

The Texas Natural Resource Conservation Commission (commission) adopts new Chapter 25, Environmental Testing Laboratory Accreditation and Certification, Subchapter A, General Provisions, §§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. Sections 25.4, 25.6, 25.14, 25.20, and 25.56 are adopted *with changes* to the proposed text as published in the May 10, 2002 issue of the *Texas Register* (27 TexReg 3916). Sections 25.1, 25.2, 25.8 - 25.10, 25.12, 25.16, 25.18, 25.22, 25.24, 25.26, 25.30, 25.32, 25.34, 25.36, 25.38, 25.50, 25.52, 25.54, 25.58, 25.60, 25.62, 25.64, 25.66, 25.68, 25.70, 25.74, 25.76, and 25.78 are adopted *without changes* to the proposed text and will not be republished.

#### BACKGROUND AND SUMMARY OF THE FACTUAL BASIS FOR THE ADOPTED 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 adopted 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 adopted rules are necessary for the implementation and administration of HB 2912, §§1.12, 6.01, 18.02, and 18.03. Adopted new Chapter 25 establishes an accreditation program for environmental testing laboratories providing data for commission decisions for all media and continues the existing environmental laboratory certification program for laboratories providing data to the commission for decisions relating to compliance with the SDWA. The adopted 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*

Adopted 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 section also states the agency's 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.

Adopted 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 (NELAP) 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, 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 adopted 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 prepares and 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. The commission

added the words “prepares and” to §25.4(d) to clarify that this subsection applies to accreditation requirements to environmental testing laboratory results prepared and submitted on or after the third anniversary of the date the commission publishes notice that its accreditation program has met NELAC standards. The revision will allow the commission to accept data prepared before the third anniversary but submitted on or after that date. 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).

Adopted 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 testing laboratory that is inspected at least every three years by the executive director; and prepares the data for a permit, registration, or other authorization, and the permit, registration, or other authorization issued by the commission to the operator of the laboratory; 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. The commission revised §25.6(1) to clarify that it applies to data provided for any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions. The rules do not authorize unaccredited in-house environmental testing laboratories to provide data to the commission for use in commission decisions if the data are not related to the environmental testing laboratory operator's permit, authorization, compliance matters, enforcement actions, or corrective actions. This section implements TWC, §5.127.

Adopted 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*

Adopted 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 adopted 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 adopted 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 adopted 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 NELAC's goal 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.

Adopted 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. The commission revised §25.14(b) by replacing the word “when” with the word “that” to clarify the intent of this subsection. This section implements NELAC, §4.2, Period of Accreditation, and §4.5.1, Interim Accreditation.

In adopted 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 adopted 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 adopted new §25.20, Proficiency Test Sample Analyses, subsection (a) requires environmental testing laboratory personnel to periodically analyze proficiency test samples before accreditation is granted. For initial accreditation, the adopted rule requires the operator of an environmental testing laboratory to ensure that two proficiency test samples are successfully analyzed, if available, 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, if available, according to NELAC standards. If a laboratory does not meet requirements for ongoing analyses of proficiency test samples, the adopted 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. Subsection (c) 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. In subsections (a) and (b), the commission added the words, "if available" to the rule language to clarify that an environmental testing laboratory is not required to analyze a proficiency test sample for a field of accreditation if a proficiency test sample is not available from an approved proficiency test provider. Finally, subsection (d) 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 adopted 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.

Adopted new §25.24, Duties and Responsibilities of Accredited Environmental Testing 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 adopted 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.

Adopted 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 adopted 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.

Adopted 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 adopted 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 total 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 actual 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 adopted 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, time required for environmental testing laboratory inspection, and numbers of analyses. The relative complexity, difficulty, 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 adopted 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 adopted 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 adopted accreditation fees also include fees for adding one or more fields of accreditation; replacing an accreditation certificate; and reinstating a suspended accreditation. These fees were assigned to ensure the agency receives revenue from activities outside of the routine accreditation process.

In adopted 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 adopted 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 adopted 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 adopted 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*

Adopted 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 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 adopted 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 adopted 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 adopted 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.

Adopted 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. The commission revised §25.56(b) by replacing the word “when” with the word “that” to clarify the intent of this subsection. This section continues the Safe Drinking Water Certification Program as it was administered by TDH, except that the term of the certification will be one year instead of two years.

In adopted new §25.58, Renewal Applications 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.

Adopted 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.

Adopted 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 at least 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 certification. If a laboratory does not meet requirements for ongoing analysis of proficiency test samples, the adopted rule allows a laboratory to participate in supplemental proficiency test studies.

Subsection (c) 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 (d) 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.

Adopted 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 EPA or another state within 30 days if the laboratory submitted the required application, was already certified for the applicable fields of certification by 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.

Adopted 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.

Adopted 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.

Adopted 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 will be based on the types of analyses a laboratory performs and for which the laboratory chooses to seek certification. The adopted 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. Subsection (g) states that all fees are nonrefundable.

The adopted 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 adopted 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 adopted certification fees include annual administrative fees. The adopted 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 adopted 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.

Adopted 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 certification or 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 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.

Adopted new §25.76, Suspension of Certification, allows the commission to suspend an environmental testing laboratory's certification in whole or in part for one month 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 who 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.

Adopted 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 wait a minimum of one year before reapplying for certification and 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.

#### FINAL REGULATORY IMPACT ANALYSIS DETERMINATION

The commission has reviewed the adopted 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 adopted 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 adopted 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 adopted rules do not exceed a standard set by federal law. These adopted 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 ASSESSMENT

The commission has prepared a takings impact assessment for these adopted 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 adopted 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 adopted 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 adopted rules will substantially advance the implementation of the requirements under TWC, Chapter 5, Subchapter R. Promulgation and enforcement of these adopted rules will not affect private real property. Therefore, the commission has determined that these adopted new rules will not result in a takings.

#### CONSISTENCY WITH THE COASTAL MANAGEMENT PROGRAM

The executive director reviewed the adopted rulemaking and found that the adopted 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 adopted rules are not subject to the CMP.

#### PUBLIC COMMENT

A public hearing was held in Fort Worth, on May 29, 2002 in the Fort Worth Regional Office, as well as in Austin on June 4, 2002 at the Texas Natural Resource Conservation Commission, and in Houston, on June 5, 2002 at the City of Houston Pollution Control Building Auditorium. No comments were received at the hearings. The comment period closed on Monday, June 10, 2002. The commission received written comments from the City of Austin Water and Wastewater Utility (COA); Environmental Laboratory Department Eastman Chemical (Eastman Chemical); Harris County Public Health & Environmental Services Pollution Control Division (HCPCD); Occidental Chemical Corporation (OxyChem); Texas Chemical Council (TCC); Texas Cooperative Extension (TCE); and Texas Parks and Wildlife (TPW).

COA, Eastman Chemical, HCPCD, OxyChem, TCC, TCE, and TPW generally supported the commission's steps to ensure that data used in regulatory decisions are accurate and reliable. No commenter generally opposed the proposal. COA, Eastman Chemical, HCPCD, OxyChem, TCC, TCE, and TPW suggested changes to the proposal as stated in the RESPONSE TO COMMENTS section of this preamble.

## RESPONSE TO COMMENTS

### *General*

TCE commented that including the analysis of agronomic soil, manure, and animal and food processing effluent in the proposed rule is not practical because currently there is no national or regional accreditation program for agronomic soil, manure, or effluent testing laboratories. TCE also commented that including the analysis of agronomic soil, manure, and animal and food processing effluent in the proposed rule is not practical because there are no “guaranteed soil, manure, or effluent samples” currently available.

**The commission is not aware of a nationally- or regionally-recognized accreditation program for agronomic soil, manure, or agronomic effluent testing laboratories (laboratories that analyze concentrated animal feeding operation (CAFO) samples). TWC, §5.127(a), however, states that the commission may accept data for use in commission decisions only if the data is from an accredited environmental testing laboratory except as provided in TWC, §5.127(b). TWC, §5.802, requires that the environmental testing laboratory accreditation program must be consistent with NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually acceptable national standards for accrediting environmental testing laboratories. The commission has determined that the standards adopted by NELAC are appropriate for laboratories that analyze CAFO samples because the standards adopted by NELAC include provisions that provide the flexibility needed to address the concerns raised by this commenter and insure the**

**commission's need for accurate data is met. The commission made no changes to the rule in response to this part of the comment. Further, the commission assumes "guaranteed soil, manure, or effluent samples" refers to single blind proficiency testing samples or certified reference materials. Analysis of proficiency test samples or use of certified reference materials is only one component of an environmental testing laboratory's quality system and method proficiency. To become accredited and maintain accreditation an environmental testing laboratory must meet the quality systems requirements contained in NELAC, Chapter 5 and the requirements of this chapter. To clarify that an environmental testing laboratory is not required to analyze a proficiency test sample if one is not available from an approved provider, the commission has added "if available" language to §25.20(a) and (b).**

TCE commented that including the analysis of agronomic soil, manure, and animal and food processing effluent in the proposed rule is not practical because with few exceptions, the methods used for soil, manure, and animal effluent testing are not recognized by EPA or Association of Analytical Chemists (AOAC).

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories except as provided in TWC, §5.127(b). TWC, §5.802, requires that the laboratory accreditation program must be consistent with NELAP. NELAC standards do not require that the methods used for soil, manure, and animal effluent testing be recognized by EPA or AOAC. Under NELAC standards environmental testing laboratories may be accredited for fields of accreditation that do not use EPA or AOAC methods.**

**NELAP is the overall environmental testing laboratory accreditation program including NELAC.**

**NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. Moreover, the analytical requirements and test methods for CAFO samples are specified in 30 TAC Chapter 321, Subchapter B. The commission made no change to the rule based on this comment.**

TCE commented that including the analysis of agronomic soil, manure, and animal and food processing effluent in the proposed rule is not practical because the matrix influence these sample types is considerably different from the matrix influences of traditional environmental samples.

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories except as provided in TWC, §5.127(b). TWC, §5.802, requires that the laboratory accreditation program must be consistent with NELAP.**

**NELAP is the overall environmental testing laboratory accreditation program including NELAC.**

**NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. The commission has determined that the standards adopted by NELAC are appropriate for laboratories that analyze CAFO samples because the standards adopted by NELAC contain provisions to provide the needed flexibility to address the concerns raised by this comment and ensure the commission's need for accurate data is met. The commission made no change to the rule based on this comment.**

TCE commented that including the analysis of agronomic soil, manure, and animal and food processing effluent in the proposed rule is not practical because that the samples do not require heavy metal analysis and subsequently do not fall under SW-846 guidelines.

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories except as provided in TWC, §5.127(b). TWC, §5.802, requires that the laboratory accreditation program must be consistent with NELAP. NELAC standards do not require that the methods used for soil, manure, and animal effluent testing be from SW-846. Under NELAC standards environmental testing laboratories may be accredited for fields of accreditation other than heavy metals or other analyses described by SW-846. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually- acceptable national standards for accrediting environmental testing laboratories. The commission made no change to the rule based on this comment.**

TCE commented that the proposed rules will negatively affect CAFO and laboratories performing routine analysis of CAFO samples by increasing the cost of analysis to CAFO operators by a factor of ten.

**The commission cannot verify that environmental testing laboratories will increase analytical fees to CAFOs by a factor of ten. The legislature determined that even if the analytical cost increases,**

**all environmental testing laboratories that provide data to the commission for decision-making must be accredited, except as provided in TWC, §5.127(b). In TWC, §5.803(b), the legislature directed the commission to establish a schedule of reasonable accreditation fees designed to recover the costs of the accreditation program. The legislature determined that even if the analytical cost increases, all environmental testing laboratories that provide data to the commission for decision-making must be accredited, except as provided in TWC, §5.127(b). The commission cannot verify that environmental testing laboratories will increase analytical fees to CAFOs by a factor of ten. The executive director's staff has evaluated the anticipated costs of the environmental testing laboratory accreditation and certification program and has determined that the proposed fees are reasonable. The commission made no change to the rule in response to this comment.**

TCE commented that the proposed rules will negatively affect CAFOs and laboratories performing routine analysis of CAFO samples by eliminating existing testing laboratories ability to analyze soil, manure, or effluent.

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories except as provided in by TWC, §5.127(b).**

**TWC, §5.802, requires that the laboratory accreditation program must be consistent with NELAP. The commission will accredit all environmental testing laboratories that meet the requirements of this chapter. Environmental testing laboratories currently performing analysis for CAFOs may continue to analyze CAFO samples, provided the laboratory obtains accreditation**

**from the commission. Additionally, these rules do not specify which environmental testing laboratory a CAFO must use, only that the data must be from an accredited environmental testing laboratory if it is supplied to the commission for decision-making. The commission made no change to the rule in response to this comment.**

TCE commented that the proposed rules will negatively affect CAFO and laboratories performing routine analysis of CAFO samples, because the overall number of samples taken by CAFOs will be reduced. Thus, implementation of best management practices will be reduced to limit the CAFOs' or effluent generators' cost.

**CAFO operators must meet the specific minimum best management practices required under Chapter 321, Subchapter B. CAFO operators are also encouraged to install and operate additional best management practices to help ensure compliance with environmental protection goals. Additionally, §321.42 delineates where samples must be taken, as well as the required analysis. The commission does not agree that CAFO operators will compensate for the increasing expenses by reducing activities required by permit or regulation designed to reduce environmental impacts. The commission did not make changes to the rule based on this comment.**

TCE commented that the proposed rules will negatively affect CAFOs and laboratories performing routine analysis of CAFO samples by stifling the current method evaluation research studying the impact of manure or effluent applications on soil nutrient levels, plant and crop response, or environmental consequences.

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories except as provided in TWC, §5.127(b). TWC, §5.802, requires that the laboratory accreditation program must be consistent with NELAP. If the laboratory data will not be used by the commission in a decision-making process, the data does not have to be from an accredited environmental testing laboratory. Thus, the environmental testing laboratory accreditation program will not impact research studies on the impact of manure or effluent applications on soil nutrient levels, plant and crop response, or environmental consequences. The commission made no change to the rule in response to this comment.**

TCE commented that the soil testing industry recognizes the need for oversight of data reported to CAFOs and other agronomic-based application fields.

**The commission appreciates the comment in support of the rule.**

TCE suggested that the commission evaluate laboratories that perform analytical work for CAFOs by reviewing the laboratories' standard operating procedures to insure the laboratories are in line with standard, accepted agronomic laboratory protocols. Additionally, TCE suggested the commission perform physical audits of laboratories that provide service to CAFOs to determine if the laboratories follow accepted agronomic laboratory protocols.

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories except as provided in TWC, §5.127(b). TWC,**

**§5.802, requires that the laboratory accreditation program must be consistent with NELAP.**

**Since laboratories that analyze CAFO samples will be submitting data to the commission to be used in the commission’s decision-making process, the executive director must use NELAC standards in evaluating the laboratories that analyze CAFO samples. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. To become accredited, NELAC standards require, among other things, evaluation of an environmental testing laboratory’s standard operating procedures and quality systems and a physical audit. The commission made no changes to the rule in response to this comment.**

TCE “suggest{ed} that these labs be a part of a proficiency testing program such as the North American Proficiency Testing Program, administered through the Soil Science Society of America.”

**The commission interprets that “these labs” refers to environmental testing laboratories serving the CAFO industry. TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories except as provided in TWC, §5.127(b). TWC, §5.802, requires that the laboratory accreditation program must be consistent with NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-**

**acceptable national standards for accrediting environmental testing laboratories. Thus, if a CAFO submits data to the commission for use in a commission decision, the data must be from a NELAC accredited environmental testing laboratory. The rules, however, do not prevent an environmental testing laboratory from also participating in a proficiency testing program administered by the North American Proficiency Testing Program. NELAC standards require a proficiency test sample provider must be approved by the National Institute for Standards and Technology National Voluntary Laboratory Accreditation Program, NELAC, §2.3.1; thus if the Soil Science Society of America wants to become an approved proficiency test provider for the NELAC program it must meet NELAC standards. The commission made no change to the rule in response to this comment.**

COA asked if field and treatment plant tests and measurements such as turbidity, pH, chlorine residual, and alkalinity that have historically been conducted by certified operators and reported to the commission for compliance purposes would be covered under this rule. According to COA these tests are routinely performed in the treatment plant or in the field.

**TWC, §5.127(a), states the commission may only accept data for use in commission decisions from accredited environmental testing laboratories regardless of the analyte, except as provided in TWC, §5.127(b). TWC, §5.127(b), states in part that the commission may, under certain conditions, accept data from an in-house or on-site environmental testing laboratory that is not accredited. Thus, if a regulated entity sends its samples to a commercial laboratory for analysis and the data is used for a commission decision, the laboratory must be accredited. If the**

**regulated entity's in-house or on-site environmental testing laboratory analyzes the samples, the environmental testing laboratory does not have to be accredited. The 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. Thus, if the sample is analyzed in the field, this rule does not apply; however, if the same sample is analyzed in an environmental testing laboratory, the laboratory must be accredited except as provided in TWC, §5.127(b). The commission will monitor NELAC's development of field activity standards and may include accreditation standards for field measurements at a later date. If the data is not used for a commission decision, it does not have to be from an accredited environmental testing laboratory. The commission made no change to the rule in response to this comment.**

COA commented that they appreciate the efforts by staff in holding stakeholder meetings and speaking at association meetings.

**The commission appreciates the comment in support of the rule.**

Eastman Chemical commented that the rules create a double standard for environmental testing laboratories in Texas by requiring that the standard for a commercial lab that produces data for use by the commission in decision making must be accredited by NELAC and that an "in-house" environmental testing laboratory that produces data for use by the commission in decision-making does not have to be NELAC accredited and only has to meet an "inspection" standard. Eastman Chemical commented that "common sense and good science" require that all environmental testing laboratories in

Texas that produce data for use by the commission in its decision-making processes should be held to similar standards.

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories, except as provided in TWC, §5.127(b).**

**TWC, §5.127(b), states in part that the commission may accept data from an in-house or on-site environmental testing laboratory that is not accredited if it is inspected periodically. Thus, the commission cannot require in-house environmental testing laboratories to become accredited. The commission made no change to the rule based on this comment.**

Eastman Chemical suggested to insure similar standards that the commission use “laboratory-experienced and laboratory-trained inspectors” to inspect in-house laboratories because laboratory inspections are complex since each inspection requires the inspector to have “a thorough understanding of analytical chemistry, statistics, and quality assurance/quality control techniques.” Eastman Chemical suggested that to ensure consistency in inspection standards the commission require that use the same inspectors who conduct the NELAC inspections also conduct the inspections for the in-house laboratories.

**TWC, §5.802, states the environmental testing laboratory accreditation program must be consistent with standards approved by NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to**

**establish mutually acceptable national standards for accrediting environmental testing laboratories. NELAC §3.2 provides minimum requirements for environmental testing laboratory assessment personnel, including education, basic training, refresher training, and technical training. Staff conducting accreditation inspections will meet NELAC standards for assessors. Staff inspecting in-house or on-site environmental testing laboratories, however, are not required to meet the same requirements because inspections of in-house or on-site environmental testing laboratories are not required to meet NELAC standards. Moreover, the commission intends to ensure all inspections, including those of in-house and on-site environmental testing laboratories, are rigorously conducted by trained staff. The commission, however, has determined that because of the drain on the commission's resources it is not practicable to have all in-house and on-site inspections conducted by laboratory-experienced and laboratory-trained personnel. The commission may use accreditation staff to inspect certain in-house or on-site environmental testing laboratories, especially those performing complex or wide-ranging analyses. The commission made no change to the rule based on this comment.**

Eastman Chemical suggested to insure similar standards that the commission consolidate and standardize permit provisions related to analytical requirements because "the current permit system is inadequate to ensure that environmental laboratories in Texas have sufficient guidance and/or control to uniformly generate decision-making data according to any commonly-accepted quality standard."

**The commission acknowledges analytical requirements in permits and other authorizations have changed over time and may differ among regulatory programs; however, the comment is beyond**

**the scope of this rulemaking. The commission made no change to the rule in response to this comment.**

*Subchapter A, General Provisions*

COA commented that the definitions of “in-house laboratory” and “on-site laboratory” in §25.2 add confusion about the types of laboratories and suggested using one definition for “environmental testing laboratory.”

**TWC, §5.127(a), states that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories, except as provided in TWC, §5.127(b).**

**TWC, §5.127(b), states in part that the commission may accept data from an in-house or on-site environmental testing laboratory that is not accredited if it is inspected periodically. Thus, the definitions are needed to clarify which laboratories are in-house and on-site environmental testing laboratories. The commission made no change to the rule in response to this comment.**

TPW commented that the provisions in §25.4(c) requiring laboratories to be accredited if the laboratory provides data to third parties limit the opportunity for in-house laboratories to perform pro bono work. According to TPW “it is well understood that the TNRCC cannot, by itself, conduct all the environmental monitoring which is required in the state. The TNRCC needs to build partnerships to see that adequate monitoring is conducted.”

**The commission acknowledges that the requirement for an environmental testing laboratory to be accredited may discourage some environmental testing laboratories from providing pro bono services to the commission. The rules, however, address a fundamental risk identified by the Sunset Advisory Commission (Sunset Commission). According to the Sunset Commission, unaccredited environmental testing laboratories are more likely to produce inaccurate data for agency decision-making, which results in increased risks to public health and the environment and increased agency costs. Sunset Advisory Staff Report, Texas Natural Resource Conservation Commission, 2000, Page 49. To address this concern, the legislature enacted TWC, §5.127(a) stating that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories, except as provided in TWC, §5.127(b). Thus, the commission has determined that it is inappropriate to accept data from an unaccredited environmental testing laboratory, even if the data is provided to the commission pro bono. Moreover, the commission has determined that because the environmental laboratory accreditation program will help insure that the data submitted to the commission will be of high quality it will be an effective tool in developing partnerships to insure that adequate monitoring is conducted. The commission made no change to the rule in response to this comment.**

TPW commented that requiring environmental testing laboratories that provide pro bono work to be accredited could result in significant cost to smaller regulated entities; thus, TPW suggested adding the words, “as a fee-for-service operation” in §25.4(c).

**The commission cannot verify that environmental testing laboratories will increase analytical fees to small regulated entities. Additionally, TWC, §5.127(a), requires that data used in commission decisions be from an accredited environmental testing laboratory, except as provided in TWC, §5.127(b). Therefore, the commission has determined that even if the analytical cost to small regulated entities increases, all environmental testing laboratories that provide data to the commission for decision- making must be accredited, except as provided in TWC, §5.127(b). The commission made no change to the rule in response to this comment.**

TPW suggested that, while the intent of the rule is to ensure that the commission receives reliable data, the provisions in §25.4(c) could actually limit the amount of data assessment provided to the commission and “be counterproductive if it reduces the amount of good data that can be used by the TNRCC.”

**The commission acknowledges requiring environmental testing laboratories that provide pro bono work to be accredited may reduce the volume of data received by the commission. The need for reliable data was identified by the Sunset Commission in the Sunset Advisory Staff Report, Texas Natural Resource Conservation Commission, 2000, Page 49; thus, the legislature enacted TWC, §5.127(a). To help ensure that the data the commission receives is reliable, the commission may only accept data for use in commission decisions from accredited environmental testing laboratories as provided in TWC, §5.127(a). TWC, §5.127(b), only authorizes the use of data from unaccredited environmental testing laboratories in a few limited instances. All other data must be from an accredited environmental testing laboratory. Thus, even if the volume of data is**

**reduced the commission has determined that the need to insure the reliability of the data overrides the possible reduction in the volume. Additionally, the commission has determined that because the laboratory accreditation program will insure the reliability of the data the program will not be counterproductive to the commission's decisions-making processes. The commission made no change in the rule in response to this comment.**

Regarding §25.4(c), TCC commented that there are situations where two or more companies will share treatment and laboratory services within an operating facility. TCC believes that these types of laboratories should not be required to become accredited; therefore, TCC recommended that the language in §25.4(c) be changed to read, "An in-house environmental testing laboratory is accredited if it provides analytical data to an off-site third party and the data are used for a commission decision relating to a..."

**According to TWC, §5.127(b)(1), the commission may accept analytical data from an unaccredited in-house or on-site laboratory, provided the environmental testing laboratory is inspected periodically. The legislature, however, did not provide any guidance regarding the definition of an in-house or on-site environmental testing laboratory. The commission, therefore, determined this provision should only apply to analytical data provided by a laboratory to the laboratory's operator because the environmental testing laboratory's operator assumes the risk of inaccurate analytical data from its in-house laboratory. Furthermore, the commission determined that it is not appropriate to extend this provision to include data generated for a separate entity that occupies the same physical location as the environmental testing laboratory because the entity**

**cannot assume the risk of inaccurate analytical data from another entity's in-house laboratory.**

**The commission made no change to the rule in response to this comment.**

Regarding §25.4(d), TPW recommends that the commission "grandfather" data collected using state and federal money. TPW stated that data is currently being collected but the data may be submitted to the commission after laboratories are required to be accredited. TWP suggested adding, "...except for data collected under contract or grant from a state or federal agency prior to that date..." to §25.4(d).

**The commission agrees in part with the comment and has revised §25.4(d) to apply accreditation requirements to environmental testing laboratory results prepared and submitted on or after the third anniversary of the date the commission publishes notice its accreditation program has met NELAC standards. HB 2912, §18.03(d), 77th Legislature, 2001, states that TWC, §5.127, applies only to 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 has met NELAC standards. This revision will allow the commission to accept data prepared before the third anniversary but submitted on or after that date. This revision will apply to all types of data, not just to data collected under a contract or grant from a state or federal agency. The commission, however, notes certain agency programs may require environmental testing laboratory accreditation as a condition for a grant or contract before accreditation requirements become mandatory.**

OxyChem commented that in §25.6(1)(A), it is not clear how the executive director would carry out the inspection that is required to be conducted every three years. Specifically, OxyChem asked who initiates the inspection, what laboratory operations would be inspected, and when must inspection findings be implemented.

**TWC, §5.127(b)(1), states in part that the commission may accept analytical data from an unaccredited in-house or on-site laboratory if the laboratory is inspected periodically. An in-house or on-site environmental testing laboratory will be inspected according to the terms of the permit, registration, or other authorization issued by the commission to the operator of the laboratory. The executive director will initiate the inspection, determine what laboratory operations will be inspected, and determine when corrective actions must be implemented. The commission made no changes to the rule based on this comment.**

Regarding §25.6(1)(B), TPW commented that it is not clear if entities that operate an in-house laboratory can submit data for the purposes listed in §25.4(b). TPW recommended clarifying that entities operating an in-house laboratory may submit data to the commission for all purposes listed in §25.4(b).

**Section 25.6(1) allows the commission to accept data from an unaccredited laboratory if the laboratory is an in-house or on-site laboratory. Section 25.2(9) and (15) define an in-house and an on-site laboratory as one that provides data to the laboratory's operator for permits or authorizations issued to and compliance, enforcement, or corrective actions related to the**

**laboratory's operator. The commission clarified that §25.6(1) applies to data provided for any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions. The rules do not authorize unaccredited in-house environmental testing laboratories to provide data to the commission for use in commission decisions, if the data is not related to the environmental testing laboratory's operator's permit, authorization, compliance matters, enforcement actions, or corrective actions.**

*Subchapter B, Environmental Testing Laboratory Accreditation and Subchapter C, Environmental Testing Laboratory Certification*

OxyChem commented that the requirement for annual accreditations in §25.14(a) is too frequent and that accreditation every three years is sufficient. OxyChem commented that an annual accreditation period places too much of a burden on environmental testing laboratories and accrediting authorities. Additionally, OxyChem commented that the quality of data does not change from year to year and that because environmental testing laboratories have stringent quality assurance/quality control (QA/QC) programs it is rare that data quality is compromised.

**TWC, §5.802, states the environmental testing laboratory accreditation program must be consistent with standards approved by NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. NELAC standards require a one-year term of accreditation (NELAC §4.2). Thus,**

**the commission must implement an annual accreditation program. A three-year accreditation period would conflict with TWC, §5.802. While the commission acknowledges that many unaccredited environmental testing laboratories have stringent QA/QC programs, this rule provides the commission with assurance that data from an environmental testing laboratory is of high quality. These rules require all environmental testing laboratories to maintain stringent QA/QC programs by establishing definite minimum QA/QC standards. Since NELAC requires an annual accreditation period and TWC, §5.802, requires the commission to implement an accreditation program that conforms with NELAC, the commission's environmental testing laboratory accreditation program must require environmental testing laboratories to renew accreditations annually. The commission made no changes to the rule in response to this comment.**

OxyChem commented that in §25.18(a)(2), an environmental testing laboratory assessment period of three years is sufficient. OxyChem commented that a two-year environmental testing laboratory assessment period places too much of a burden on environmental testing laboratories and accrediting authorities. OxyChem commented that the quality of data does not change from year to year and that because environmental testing laboratories have stringent QA/QC programs it is rare that data quality is compromised.

**TWC, §5.802, states the environmental testing laboratory accreditation program must be consistent with standards approved by NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of**

**state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. NELAC standards require environmental testing laboratory assessments once every two years (NELAC §3.3.1). Thus, the commission must implement a program that assesses environmental testing laboratories at least once every two years. A three-year assessment period would conflict with TWC, §5.802. While the commission acknowledges that many unaccredited environmental testing laboratories have stringent QA/QC programs, this rule provides the commission with assurance that data from an environmental testing laboratory is of high quality. These rules require all environmental testing laboratories to maintain stringent QA/QC programs by establishing definite minimum QA/QC standards. Since NELAC requires assessments once every two years and TWC, §5.802, requires the commission to implement an accreditation program that conforms with NELAC, the commission's environmental testing laboratory accreditation program must require environmental testing laboratory assessments at least every two years. The commission made no changes to the rule in response to this comment.**

COA commented that the provisions in §25.14(b) and §25.56(b) that require the executive director to schedule an assessment within six months of receiving a completed application from an environmental testing laboratory should not hold true if the laboratory is "ready and willing to complete the assessment, and the commission is unable to schedule the assessment because of budgets, staffing, or otherwise." COA suggested the following language for §25.14(b) and §25.56(b): "The executive director may issue interim certification/accreditation for up to 12 months to an environmental testing laboratory that meets standards for certification/accreditation and requirements of this chapter or obtains

a third party audit. If the laboratory does not provide reasonable access for the executive director to schedule an assessment within six months of commission receipt of the application, the interim certification is cancelled. If the executive director is not able, due to no fault of the laboratory, to schedule the assessment, then the interim certification remains in effect.”

**Sections 25.14(b) and 25.56(b) authorize the executive director to issue an interim accreditation or certification to an environmental testing laboratory that meets the accreditation or certification standards, except that the executive director has not been able to schedule an environmental testing laboratory assessment. The commission has revised the rule to clarify the intent of these sections. Because §25.14(b) and §25.56(b) provide a mechanism for interim accreditation or certification, the proposed language for third-party audits is not necessary. Furthermore, a third-party audit may not meet NELAC accreditation or Texas certification standards. The commission will not issue an accreditation or certification to an environmental testing laboratory that does not provide access to its facilities during normal business hours.**

COA commented that in §25.18(b), assessments can be either announced or unannounced. COA commented that assessments for “initial, routine, and re-accreditation or re-certification” should be announced and that assessments for “follow-up to corrective actions, failed proficiency test samples, safety violations, suspected criminal or fraudulent practices” should be unannounced. COA stated that announced inspections allow both the environmental testing laboratory staff and the commission staff to be prepared by having ready “quality control data, personnel proficiency data, performance testing data, and other information” that would make the assessment run smoothly and efficiently.

**TWC, §5.802, states the environmental testing laboratory accreditation program must be consistent with standards approved by NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. These standards state environmental testing laboratory assessments may either be announced or unannounced and the accrediting authority is not required to provide advance notice (NELAC §3.3.4). Thus, the commission may conduct either announced or unannounced inspections. The commission made no change to the rule in response to this comment.**

COA commented that the language in §25.20 and §25.34 could be interpreted to mean that if different analytic methods are used for an analyte category and that if a laboratory fails one method but passes the other method, then the laboratory fails for the entire category. COA suggested that the commission allow environmental testing laboratories to retain certification for each method passed during the proficiency test.

**Sections 25.20 and 25.34 allow an environmental testing laboratory to retain its accreditation for a specific field of accreditation if the environmental testing laboratory meets its proficiency testing requirements for that specific field of accreditation. Field of accreditation refers to a unique combination of matrix, method, and analyte. Section 25.20 requires environmental testing laboratories to successfully analyze proficiency testing samples according to NELAC standards. NELAC §2.7.4 provides that failing a proficiency test sample only affects the accreditation status**

**of that specific field of accreditation. NELAC §4.4.3 describes situations in which an environmental testing laboratory's entire accreditation will be suspended or revoked. These situations are included in §25.34, which provides an environmental testing laboratory's accreditation may be suspended "in whole or in part" for failing to successfully complete required proficiency tests. Therefore, §25.20 and §25.34 allow an environmental testing laboratory to retain its accreditation for a specific field of accreditation if the environmental testing laboratory meets NELAC standards for that field. The commission made no change in the rule in response to these comments.**

OxyChem commented that in §25.20(b), the requirement for two proficiency tests per year is "onerous without tangible benefit." OxyChem commented that environmental testing laboratories that conduct frequent analysis in one category are familiar with that category and experience little deviation from quality analysis and that if an environmental testing laboratory does not conduct frequent analysis in one category that semi-annual proficiency tests "would be overkill."

**TWC, §5.802, states the environmental testing laboratory accreditation program must be consistent with standards approved by NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. These standards require two proficiency testing studies per year, where available (NELAC §2.4.1). Annual proficiency test samples would be inconsistent with NELAC standards.**

**Thus, for consistency with NELAC the commission has determined that it is appropriate to require two proficiency test samples per year. The commission made no change to the rule in response to these comments.**

TPW commented that the requirement in §25.20(b) for semi-annual proficiency test samples is not needed and that the commission could ensure that accurate and appropriate analyses are being conducted at environmental testing laboratories by requiring the laboratories to maintain quality assurance documentation. TPW further commented that annual proficiency tests are the standard with the federal government, and that doubling the number of samples will not increase the performance of the laboratory nor the accuracy of the data. Moreover, according to TPW, semi-annual proficiency testing is labor intensive and costly.

**TWC, §5.802, states the environmental testing laboratory accreditation program must be consistent with NELAP. NELAP is the overall environmental testing laboratory accreditation program including NELAC. NELAC is the voluntary organization of state, territorial, federal environmental officials, and interest groups whose primary purpose is to establish mutually-acceptable national standards for accrediting environmental testing laboratories. Semi-annual analysis of proficiency test samples is only one part of the NELAP accreditation process. To obtain and maintain accreditation an environmental testing laboratory must, among other things, keep quality assurance documentation. Because NELAC standards require environmental testing laboratories to do more than simply maintain records, the commission must follow suit.**

**Furthermore, it is not clear which federal proficiency test program TPW is referring to. The**

**commission notes that the water pollution (WP) and water supply (WS) proficiency evaluation (PE) programs, both federal programs, include two sets of PE samples per year. The EPA privatized these PE sample programs in 1999. The legislature directed the commission to implement the environmental testing laboratory accreditation program following NELAC standards. NELAC standards require an environmental testing laboratory to analyze two proficiency test samples per year, where available, for each field of accreditation for which it seeks or wants to maintain accreditation (NELAC §2.4.1). Thus, any environmental testing laboratory that desires NELAP accreditation must meet NELAC standards. The commission is aware that simply requiring an environmental testing laboratory to analyze two sets of proficiency test samples per year does not guarantee that the environmental testing laboratory's performance will be better or that the data generated by the environmental testing laboratory will be more accurate. The commission also acknowledges that semi-annual analyses of proficiency testing samples imposes additional costs on environmental testing laboratories. According to NELAC standards, environmental testing laboratories must analyze two proficiency testing samples per year, if a proficiency test sample is available for the field of accreditation (NELAC §2.4.1). Thus, only requiring annual proficiency test samples would be inconsistent with NELAC standards. The commission made no change to the rule in response to this comment.**

COA commented that it liked the provision in §25.26 and §25.68 that allows an environmental testing laboratory to withdraw in whole or in part from the environmental laboratory testing accreditation and certification program at any time.

**The commission appreciates the comment in support of the rule.**

Eastman Chemical commented that the fee structure proposed in the rules is “reasonable and established on the logical basis of matrices.”

**The commission appreciates the comment in support of the rule.**

TPW requests that the commission waive the accreditation fees in §25.30 and the certification fees in §25.70 for state agencies.

**TWC, §5.803(b), states the commission shall establish a schedule of reasonable accreditation fees designed to recover the costs of the accreditation program. The commission determined costs should be apportioned among all regulated entities. TWC, §5.803, requires that the commission set fees to recover the cost of the environmental testing laboratory accreditation program. If the commission exempted state agencies from paying accreditation and certification fees it would place an unfair burden on the environmental testing laboratories still required to pay the fees. Additionally, because state agencies are not exempt from paying permitting or other fees, the commission has determined it would not be appropriate to exempt state agencies from the accreditation fees. The commission made no change to the rule in response to these comments.**

Regarding §25.30, HCPCD commented that the fees associated with the environmental testing laboratory accreditation program should be waived if a governmental agency provides data free of charge (pro bono) to the commission.

**These rules address a fundamental risk identified by the Sunset Commission. According to the Sunset Commission, unaccredited environmental testing laboratories are more likely to produce inaccurate data for agency decision-making, which results in increased risks to public health and the environment and increased agency costs (Sunset Advisory Staff Report, Texas Natural Resource Conservation Commission, 2000, Page 49). To address this concern, the legislature enacted TWC, §5.127(a), stating that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories, except as provided in TWC, §5.127(b). Thus, the commission has determined that it is inappropriate to accept data from an unaccredited environmental testing laboratory, even if the data is provided to the commission by a governmental agency pro bono. Moreover, TWC, §5.803(b), states the commission shall establish a schedule of reasonable accreditation fees designed to recover the costs of the accreditation program. The commission determined costs should be apportioned among all regulated entities. Since pro bono data provided to the commission must be from accredited environmental testing laboratories, the commission has determined that it would not be appropriate to exempt governmental agencies from paying accreditation and certification fees because it would place an unfair burden on the environmental testing laboratories still required to pay the fees. The commission made no change to the rule in response to these comments.**

Regarding §25.30, HCPCD commented that the fee structure established by the environmental testing laboratory accreditation program may discourage governmental laboratories from providing pro bono services to the commission.

**The commission acknowledges that the fee structure established by the environmental testing laboratory accreditation program may discourage some governmental laboratories from providing pro bono services to the commission. The rules, however, address a fundamental risk identified by the Sunset Commission. According to the Sunset Commission 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. Sunset Advisory Staff Report, Texas Natural Resource Conservation Commission, 2000, Page 49. To address this concern, the legislature enacted TWC, §5.127(a), stating that the commission may only accept data for use in commission decisions from accredited environmental testing laboratories, except as provided in TWC, §5.127(b). Thus, the commission has determined that it is inappropriate to accept data for use in commission decisions from an unaccredited environmental testing laboratory, even if the data is provided by a governmental laboratory to the commission pro bono. The commission made no change to the rule in response to this comment.**

Regarding §25.30, HCPDC commented that they believe the fee structure in the rules was written to address the oversight of commercial environmental testing laboratories. Additionally, according to HCPDC the accreditation fees are a normal cost of doing business for commercial environmental testing laboratories.

**According to TWC, §5.803(b), fees are intended to cover the costs of the accreditation program including costs associated with application review, environmental testing inspections, and preparation of reports. The fee structure was developed to produce sufficient funds to operate the environmental testing laboratory accreditation program, without respect to whether an environmental testing laboratory is a commercial operation. If the commission exempted governmental agencies from paying accreditation and certification fees it would place an unfair burden on the environmental testing laboratories still required to pay the fees. Additionally, because governmental agencies are not exempt from paying permitting or other fees, the commission has determined it would not be appropriate to exempt governmental agencies from the accreditation fees. The commission has made no change to the rule in response to this comment.**

COA commented that the fees in §25.30 and in §25.70 are reasonable.

**The commission appreciates the comment in support of the rule.**

TPW asked if the language in proposed §§25.32(b)(2), 25.36(a)(10), 25.74(b)(2), and 25.78(a)(10), means that laboratory accreditation or certification can be denied or revoked for non-payment of any commission imposed fee. TPW commented that if this is the case, this requirement seems onerous and suggested that language for non-payment of fees other than accreditation fees and certification fees be removed from the rule.

**The commission responds that the intent of §§25.32(b)(2), 25.36(a)(10), 25.74(b)(2), and 25.78(a)(10), is that an environmental laboratory's accreditation or certification can be denied or revoked for non-payment of any commission imposed fees, penalties, or taxes within the commission's jurisdiction or rule adopted under such a statute. These sections are consistent with other agency rules and are necessary for the commission to conform to standard business and revenue collection practices and to meet its fiduciary duty to the citizens of the state. The fees and taxes are standard business expenses for environmental testing laboratories and ensuring that these fees and taxes are paid provides a level playing field for the regulated entities. The commission notes that 30 TAC Chapter 70 authorizes the commission to provide relief to a regulated entity experiencing financial hardships which may lower or eliminate an administrative penalty if the regulated entity can establish an inability to pay. The commission made no change to the rule based on this comment.**

OxyChem commented that in §25.56(a), a certification period of three years is sufficient because data quality does not change much over one year.

**The commission currently issues two-year certifications (25 TAC §73.25(e)(8)(A) and HB 2912, 77th Legislature, §18.02(b)). The commission has determined that it will be both more efficient and cost effective to administer only one environmental testing laboratory oversight program to insure the quality of the data used in commission's decisions is of high quality. Thus, after the environmental testing laboratory accreditation program is implemented, the commission will eliminate the environmental testing laboratory certification program. To ease the transition from**

**the environmental testing laboratory certification program to the environmental testing laboratory accreditation program, the commission will operate the certification program under the guidelines of the accreditation program. The environmental testing accreditation program requires an annual accreditation period; therefore, the commission has determined that it is appropriate to modify the existing certification period to one year. Additionally, while it may be true that the quality of data produced by an environmental testing laboratory may not change much over one year, the rules address a fundamental risk identified by the Sunset Commission. According to the Sunset Commission 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 (Sunset Advisory Staff Report, Texas Natural Resource Conservation Commission, 2000, Page 49). The commission has made no change in the rule in response to this comment.**

COA commented that in §25.60(b), assessments can be either announced or unannounced. COA commented that assessments for “initial, routine, and re-accreditation or re-certification” should be announced and that assessments for “follow-up to corrective actions, failed proficiency test samples, safety violations, suspected criminal or fraudulent practices” should be unannounced. COA stated that announced inspections allow both the environmental testing laboratory staff and the commission staff to be prepared by having ready “quality control data, personnel proficiency data, performance testing data, and other information” that would make the assessment run smoothly and efficiently.

**The commission has determined that it will be both more efficient and cost effective to administer only one environmental testing laboratory oversight program to insure the quality of the data used in commission's decisions is of high quality. Thus, after the environmental testing laboratory accreditation program is implemented, the commission will eliminate the environmental testing laboratory certification program. To ease the transition from the environmental testing laboratory certification program to the environmental testing laboratory accreditation program, the commission will operate the certification program under the guidelines of the accreditation program. The environmental testing accreditation program provides that environmental testing laboratory assessments may either be announced or unannounced and the accrediting authority is not required to provide advance notice (NELAC §3.3.4). Thus, the commission has determined that it is appropriate to conduct either announced or unannounced certification inspections. The commission made no change to the rule in response to this comment.**

COA commented that the language in §25.62 and §25.76 could be interpreted to mean that if different methods are used in one analyte category and that if a laboratory failed one method but passed the other method, then the laboratory fails for the entire category. COA suggested that the commission allow environmental testing laboratories to retain certification for each method passed during the proficiency test.

**Sections 25.62 and 25.76 allow an environmental testing laboratory to retain its certification for a specific field of certification if the environmental testing laboratory meets its proficiency testing requirements for that specific field of certification. Field of certification refers to a unique**

combination of matrix, method, and analyte. Section 25.62 requires proficiency testing samples to be successfully analyzed before and after a certification is issued. Section 25.50 requires the certification of an environmental testing laboratory that analyzes samples for compliance with the SDWA be based on the requirements of this chapter and EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water*, 4th Edition, March 1997 and the *Lab Cert Manual Errata*, Labcert Bulletin, April 1999. EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water* provides that a proficiency testing failure should only affect the status of a specific field of certification (III-8). Section 25.76 provides that an environmental testing laboratory's certification may be suspended "in whole or in part" for failing to successfully complete required proficiency tests. Therefore, §25.62 and §25.76 allow an environmental testing laboratory to retain its certification for a specific field of certification if the environmental testing laboratory meets certification standards for that field. The commission made no change in the rule in response to these comments.

OxyChem commented that the requirement in §25.78(b), that an environmental testing laboratory consecutively fail three proficiency tests before the environmental testing laboratory's certification was revoked was reasonable.

**The commission appreciates the comment in support of the rule.**

## **SUBCHAPTER A: GENERAL PROVISIONS**

### **§§25.1, 25.2, 25.4, 25.6, 25.8**

#### **STATUTORY AUTHORITY**

The new sections are adopted 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 adopted 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.

**§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 prepared and 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, for any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions, that is not accredited according to this chapter if the laboratory:

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

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

(B) prepares the data for 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 adopted 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 adopted 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.

**§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 that 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, if available, 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, if available, 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 adopted 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 adopted 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.

**§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 that 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;

(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.

**§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 Case 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.