certification - \$250.

(g) All fees are nonrefundable.

**§25.74. Denial of Certification Application.**

(a) Insufficiency. The executive director may deny an initial or renewal application for environmental testing laboratory certification for insufficiency. The executive director shall notify the laboratory of the intent to deny the application and advise the applicant of the opportunity to file a motion to overturn under §50.139 of this title (relating to Motion to Overturn Executive Director's Decision). The executive director may determine an application is insufficient if laboratory personnel fail to:

(1) submit a completed application;

(2) submit the required fees;

(3) successfully analyze and report proficiency test samples;

(4) implement a quality system;

(5) document that laboratory personnel meet personnel qualifications of education, training, and experience;

(6) allow the executive director entry during normal business hours for an environmental testing laboratory assessment;

(7) pass required environmental testing laboratory assessments;

(8) submit a report identifying actions the environmental testing laboratory will take to correct the deficiencies identified in the environmental testing laboratory assessment report within 30 days of receiving an assessment report; or

(9) implement actions to correct the deficiencies identified in the environmental testing laboratory assessment report within the time approved by the executive director.

(b) Cause. After notice and opportunity for hearing, the commission may deny an environmental testing laboratory's initial or renewal application for certification if:

(1) laboratory personnel misrepresent any fact pertinent to receiving or maintaining certification; or

(2) the laboratory or its operator is indebted to the state for a fee, penalty, or tax imposed by a statute within the commission's jurisdiction or a rule adopted under such a statute.

(3) any other reason which causes the executive director to determine that quality of the data being produced by the laboratory's personnel is unreliable or inaccurate, based on the facts of the case.

**§25.76. Suspension of Certification.**

(a) After notice and opportunity for hearing according to Chapter 80 of this title (relating to Contested Case Hearings), the commission may suspend an environmental testing laboratory's certification, in whole or in part, for at least 30 days and up to six months. Reasons to suspend an environmental testing laboratory's certification include failing to:

(1) maintain a quality system;

(2) comply with minimum performance and quality assurance standards;

(3) maintain records of the laboratory's personnel, operations, data, or analysis;

(4) successfully complete required proficiency tests;

(5) employ staff that meet required personnel qualifications for education, training, and experience; or

(6) notify the executive director of changes in certification criteria.

(b) Certification shall be reinstated if the executive director determines the environmental testing laboratory's personnel have:

(1) effectively corrected and taken steps to prevent a recurrence of the deficiencies that led to the suspension of certification;

(2) complied with all requirements imposed by the executive director or the commission; and

(3) submitted an application for reinstatement which conforms to the standards for certification and this chapter.

**§25.78. Revocation of Certification.**

(a) After notice and opportunity for hearing according to Chapter 80 of this title (relating to Contested Cae Hearings), the commission may revoke a laboratory's certification, in whole or in part, if the laboratory:

(1) fails to correct deficiencies that led to a suspension of certification within six months of the notice of suspension;

(2) fails to submit an acceptable report identifying actions the environmental testing laboratory will take to correct deficiencies identified in the environmental testing laboratory assessment;

(3) fails to implement actions to correct deficiencies identified during an environmental testing laboratory assessment;

(4) fails to complete required proficiency test studies;

(5) submits proficiency test sample results generated by another laboratory as its own;

(6) misrepresents any fact pertinent to receiving and maintaining certification;

(7) fails to allow the executive director entry during normal business hours for an environmental testing laboratory assessment;

(8) is convicted of charges relating to the falsification of any report relating to a laboratory analysis;

(9) fails to remit fees within the time limit established by the executive director; or

(10) is indebted to the state for a fee, penalty, or tax imposed by a statute within the commission's jurisdiction or a rule adopted under such a statute.

(b) The commission shall revoke an environmental testing laboratory's certification for each applicable field of certification if, after being suspended due to failure of proficiency test samples, a

laboratory fails to successfully analyze the next proficiency test sample.

(c) A laboratory whose certification is revoked must wait a minimum of one year before reapplying for certification. The laboratory must meet all requirements for a new certification, including an environmental testing laboratory assessment.