TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Laboratory Accreditation Procedures and Revision History

No.	Title	Rev.	Iss. Date Eff. Date	Superseded
1.0	**Program Management: Quality Management Plan, Quality Policy Statement, Operational Standards, Organization, Key Personnel, and Internal Quality Assurance Audits**	8	24 Jan 23 30 Jan 23	Rev. 7
1.1	**Terms and Definitions**	7	05 Feb 24	Rev. 6
1.2	**Technical Advisory Group**	4	02 Mar 23 03 Mar 23	Rev. 3
1.3	**Fields of Accreditation**	5	03 Mar 23 03 Mar 23	Rev. 4
1.4	**Accreditation Application**	3	02 Mar 23 03 Mar 23	Rev. 2
2.0	**Scheduling Audits**	7	02 Mar 23 03 Mar 23	Rev. 6
2.1	**Auditor Qualification**	7	15 Mar 19 29 Mar 19	Rev. 6
2.2	**Laboratory Accreditation Audits**	9	03 Mar 23 03 Mar 23	Rev. 8
2.3	**Laboratory Accreditation Desk Audits**	1	01 Mar 21 03 Mar 21	Rev. 0
2.4	**On-site Observation of Assessors**	1	11 Mar 19 14 Mar 19	Rev. 0
3.1	**Receipt and Administrative Review of Accreditation Applications**	4	03 Mar 23 15 Mar 21	Rev. 3
3.2	**Technical Review of Applications for Primary Accreditation**	3	01 Mar 17 15 Mar 17	Rev. 2
3.3	**Review of Applications for Secondary Accreditation**	3	15 Mar 19 29 Mar 19	Rev. 2
3.4	**Final Action on Accreditation Applications**	3	12 Mar 21 15 Mar 21	Rev. 2
4.1	**National Laboratory Accreditation Database**	4	15 Mar 19 29 Mar 19	Rev. 3
4.2	~~**Notification of Accreditation Program Changes**~~	Rescinded	24 Oct 12	Rev. 1

5.1	**Confidential Business and National Security Information**	3	15 Mar 19 29 Mar 19	Rev. 2
5.2	**Evaluation of Changes in a Laboratory's Key Accreditation Criteria**	2	01 Mar 17 15 Mar 17	Rev. 1
5.3	**Receipt and Evaluation of Proficiency Test Samples**	7	05 Feb 24	Rev. 6
5.4	**Reports of Potential Non-conformances and Potentially Illegal Laboratory Practices**	3	05 Sep 18 06 Sep 18	Rev. 2
6.0	**Suspension and Revocation**	4	03 Mar 23 03 Mar 23	Rev. 3
6.1	**Voluntary Reduction or Withdrawal of Accreditation**	4	31 Mar 21 29 Mar 21	Rev. 3
7.0	**Document and Records Management**	3	01 Mar 17 15 Mar 17	Rev. 2
7.1	**Laboratory Accreditation Procedures**	3	15 Mar 19 29 Mar 19	Rev. 2
7.2	**Records Specialist Procedures**	2	27 Oct 23 01 Nov 23	Rev. 1
7.2	**Guidance for Laboratory Accreditation Procedure 7.2**	0	27 Oct 23 01 Nov 23	N/A

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 1.0

PROGRAM MANAGEMENT: QUALITY MANAGEMENT PLAN, QUALITY POLICY STATEMENT, OPERATIONAL STANDARDS, ORGANIZATION, KEY PERSONNEL, AND INTERNAL QUALITY ASSURANCE AUDITS

Issue Date: 1/15/21 Revision: 7

Effective Date: 1/20/21 Supersedes: Revision 6

Ken Lancaster 1/15/21
Program Manager Date

1/15/2021
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes the quality management plan, quality policy, operational standards, organization, key personnel, and internal quality assurance audit program for the laboratory accreditation program.

2.0 RESPONSIBILITIES

Laboratory accreditation staff are responsible for performing accreditation activities according to operational standards. (See also Figure 2.)

The Program Manager is responsible for:

- managing the accreditation program;
- reviewing the management system annually;
- reporting as necessary to top management on program performance and any need for improvement; and
- signing accreditation certificates.

The Team Leader is responsible for day-to-day direction of accreditation work activities including planning and reviewing audits of environmental laboratories. The Work Group Leader may assist the Team Leader in these activities as directed. In addition, the Team Leader serves as the Deputy Program Manager, fulfilling the duties of the Program Manager as needed.

The Quality Assurance Specialist is responsible for monitoring the accreditation program's quality system and its implementation as well as conducting internal assessments of the laboratory accreditation program.

3.0 PROCEDURES

3.1 Quality Management Plan

The Texas Commission on Environmental Quality's (TCEQ's) current *Quality Management Plan* shall be the quality management plan for the laboratory accreditation program.

3.2 Quality Policy Statement

The "Agency Goals and Philosophy" of the Texas Commission on Environmental Quality's current *Quality Management Plan* shall be the quality policy for the laboratory accreditation program.

3.3. Operational Standards

The authority to create a laboratory accreditation program in Texas has been established by Texas Water Code, Chapter 5, Subchapter R (Sections 5.801 *et seq*) and other statutes and rules adopted by the State of Texas and the Texas Commission on Environmental Quality.

The laboratory accreditation program shall operate according to, and laboratory accreditation staff shall comply with, applicable requirements contained in:

- Texas Water Code Chapter 5, Subchapter R (Sections 5.801 *et seq*) and other statutes adopted by the State of Texas;
- 30 Texas Administrative Code (TAC) Chapter 25, Subchapters A and B, and other rules adopted by the Texas Commission on Environmental Quality;
- National Environmental Laboratory Accreditation Program (NELAP) standards, policies, and procedures concerning the accreditation program, including standards of professional conduct for auditors;
- agency-wide policies and procedures, including Operational Policies and Procedures (OPPs) concerning professional guidelines, general workplace policies, and the *Quality Management Plan*; and
- procedures implemented by the laboratory accreditation program.

Laboratory accreditation operations and activities performed by laboratory accreditation staff shall be confined to requirements, audits, and decision-making processes for an accredited laboratory and to those matters specifically related to the fields of testing of the accreditation being sought by a laboratory.

Laboratory accreditation operations and activities performed by laboratory accreditation staff shall:

- not restrict the size, large or small, of any laboratory seeking accreditation;
- not require membership or participation in any laboratory or other professional association;
- not impose any financial conditions or restrictions for participation in the accreditation program other than the fees authorized by law or rule;
- ensure any related bodies do not compromise the confidentiality, objectivity, and impartiality of program operations or accreditations issued by TCEQ.

3.4 Certificates

The Program Manager may sign laboratory accreditation certificates. The Monitoring Division Deputy Director, Director for the Office of Compliance and Enforcement, and the Texas Commission on Environmental Quality's Executive Director and Deputy Executive Directors may also sign laboratory accreditation certificates.

3.5 Organization

The laboratory accreditation program shall be organized as a program within the Texas Commission on Environmental Quality's Office of Compliance and Enforcement, Monitoring Division, Laboratory and

Quality Assurance Section. The agency's organizational arrangements are shown at www.tceq.texas.gov/agency/organization. Program organization is shown in Figure 1.

3.6 Key Personnel

The Laboratory and Quality Assurance Section Manager shall be the Program Manager for Laboratory Accreditation and the individual responsible for day-to-day management of the Texas Commission on Environmental Quality's environmental laboratory accreditation program.

The Laboratory Accreditation Team Leader shall be the individual responsible for day-to-day direction of laboratory accreditation work activities with the assistance of the Work Leader. The accreditation Team Leader may assume duties of the Program Manager on an as needed basis.

Key personnel for the laboratory accreditation program shall include the Program Manager, the Laboratory Accreditation Team Leader, and the Laboratory Accreditation Work Group Leader (Figure 1).

3.7 Internal Quality Assurance Audits

The Quality Assurance Specialist shall conduct systematic quality assurance audits of the laboratory accreditation program. The Quality Assurance Specialist shall assess, and the Program Manager shall review information and documents concerning the:

- program's compliance with standards for accreditation, including the program's quality system;
- adequacy of the accreditation program's documents, procedures, and resources;
- effectiveness of the program's operations and quality system;
- authority for laboratory accreditation;
- auditor training and internal audit program;
- list of names of qualified laboratory auditors and technical support personnel with areas of responsibility, education, and experience;
- requirements for granting, maintaining, denying, withdrawing, suspending, and revoking laboratory accreditation;
- laboratory accreditation process, including extending or reducing its activities and reacting to demands of interested parties;
- laboratory accreditation fees;
- rights and duties of accredited laboratories; and
- listing of laboratories accredited by the Texas Commission on Environmental Quality.

Internal audits should normally be conducted annually. With the concurrence of the Program Manager, the Quality Assurance Specialist may reduce the frequency of internal audits to every three years if the audit results and other evidence demonstrate the quality system has been effectively implemented and has proven stability.

NOTE: Renewal of the program's recognition as an accrediting body without conditions is objective evidence the program demonstrated acceptable performance during on-site evaluations.

The Quality Assurance Specialist must be qualified, independent of the activities to be audited, and knowledgeable in accreditation, auditing, and the requirements of standards for accreditation.

The audits shall be planned, scheduled, and conducted according to requirements contained in the standards for accreditation, OPPs 18.09.01 and 18.09.02, and Chapter 10 of the Texas Commission on Environmental

Quality's *Quality Management Plan*. A written record of the review, including any identified opportunities for improvement, shall be maintained. The Program Manager or designee shall revise documents pertaining to the accreditation program within 30 days when the review reveals that the program has changed or is otherwise different.

3.8 Nonconformances and Preventive Actions

Nonconformances identified during the course of work, from complaints, or in internal quality assurance audits shall be addressed as specified in the Texas Commission on Environmental Quality's *Quality Management Plan*.

Preventive actions and opportunities for improvement can arise from internal audits, management reviews, and the Continuous Improvement Process (CIP). Effectiveness of preventive actions will be assessed, at a minimum, during annual management reviews. Staff members are encouraged to suggest ways of improving processes and procedures using the CIP as follows.

- Obtain all forms described below from the "Forms" folder on the shared drive.
- Staff members or management who determine there is an opportunity to improve a process or procedure submit a *Continuous Improvement Recommendation* Form to the QA Specialist and Program Manager or designee for review.
- The QA Specialist and Program Manager or designee assign a unique CIP number, review the recommendation, and determine if it should be implemented, not implemented, or warrants investigation.
- If the action is not to be implemented, the reason is documented in the comments section and the CIP is closed.
- If the action is to be implemented, the CIP is closed, appropriate changes are made in associated quality documents (LAP, QMP, etc.), and the changes are implemented upon approval of these documents.
- If the action warrants investigation, the QA Specialist and Program Manager or designee develop and approve an action plan containing a trial period and assign an effective date to the action plan. The effective date must be at least one day after the approval date. The effective date is documented on the *Continuous Improvement Action Plan* form. If revisions to the plan are needed, the *Continuous Improvement Action Plan Addendum* form is used to document the revised plan, approval, and effective date of the new action plan.
- Staff implements the new procedure on the effective date.
- At the conclusion of the trial period, the QA Specialist and Program Manager or designee document the metrics of the action plan and determine if the new process or procedure will be formally implemented. This is documented on the *Continuous Improvement Evaluation* Form.
- If the new process or procedure will not be formally implemented, a CIP inactivation date is assigned and recorded on the *Continuous Improvement Evaluation* Form, and staff reverts to the previous process or procedure. The reason the procedure will not be implemented is documented in the comments section.
- If the new process or procedure will be formally implemented, staff continues to follow the new process or procedure documented in the action plan until the revision of the associated quality document (LAP, QMP, etc.).
- The CIP documentation is retained.

3.9 Management Reviews

The Program Manager shall review the management system to ensure its continuing adequacy and effectiveness in satisfying relevant requirements, including standards for accreditation and stated policies and objectives. The review shall consider, where available, current performance and improvement opportunities related to:

- results of audits;
- results of peer evaluation;
- feedback/demands from interested parties;
- new areas of (extending) accreditation;
- trends in nonconformities;
- status of corrective actions;
- status and opportunities for preventive actions;
- status of actions from earlier management reviews;
- fulfillment of objectives;
- changes that could affect the management system;
- appeals; and
- analysis of complaints.

The results of the review shall include actions to:

- improve the management system and its processes;
- improve services and accreditation processes in conformity with relevant standards and expectations of interested parties;
- address resource needs; and
- define or redefine policies, goals and objectives.

The review of the previous fiscal year activities will be conducted by December 31st of each calendar year.

4.0 DOCUMENTS AND RECORDS

OPPs 18.09.01 and 18.09.02 and Chapter 10 of the Texas Commission on Environmental Quality's *Quality Management Plan* define documents and records associated with planning, scheduling, and conducting quality assurance audits.

Other documents and records produced by this procedure include:

- internal audit records, including corrective actions taken;
- management review records, including actions taken;
- Personnel Commitment Forms; and
- CIP Forms.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 2/9/09
Revision 2, Effective date: 2/10/12
Revision 3, Effective date: 10/24/12
Revision 4, Effective date: 6/5/15
Revision 5, Effective date: 10/23/15
Revision 6, Effective date: 1/17/19

Revisions to this document:

- Updated the titles of the Monitoring Division Director to Monitoring Division Deputy Director and Deputy Director for the Office of Compliance and Enforcement to Director for the Office of Compliance and Enforcement. Updated the webpage information for the TCEQ organizational structure. *Section 3.4 and Section 3.5*

Figure 1
LABORATORY ACCREDITATION PROGRAM AND KEY PERSONNEL

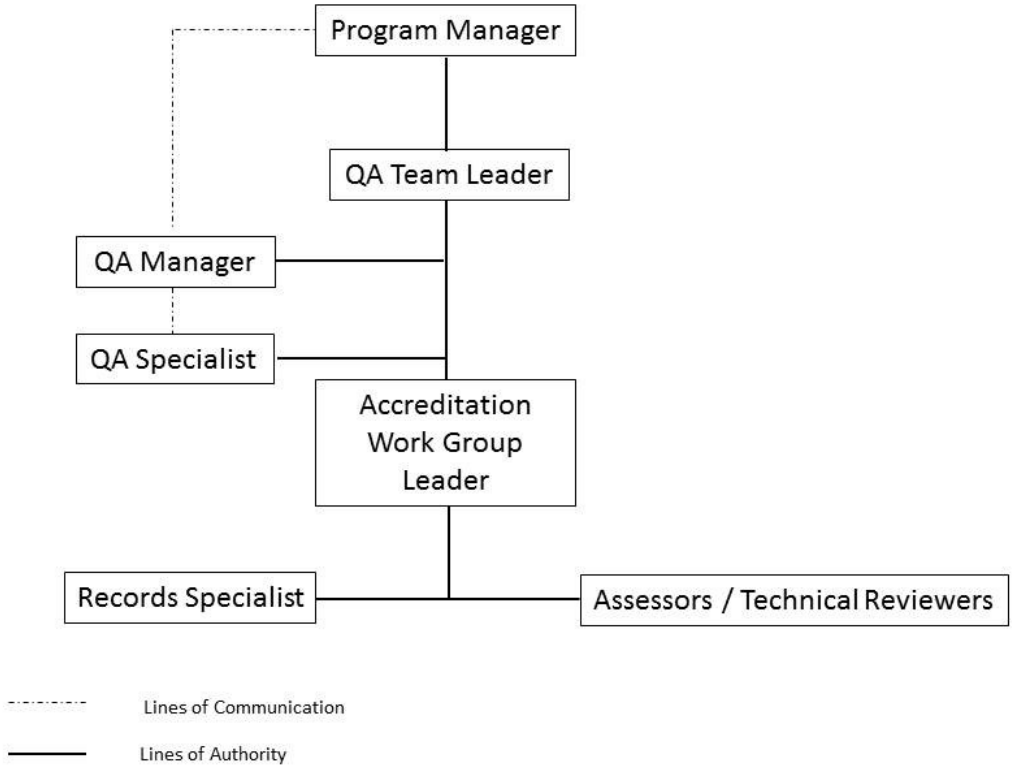

Figure 2
Example Personnel Commitment Form

I have read, understand, and will comply with rules pertaining to the laboratory accreditation program (LAP 1.0, Section 3.3 Operational Standards).

_____ _____

Signature Date

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 1.1

TERMS AND DEFINITIONS

Effective Date: 02/05/2024 Revision: 7

Supersedes: Revision 6

02/01/2024
Program Manager Date

02/02/2024
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes terms and definitions relating to the accreditation of environmental laboratories.

2.0 RESPONSIBILITIES

This procedure does not assign responsibilities.

3.0 TERMS AND DEFINITIONS

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in required documents.

Accreditation: Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. An authorization granted to a laboratory that meets requirements of 30 TAC Chapter 25, Subchapters A and B, conveying formal demonstration of its competence to carry out specific tasks. Primary accreditation is issued to a laboratory based on the laboratory's conformance to the standards for accreditation and other requirements adopted by the Texas Commission on Environmental Quality, e.g., payment of fees. Secondary accreditations are issued to a laboratory based on an accreditation issued by another NELAP accreditation body and other requirements adopted by the Texas Commission on Environmental Quality.

Accreditation Application: For primary accreditation, an accreditation application consists of a completed accreditation application form, fee receipt, laboratory quality manual, laboratory procedures, performance data (e.g., data for detection limits and demonstrations of capability), and any required proficiency test results submitted by a proficiency test provider. For secondary accreditation, an accreditation application consists of a completed accreditation application form and fee receipt.

Accreditation Body: Authoritative body that performs accreditation. Note: The authority of an accreditation body is generally derived from government.

Accreditation Body Logo: Logo used by an accreditation body to identify itself.

Accreditation Certificate: Formal document or a set of documents, stating that accreditation has been granted for the defined scope.

Accreditation Symbol: Symbol issued by an accreditation body to be used by accredited laboratories to indicate their accreditation status.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.

Advisory Group: Any group that includes non-agency members that is created by the executive director or agency staff for the purpose of seeking advice, recommendations, input, or suggestions from interested persons on a rule or other policy matter within the agency's jurisdiction. The term includes stakeholder groups, workgroups, ad hoc work groups, ad hoc stakeholder groups, advisory committees, advisory councils, regulatory forums, etc. An advisory group does not include a public meeting or public hearing conducted by the agency.

Amendment - A change to a scope of accreditation for a laboratory.

Analyst: The designated individual who performs the "hands-on" analytical methods and associated techniques, and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

Analyte: A substance, organism, physical parameter, property, or chemical constituents(s) for which an environmental sample is being analyzed.

Analytical Uncertainty: A subset of the Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.

Analytical Method: A scientific technique for determining the chemical, molecular, or pathogenic components of environmental media.

Appeal: Request by a laboratory for reconsideration of any adverse decision made by the accreditation body related to the laboratory's desired accreditation status. Note: Adverse decisions include the following: refusal to accept an application, refusal to proceed with an assessment, corrective action requests, changes in accreditation scope, decisions to deny, suspend, or withdraw accreditation, and any other action that impedes attainment of accreditation.

Assessment: Process undertaken by an accreditation body to assess the competence of a laboratory, based on particular standard(s) and/or other normative documents and for a defined scope of accreditation. Note: Assessing the competence of a laboratory involves assessing the competence of the entire operations of the laboratory, including the competence of the personnel, the validity of the conformity assessment methodology and the validity of the conformity assessment results.

Assessment Checklist: A document that lists items and activities to be assessed, questions to be asked, and includes forms to be used during an assessment.

Assessment Objective: The purpose of an assessment.

Assessment Plan: A document that identifies the laboratory being assessed, assessment scope, assessment objective, schedule, members of an assessment team, and other information relating to an assessment.

Assessment Sample: The items and activities selected for purposes of an assessment.

Assessment Scope: The organizations, items, activities, assessment bases, and time period that will be assessed.

Assessor: Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a laboratory.

Assessor-in-Training: A person training to become an assessor. An assessor-in-training is not qualified to conduct unsupervised assessments.

Balanced Representation: For advisory groups, membership represents a diversity of viewpoints on issues to be discussed. Characteristics of balanced representation include geography; income levels; ethnicity; business (different sizes and types); governments (different sizes and levels); trade groups, associations, or organizations; consumer and public interest groups; industries or occupations regulated or directly affected by the agency; consumers of services provided either by the agency or by industries and occupations regulated by the agency.

Batch: Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.

- A **preparation batch** is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the abovementioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group.
- An **analytical batch** can include prepared samples originating from various quality system matrices and can exceed twenty (20) samples.

Bias: The systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Blank: A sample that has not been exposed to the analyzed sample stream to monitor contamination during sampling, transport, storage, or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

- **Method Blank**: A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

- In calibration support equipment, the values realized by standards are established with reference materials that are traceable to the International System of Unit (SI).
- In calibration according to methods, the values realized by standards are typically established using Reference Materials that are either purchased by the laboratory with a certificate of analysis (COA) or purity or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

Calibration Curve: The mathematical relationship between the known values of a series of calibration standards and their instrument response.

Calibration Standard: A substance or reference material used for calibration.

Certified Reference Material (CRM): Reference material, accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute.

Chain of Custody Form: Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses.

Comments: Statements made by assessors in an assessment report to assist a laboratory. Comments do not require corrective action or response from the laboratory.

Complaint: An expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited laboratory, where a response is expected.

Confidential Business Information: Any document or record provided by a laboratory while applying for or maintaining accreditation that is labeled as "Confidential Business Information," "Trade Secret," or similar phrase.

Confirmation: Verification of the identity of a component using an approach with a different scientific principle from the original method.

Conflict of Interest: A condition or circumstance that makes a person unable or potentially unable to act or deliver services impartially resulting from activities or relationships with other persons, or a condition or circumstance that makes a person obtain or potentially obtain an unfair competitive advantage.

Conformity: An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also, the state of meeting the requirements.

Conformity Assessment Body (CAB): Body that performs conformity assessment services and that can be the object of accreditation.

Consultancy: Participation in any of the activities of the conformity assessment body subject to accreditation. Examples include preparing or producing manuals or procedures for a CAB, participating in the operation or management of the system of a CAB, giving specific advice or specific training towards the development and implementation of the management system and/or competence of a CAB, and/or giving specific advice or specific training for the development and implementation of the operational procedures of a CAB. Consultancy does not include information and assistance provided by governmental agencies.

Contractor: Any organization or individual that contracts to furnish services or items or to perform work; a supplier in a contractual relationship.

Controlled Document: A document which is identifiable and for which revisions and removal from use can be tracked. The process of document control manages the revisions of documents, ensuring that only the latest version is available to its users. At a minimum, the document control process must perform the following functions: edit, review, approval, revision, and distribution.

Corrective Action: An action taken to address the effect(s) of a nonconformity, defect, or other undesirable situation (e.g., repair, rework); eliminate the causes of the nonconformity, defect, or other undesirable situation; and prevent recurrence.

Critical Nonconformity: A nonconformity having a significant effect on data quality of defensibility including any repeat nonconformities from a previous assessment.

Customer: Any individual or organization for whom items or services are furnished or work is performed in response to requirements and expectations.

Data Integrity: The condition that exists when data are sound, correct, and complete, and accurately reflect activities and requirements.

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculation, standard curves, and concentration factors, and collating them into a more useful form.

Demonstration of Capability: A procedure to establish the ability of the analyst to perform analyses with acceptable accuracy and precision.

Deputy Program Manager for Laboratory Accreditation: An individual who can fulfill the roles of the Program Manager as needed.

Division Director: A functional title that refers to the Monitoring Division Director.

Document: Written, electronic, or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Expert: Person assigned by an accreditation body to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed.

Extending Accreditation: Process of enlarging the scope of accreditation.

Field of Accreditation (FoA): The matrix, technology/method, and analyte combinations for which an environmental testing laboratory may be accredited.

Field of Proficiency Testing (FoPT): Matrix, technology/method, analyte combinations for which the composition, spike concentration ranges, and acceptance criteria have been established by the Proficiency Testing Program Executive Committee.

Finding: See nonconformity.

Holding Times: The maximum time that can elapse between two (2) specified activities.

Interested Parties: Parties with direct or indirect interest in accreditation. NOTE: Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests of those who use or rely on accredited conformity assessment services.

Internal Audit: Audit conducted by the Quality Assurance Specialist to measure the performance, effectiveness, and conformance of the environmental laboratory accreditation program to operational standards.

Internal Standard: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.

International Organization for Standardization (ISO): An independent, non-governmental international organization. It brings global experts together to agree on best practices, from making products to managing processes.

Key Accreditation Criteria: A laboratory's ownership, location, key personnel, major instrumentation, and other items and activities for which a change could alter or impair a laboratory's capability and quality.

Laboratory/Environmental Laboratory: A scientific laboratory that performs analyses to determine the chemical, molecular, or pathogenic components of environmental media for regulatory purposes. The laboratory performs conformity assessment services and that can be the object of accreditation.

Laboratory Accreditation Assessment: The process used to measure the performance, effectiveness, and conformity of an environmental laboratory to the standards for accreditation. An assessment may include a physical inspection of a laboratory and its operations.

Laboratory Accreditation Procedure (LAP): A written document establishing organizational arrangements, roles, responsibilities, systems, processes, standards, and requirements for the laboratory accreditation program.

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes and taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

Lead Assessor: Assessor who is given the overall responsibility for specified assessment activities and is qualified to organize and direct assessments.

Limit of Detection (LOD): The minimum result, which can ben reliably discriminated from a blank with a predetermined confidence level.

Limit of Quantitation (LOQ): The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

Lot: A definite amount of material produced during a single manufacturing cycle and intended to have uniform character and quality.

Management: Those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management System: A structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management System Review: A review to evaluate and document the management policies and procedures used to plan, implement, assess, and correct the technical activities for environmental programs,

as well as note good practices and suggested changes for improving the quality systems that support data for defensible environmental decisions. The MSR may be based upon document review, file examination, and interviews of managers and staff responsible for environmental data and operations. The review consists of the following areas: adequacy and completeness of the policies, procedures, and deviations to meet the objectives of the accreditation program; workload, accreditation program information, and adequacy of resources (e.g., staffing, subcontracts, quality policy statements); managerial reports, including budgets relating to the accreditation program; previous management system review, including a status of action items; internal and external issues that are relevant; outcome of internal audit; accreditation and/or assessment reports prepared by any external body; corrective and preventive actions which includes reviewing corrective and preventive actions for continued effectiveness, compliance, and applicability or necessity, as applicable; surveys, complaints, and personnel feedback; other relevant factors that have impacted the management system (e.g., quality control activities, resources, and staff training); and recommended management system improvements for consideration.

Matrix: The substrate of a test sample, including drinking water, non-potable water, solid and chemical materials, air and emissions, and biological tissue.

Matrix Duplicate: A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision.

Matrix Spike (spiked sample or fortified sample): A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

Measurement System: A method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).

Method: A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Method Detection Limit (MDL): One way to establish a limit of detection.

Minutes: For advisory groups, a note or summary covering points to be remembered from a meeting.

Mobile Laboratory: A portable, enclosed structure with necessary and appropriate accommodation and environmental conditions for a laboratory, within which testing is performed by analysts.

National Environmental Laboratory Accreditation Program (NELAP): The voluntary organization of state, territorial, and federal accreditation bodies whose primary purpose is to grant mutually acceptable accreditations to environmental testing laboratories.

National Institute of Standards and Technology (NIST): A federal agency of the US Department of Commerce's Technology Administration that is designed as the United States national metrology institute (NMI).

Nonconformity: An assessment conclusion referenced to a laboratory accreditation standard and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement. Non-fulfillment of a specified requirement.

Objective Evidence: Information that can be proved true, based on facts obtained through observation, measurement, test, or other means. Objective evidence may include written and electronic documents and records, visual observations, verbal statements, labels, tags, markings, and tests.

Observation: A statement of fact made during an assessment that is supported by objective evidence.

Observer: A member of an assessment team that is not qualified as an assessor or technical specialist. An observer may perform tasks that support an assessment under the guidance and direction of an assessor or technical specialist.

Operating Policies and Procedure (OPP): A document containing information about the Texas Commission on Environmental Quality's policies, practices, and benefits that applies to all agency employees.

Precision: The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.

Preservation: Any conditions under which a sample must be kept to maintain chemical and/or biological integrity prior to analysis.

Primary Accreditation Body (Primary AB): The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation (TCEQ assess with TNI standards).

Procedure: A specified way to carry out an activity or process.

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

Proficiency Testing Program: The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

Proficiency Testing Provider (PT Provider): A person or organization accredited by a TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

Proficiency Test (PT) Sample: A sample, the composition of which is unknown by a 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.

Program Manager for Laboratory Accreditation (Program Manager): A functional title that refers to the individual responsible for day-to-day management of the environmental laboratory accreditation program.

Protocol: A detailed, written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.

Quality Assurance (QA): An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Assurance Manager: A functional title that refers to the individual that coordinates development and implementation of the agency's quality assurance program.

Quality Assurance Specialist for Laboratory Accreditation (Quality Assurance Specialist): A functional title that refers to the lead Quality Assurance Specialist for the laboratory accreditation program.

Quality Control (QC): The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

Quality Control Sample: A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.

Quality Improvement: A management program for improving the quality of operations.

Quality Management Plan: A formal document or manual, describing the quality system in terms of organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory to ensure the quality of its product and the utility of its product to its users.

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, documenting, and assessing work performed by the environmental testing laboratory for quality assurance and quality control.

Quality System Matrix: These matrix definitions are to be used for purposes of batch and QC requirements:

- **Air and Emissions:** Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device.
- **Aqueous:** Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, ground water effluents, and TCLP or other extracts.
- **Biological Tissue:** Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

- **Chemical Waste:** A product or by-product of an industrial process that results in a matrix not previously defined.
- **Drinking Water:** Any aqueous sample that has been designated a potable or potential potable water source.
- **Non-Aqueous Liquid:** Any organic liquid with <15% settleable solids.
- **Saline/Estuarine:** Any aqueous sample from an ocean or estuary, or other saltwater source such as the Great Salt Lake.
- **Solids:** Includes soils, sediments, sludges, and other matrices with >15% settleable solids.

Raw Data: The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.

Record: A document that furnishes objective evidence of activities performed or results achieved.

Records Index: A document that specifies organization and contents of laboratory accreditation documents and records.

Records Retention Schedule: A document that specifies the length of time a record series must be retained in active and inactive storage before final disposition.

Records Specialist for Laboratory Accreditation (Records Specialist): A functional title that refers to the individual responsible for organizing, controlling, receiving, labeling, and maintaining laboratory accreditation records.

Reducing Accreditation: Process of canceling accreditation for part of the scope of accreditation.

Reference Material: Material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Reference Method: A published method issued by an organization generally recognized as competent to do so (for Modules 3-7 in TNI). When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another reference method of the same matrix and technology (for ISO language).

Reference Standard: Standard used for the calibration of working measurement standards in each organization or at a given location.

Revision: A reissued quality assurance document (e.g., LAP). A reissued document is usually identified by a revision, or version, number (e.g., TCEQ Quality Management Plan, Rev. 04) to distinguish it from a superseded and out-of-date document.

Revocation: The total or partial withdrawal of a laboratory's accreditation by an Accreditation Body.

Root Cause: The underlying cause of an adverse condition which, when corrected, will prevent further recurrence of the condition.

Sampling: Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

Scope of Accreditation: Specific conformity assessment services for which accreditation is sought or has been granted. See also Field of Accreditation.

Secondary Accreditation Body (Secondary AB): An accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of accreditation from a Primary Accreditation Body for the same field of accreditation.

Selectivity: The ability to analyze, distinguish, and determine a specific analyte from another component that may be a potential interferent or that may behave similarly to the target analyte within the measurement system.

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.

Standard: The document describing the elements of the laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies.

Standard Operating Procedure (SOP): Written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine and repetitive tasks.

Surveillance: Set of activities, except reassessment, to monitor the continued fulfillment by accredited laboratories of requirements for accreditation. Note: Surveillance includes both surveillance on-site assessments and other surveillance activities, such as the following: inquiries from the accreditation body to the laboratory on aspects concerning the accreditation; reviewing the declarations of the laboratory with respect to what is covered by the accreditation; requests to the laboratory to provide documents and records (e.g. assessment reports, results of internal quality control for verifying the validity of laboratory services, complaint records, management review records); and/or monitoring the performance of the laboratory (e.g. results of proficiency test participation).

Suspending Accreditation: Process of temporarily making accreditation invalid, in full or for part of the scope of accreditation.

Team Leader for Laboratory Accreditation (Team Leader): A functional title that refers to the individual responsible for day-to-day direction of laboratory accreditation work activities.

Technical Review: A process by which a documented critical review of work is or has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical certification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Specialist: A member of an assessment team that has specific scientific or other expertise but is not qualified as an assessor.

Technology: Specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Texas Administrative Code (TAC): A compilation of rules adopted by state agencies.

Traceability: Ability to trace the history, application, or location of an entity by means of recorded identifications.

Verification: Confirmation by examination and objective evidence that specified requirements have been met.

Withdrawing Accreditation: Process of canceling accreditation in full.

Witnessing: Observation of the accrediting body carrying out conformity assessment services within its scope of accreditation. This may also apply to assessors observing testing performed in the laboratory during an assessment.

Work Group Leader for Laboratory Accreditation (Work Group Leader): A functional title that refers to the individual responsible for assisting the Team Leader with day-to-day direction of the laboratory accreditation work activities.

Written Request: Correspondence, electronic mail, and facsimile.

4.0 DOCUMENTS AND RECORDS

No documents or records are produced by this procedure.

5.0 REVISION HISTORY

Revision 0, Effective Date: 6/1/05
Revision 1, Effective Date: 2/10/12
Revision 2, Effective Date: 6/25/12
Revision 3, Effective Date: 03/15/17
Revision 4, Effective Date: 03/29/19
Revision 5, Effective Date: 01/31/20
Revision 6, Effective Date: 02/17/22
Revisions to this document:

Revised document to include and/or modify definitions for amendment, assessor, preparation batch, analytical batch, method blank, calibration, chain of custody form, comment, complaint, confirmation, conformity, controlled documents, critical nonconformity, customer, data reductions, field of proficiency testing, findings, interested parties, International Organization for Standardization, laboratory/environmental laboratory, laboratory control sample, management, management system, management system review, matrix duplicate, matrix spike, matrix spike duplicate, measurement system, method detection limit, nonconformity, preservation, primary accreditation body, proficiency testing provider, quality control sample, quality improvement, quality system matrix, raw data, reference method, revision, revocation, root cause, sampling, secondary accreditation body, selectivity, and technical review. Discontinued use of issued date.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 1.2

TECHNICAL ADVISORY GROUP

Issue Date: ___03/02/23_____ Revision: 4

Effective Date: _____03/03/23_____ Supersedes: Revision 3

	03/02/2023		03/02/2023
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for establishing and operating a laboratory accreditation technical advisory group, as needed.

2.0 RESPONSIBILITIES

The Program Manager or designee is responsible for:

- establishing a technical advisory group;
- preparing and routing an Advisory Group/Committee Creation Form;
- inviting individuals to become advisory group members; and
- periodically convening advisory group meetings.

The Records Specialist or designee is responsible for:

- establishing and maintaining an internet website for advisory group information;
- providing the advisory group's internet address to External Relations Division; and
- preparing and posting meeting minutes on the advisory group's internet site.

3.0 PROCEDURES

3.1 Creation of Technical Advisory Group

With the approval of the Director for the Office of Compliance and Enforcement, the Program Manager may establish a technical advisory group to assist and advise the Texas Commission on Environmental Quality on technical matters relating to the accreditation program.

The group shall be formed and shall operate according to:

- Texas Water Code Section 5.107;
- rules governing advisory groups (30 TAC Chapter 5);
- rules governing the accreditation program (30 TAC Chapter 25, Subchapters A and B); and
- *Guidance for Implementing HB 2912, Section 1.10*.

In establishing the group, the Program Manager shall seek to include a balanced representation and identify:

- specific and potential issues to be addressed by the group;
- potential committee members, their affiliations, and interests; and
- agenda(s) for any planned meeting(s).

The Program Manager shall forward a completed Advisory Group/Committee Creation Form to the External Relations Division, Office of Public Interest Counsel, and the Small Business & Local Government Assistance Section within the Program Support & Environmental Assistance Division for review and comment. These organizations shall have one week to provide comments.

Upon approval by the Director for the Office of Compliance and Enforcement, the Program Manager shall invite potential members to become committee members and forward a copy of the signed Advisory Group/Committee Creation Form to the Monitoring Division Director.

3.2 Membership Term

Group members shall be appointed to two-year terms and may be reappointed.

3.3 Technical Advisory Group

The Records Specialist or designee shall establish an internet site for information concerning the technical advisory group. The Records Specialist or designee shall, at a minimum, make the following information available to the public on the web site:

- names and affiliations of group members; and
- meeting minutes.

Information available to the public on the internet site shall not include any contact information, such as telephone numbers, addresses, or electronic mail addresses for any non-agency personnel.

The Records Specialist or designee shall provide the group's internet address to the External Relations Division for posting on the agency's central advisory group/committee internet site.

3.4 Meeting Conduct

The Program Manager or designee shall periodically convene technical advisory group meetings.

Group meetings should be structured in a way that does not favor one interest over another and provides an opportunity for all members to be heard. Group members should indicate their attendance by signing in or by taking roll.

Within 30 days of a group meeting, the Records Specialist or designee shall prepare and post on the group's internet site meeting minutes to document group actions, such as votes, endorsements, and resolutions.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- completed and signed Advisory Group/Committee Creation Form;
- names and affiliations of group members; and
- group meeting minutes.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 Revision History

Revision 0, Effective Date: 6/01/05
Revision 1, Effective Date: 2/10/12
Revision 2, Effective Date: 3/15/17
Revision 3, Effective Date: 3/03/21

The following revisions were made to this document:

- Updated division names to reflect organizational changes in the agency. *Sections 3.1 and 3.3*
- Updated division names to reflect organizational changes in the agency. *Section 3.1*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 1.3

FIELDS OF ACCREDITATION

Issue Date: 03/03/23 Revision: 5

Effective Date: 03/03/23 Supersedes: Revision 4

	03/03/2023		03/03/2023
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for adopting and revising fields of accreditation for the laboratory accreditation program.

2.0 RESPONSIBILITIES

The Program Manager is responsible for identifying, approving, and revising fields of accreditation and changes to fields of accreditation.

The Records Specialist is responsible for updating, maintaining, and controlling fields of accreditation.

3.0 PROCEDURES

3.1 Fields of Accreditation

The Program Manager shall identify the fields of accreditation available through the laboratory accreditation program. The Records Specialist or designee shall maintain a listing of the fields of accreditation as well as a history of changes to the fields of accreditation on the agency's internet site.

The Program Manager shall ensure the fields of accreditation include all matrices, technologies/analytical methods, and analyte combinations relating to agency decisions, including decisions concerning permits and other authorizations, compliance matters, and enforcement and corrective actions as directed by the program areas.

3.2 Changes to Fields of Accreditation

The Program Manager shall revise the list of fields of accreditation available through the laboratory accreditation program as necessary to include matrices, technologies/analytical methods, and analyte combinations relating to agency decisions and remove fields no longer required for agency decisions. In doing so, the Program Manager shall, to the extent possible, consider such factors as the needs of interested parties, current and anticipated program and personnel competence, the suitability of any program

extensions, available and anticipated resources, including staff and auditor training, as well as related considerations, e.g., external expertise, application and guidance documents.

Changes to the fields of accreditation are effective after approval by the Program Manager or their designee.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include fields of accreditation and changes to fields of accreditation.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 1, Effective Date: 11/20/08
Revision 2, Effective Date: 2/10/12
Revision 3, Effective Date: 03/15/17
Revision 4, Effective Date: 03/03/21

The following revisions were made to this document:

- Added clarification that the Program Manager maintains the fields of accreditation in conjunction with program area FOA requests to reflect current practice. *Section 3.1*
- Update to clarify wording. *Section 3.2*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 1.4

ACCREDITATION APPLICATION

Issue Date: 03/02/23 Revision: 3

Effective Date: 03/03/23 Supersedes: Revision 2

	03/02/2023		03/02/2023
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for adopting and revising application forms for the laboratory accreditation program.

2.0 RESPONSIBILITIES

The Program Manager is responsible for approving application forms.

The Records Specialist is responsible for preparing, maintaining, and controlling application forms.

3.0 PROCEDURES

With the approval of the Program Manager, the Records Specialist shall prepare and maintain one or more application forms to be used by laboratories applying for accreditation; these forms can include applications for initial accreditation, applications to renew or modify accreditation, and applications to reinstate suspended applications (Figure 1).

3.1 Application

At a minimum, applications shall include elements required by the standards for accreditation, including:

- legal name of laboratory;
- laboratory mailing and billing address(es);
- address and geographical location(s) of laboratory;
- laboratory description;
- legal status;
- human and technical resources;
- relationship within larger corporate entity, if applicable;
- name and address of owner;
- name(s) and telephone number(s) of lead and any other technical manager(s);
- name and telephone number of quality assurance officer and laboratory contact person;

- hours of operation;
- primary accreditation body;
- fields of accreditation requested (on a separate fields of accreditation sheet);
- certification of compliance by laboratory management;
- fees;
- laboratory FAX number;
- laboratory identification number(s);
- unique vehicle identification number(s) for mobile laboratory(ies)
- technical manager qualification form for technical managers and
- other information (e.g. manuals, standard operating procedures, completed checklists).

Application forms are effective upon approval by the Program Manager.

3.2 Changes to Application Forms

With the approval of the Program Manager, the Records Specialist shall revise the application form(s) as necessary and ensure the current revision is available internally to laboratory accreditation staff and externally to applicants.

Changes to the application form(s) are effective upon approval by the Program Manager.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include application forms and changes to application forms.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective Date: 6/01/05
Revision 1, Effective Date: 2/10/12
Revision 2, Effective Date: 3/03/21

The following revisions were made to this document:

- Added an issue date to allow time for staff to read and understand LAP before implementation. *Approval section*
- Clarified that not all the application forms listed are required ("can include") to reflect current practices. *Section 3.0*
- Clarified that fields of accreditation requested are on a separate sheet to reflect current practices. *Section 3.1*
- Added a Revision History section to improve documentation of previous revisions of this LAP and to document changes made to this current revision. *Section 5.0*
- Changed "personnel qualification worksheets" to "technical manger qualification form". *Section 3.1*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 2.0

SCHEDULING ASSESSMENTS

Issue Date: ____03/02/23____ Revision: 7

Effective Date: ___03/03/23__ Supersedes: Revision 6

	03/02/2023		03/02/2023
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for scheduling assessments of environmental laboratories seeking accreditation.

2.0 RESPONSIBILITIES

The Program Manager or designee is responsible for:

- preparing, revising, and maintaining a schedule of assessments; and
- approving the assessment schedule.

3.0 PROCEDURES

The Program Manager or designee shall, to the extent practicable, schedule assessments to ensure:

- laboratories applying for initial accreditation are assessed within six months of submitting a complete application;
- accredited laboratories are assessed at least once every two years, plus or minus six months;
- laboratories granted interim accreditation are assessed during the term of the interim accreditation;
- in cases where prior assessment deficiencies are of such severity as to possibly warrant downgrading the laboratory's accreditation status, any follow-up assessments determined by the Program Manager to be necessary are completed and reported within 30 days of receiving a laboratory's corrective action plan;
- in cases where changes in key accreditation criteria require an assessment, a laboratory's capability and quality are assessed in a timely manner;
- the program has adequate resources to perform the assessments as required;
- complaints about accredited laboratories requiring an assessment are investigated in a timely manner; and
- appeals about denials, suspensions, or revocations requiring an assessment are addressed in a timely manner.

The Program Manager or designee may also schedule assessments as necessary for cause, including additional assessments before a final accreditation decision is made, if deficiencies listed in an initial assessment report are substantial or numerous.

3.1 Assessment Schedule

The Program Manager or designee shall prepare a schedule of planned assessments and perform a review to ensure the program has sufficient resources to conduct the scheduled assessments in a timely manner. At a minimum, the schedule shall include the name of the laboratory being assessed, the month or calendar quarter of the assessment, identification of the entity conducting the assessment (i.e. TCEQ, company name of contract assessor), and the Lead Assessor if assessment is being performed by TCEQ.

The following factors are considered when determining the new assessment schedule.

- Length of an on-site assessment: The length of an on-site assessment is determined by the scope of the laboratory's accreditation, the number of assessors on an assessment team, and the size of the laboratory.
- Number of assessors on an assessment team: Laboratories are assigned an adequate number of assessors to complete the assessment in a reasonable period. The assignment of assessors to an assessment team is based on the scope of the laboratory's accreditation, size of the laboratory, and qualifications of individual assessors.
- Qualifications of individual assessors: Each assessor on the assessment team must be qualified and approved by the Program Manager before performing unsupervised assessments. Assessors that have not been approved by the Program Manager must be supervised by a qualified assessor during assessments.
- Composition of prior assessment team: The Program Manager or designee will review which assessors were on the previous assessment, including any complaints, before determining the assessment team. To the extent possible, the same assessors should not routinely assess the same laboratories. Previous complaints shall be considered when assigning an assessor to an assessment team.
- Conflicts of Interest: The Program Manager or designee will not assign an assessor to an assessment team if there is a known conflict of interest.
- Use of contract assessors: The list of all laboratories to be assessed by a contractor is sent out by the Program Manager or designee to all qualified contractors for bidding. The contractor returns the bid, which includes target date of assessments, audit hours, audit cost, travel cost, a not-to-exceed total cost, and any potential conflicts. The Program Manager or designee considers all of these factors, in addition to who performed previous assessments of the laboratory, when determining the successful bidder. Laboratory assessments are assigned to contract assessors when:
    - the laboratory is out of state; or
    - all TCEQ assessors are otherwise unavailable.

The Program Manager or designee should ensure that all laboratories requiring an assessment are included in the schedule.

The Program Manager or designee may revise the assessment schedule, as necessary, to reflect additions, deletions, and changes.

3.2 Approval

The Program Manager, Team Leader, or designee shall approve the assessment schedule before implementation.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include the assessment schedule and bids from contractors.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain these records for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 11/14/08
Revision 2, Effective date: 2/9/09
Revision 3, Effective date: 2/10/12
Revision 4, Effective date: 10/24/12
Revision 5, Effective date: 03/15/17
Revision 6, Effective date: 03/03/21

Revisions to this document:

- Only grammatical revisions were made to the document.
- Removed statement about when the schedule is created. *Section 3.1*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 2.1

ASSESSOR QUALIFICATIONS

Issue Date: 3/15/19 Revision: 7

Effective Date: 3/29/19 Supersedes: Revision 6

Ken Lancaster 3/15/19
Program Manager Date

Karen Allen 3/15/2019
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for the qualification of laboratory assessors.

2.0 RESPONSIBILITIES

Assessors are responsible for:

- demonstrating minimum education and experience;
- completing initial and ongoing training;
- disclosing actual or potential conflicts of interest; and
- signing qualification statements and commitments to comply with accreditation program rules and standards of conduct.

Lead assessors are responsible for:

- demonstrating minimum education and experience;
- completing initial and ongoing training;
- regularly participating in audits or training, professional organizations, or studies relating to auditing;
- disclosing actual or potential conflicts of interest; and
- signing qualification statements and commitments to comply with accreditation program rules and standards of conduct.

The Program Manager or designee is responsible for:

- determining initial and ongoing training requirements;
- approving training courses;
- documenting initial and ongoing qualifications;
- ensuring records of training, experience, and monitoring are kept up-to-date;
- approving assessors and lead assessors;
- monitoring assessor performance;
- ensuring assessors and lead assessors are familiar with accreditation procedures, criteria, and regulations;
- verifying assessors and lead assessors have undergone required training;

- ensuring assessors and lead assessors have a thorough knowledge of relevant audit methods; and
- ensuring assessors and lead assessors are able to communicate effectively, orally and in writing; and have appropriate personal attributes.

3.0 PROCEDURES

3.1 Technical Disciplines

The Program Manager has defined the following technical disciplines:

- Inorganic Chemistry, including Asbestos – Safe Drinking Water Act (SDWA)
- Organic Chemistry – SDWA
- Microbiology – SDWA
- Cryptosporidium- SDWA
- Radiochemistry – SDWA
- Inorganic Chemistry
- Organic Chemistry
- Microbiology
- Metals
- Whole Effluent Toxicity
- Radiochemistry

3.2 Initial Qualification of Assessors

An assessor must be an experienced professional that holds at least a Bachelor's degree in a scientific discipline or have equivalent verified experience in auditing environmental laboratories. An assessor must also successfully complete a training program that includes:

- completion of an approved course in auditing quality systems, such as a basic assessor training course, including attainment of a passing score on the written examination for the course;

- completion of approved technical training courses for all technical disciplines the assessor will audit, including attainment of a passing score on the written examination for each course;

- for assessors with documented experience auditing environmental laboratories, participation in at least one on-site audit under the supervision and observation of a qualified assessor;

- for assessors with no documented experience auditing environmental laboratories, observation of at least two on-site assessments followed by participation in at least two on-site assessments under the supervision and observation of a qualified assessor; and

- formal approval by the Program Manager or designee to perform unsupervised audits based in part on the documented supervising assessor's conclusions.

Figure 3 shows the form that will be used to document the observation of an assessor-in-training.

An assessor may meet these requirements through prior education, training, and experience; education, training, and experience acquired while employed by TCEQ; or a combination of these.

The basic assessor training course and technical training courses may include in-house, commercially available, or combinations of in-house and commercially available training approved by the Program Manager or designee.

The Program Manager or designee has determined technical training courses offered by the U.S. Environmental Protection Agency and its contractors concerning the analysis of microbiological and chemical samples for compliance with the SDWA meet accreditation program requirements.

Participation in audits minimally includes participation in the on-site assessment, but may also include the planning, reporting, and closure activities described in LAP 2.2, Laboratory Accreditation Audits.

Assessors who were employed by the agency when it received approval as an accreditation body have at least a Bachelor's degree in a scientific discipline or equivalent experience in environmental laboratory auditing, have previously conducted four audits, and are judged proficient by the Program Manager or designee are exempt from the requirement to undergo training with a qualified lead assessor unless other requirements (e.g., drinking water delegation agreement) mandate specific or additional technical training.

The Program Manager or designee shall verify each assessor's conformance to minimum assessor qualifications and document any exemptions to training requirements by completing a Laboratory Assessor Qualification Record (Figure 1).

Assessors must also:

- sign qualification statements (Figure 2) attesting they meet the education and training required by the standards for accreditation;
- sign statements (Figure 2) stating their commitment to follow accreditation program rules, including those regarding confidentiality, conflict of interest, and standards of conduct before they participate in their first assessment or whenever the rules to the accreditation of laboratories change;
- be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;
- have a thorough knowledge of the relevant audit methods and audit documents;
- be thoroughly familiar with the various forms of laboratory documents and records reviewed during an audit;
- be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;
- have a working knowledge and be conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling and preservation procedures;
- be able to communicate effectively, both orally and in writing; and
- have appropriate personal attributes.

In all cases, assessors must successfully demonstrate their knowledge, skills, and abilities relating to these areas through effective participation in the planning, on-site assessment, reporting, and closure activities described in LAP 2.2, *Laboratory Accreditation Audits*. Assessors may acquire and demonstrate their knowledge, skills, and abilities relating to these areas through prior education and training; successful completion of on-the-job training; self-study; in-house and commercially

available training; other means as determined by the Program Manager, Team Leader, or designees; or combinations of these.

The Program Manager or designee shall verify an individual's training and experience conform to the preceding minimum requirements for initial assessor qualification and the individual is capable of performing effectively as an assessor, i.e., effectively performing the activities described in LAP 2.2, *Laboratory Accreditation Audits*. The Program Manager or designee shall document the verification and qualification, identifying the specific technical discipline(s) the assessor has demonstrated competence to assess by completing a Laboratory Assessor Qualification Record (Figure 1).

For assessors-in-training, a tabular listing, spreadsheet, or other record that includes the supervising qualified assessor's evaluation of the individual's ability to perform unsupervised audits may be attached to the Laboratory Assessor Qualification Record in lieu of completing section entitled, "Audit Participation." This initial assessor qualification and documentation is in addition to the agency's formal system for communicating performance expectations, achievements, and recommendations for improving performance (Operating Policies and Procedures (OPP) *Performance Management,* OPP 10.02.01).

The Program Manager or designee may waive, amend, or adjust qualification requirements as necessary to assure effective implementation of the accreditation program. The waiver, amendment, or adjustment to qualification requirements must be documented.

3.3 Initial Qualification of Lead Assessors

At a minimum, a lead assessor must have the education and experience, and successfully complete the training of an assessor as well as training addressing the organization and direction of audits.

Training addressing the organization and direction of audits includes participation in audits; in-house and commercially available training; participation in professional organizations; studies relating to auditing; completion of at least one audit as lead assessor under supervision; or combinations of these. Figure 4 shows the form that will be used to document the observation of a lead assessor-in-training.

The Program Manager or designee shall verify that an individual's training and experience conform to the preceding minimum requirements for initial lead assessor qualification and the individual is capable of performing effectively as a lead assessor, i.e., effectively performing the activities of a lead assessor described in LAP 2.2, *Laboratory Accreditation Audits*. The Program Manager or designee shall document the verification and qualification and identify the specific technical discipline(s) the assessor has demonstrated competence to audit, by completing a Laboratory Assessor Qualification Record (Figure 1). This initial lead assessor qualification and documentation is in addition to the agency's formal system for communicating performance expectations, achievements, and recommendations for improving performance (Operating Policies and Procedures *Performance Management,* OPP 10.02.01).

The Program Manager or designee may waive, amend, or adjust qualification requirements as necessary to assure effective implementation of the accreditation program. The waiver, amendment, or adjustment to qualification requirements must be documented.

3.4 Ongoing Assessor Qualification and Maintenance of Proficiency

Assessors are expected to maintain proficiency on an ongoing basis. Refresher training will be provided as available and as deemed necessary by the Program Manager or designee to ensure

assessors are aware of changes to accreditation standards and/or approved analytical methodology and to enhance and improve audit skills. The refresher training will cover the following:

- changes to the standards for accreditation and any resulting checklist changes;
- new standards interpretations;
- technical changes and the resulting checklist changes associated with approved methodology;
- audit skills and techniques; and
- current developments.

At a minimum, assessors shall maintain their proficiency by successfully completing assigned refresher training and participating in audits.

Refresher training includes in-house, commercially available, or combinations of in-house and commercially available training approved by the Program Manager or designee as meeting the requirements of the accreditation program.

The Program Manager or designee shall verify that an individual's training and experience conform to the preceding minimum requirements for ongoing assessor qualification and the individual continues to be capable of performing effectively as an assessor, i.e., effectively performing the activities described in LAP 2.2, *Laboratory Accreditation Audits*. This verification will be based on monitoring, such as on-site observations, review of audit reports, laboratory feedback, and peer monitoring, which will also be used to identify training needs and other actions intended to improve assessor performance. The conduct of the observations, the resulting evaluation by the Program Manager, and documentation requirements are described in LAP 2.4, *Ongoing Observation and Evaluation of Assessors*. This ongoing assessor qualification and documentation is in addition to the agency's formal system for communicating performance expectations, achievements, and recommendations for improving performance (Operating Policies and Procedures *Performance Management,* OPP 10.02.01).

The Program Manager or designee may waive, amend, or adjust qualification requirements as necessary to assure effective implementation of the accreditation program. The waiver, amendment, or adjustment to qualification requirements must be documented.

3.5 Ongoing Lead Assessor Qualification and Maintenance of Proficiency

Lead assessors shall maintain their proficiency by successfully completing refresher training for assessors and participating in:

- audits;
- training, professional organizations, or studies relating to auditing; or
- a combination of these.

The Program Manager or designee shall verify that an individual's training and experience conform to the preceding minimum requirements for ongoing lead assessor qualification and the individual continues to be capable of performing effectively as a lead assessor, i.e., effectively organizing and performing the activities of a lead assessor described in LAP 2.2, *Laboratory Accreditation Audits*. This verification will be based on monitoring, such as on-site observations, review of audit reports, laboratory feedback, and peer monitoring, which will also be used to identify training needs and other actions intended to improve assessor performance. The conduct of the observations, the resulting evaluation by the Program Manager, and documentation requirements are described in LAP 2.4, *Ongoing Observation and Evaluation of Assessors*.

This ongoing lead assessor qualification and documentation is in addition to the agency's formal system for communicating performance expectations, achievements, and recommendations for improving performance (Operating Policies and Procedures *Performance Management,* OPP 10.02.01).

The Program Manager or designee may waive, amend, or adjust qualification requirements as necessary to assure effective implementation of the accreditation program. The waiver, amendment, or adjustment to qualification requirements must be documented.

3.6 Standards of Conduct

Assessors and lead assessors shall also comply with standards of conduct contained in OPP Chapter 12, *Professional Guidelines and General Workplace Policies*, and the standards for accreditation concerning professional conduct for assessors. Assessors and audit team members shall:

- act in an impartial and non-discriminatory manner;
- have no interests at play other than those of the accreditation body during the entire accreditation process;
- act impartially and not give preferential treatment to any organization or individual;
- not hold financial interests that conflict with the conscientious performance of their duties;
- not engage in financial transactions using information gained through their positions as assessors to further any private interest;
- not knowingly make unauthorized commitments or promises of any kind purporting to bind an accreditation body;
- attempt to avoid any actions that could create the appearance that they are violating any of the standards of professional conduct outlined here; and
- not have provided consultancy to a laboratory which might compromise the accreditation process and decision.

3.7 Conflict of Interest

As soon as possible and before participating in any audit, an assessor must disclose any existing, former, or envisaged link or competitive position between themselves and the laboratory to be assessed as well as any present or former relationships, associations, or investments that might reasonably influence or appear to influence the assessor's judgment, discretion, or impartiality. The disclosure shall be made in writing to the Program Manager or designee. Failure to provide this information will make the proposed assessor ineligible to participate in the audit program

If an assessor becomes aware of previously unforeseen conflicts of interest during the on-site assessment, the lead assessor shall consult with the Program Manager or designee, as soon as practicable, to determine how to proceed. The Program Manager shall take action to ensure that the assessment can proceed without compromising the integrity and impartiality of the assessment, if possible. Otherwise, the assessment shall be terminated. A new assessment team will be appointed as soon as practicable such that the laboratory's accreditation is not jeopardized.

When possible, the Program Manager will ensure that an assessor that has previously worked at a laboratory will not be assigned to assess that laboratory for at least five years from the date of their last employment with the laboratory to be assessed. If not possible, the Program Manager will employ other measures to ensure there is no conflict of interest, such as the Program Manager or designee observing the audit.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- assessor qualification forms and any attachments, e.g. work experience, supervising assessor observations, and results of monitoring;
- assessor qualification, commitment, and conflict of interest form(s); and
- equivalent records for contracted individual external assessors and experts, including the positions held in their organizations.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 11/14/08
Revision 2, Effective date: 2/9/09
Revision 3, Effective date: 2/10/12
Revision 4, Effective date: 10/24/12
Revision 5, Effective date: 06/05/15
Revision 6, Effective date: 05/08/17

The following revisions were made to this document:

- Removed references to timing and conduct of onsite observations and referenced LAP 2.4 since timing is covered in LAP 2.4. *Sections 3.4 and 3.5*
- Added a procedure for dealing with unforeseen conflict of interest that arise during an onsite assessment to ensure that the requirements in the TNI Standard are satisfied. *Section 3.7*

Figure 1
Example Laboratory Assessor Qualification Record

RECORD OF ASSESSOR QUALIFICATION							
Name:				Title:			
Organization:							
Mailing Address:							
City:		State:		Zip Code:			
Education							
Degree	Field of Study	University/College				Date	
Assessor/Lead Assessor Training							
Basic Assessor Training:							
Basic Assessor Training:							
Technical Training for Assessors:							
Technical Training for Assessors:							
Technical Training for Assessors:							
Assessor Refresher/Update Training:							
Assessor Refresher/Update Training:							
Professional Accomplishment:							
Professional Accomplishment:							
Lead Assessor Training:							
Technical Disciplines							
Inorganic Chemistry - SDWA		Radiochemistry - SDWA		Metals			
Organic Chemistry - SDWA		Inorganic Chemistry		Whole Effluent Toxicity			
Microbiology - SDWA		Organic Chemistry		Radiochemistry			
Cryptosporidium - SDWA		Microbiology					
*EPA DW Certification Courses							
Audit Observations (*no participation, observation only*)							
Auditee						Date	
Audit Participation *(assessor-in-training only)*							
Auditee						Date	

Audit Participation *(lead assessor-in-training)*	
Auditee	Date

Evaluation as Participatory Member for Assessing Quality Systems	
Date:	
Approval Initials:	

Evaluation as Participatory Member for Assessing Methods	
Date:	
Approval Initials:	

Evaluation as Lead Assessor	
Date:	
Approval Initials:	

Figure 2
Example Laboratory Assessor Commitment and Qualification Statement and Conflict of Interest Disclosure Form

☐ I meet the education and training relating to the qualification of laboratory accreditation assessors required by the standards and will comply with applicable agency rules concerning laboratory accreditation, including those relating to confidentiality and independence from commercial and other interests and any prior associations with laboratories to be assessed.

☐ To the best of my knowledge, I do not have any present or former relationships, associations, or investments that might reasonably influence or appear to influence my judgment, discretion, or impartiality. If I become aware of a previously unforeseen conflict of interest during an assessment, I will contact the Laboratory Accreditation Program Team Leader, as soon as practicable, to determine how to proceed.

☐ I do have present or former relationships, associations, or investments that may reasonably appear to influence my judgment, discretion, or impartiality. The relationships, associations, or investments are:

_____
Name

_____ _____
Signature Date

Figure 3
Example Assessor-in-Training Observation Form

Assessor-in-Training:
Observer:
Laboratory:
Assessment Date(s):

Assessment Participation *(check all that apply)*

☐ Quality Systems (specify components):

-
-
-
-

☐ Analytical Methods (list methods and matrices):

-
-
-
-
-
-

☐ Wrote findings

Conclusions

Did the assessor-in-training demonstrate knowledge of accreditation procedures and criteria and other related requirements; a thorough knowledge of relevant assessment methods; the ability to communicate effectively, both in writing and orally; and appropriate personal attributes and is he/she capable of performing independent assessments for **methods**?: (c*heck one and provide additional comments; if "No" is checked provide more information below*)

☐ Yes ☐ No ☐ N/A

Did the assessor-in-training demonstrate knowledge of accreditation procedures and criteria and other related requirements; a thorough knowledge of relevant assessment methods; the ability to communicate effectively, both in writing and orally; and appropriate personal attributes and is he/she capable of performing independent assessments for **quality systems?:** (c*heck one and provide additional comments; if "No" is checked provide more information below)*

☐ Yes ☐ No ☐ N/A

The assessor-in-training is not prepared to perform independent assessments and should participate in additional supervised assessments. The following areas need improvement (*check all that apply and provide additional comments*):

- ☐ Knowledge of accreditation procedures and criteria and other related requirements
- ☐ Knowledge of relevant audit methods
- ☐ Ability to communicate effectively, orally
- ☐ Ability to communicate effectively, in writing
- ☐ Personal attributes
- ☐ Other:_____

Additional Comments *(e.g., quantity/quality of work, opportunities for improvement, positive feedback)*

_____ _____

Observer Date

Figure 4
Example Lead Assessor-in-Training Observation Form

Lead Assessor-in-Training:
Observer:
Laboratory:
Assessment Date(s):

Assessment Participation *(check all that apply)*

- ☐ Prepared assessment schedules, plans, and checklists
- ☐ Provided written notification to auditee and requested and received written confirmation from the laboratory
- ☐ Provided assessment plans, checklists, and reference documents to assessment team members
- ☐ Determined roles and responsibilities of assessment team members
- ☐ Prepared travel authorizations and reserved vehicle for trip
- ☐ Conducted opening meeting
- ☐ Conducted daily debriefs, if applicable and exit meeting
- ☐ Wrote and submitted report to the laboratory

Conclusions

Did the lead assessor-in-training demonstrate the ability to lead an assessment, including the ability to plan the assessment; notify the laboratory and obtain written confirmation; determine roles and responsibilities of the assessment team; provide necessary documents to the assessment team; plan travel; conduct effective meetings; communicate effectively in writing; write a report that accurately and clearly presents the findings; and meet applicable deadlines and is he/she capable of performing independent assessments as a **lead assessor**?: (*check one and provide additional comments; if "No" is checked provide more information below*)

☐ Yes ☐ No

The lead assessor-in-training is not prepared to lead assessments independently and should participate in additional supervised assessments. The following areas need improvement (*check all that apply and provide additional comments*):

- ☐ Preparing assessment schedule/plan and notifying the laboratory
- ☐ Determining roles and responsibilities and providing documents to the assessment team
- ☐ Making travel plans
- ☐ Conducting effective meetings
- ☐ Writing the report
- ☐ Meeting applicable deadlines
- ☐ Other:_____

Additional Comments *(e.g., quantity/quality of work, opportunities for improvement, positive feedback)*

_____ _____

Observer Date

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 2.2

LABORATORY ACCREDITATION AUDITS

Issue Date: 03/03/23 Revision: 9

Effective Date: 03/03/23 Supersedes: Revision 8

	03/03/2023		03/03/2023
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for conducting audits pertaining to the accreditation of environmental laboratories. The current standards for accreditation, that were adopted by the National Environmental Laboratory Accreditation Program (NELAP) for laboratories performing environmental analyses and accreditation bodies accrediting environmental laboratories, are used.

2.0 RESPONSIBILITIES

Auditees are responsible for:

- participating constructively and effectively in audits;
- identifying liaisons and points-of-contact;
- identifying confidential business information;
- providing the audit team with access to facilities, personnel, documents, records, data, analyses, and operations;
- providing duplicates of documents and records requested by the audit team;
- providing equipment and other resources needed to conduct an audit and mutually agreed upon by the lead auditor and the auditee; and
- completing follow-up actions.

Auditors and technical specialists are responsible for:

- preparing portions of audit plans, checklists, and reports assigned by the lead auditor;
- familiarizing themselves with audit plans, checklists, reference documents, test methods, and measurements; and
- conducting audit tasks assigned by lead auditors.

Lead auditors are responsible for:

- preparing audit schedules, plans, checklists, and reports;

- providing written notifications to auditees;
- providing audit plans, checklists, and reference documents to audit team members;
- communicating travel plans (e.g., dates for hotel stays, hotel being used, etc.) to audit team members
- selecting and determining roles and responsibilities of audit team members;
- briefing audit team members and observers about audits, roles and responsibilities, and any assigned tasks;
- directing the audit entrance and exit meetings as well as the audit;
- suspending an audit, if necessary;
- forwarding technical review documents and completed audit records to the Program Manager or designee;
- sending audit reports to auditees; and
- evaluating corrective action responses and responding to auditees.

The Team Leader or designee is responsible for approving:

- audit team members; and
- audit reports.

Observers and technical specialists are responsible for participating in audits according to arrangements agreed upon with lead auditors. Members of the audit team that provide technical assistance (technical specialists) must meet the requirement of the standard concerning conflicts of interest and professional conduct. Technical specialists who are not qualified as auditors are not eligible to conduct interviews in the absence of the auditor nor cite deficiencies.

The Program Manager is responsible for approving unannounced audits.

3.0 PROCEDURES

3.1 Audit Planning

3.1.1 Selection and Composition of Audit Teams

With the concurrence of the Program Manager, the Team Leader or designee shall determine the composition of audit teams. Audit teams shall include a designated lead auditor and may include additional auditors, lead technical specialists, technical specialists, and observers.

Based on the type of audit and the scope of accreditation of the accredited (or applicant) laboratory, the Team Leader or designee shall ensure the audit team has sufficient personnel, knowledge, skills, training, qualifications, personal attributes, and organizational authority and freedom to perform assigned duties in a timely manner.

The Quality Assurance Manager, quality assurance staff, and designees may, at the request of the Quality Assurance Manager, participate in an audit as an observer.

An auditee may not select audit team members. However, the auditee may object to the appointment of a particular technical specialist or auditor.

Audit team members shall report to the Program Manager as soon as possible, and if at all possible before an audit occurs, any personal issues or activities (e.g., present or former relationships, associations, or

investments) that may constitute a conflict of interest or conflict with OPP Chapter 12, *Professional Guidelines and General Workplace Policies*. The Program Manager shall remove an individual from an audit team if the objections, reported issues, or activities:

- constitute, or could reasonably be construed as constituting a conflict of interest; or
- could jeopardize the achievement of audit objectives.

The Program Manager's decision regarding whether present or former relationships, associations, or investments might influence or reasonably appear to influence an auditor's judgment, discretion, or impartiality and, as a result, whether an auditor may participate in an audit may not be appealed. Figure 1 from this LAP shall be utilized by all assessors.

3.1.2 Audit Team Roles and Responsibilities

The lead auditor shall determine audit activities to be performed by audit team members. The lead auditor shall ensure a sufficient number and variety of systems, methods, and analytical activities are observed to be representative of the laboratory's current and past competence within the scope of accreditation. The scope and complexity of the laboratory's fields of accreditation, as well as areas examined during previous audits, shall be considered when selecting activities to be observed. Activities to be performed by audit team members shall conform to standards for accreditation, which include standards for professional conduct of auditors.

(NOTE: The lead auditor's audit tasks should be minimized in any audit involving multiple auditors or technical specialists.)

3.1.3 Audit Scope and Objectives

Audits assess the performance, effectiveness, and conformity of an environmental laboratory to relevant audit bases. For initial accreditation, the audit scope shall, at a minimum, include the following:

Audit Bases:

- the standards for accreditation that were adopted by NELAP for laboratories performing environmental analyses;
- program standards, including changes to program standards;
- 30 TAC §25, Subchapters A and B; and
- rules, test methods, procedures, and requirements relating to a laboratory's application for accreditation, including participation in and results of proficiency testing.

Items and Activities:

- accreditation application;
- operational components such as facilities, personnel, documents, records, data, and analyses for the scope of accreditation for which a laboratory seeks accreditation; and
- any other items and activities identified in the standards for accreditation.

As required by an EPA mandate, all relevant approved drinking water methods listed in 40 CFR §141 must be audited if a laboratory is to analyze public drinking water samples (including source water). More in-depth procedures for determining the audit scope are provided in Section 3.2.3.

The time period audited during initial audits shall include a period of up to 18 months prior to the date a laboratory submits an application for accreditation.

For biennial audits of accredited laboratories, the audit scope shall include all of the audit bases listed above for an initial audit as well as the following:

- prior audits and corrective action plans; and
- any complaints received by TCEQ.

The time period audited during biennial audits shall include a period up to the date of the last audit or a longer period the lead auditor determines is appropriate in order to meet audit objectives, e.g., verifying completion of corrective actions from a prior audit.

For other audits (e.g., follow-up, complaints, changes in key accreditation criteria), the lead auditor shall determine the audit scope needed to accomplish the audit objective(s).

3.1.4 Audit Schedule

The lead auditor shall determine a detailed audit schedule, including starting and ending dates, sequence of work, and daily work schedules.

(NOTE: A number of factors can affect audit schedules such as: 1) the number of individuals on an audit team, 2) the number and complexity of the organizations, items, documents, records, and activities being audited, 3) holidays, 4) prior commitments, 5) the availability of key personnel, 6) access to facilities, and 7) work schedules.)

3.1.5 Objective Evidence, Audit Tests, and Samples

The lead auditor shall to the extent possible determine the types of objective evidence that are available, relevant, and to be examined during the audit.

(NOTE: Although it may not always be possible or feasible to determine every type of objective evidence before an audit, this should be the goal.)

The lead auditor shall to the extent possible determine audit tests to be made during an audit as well as methods of selecting objective evidence, e.g., judgmental sampling, random sampling.

(NOTE: Audit tests may be qualitative, e.g., interviews to determine standard practices, and visual observations to determine the presence of documents and records or conformance to requirements, or quantitative, e.g., calculations and direct measurements to verify results.)

3.1.6 Audit Plan

The lead auditor shall prepare an audit plan for each audit. An audit plan shall, at a minimum, include:

- name and address of the auditee;
- audit scope and objectives, including any corrective actions to be verified during the audit;
- schedule;
- name(s), credentials, and affiliation(s) of audit team members;

- conflict of interest form (Figure 1);
- audit appraisal form (Figure 2);
- confidential business information form (see Laboratory Accreditation Procedure 5.1, Confidential Business and National Security Information);
- entrance and exit meeting attendance form(s);
- name and telephone number of the auditee's contact person(s); and
- information concerning how the auditee may obtain audit information.

The audit plan is sent to the laboratory at least 30 days prior to the start of the audit, when possible. The lead auditor must obtain confirmation from the laboratory that they received the audit plan.

3.1.7 Audit Checklist

The lead auditor shall use an approved checklist (e.g., the quality systems checklist developed by TNI's Laboratory Quality Systems Expert Committee), if available. The current approved checklist is maintained on the internal network drive (H: drive). If an approved checklist is not available or is insufficient to assess a laboratory's entire scope of accreditation, the lead auditor shall prepare one or more checklists as necessary to address the audit scope and objectives. An audit checklist shall, at a minimum, include questions to be asked and forms to be used. Procedural checklists should be considered when an audit will assess compliance or complex technical activities or verify steps in a process [e.g., analytical methods].

The lead auditor may designate auditors and technical specialists to prepare all or part of the audit checklists.

3.1.8 Audit Notification

For announced and extraordinary audits, e.g., audits related to complaints or significant changes related to a laboratory's accreditation, the lead auditor shall notify auditees in writing at least 30 days prior to the planned date of the entrance meeting. Shorter lead times may occur with the concurrence of the Program Manager, or designee, and the laboratory.

An audit notification must include:
- an audit notification letter or memorandum;
- a copy of the audit plan;
- copies of standardized checklists to be used if there are no copyright restrictions or information on how to obtain copyrighted checklists;
- a request, where applicable, that the auditee confirm in writing its concurrence with any contract auditor or state any objections to the use of the contract auditor; and
- a description of any special requirements, such as work space, key personnel, and specific documents and records.

The lead assessor must obtain written confirmation prior to the assessment verifying the laboratory's concurrence with assessment date(s) and schedule.

(NOTE: Copyright restrictions may prevent distribution of audit checklists. If an audit checklist contains copyrighted language (e.g., ISO language), the lead auditor shall advise the auditee how to obtain the checklist. This can be accomplished by providing a link to a website containing the checklists.)

The lead auditor may not notify an auditee in advance of an unannounced audit.

With the approval of the Program Manager, a lead auditor may plan and lead an unannounced audit, if it is unlikely audit objectives can be accomplished through an announced audit. Unannounced audits may not be used to assign known objectionable auditors. Laboratories may still object to individual auditors at the start of unannounced audits, though they may not do so primarily to avoid or delay the audit.

(NOTE: In certain cases, such as audits of secure facilities, the names of the audit team members, security clearances, and other information, e.g., proof of nationality, may be required in advance in order for the auditee to arrange access to the facility.)

3.1.9 Audit Team Orientation

Prior to conducting an audit, the lead auditor shall ensure audit team members receive a copy of the audit plan and checklist(s) and have access to relevant documents. The lead auditor shall also ensure audit team members are informed of:

- individual roles, responsibilities, and assigned tasks;
- any anticipated changes in the audit plan or schedule; and
- logistical arrangements (e.g., travel, lodging, documents).

Prior to the audit, audit team members shall familiarize themselves with relevant parts of the audit plan and checklist, reference documents (i.e., analytical methods and the current TNI standard), accreditation application, assigned tasks, and relevant laboratory documentation for the tests and activities to be audited.

3.2 On-Site Audit

3.2.1 Entrance Meeting

The lead auditor shall direct an entrance meeting as part of the on-site phase of an audit, unless the auditee's management is unable or unwilling to participate in the meeting. During the entrance meeting, the lead auditor or designee(s) shall:

- introduce members of the audit team;
- review the scope and purpose of the audit;
- review the audit plan, including applicable standards and primary areas, test methods, documents, and records to be examined;
- the audit process;
- confirm roles and responsibilities of key personnel and staff;
- describe procedures related to confidential business information, including the auditee's right to claim any portion of the information requested during the audit as confidential business information;
- describe procedures related to national security information (if applicable);
- identify any auditee points-of-contact and liaisons;
- establish the time and location of any interim meetings with the auditee's representatives;
- confirm access to and the availability of key personnel, documents, records, and required resources (e.g., work areas, telephones, copiers);
- clarify any special security or safety procedures and equipment to be used by the audit team while in the facility;
- determine any changes to the audit plan or schedule that may be needed;
- confirm the location and approximate time of the exit meeting;

- provide a copy of the audit appraisal form; and
- answer questions.

During the entrance meeting, the auditee should be encouraged to describe the status of the laboratory's operations and quality assurance program and identify any concerns related to accreditation or the audit. The lead auditor or designee shall collect a written record of attendance at the entrance meeting. For contract auditors, the record of attendance shall also include a statement to the effect that, by signing the record, the auditee agrees to the use of the auditor(s) comprising the audit team. Neither the lead auditor nor any member of the audit team may waive responsibility on the part of a laboratory for injuries incurred by a member of the team during the audit.

3.2.2 Auditee Work Areas, Documents, Records, and Personnel

The audit team shall have reasonable access to all facilities, personnel, documents, records, data, analyses, and operations that the lead auditor determines are necessary for accreditation. Members of the audit team may observe operations, interview personnel, duplicate documents and records (or request the auditee to provide a duplicate of documents and records), and record items and activities that, in the judgment of the lead auditor, are reasonably necessary for the audit.

The audit team shall maintain information identified before, during, or after an audit by an auditee as confidential business information according to Laboratory Accreditation Procedure 5.1, Confidential Business and National Security Information.

The lead auditor shall also ensure all premises at which key activities are performed and which are covered by the scope of accreditation are visited.

3.2.3 Audit Activities

The audit team shall perform assigned tasks according to the audit plan, schedule, checklist(s), and assignments made by the lead auditor. Auditors shall document elements of any required records review on approved checklists, if available. Auditors shall specify the laboratory records, documents, equipment, procedures, or staff evaluated and the observations that contributed to the evaluation of "No" for each audit checklist item. This information must be documented in the comments section or referenced on the checklist.

The audit team shall review laboratory documents and records for accuracy, completeness, and use of proper methodology. The audit team should normally request that the analyst(s) conducting a test give a step-by-step description of exactly what is done and what equipment and supplies are needed to complete an analysis. The audit team shall assess calculations, data transfers, calibration procedures, quality control/quality assurance practices, adherence to standard operating procedures, and report preparation for the complete scope of accreditation with the appropriate analyst(s).

(NOTE: To minimize work disruptions, activities involving auditee personnel should normally occur between 8:30 and 11:30 am and 1:30 and 4:30 pm.)

The audit team shall confirm through the inspection of documents and records, before or during the on-site phase of the audit, that laboratory procedures and manuals:

- include all audit areas required by the standards for accreditation;
- include all test methods for which a laboratory seeks or maintains accreditation;

- include or reference applicable performance elements; and
- are controlled according to the laboratory's quality system.

The audit team shall also verify through visual observation that the latest versions of all laboratory procedures and manuals are in use. The audit team shall verify through visual inspection of work areas, observation, records, or interviews of laboratory personnel, or combinations of these that analysts:

- adhere to laboratory procedures and method manuals; and
- complete performance requirements associated with test methods as required, including requirements associated with proficiency test samples and sample analysis.

If a laboratory is seeking to obtain or maintain accreditation for drinking water methods approved in 40 CFR §141, the lead assessor must determine the drinking water FOAs for the laboratory being assessed using the *Drinking Water Assessment Checklist.* The lead auditor shall mark the respective methods in the "DW FOA" column of the *Drinking Water Assessment Checklist* prior to developing the audit plan. Each accredited drinking water method must be evaluated during the assessment. The audit team must ensure these methods have been implemented as written without unauthorized performance-based modifications. If the auditee is not accredited for any drinking water methods, the lead auditor will mark the "No DW Methods" box at the top of the first page, and only retain that page. The checklist is submitted as part of the audit package.

Where a laboratory seeks accreditation for two or more test methods (other than drinking water methods listed in 40 CFR §141) for a technology, the audit team shall verify these elements for at least one method. Due to time and resource constraints, every method/technology may not be audited. The lead auditor should select a representative number of methods and/or technologies to be audited. However, if the laboratory is seeking accreditation for drinking water methods listed in 40 CFR §141, the lead auditor should first select each drinking water method to be audited and then select a representative number of methods/technologies for non-drinking water methods. If needed, the lead auditor should consult with the Program Manager when determining how to best audit a representative number of methods/technologies and audit every drinking water method.

Where noncontiguous facilities are accredited as a single entity, the audit team shall visit each facility during each assessment to determine if they meet the requirements for noncontiguous facilities in 30 TAC Chapter 25, Subchapter B. The lead auditor shall ensure that the quality system and at least one method is assessed at each location.

The audit team shall verify through the inspection of documents and records that:

- analytical results are traceable to raw data, calibration data, and quality control indicators; and
- documents associated with reported results validate or verify the correct execution of test methods.

The lead auditor may change the audit plan, schedule, checklist, work assignments, and other activities as necessary to ensure the efficiency and effectiveness of the audit. The lead auditor shall document any changes to the audit plan and schedule and advise the auditee.

With the concurrence of the lead auditor, an auditor or technical specialist may pursue relevant issues and questions raised in the course of an audit, whether or not these issues and questions were included in the audit plan and checklist. The auditor or technical specialist shall document the issues and questions, their relevance, applicable audit bases, objective evidence examined, and results and provide this information to the lead auditor.

Where the audit team cannot reach a conclusion about a finding, the team should refer the finding to the Team Leader or designee for clarification.

3.2.4 Communication with Auditee

The audit team should strive to keep the auditee's point(s)-of-contact and liaison(s) apprised of an audit's progress and any deficiencies identified during the audit. This may be accomplished by daily briefings or less formal discussions with the auditee's representative(s) during the audit.

3.2.5 Preliminary Audit Results

Periodically during an audit or before the exit meeting, the lead auditor should meet with the audit team and review preliminary results of the audit. With the concurrence of the lead auditor, the audit team should determine:

- potential observations, relevant findings, significant conditions, and, if appropriate, comments;
- standards and objective evidence relating to any potential audit findings;
- corrective actions taken by the auditee during the audit;
- completeness and effectiveness of any previous corrective actions; and
- an overall assessment of the auditee's operations and quality assurance program.

The lead auditor may eliminate, revise, or combine preliminary audit results or instruct audit team members to undertake additional work to verify preliminary results.

For multi-day audits, preliminary audit results are presented to available laboratory management at the end of each audit day.

3.2.6 Exit Meeting

Before leaving a laboratory, the lead auditor shall direct an exit meeting, unless the auditee's management is unable or unwilling to participate in the meeting. During an exit meeting, the lead auditor, or designee(s), shall:

- restate the scope and objectives of the audit; identify any documents, records, or other information claimed as confidential business information by the auditee;
- summarize the preliminary results of the audit, including an overall audit of the auditee's operations and quality assurance program, the effectiveness of any previous corrective actions, and any positive and negative findings;
- note the audit team may identify additional deficiencies in the audit report;
- state when the audit report will be available to the auditee;
- describe any follow up actions to be taken by the auditee or the agency, including potential follow-up audits;
- describe the schedule for awarding or renewing accreditation; and
- answer questions.

Exit meetings shall be verbal.

The audit team may not debate the results of an audit with the auditee during the exit meeting. The audit team shall identify and document any findings with which the auditee disagrees. The audit team may also

consider objective evidence not previously made available and corrective actions taken by the auditee during the audit.

The lead auditor, or designee, shall collect a written record of attendance during the exit meeting.

(NOTE: The audit team should depart the auditee's facility as soon as possible after the exit meeting.)

3.2.7 Suspension of Audits

The lead auditor shall suspend an audit and instruct the audit team to leave an auditee's facility if the auditee refuses to admit the audit team to the facility for the audit or continuation of an audit could jeopardize the health or safety of any team member.

The lead auditor may also suspend an audit and instruct the audit team to leave an auditee's facility if:

- audit objectives cannot be achieved;
- auditee fails to provide reasonable access to any facilities, personnel, documents, records, data, analyses, and operations the lead auditor determines are necessary for the audit; or
- auditee fails to participate effectively and constructively in the audit.

The lead auditor shall advise the auditee's representative(s) and the Program Manager as soon as possible of a decision to suspend an audit and the reasons for suspending the audit.

3.3 Audit Report

The lead auditor shall prepare a written audit report describing the results of an audit. Each auditor on the audit team will write their deficiencies as detailed in Section 3.3.1 and provide the deficiencies to the lead auditor. The lead auditor will compile all deficiencies and produce the final report.

3.3.1 Contents of Audit Reports

An audit report shall, at a minimum, include:

- name and address of the auditee;
- date(s) of the audit;
- assessment number (obtained from the audit schedule);
- audit scope and objectives;
- executive summary;
- summary of any audit findings to include an overall view of the laboratory's operations, quality assurance program, and status of any previous corrective actions (i.e., documentation of existing conditions at the laboratory must be included in each report to serve as a baseline for future contacts with the facility);
- audit observations and any (positive and negative) audit findings;
- comments intended to improve the effectiveness of the auditee's operations and quality assurance program;
- audit findings with which the auditee takes exception;
- follow up actions taken or to be taken by the audit team or auditee;
- physical locations, items, and activities audited;
- references to relevant documents (e.g., regulations, standards, procedures, prior audit and corrective action reports, procurement documents, planning documents, progress reports);

- references to objective evidence examined during the audit;
- names and affiliations of audit team members;
- itemized list of what each auditor assessed including method number;
- names of individuals interviewed during the audit;
- names of individuals participating in entrance and exit meetings; and
- any other information that may assist in determining fulfillment of requirements and the competence of the laboratory.

Audit reports shall contain sufficient evidence to support all audit findings and the overall evaluation of the laboratory. Negative findings shall include a reference to the relevant standard(s). All negative findings require response and corrective actions. Some findings are labeled as critical. A finding having a significant negative effect on data quality or defensibility, if not corrected, is characterized as a critical finding. Critical findings are identified in the executive summary of the report and are flagged throughout the report. If a finding is a repeat deficiency from a previous audit report, the finding is labeled as such and the audit report shall include a reference to Title 30 of the Texas Administrative Code (TAC) §25.32 for each repeat deficiency (30 TAC §25.32 details requirements for denial or revocation based on the laboratory's failure to correct deficiencies). Negative findings shall be written and placed in the appropriate management and technical categories shown in Figure 3. The audit report must include sufficient information when referencing objective evidence. For example, information such as title, revision number, and/or effective date can be used to identify objective evidence like an SOP.

The audit report may include comments intended to improve the efficiency or effectiveness of the auditee's quality assurance program. Comments do not require a response from the laboratory.

An audit report shall not contain any confidential business information. (See also Laboratory Accreditation Procedure 5.1, *Confidential Business and National Security Information*.)

3.3.2 Approval of Audit Reports

The Program Manager, Team Leader or designee shall approve audit reports prior to distribution.

3.3.3 Distribution of Audit Reports

The Program Manager or designee shall forward the audit report to the auditee within 30 days of the exit meeting.

The lead auditor may not release an audit report to the public until audit findings have been finalized and the report has been distributed to the auditee.

3.3.4 Corrective Action Plans

An audit report containing one or more negative findings shall require an auditee to submit a corrective action plan to the lead auditor within 30 days of receiving the report. For each negative finding, the plan shall, at a minimum, include:

- specific corrective actions taken or planned to address the deficiencies in the assessment report;
- actions taken or planned to prevent recurrence;
- whether clients were notified if deficiencies cast doubt on the validity of results;
- means to verify effectiveness of corrective actions and actions to prevent recurrence;

- timetables for completing each correction, corrective and preventive action, client notification, and verification of effectiveness; and
- means to document completion of each action.

The lead auditor may require the auditee to submit documentation showing the implementation of corrective action(s) within the timeframe specified in the corrective action report. If the auditee fails to submit a corrective action plan within 30 days, the lead auditor consults with the Program Manager on how to proceed. If the auditee fails to provide a corrective action plan in a timely manner, the Program Manager or designee shall advise the auditee in writing that the laboratory failed the audit.

3.4 Evaluation of Corrective Action Plans

Within 45 days of receiving a corrective action plan, or a revised corrective action plan, the lead auditor or designee shall advise the auditee in writing whether or not the plan would effectively address negative audit findings in a timely manner. The lead auditor must complete a Corrective Action Response Checklist and obtain approval from the Program Manager or designee prior to notifying the auditee. If the CAR cannot be reviewed within 45 days, an extension can be granted by the Program Manager or designee if appropriate. Extensions will be tracked through the CAR tracking spreadsheets.

If a corrective action plan does not effectively address negative audit findings in a timely manner, the lead auditor shall advise the auditee of the deficiencies in the corrective action plan and direct the auditee to submit a revised plan within 30 days. The lead auditor must complete a Corrective Action Response Checklist and obtain approval from the Program Manager or designee prior to notifying the auditee. If the auditee fails to submit a revised corrective action plan within 30 days, the Lead Auditor consults with the Program Manager on how to proceed. If the auditee fails to provide a revised corrective action plan in a timely manner, the Program Manager or designee shall advise the auditee in writing that the laboratory failed the audit. If a revised corrective action plan does not address negative audit findings in a timely manner, the Program Manager or designee shall also advise the auditee in writing that the laboratory failed the audit.

3.5 Audit Closure

The lead auditor shall assemble and submit audit records defined in Section 4.0 to the Records Specialist or designee. The lead auditor shall turn over audit records within 45 days of:

- the date of an exit meeting, if the audit report did not include any negative findings;
- determining a corrective action plan effectively addressed negative audit findings in an audit report in a timely manner; or
- determining a laboratory failed an audit.

Follow-up audits shall be scheduled, planned, and conducted as necessary according to laboratory accreditation procedure 2.0, Scheduling Audits, and this procedure.

An audit shall be closed when the lead auditor receives acceptable responses for the negative findings.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include the following:

- audit notification correspondence;

- audit plans;
- completed audit checklists;
- audit notes;
- audit reports;
- corrective action plans; and
- corrective action plan acceptance or rejection documentation and correspondence.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain these records for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 06/01/05
Revision 1, Effective date: 02/09/09
Revision 2, Effective date: 2/10/12
Revision 3, Effective date: 10/24/12
Revision 4, Effective date: 12/1/15
Revision 5, Effective date: 01/29/16
Revision 6, Effective date: 06/06/18
Revision 7, Effective date: 08/01/18
Revision 8, Effective date: 03/03/21

Revisions to this document:

- Added language to allow for shorter timelines for audit plan submittal and audit notification to increase flexibility. *Sections 3.1.6 and 3.1.8*
- Removed requirement to send audit plans via certified mail to allow for flexibility in sending audit plans via email. Also added requirement that lead auditor obtain confirmation in writing from the lab that the audit plan was received to reflect actual practice. *Section 3.1.6*
- Added requirement to provide the laboratory information on how to obtain copyrighted checklists as part of audit notification to ensure requirements of the TNI Standard are met. *Section 3.1.8*
- Added requirement to describe the audit process during the entrance meeting to improve communication with the laboratory. *Section 3.*2.1
- Added language to clarify that the Lead Auditor is responsible for marking the "No DW Methods" box on the *Drinking Water Assessment Checklist* to reflect actual practice. *Section 3.2.3*
- Revised requirements for the laboratory's corrective action plan to reflect current wording in the CAP Template given to laboratories. *Section 3.3.4*
- Changed the name of the M-2 bucket on the audit report to Management Systems to better reflect the nature of the associated deficiencies. *Figure 3*
- Clarified additional duties related to travel from lead assessor. *Section 2*
- Clarified the usage of Figure 1 for all assessors. *Section 3.1.1*

Figure 1
Example Conflict of Interest Form

The Program Manager for the laboratory accreditation program has considered present and former relationships, associations, or investments that might influence or appear to influence the audit team's judgment, discretion, or impartiality and has determined no conflict of interest exists.

Figure 2
Audit Appraisal Form

(To be Completed After the Audit Process is Complete)

Please take the time to tell us how well this audit met your needs. The Texas Commission on Environmental Quality and the National Environmental Laboratory Accreditation Program will use this information to improve the audit process and future audits.

Laboratory Information

Laboratory Name: _____ Audit Dates: __

Laboratory Address: _____

Your Name: _____ Title: _____

Audit Evaluation: Please circle the appropriate number with 1 being poor and 5 being excellent.

1.	The auditor's questions/comments were pertinent to laboratory operations.	1	2	3	4	5
2.	The auditors thoroughly evaluated records for each field of accreditation.	1	2	3	4	5
3.	The auditors were knowledgeable of the standards.	1	2	3	4	5
4.	The auditors were knowledgeable of the methods reviewed.	1	2	3	4	5
5.	The auditors interacted with staff in a courteous and professional manner.	1	2	3	4	5
6.	Audit results were presented during the exit meeting.	1	2	3	4	5
7.	Audit findings reflect normal laboratory operations.	1	2	3	4	5
8.	The audit was/will be helpful to laboratory staff and operations.	1	2	3	4	5
9.	Overall, the accreditation program is/will be beneficial.	1	2	3	4	5

Please attach additional sheets to describe any problems with the audit, recommend how to improve the audit process, or provide any other comments.

Please return copies of the evaluation to:

Program Manager
Laboratory Accreditation Program
Texas Commission on Environmental Quality
P.O. Box 13087, MC-165
Austin, TX 78711-3087

Figure 3
Management and Technical Finding Categories

Management Findings Categories:

M-1 Organization
M-2 Management Systems
M-3 Document and Records Control
M-4 Review of Requests, Tenders, and Contracts
M-5 Subcontracting
M-6 Purchasing Services and Supplies
M-7 Client Service
M-8 Complaints
M-9 Control of Nonconforming Testing
M-10 Internal Audits, Data Integrity Investigations
M-11 Management Reviews
M-12 Corrective Actions
M-13 Preventive Actions, Improvement

Technical Findings Categories:

T-1 Analytical and Program Requirements
T-2 Test Methods and Method Validation
T-3 Personnel
T-4 Proficiency Testing
T-5 Accommodation and Environnemental Conditions
T-6 Uncertainty of Measurements
T-7 Control of Data
T-8 Maintenance and Calibration of Support Equipment
T-9 Maintenance and Calibration of Analytical Instrumentation
T-10 Measurement Traceability
T-11 Reference Standard and Reference Materials
T-12 Sampling
T-13 Sample Receipt and Handling
T-14 Assurance of Testing Quality
T-15 Reporting

Note: The category numbers may be changed if there are no findings in one or more category.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 2.3

LABORATORY ACCREDITATION DESK AUDITS

Issue Date: 3/1/21 Revision: 1

Effective Date: 3/3/21 Supersedes: Revision: 0

Ken Lancaster 2/26/21
Program Manager Date

2/26/2021
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for conducting desk audits relating to the accreditation of environmental laboratories using the current standards for accreditation of environmental laboratories adopted by the National Environmental Laboratory Accreditation Program (NELAP), including those for accreditation bodies. Desk audits are conducted by the Texas Commission on Environmental Quality (TCEQ) Laboratory Accreditation Program when TCEQ is one of multiple NELAP accrediting bodies (AB) offering primary accreditation to a laboratory. A desk audit can be performed by TCEQ staff for initial or continuing accreditation. The AB who first granted primary accreditation is responsible for the on-site assessment; TCEQ will conduct a sampling desk audit of the parameters, methods, and matrices (i.e., fields of accreditation) for which it is the primary AB.

2.0 RESPONSIBILITIES

Auditees are responsible for:

- participating constructively and effectively in desk audits;
- identifying liaisons and points-of-contact;
- identifying confidential business information;
- providing the audit team with access to personnel, documents, records, and data;
- providing documents and records requested by the audit team;
- providing other resources needed to conduct a desk audit and mutually agreed upon by the lead auditor and the auditee; and
- completing follow-up actions.

Auditors and technical specialists are responsible for:

- preparing portions of audit plans, checklists, and reports assigned by lead auditors;
- familiarizing themselves with audit plans, checklists, reference documents, tests, and measurements; and
- conducting desk audit tasks assigned by lead auditors.

Lead auditors are responsible for:

- preparing audit schedules, plans, checklists, and reports;
- providing written notifications to auditees;
- providing audit plans, checklists, and reference documents to audit team members;
- selecting and determining roles and responsibilities of audit team members;
- briefing audit team members about audits, roles and responsibilities, and any assigned tasks;
- directing the audit;
- suspending an audit, if necessary;
- sending audit reports to auditees;
- forwarding technical review documents and completed audit records to the Program Manager or designee; and
- evaluating corrective action responses and responding to auditees.

The Team Leader or designee is responsible for:

- approving audit team members; and
- approving audit reports.

Technical specialists are responsible for participating in audits according to arrangements agreed upon with lead auditors. Members of the audit team that provide technical assistance (technical specialists) must meet the requirement of the standard concerning conflicts of interest and professional conduct. Technical specialists who are not qualified as auditors are not eligible to conduct interviews in the absence of the auditor or cite deficiencies.

3.0 PROCEDURES

3.1 Audit Planning

3.1.1 Selection and Composition of Audit Teams

With the concurrence of the Program Manager, the Team Leader or designee shall determine the composition of audit teams. Audit teams shall include a designated lead auditor and may include additional auditors and technical specialists.

Based on the scope of accreditation of the accredited (or applicant) laboratory, the Team Leader or designee shall ensure the audit team has sufficient personnel, knowledge, skills, training, qualifications, personal attributes, and sufficient organizational authority and freedom to perform assigned duties in a timely manner.

An auditee may not select audit team members. However, the auditee may object to the appointment of a particular technical specialist or auditor.

Audit team members shall report to the Program Manager as soon as possible, and if at all possible before an audit occurs, any personal issues or activities (e.g., present or former relationships, associations, or investments) that may constitute a conflict of interest or conflict with OPP Chapter 12, *Professional Guidelines and General Workplace Policies*.

The Program Manager shall remove an individual from an audit team if the objections, reported issues, or activities:

- constitute, or could reasonably be construed as constituting, a conflict of interest; or
- could jeopardize the achievement of audit objectives.

The Program Manager's decision regarding whether present or former relationships, associations, or investments might influence or reasonably appear to influence an auditor's judgment, discretion, or impartiality and, as a result, whether an auditor may participate in an audit, may not be appealed.

3.1.2 Audit Team Roles and Responsibilities

The lead auditor shall determine audit activities to be performed by audit team members. The lead auditor shall ensure a sufficient number and variety of systems, methods, and analytical activities are reviewed to be representative of the laboratory's current and past competence within the scope of accreditation. The scope and complexity of the laboratory's fields of accreditation, as well as areas examined during previous desk audits, shall be considered when selecting activities to be reviewed. Activities to be performed by audit team members shall conform to standards for accreditation, which includes standards for professional conduct of auditors.

3.1.3 Audit Scope and Objectives

Audits assess the performance, effectiveness, and conformity of an environmental laboratory to relevant audit bases. Desk audits are limited to an analytical method review of the analytes, methods, and matrices (i.e., fields of accreditation) for which TCEQ is the primary AB; the primary AB that conducts the on-site assessment will assess the effectiveness of the laboratory's quality system. If, in the course of conducting the desk audit, the audit team finds an issue with the laboratory's quality system, the lead auditor notifies the Program Manager.

For initial accreditation, the desk audit scope shall, at a minimum, include the following:

Audit Bases:

- the standards for accreditation that were adopted by NELAP for laboratories performing environmental analyses;
- program standards, including changes to program standards;
- 30 TAC Chapter 25, Subchapters A and B; and
- rules, test methods, procedures, and requirements relating to a laboratory's application for accreditation, including participation in and results of proficiency testing

Items and Activities:

- accreditation application;
- operational components such as personnel, documents, records, data, and analyses for the scope of accreditation for which a laboratory seeks accreditation; and
- any other items and activities identified in the standards for accreditation.

As required by an EPA mandate, all relevant approved drinking water methods listed in 40 CFR §141 must be audited if a laboratory is to analyze public drinking water samples (including source water). More in-depth procedures for determining the audit scope are shown in Section 3.2.2.

The time period audited during initial desk audit shall include a period of up to 18 months prior to the date a laboratory submits an application for accreditation.

For biennial desk audits of accredited laboratories, the audit scope shall include all of the audit bases listed above for an initial audit as well as the following:

- prior audits and corrective action plans; and
- any complaints received by TCEQ.

The time period audited during biennial audits shall include a period up to the date of the last desk audit or a longer period the lead auditor determines is appropriate in order to meet audit objectives, e.g., verifying completion of corrective actions from a prior audit.

3.1.4 Objective Evidence, Audit Tests, and Samples

The lead auditor shall determine which analytes, methods, and matrices for which TCEQ is the primary AB by reviewing the laboratory's current scope of accreditation.

The lead auditor shall request the following documentation to conduct the desk audit; as applicable, these documents should be requested for the analytes, methods, and matrices for which TCEQ is the primary AB:

- last on-site NELAP assessment report and the laboratory's corrective action response to the NELAP assessment;
- last internal audit and corrective actions that resulted from the internal audit;
- most recent Quality Assurance Manual (however named);
- standard operating procedures;
- demonstrations of capability;
- proficiency testing results, if applicable;
- method detection limit studies; and
- at least two data packages for each method and matrix to be audited.

(NOTE: A data package should include information to trace the sample from sample receipt through reporting results. This should include the following types of documentation: chain of custody, logbook pages, bench sheets, extraction/prep information, raw data, calibration information, final report, etc.)

3.1.5 Audit Plan

The lead auditor shall prepare an audit plan for each audit. An audit plan shall, at a minimum, include:

- name and address of the auditee;
- audit scope and objectives, including any corrective actions to be verified during the audit;
- name(s) and affiliation(s) of audit team members;
- list of documents the laboratory must provide for the desk audit (Section 3.1.4);
- due date by which the laboratory must submit the requested documents;
- conflict of interest form (see Figure 1 in Laboratory Accreditation Procedure 2.2, Laboratory Accreditation Audits);
- audit appraisal form (see Figure 2 in Laboratory Accreditation Procedure 2.2, Laboratory Accreditation Audits);
- confidential business information form (see Laboratory Accreditation Procedure 5.1, Confidential Business and National Security Information);

- entrance and exit meeting attendance form(s);
- name and telephone number of the auditee's contact person(s); and
- information concerning how the auditee may obtain audit information.

The audit plan is sent to the laboratory at least 30 days prior to the start of the audit, when possible. The lead auditor must obtain confirmation from the laboratory that they received the audit plan.

3.1.6 Audit Checklist

The lead auditor shall use an approved checklist for conducting desk audits (e.g., the quality systems checklist developed by TNI's Laboratory Quality Systems Expert Committee), if available. The current approved checklist is maintained on the internal network drive (H: drive). If an approved checklist is not available or is insufficient to assess a laboratory's scope of accreditation, the lead auditor shall prepare one or more checklists as necessary to address the audit scope and objectives. An audit checklist shall, at a minimum, include questions to be asked and forms to be used. Procedural checklists should be considered when an audit will assess compliance or complex technical activities or verify steps in a process [e.g., analytical methods].

The lead auditor may designate auditors and technical specialists to prepare all or part of the audit checklists.

3.1.7 Audit Notification

The lead auditor shall notify auditees in writing at least 30 days prior to the start of the audit. Shorter lead times may occur with the concurrence of the Program Manager, or designee, and the laboratory.

An audit notification must include:

- an audit notification letter or memorandum;
- a copy of the audit plan; and
- copies of standardized checklists to be used if there are no copyright restrictions or information on how to obtain copyrighted checklists

(NOTE: Copyright restrictions may prevent distribution of audit checklists. If an audit checklist contains copyrighted language (e.g., ISO language), the lead auditor shall advise the auditee how to obtain the checklist. This can be accomplished by providing a link to a website containing the checklists.)

3.1.8 Audit Team Orientation

Prior to conducting an audit, the lead auditor shall ensure audit team members receive a copy of the audit plan and checklist(s) and have access to relevant documents. The lead auditor shall also ensure audit team members are informed of:

- individual roles, responsibilities, and assigned tasks; and
- any anticipated changes in the audit plan or schedule.

Prior to the audit, audit team members shall familiarize themselves with relevant parts of the audit plan and checklist, reference documents (e.g. analytical methods and the current TNI standard), accreditation application, assigned tasks, and relevant laboratory documentation to be audited.

3.2 Desk Audit

3.2.1 Entrance Meeting

The lead auditor shall direct an entrance meeting remotely as part of the desk audit, unless the auditee's management is unable or unwilling to participate in the meeting. During the entrance meeting, the lead auditor or designee(s) shall:

- introduce members of the audit team;
- describe the scope and purpose of the audit;
- discuss the audit plan, including applicable standards and test methods, documents, and records to be examined;
- describe the audit process;
- confirm roles and responsibilities of key personnel and staff;
- describe procedures related to confidential business information, including the auditee's right to claim any portion of the information requested during the audit as confidential business information;
- describe procedures related to national security information (if applicable);
- identify any auditee points-of-contact and liaisons;
- determine any changes to the audit plan or schedule that may be needed;
- provide a copy of the audit appraisal form; and
- answer questions.

During the entrance meeting, the auditee should be encouraged to describe the status of the laboratory's operations and quality assurance program related to the analytes, methods, and matrices (i.e., fields of accreditation) for which TCEQ is the primary AB and identify any concerns related to accreditation or the audit. The lead auditor or designee shall collect a written record of attendance at the entrance meeting.

3.2.2 Desk Audit Activities

The audit team shall perform assigned tasks according to the audit plan, schedule, checklist(s), and assignments made by the lead auditor. Auditors shall document elements of any required records review on approved checklists, if available. Auditors shall specify the laboratory records, documents, or procedures evaluated and the observations that contributed to the evaluation of "No" for each audit checklist item. This information must be documented in the comments section or referenced on the checklist.

The audit team shall review the laboratory documents and records requested in Section 3.1.4 for accuracy, completeness, and use of proper methodology. The audit team shall assess calculations, data transfers, calibration procedures, quality control/quality assurance practices, adherence to analytical method, and report preparation for the scope of accreditation for which TCEQ is the primary AB.

The audit team shall confirm, through the inspection of documents and records, that laboratory procedures and manuals include all test methods for which a laboratory seeks or maintains accreditation for which TCEQ is the primary AB.

If a laboratory is seeking to obtain or maintain accreditation for drinking water methods approved in 40 CFR §141, the lead assessor must determine the drinking water FOAs for the laboratory being assessed using the *Drinking Water Assessment Checklist.* The lead auditor shall mark the respective methods in the "DW FOA" column of the *Drinking Water Assessment Checklist* prior to developing the audit plan. Each accredited drinking water method must be evaluated during the desk audit. The audit team must ensure

these methods have been implemented as written without unauthorized performance-based modifications. If the auditee is not accredited for any drinking water methods, the lead auditor will mark the "No DW Methods" box at the top of the first page, and only retain that page. The checklist is submitted as part of the audit package.

For desk audits, the audit team should strive to audit every technology. However, due to time and resource constraints, every method/technology may not be audited. The lead auditor should select a representative number of methods and/or technologies to be audited. If needed, the lead auditor should consult with the Program Manager when determining how to best audit a representative number of methods/technologies. Where a laboratory seeks accreditation for two or more test methods (other than drinking water methods listed in 40 CFR §141) for a technology, the audit team shall verify these elements for at least one method.

The audit team shall verify through records that the laboratory meets performance requirements associated with test methods, including requirements associated with proficiency test samples and sample analysis.

The audit team shall verify through the inspection of documents and records that:

- analytical results are traceable to raw data, calibration data, and quality control indicators; and
- documents associated with reported results validate or verify the correct execution of test methods.

The lead auditor may change the audit plan, checklist, work assignments, and other activities as necessary to ensure the efficiency and effectiveness of the audit. The lead auditor shall document any changes to the audit plan and advise the auditee.

With the concurrence of the lead auditor, an auditor or technical specialist may pursue relevant issues and questions raised in the course of an audit independent of their inclusion in the audit plan and checklist. The auditor or technical specialist shall document the issues and questions, their relevance, applicable audit bases, objective evidence examined, and results, and provide this information to the lead auditor. With the lead auditor's approval, the auditor or technical specialist may then contact the laboratory to pursue relevant issues and questions that were raised during their review of the laboratory's documentation. Under no circumstances shall a team member contact the laboratory without first informing the lead auditor.

Where the audit team cannot reach a conclusion about a finding, the team should refer the finding to the Team Leader or designee for clarification.

The audit team shall maintain information identified before, during, or after an audit by an auditee as confidential business information according to Laboratory Accreditation Procedure 5.1, Confidential Business and National Security Information.

The audit team should determine:

- potential observations, relevant findings, and, if appropriate, comments;
- standards and objective evidence relating to any potential audit findings; and
- completeness and effectiveness of any previous corrective actions.

The desk assessment review should be completed within 30 days of the start of the audit. The opening meeting for the desk audit shall mark the start of the audit. The closing meeting for the desk audit shall mark the completion of the desk audit and establish the report due date (30 days following the closing of the assessment).

3.2.3 Exit Meeting

Before completing the desk audit, the lead auditor shall direct an exit meeting remotely, unless the auditee's management is unable or unwilling to participate in the meeting. During an exit meeting, the lead auditor, or designee(s), shall:

- restate the scope and objectives of the audit;
- identify any documents, records, or other information claimed as confidential business information by the auditee;
- summarize the preliminary results of the audit, the effectiveness of any previous corrective actions, and any positive and negative findings;
- note the audit team may identify additional deficiencies in the audit report;
- state when the audit report will be available to the auditee;
- describe any follow up actions to be taken by the auditee or the agency, including potential follow-up audits;
- describe the schedule for awarding or renewing accreditation; and
- answer questions.

Exit meetings shall be verbal.

The audit team may not debate the results of an audit with the auditee during the exit meeting. The audit team shall identify and document any findings with which the auditee disagrees. The audit team may also consider objective evidence not previously made available and corrective actions taken by the auditee during the audit.

The lead auditor, or designee, shall collect a written record of attendance during the exit meeting.

3.2.4 Suspension of Audits

The lead auditor shall suspend an audit if the auditee refuses to supply the necessary documentation to conduct the audit or if a review of the documentation reveals issues such that it is determined that a desk audit is not an effective means to assess the laboratory.

The lead auditor may also suspend an audit if:

- audit objectives cannot be achieved;
- auditee fails to provide reasonable access to personnel, documents, records, and data the lead auditor determines are necessary for the audit; or
- auditee fails to participate effectively and constructively in the audit.

The lead auditor shall advise the auditee's representative(s) and the Program Manager as soon as possible of a decision to suspend an audit and the reasons for suspending the audit. The Program Manager may determine that an on-site assessment is required if the audit objectives cannot be achieved through a desk audit.

3.3 Audit Report Approval, Corrective Actions, and Audit Closure

The procedures for audit report approval, corrective action evaluation, audit closure, and audit documentation mirror those found in Laboratory Accreditation Procedure 2.2, Laboratory Accreditation Audits.

4.0 REVISION HISTORY

Revision 0, Effective date: 09/16/18

Revisions to this document:

- reduced the number of data packages reviewed from 3 to 2. *Section 3.1.4*
- added entrance and exit meetings to the audit plan and clarified when and how audit team may contact auditees directly. *Sections 3.1.5 and 3.2.2*
- added evaluating corrective action responses and responding to auditees to the list of lead auditor responsibilities. *Section 2.0*
- modified the requirement to audit each method, matrix, analyte to require a sufficient number and variety of systems, methods, and analytical activities to be representative of the laboratory's current and past competence within the scope of accreditation. *Section 3.1.2*
- added EPA mandate requiring laboratories be audited for each drinking water method, for which they are accredited, that is listed in 40 CFR §141. *Section 3.1.3*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 2.4

ONGOING OBSERVATION AND EVALUATION OF ASSESSORS

Issue Date: 3/11/19 Revision: 1

Effective Date: 3/14/19 Supersedes: 0

Ken Lancaster 3/11/19
Program Manager Date

Sharon R. Coleman 3/11/2019
Quality Assurance Specialist Date

PURPOSE AND SCOPE

1.0 This procedure describes requirements for TCEQ personnel to conduct regularly scheduled observation of assessments performed by TCEQ staff and staff of contracted assessment organizations under the accreditation standards adopted by the National Environmental Laboratory Accreditation Program (NELAP). The objectives of observations are to evaluate the assessor's performance to determine if they are performing competently and recommend follow-up actions for improvement. Persons observed and evaluated under this procedure have already been qualified as assessors in accordance with the requirements of LAP 2.1, Assessor Qualifications.

2.0 RESPONSIBILITIES

The Senior Technical Auditor is responsible for:

- annually preparing an observation plan in collaboration with the Work Lead and Team Lead;
- performing and documenting results of on-site observations and off-site competency reviews; and
- recommending follow-up actions to the Program Manager to ensure and improve conformance, including identified training needs.

The Team Lead or designee is responsible for:

- collaborating in the development and approval of the annual observation plan and the resulting observation reports.
- tracking onsite observations and off-site competency reviews; and
- performing and documenting results of on-site observations and off-site competency reviews as needed.
- recommending follow-up actions to the Program Manager to ensure and improve conformance, including identified training needs.

The Program Manager or designee is responsible for:

- evaluating competency of assessors;
- recommending follow-up actions and providing feedback to the observed assessors; and
- performing and documenting results of on-site observations and off-site competency reviews as needed.

Note: The observation of the Senior Technical Auditor will be performed by either the Program Manager or Team Lead.

Note: Henceforth, the Senior Technical Auditor, Team Lead, and Program Manager are collectively referred to as the Observer when they perform observations.

3.0 PROCEDURES

3.1 Preparation of Observation Plan

In the fourth quarter of each fiscal year (e.g., July), the Senior Technical Auditor, Work Lead, and Team Lead will collaborate on preparing the observation plan for the next fiscal year. The plan will address observations of TCEQ and contract assessors. All trained and qualified TCEQ and contract assessors shall be observed on-site once every three years, unless there is sufficient supporting evidence that the assessors are continuing to perform competently. Sufficient supporting evidence will include ongoing review of reports, ongoing feedback from laboratories, and an off-site competency review as documented in Section 3.4. At a minimum, an on-site observation of each assessor will be performed at least once every six years.

3.2 Performance and Documentation of Observations

The Observer will coordinate with each TCEQ and contracted assessment team to observe the assessments on the observation plan. The assessment teams are responsible for notifying the laboratories to be assessed that an assessor will be observed by TCEQ staff.

3.3 Minimum On-Site Observation Requirements

The Observer will observe and evaluate each assessor on the annual observation plan. The following four fundamental components of an assessment must be observed at a minimum; the assessor being observed must conduct these four components under observation, if applicable:

- the entrance meeting;
- selected elements of quality systems (e.g., sample receiving, qualifications of technical managers and quality assurance officers, use of the NELAP logo, proficiency testing, effectiveness of corrective actions for previous findings, etc.);
- at least one analytical method; and
- the exit meeting.

All four components of an assessment can be observed for an assessor during an assessment at a single laboratory. If circumstances prevent observation of all four components in single assessment, the observation may be spread over assessments at multiple laboratories. In addition, the entrance meeting and exit meeting may be observed remotely via conference call. However, all four fundamental components must be observed by the same Observer in the same fiscal year.

In addition, the Observer will review the file of at least one TCEQ laboratory assessment previously performed by the assessor. The following items, at a minimum, must be reviewed:

- assessor notes, completed checklists, and final report to ensure the assessor appropriately and effectively documented issues identified during the assessment on the final report; and
- associated assessment records to ensure the assessor maintained adequate records to document assessment activities.

The Observer must complete the Assessor Observation and Evaluation Form (see Figure 1) for each on-site observation. In addition to the form, records of the observation may be supplemented by handwritten or electronically recorded notes.

3.4 Minimum Off-Site Competency Review Requirements

The Observer will review the file of at least one TCEQ laboratory assessment performed by the assessor. The assessor must have assessed selected elements of the quality system and at least one analytical method. The following items must be reviewed at a minimum;

- assessor notes;
- completed checklists;
- final assessment report;
- laboratory documents associated with items assessed;
- correspondence with the laboratory;
- entrance and exit meeting records; and
- associated assessment records.

The Observer must complete the Assessor Observation and Evaluation Form for each off-site competency review.

3.5 Observation Bases

The observation bases for TCEQ and contracted assessors are:

- TCEQ's Laboratory Accreditation Procedures (LAPs);
- the current standards for accreditation adopted by NELAP for environmental laboratories and accreditation bodies;
- the current NELAP quality systems and technical checklists;
- TCEQ's proficiency testing checklist based on requirements adopted by NELAP for environmental laboratories and accreditation bodies;
- deficiencies identified in the previous assessment at the laboratory; and
- pertinent fields of accreditation for each laboratory and the associated reference methods.

3.6 Evaluation of Assessors

Following the on-site observation or off-site competency review, the Observer shall forward the completed Assessor Observation and Evaluation Form to the Program Manager. The Program Manager or designee will evaluate the competency of the assessor, determine if additional training is needed and identify needed training, and document these activities in the Assessor Evaluation portion of the Assessor Observation and Evaluation Form. The completed Assessor Evaluation portion of the Assessor Observation and Evaluation Form will serve as the final evaluation report. The Program Manager or designee will provide feedback to the observed assessor either through individual or group training, depending on the nature of the feedback.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- the approved annual observation plan;
- the completed Assessor Observation and Evaluation Form for each assessor observed;
- supplemental handwritten and electronically recorded notes; and
- records of feedback provided through additional training.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual requirement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 09/06/2018

The following revisions were made to this document:

- Removed on-site designation, added ongoing designation, and added evaluation to the document title to better reflect the nature of the revised procedure. *Document Title*
- Clarified that the purpose of the document is to evaluate assessor competence to be consistent with the requirements in the TNI Standard. *Section 1.0*
- Added requirements of the Team Lead, including collaborating in the development of the observation plan, performing observations as needed, and tracking the onsite observations and off-site competency reviews. In addition, added a requirement of the Program Manager to perform observations as needed. Furthermore, added a requirement of the Senior Technical Auditor to conduct off-site competency reviews if on-site observations cannot be performed within frequency requirements. These were added to ensure observations are performed as required and increase flexibility in performing observations. *Section 2.0*
- Revised requirement for frequency of on-site assessments for contract assessors from one per year to as many as necessary to ensure that all assessors are observed at least once every three years unless there is supporting evidence of ongoing competency and defined requirements for supporting evidence to be consistent with the requirements in the TNI Standard. In addition, added a requirement that an on-site observation will be performed for each assessor at least once every six years to ensure that on-site observations occur. *Section 3.1*
- Added a requirement that a file review be performed as part of the on-site observation to ensure that assessors are competent in writing reports and maintaining records. *Section 3.3*

- Added requirements for an off-site competency review to be used as supporting evidence of assessor competence when on-site observations are not performed to ensure there is adequate supporting evidence. *Section 3.4*
- Removed the requirement to prepare an observation report and added the Program Manager evaluation of competence and identification of needed training onto the Assessor Observation and Evaluation Form to increase efficiency. In addition, added different options for providing feedback to assessors for clarification. *Section 3.5*
- Removed the final observation report from the documents produced by the procedure to reflect the changes to the procedure. *Section 4.0*
- Renamed the Assessment Observation Checklist to Assessor Observation and Evaluation Form and revised the content to better reflect the purpose of the observation. *Figure 1.*

Figure 1

Assessor Observation and Evaluation Form

Observed Assessor:		Observation Date(s):	
Observer/Evaluator:		Laboratory Assessed:	
Method(s) Observed:		Lab File(s) Reviewed:	

General Knowledge and Skills	Yes/No/NA	Comments
Did the assessor demonstrate an understanding of the requirements of the accreditation standard(s)?		
Did the assessor demonstrate an understanding of the accreditation body's policies and procedures?		
Did the assessor demonstrate awareness and understanding of requirements in appropriate reference documents (i.e 40 CFR, 30 TAC, etc...) in relation to their assigned assessment functions?		
Did the assessor demonstrate the knowledge necessary to effectively assess the laboratory's quality systems and processes? This may include, but not be limited to: • Quality and Management systems; • Document and Records Control; • Internal Audits and Management Reviews; • Preventive and Corrective Actions; • Contracts, Suppliers, Subcontracting; • Data Integrity and Complaints; • Completeness of records; and • Data analysis and reporting.		
Did the assessor demonstrate the technical knowledge necessary to effectively assess the laboratory's analytical method(s)?		
Did the assessor apropriately interpret and apply accreditation criteria in actual assessment situations?		

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Assessor Observation and Evaluation Form

Assessment Techniques	Yes/No/NA	Comments
Did the assessor demonstrate appropriate assessment principles and practices including: • Planning; • Preparing; • Organizing; and • Managing time.		
Did the assessor demonstrate appropriate assessment techniques including: • Interviewing; • Collecting assessment evidence; • Audit sampling; • Following up on previous issues; • Documentation of assessment activities; and • Drawing appropriate conclusions from assessment observations.		
Did the assessor demonstrate appropriate personal attributes including: • Communication skills; • Conflict management skills; and • Professionalism.		
Lead Assessor Responsibilities	**Yes/No/NA**	**Comments**
Did the assessor communicate effectively with the laboratory concerning the assessment?		
Did the assessor effectively conduct an entrance and exit meeting?		
Did the assessor appropriately and effectively document issues identified during the assessment on the final report?		
Did the assessor maintain adequate records to document assessment activities?		

Assessor Observation and Evaluation Form

Assessor Evaluation (to be completed by Program Manager)		
General Comments		
Is the assessor competent to perform assessments?		
Is additional individual training needed for this assessor as a result of this observation?		
Is additional group training needed as a result of this observation?		

Program Manager Signature

Date

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 3.1

RECEIPT AND ADMINISTRATIVE REVIEW OF ACCREDITATION APPLICATIONS

Issue Date: 03/03/23 Revision: 4

Effective Date: 03/03/23 Supersedes: Revision 3

	03/03/2023		03/03/2023
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for receiving and conducting an administrative review of applications for laboratory accreditation.

2.0 RESPONSIBILITIES

The Records Specialist or designee is responsible for:

- receiving and reviewing accreditation applications;
- creating laboratory folders;
- advising laboratories of administrative deficiencies in accreditation applications; and
- forwarding checklists and applications to the Work Group Leader or designee.

3.0 PROCEDURES

The Records Specialist or designee shall receive accreditation applications and initiate reviews in the order applications are received. Applications received in connection with the annual renewal of a laboratory's accreditation may be given precedence in order to facilitate the annual renewal process.

Within 15 calendar days of receiving an accreditation application, the Records Specialist or designee shall review the application for administrative completeness and complete an administrative review checklist (Figure 1).

For initial applications, the Records Specialist or designee shall prepare a folder for the laboratory and enter its information into the accreditation database.

If an accreditation application is complete, the Records Specialist or designee shall forward the completed administrative application review checklist, accreditation application, and supporting documents to the Work Group Leader or designee.

If an accreditation application is not complete, the Records Specialist or designee shall advise the laboratory in writing, via email, , of any deficiencies. The correspondence shall identify the deficiencies the laboratory must correct in order to complete the accreditation application (e.g., missing documents, incomplete application) and advise the laboratory of the date by which the deficiencies must be corrected. A laboratory should normally have two opportunities to correct any deficiencies. If the deficiencies are minor, the reviewer may choose to notify the laboratory via e-mail. All deficiencies should normally be corrected within three months of receiving the application. If an application still has deficiencies after six months, or if there has been no action by the laboratory to correct deficiencies for three months, the application may be forwarded to the Program Manager for formal denial action.

Upon receiving the additional documents or information from a laboratory, the Records Specialist or designee shall complete the review of the application.

The Records Specialist or designee will update the internet website with information regarding applications in progress for new laboratories that are applying for accreditation. The website will identify the laboratory name and the status of the administrative review of the application.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- laboratory accreditation folders;
- accreditation applications and supporting documents; and
- administrative review checklists.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 2/10/12
Revision 2, Effective date: 3/15/17
Revision 3, Effective date: 3/03/21

The following revisions were made to this document:

- Clarified language to reflect current practices; made notification of deficiencies by certified letter a preferred option rather than required and took out the word informal from the option to notify of deficiencies via e-mail. *Section 3.0*
- Updated notification method to laboratories due to team's remote work. *Section 3.0*

Figure 1
Example Application Review Checklist

ADMINISTRATIVE APPLICATION REVIEW CHECKLIST

Laboratory Name:		Application Date:		
Reviewer Name:		Date received by reviewer:		
		Review Date:		
Initial App. ☐ Amendment ☐	Is this the first review, or a follow-up review?			
	1st ☐ 2nd ☐ 3rd ☐ 4th ☐		Check One:	
			YES	N/A	NO
Application				
Has the laboratory submitted a complete application form? *Note: For amendment applications, an abbreviated application, including at least page one and page seven as well as any other pages indicating changes from current information, may be sufficient.*				
FoAs				
1. Has the laboratory submitted FoA sheets covering the newly requested additions?				
2. Do the submitted FoAs clearly and unambiguously show what parameter changes the lab is requesting?				
Fees				
Has the laboratory submitted the required and correct fees for the requested parameters? *Note: from the fee matrix on page five of the accreditation application*				
Proficiency Testing (PT)				
Has the laboratory submitted PT results for every required analyte-matrix-technology FoPT for which it is applying for accreditation that meet the requirements in the 2009 TNI Standard V1M1 4.1? *Note: Drinking water matrix requires PT results per method, not technology.*				
Demonstration of Capability (DOC)				
Was an initial/ongoing DOC provided for every field of accreditation for which the laboratory is applying?				
Documents				
Did the laboratory submit all required documents, including but not limited to the quality assurance manual (QAM) and standard operating procedures (SOPs)? *Note: If this is an amendment request, the QAM and other quality documents may not be required for review.*				
Comments:				
Is the application complete from an administrative perspective?	YES ☐	NO ☐		
If not, were documents, records, or corrections requested?	YES ☐	NO ☐		
Date Requested:	Format: E-mail ☐	Ltr ☐		
Date Due:				

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 3.2

TECHNICAL REVIEW OF APPLICATIONS FOR PRIMARY ACCREDITATION

Issue Date: 3/1/17 Revision: 3

Effective Date: 3/15/17 Supersedes: Revision 2

Ken Lancaster 2/24/17
Program Manager Date

Sharon Coleman 2/24/2017
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for completing the technical review of applications for primary accreditation.

2.0 RESPONSIBILITIES

The Team Leader, Work Group Leader, or designee is responsible for:

- determining whether accreditation applications and supporting documents conform to the standards for accreditation;
- documenting the results of technical review;
- communicating with laboratories as necessary;
- advising the Program Manager or designee of significant nonconformances; and
- extending review periods, as necessary, in order to receive additional information from laboratories.

The Program Manager or designee is responsible for determining whether an on-site audit is required for an accreditation application.

3.0 PROCEDURES

3.1 Technical Review Not Requiring a Laboratory Audit

The Program Manager or designee may consider a laboratory's application to add an analyte or method to its scope of accreditation without an on-site audit. An addition to the scope of accreditation via a data review of proficiency test performance (if available), demonstration of capability, quality control performance, and written standard operating procedure is at the discretion of the Program Manager or designee. An addition of a new technology or test method requiring specific equipment may require an on-site audit.

If an application for primary accreditation does not require an audit of a laboratory, the Team Leader, Work Group Leader, or designee shall complete a technical review of the application within 45 calendar days of receiving an administratively complete application from the Records Specialist or designee. The Program

Manager or Team Leader may extend the review period, as necessary, in order to receive additional documents, records, and other information from a laboratory.

The Team Leader, Work Group Leader, or designee shall determine whether the laboratory's application and supporting documents and records conform to the standards for accreditation (30 TAC Section 25.9, Standards for Environmental Testing Laboratory Accreditation). Supporting documents and records may include, but are not limited to:

- previous audit reports (if applicable);
- proficiency test sample results;
- demonstrations of capability;
- Method Detection Limit (MDL) study (if applicable);
- organization charts;
- personnel qualifications, experience, and training;
- quality manuals and procedures, including analytical procedures;
- official communications with the agency or other accrediting authorities and associated records;
- available documents from laboratory clients; and
- program regulations.

The Team Leader, Work Group Leader, or designee shall determine through the inspection of documents and records whether laboratory procedures and manuals:

- include all audit areas required by the standards for accreditation;
- include all test methods for which a laboratory seeks or maintains accreditation;
- include or reference applicable performance elements; and
- are controlled according to the laboratory's quality system.

The Team Leader, Work Group Leader, or designee shall document the results of the review by completing the applicable portions of the Technical Application Review Checklist (Figure 1). The checklist, accreditation application, and supporting documents are forwarded to the Records Specialist or designee. All records pertaining to the laboratory's application for accreditation are either stored electronically in the laboratory's folder on the Laboratory Accreditation Group's shared drive or in the laboratory's folder located in the file room. The Records Specialist forwards the checklist, accreditation application, and supporting documents to the Program Manager for final action.

The Team Leader or Work Group Leader shall advise the Program Manager or designee as soon as practicable of any significant nonconformances, i.e., a condition that, if uncorrected, could have a serious effect on safety, integrity, validity, or availability of data, operations, or systems.

3.2 Technical Review Involving a Laboratory Audit

If an application for primary accreditation requires an audit of a laboratory, the Team Leader, Work Group Leader, or designee shall complete a technical review of the application within 45 calendar days of receiving an administratively complete application from the Records Specialist or designee. The Program Manager or Team Leader may extend the review period, as necessary, in order to receive additional documents, records, and other information from a laboratory.

The Team Leader, Work Group Leader, or designee shall determine whether the laboratory's application and supporting documents and records conform to the standards for accreditation (30 TAC Section 25.9, Standards for Environmental Testing Laboratory Accreditation). Supporting documents and records include, but are not limited to:

- previous audit reports (if applicable);
- proficiency test sample results;
- demonstrations of capability;
- MDL study (if applicable);
- organization charts;
- personnel qualifications, experience, and training;
- quality manuals and procedures, including analytical procedures;
- quality manual and policies and procedures checklists;
- official communications with the agency or other accrediting authorities and associated records; available documents from laboratory clients; and
- program regulations.

The Team Leader, Work Leader, or designee shall determine through the inspection of documents and records whether laboratory procedures and manuals:

- include all audit areas required by the standards for accreditation;
- include all test methods for which a laboratory seeks or maintains accreditation;
- include or reference applicable performance elements; and
- are controlled according to the laboratory's quality system.

The Team Leader, Work Group Leader, or designee shall document the results of the review by completing the applicable portions of the Technical Application Review Checklist (Figure 1).

If the technical review indicates a laboratory's operations and quality system conform to the standards for accreditation, the Team Leader, Work Group Leader, or designee shall forward the checklist, accreditation application, and supporting documents to the Records Specialist or designee. All records pertaining to the laboratory's application for accreditation are either stored electronically in the laboratory's folder on the Laboratory Accreditation Group's shared drive or in the laboratory's folder located in the file room. Once the assessment of the laboratory has been assigned to an assessor, the lead assessor has access to all applicable records, either electronically or hard copy.

If the technical review demonstrates a laboratory's operations and quality system do not conform to the standards for accreditation, the Team Leader, Work Group Leader, or designee shall forward the checklist and accreditation application and supporting documents to the Program Manager or designee. The Program Manager or designee shall determine whether an audit will be conducted. If an audit will not be conducted, the Program Manager or designee shall notify the laboratory in writing as soon as feasible. The notification shall identify the laboratory operations and systems that do not meet the standards for accreditation.

Once the technical review is complete, the Records Specialist or designee shall update the Application in Progress section of the internet website with information regarding the status of the technical review of the application for new laboratories that are applying for accreditation.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include the technical application review checklist.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/01/05
Revision 1, Effective date: 2/10/12
Revision 2, Effective date: 6/05/15

Revisions to this document:

- Added an "Issue Date" to allow time for staff to read and understand LAP before implementation. *Approval section*
- Added "or designee" behind most mentions of the Program Manager, besides ones that reference another LAP, to increase flexibility and clarified that days were calendar days to explain intent of document. *Throughout document*
- Clarified that the review of the application was a technical review to eliminate vagueness. *Section 1.0*
- Added the responsibility of the Program Manager or designee to determine whether an on-site audit is required to reflect current practices. *Section 2.0*
- Added Work Group Leader to the procedures for performing technical reviews of applications to reflect current practice. In addition, added Program Manager to the list of staff who could extend the review period and removed "or designee" to ensure that any extensions are only granted by the Program Manager or Team Leader. *Sections 3.1 and 3.2*
- Added method detection limit study to list of supporting documents to reflect current practices. *Section 3.1*
- Added method detection limit study to list of supporting documents to reflect current practices; removed NOTE regarding leaving the checklist blank as this is not indicative of current process; and added information that Records Specialist would update website with status of technical review for new laboratories to reflect current practices. *Section 3.2*
- Deleted procedures for final technical review involving a laboratory audit to reflect current practice *Section 3.3*
- Changed documents produced from accreditation audit checklists to technical review application checklist to reflect current practices. *Section 4.0*

Figure 1
Example Technical Application Review Checklist

TECHNICAL APPLICATION REVIEW CHECKLIST

Laboratory Name: _____ Application Date: _____

Assessor Name: _____ Date received by assessor: _____

Review Date: _____

Initial App. ☐ Amendment ☐ Is this the first review, or a follow-up review?

1st ☐ 2nd ☐ 3rd ☐ 4th ☐

	Check One: YES	NO
Proficiency Testing (PT)		
1. Has the laboratory submitted unique PT results for every analyte-matrix-technology for which it is applying for accreditation? *Note: Drinking water matrix requires PT results per method, not technology.*		
2. Do the PT results appear to meet the requirements in the 2009 TNI Standard V1M1 4.1.3?		
Demonstration of Capability (DOC)		
1. Was an initial DOC provided for every field of accreditation for which the laboratory is applying? Or, if an on-going DOC was used, were there records indicating the method was in use by the laboratory at least one year prior to applying for accreditation?		
2. Did the DOCs include the information required in Section 1.6.2.1 of the 2009 TNI Standard technical modules?		
3. Did the DOCs meet the requirements under Section 1.6.2.2 or 1.6.3 of the 2009 TNI Standard technical modules?		
Additional Records		
1. Did the laboratory submit all required studies of method performance, including but not limited to method detection limits, linear dynamic ranges, and temperature distributions of incubators? *Note: If not required, check "YES."*		
2. Did these method performance studies appear to meet the requirements found in the method and/or regulation? *Note: If no studies were required, check "YES."*		
Documents		
1. Did the laboratory submit all required documents, including but not limited to the quality assurance manual (QAM) and standard operating procedures (SOPs)? *Note: If this is an amendment request, the QAM and other quality documents may not be required for review.*		
2. Did these documents appear to meet the requirements for document control found in the 2009 TNI Standard V1M2 4.3?		
3. Did the QAM meet the requirements found in the 2009 TNI Standard V1M2 4.2.8.3 and 4.2.8.4? *Note: If the QAM was not required for review, check "YES."*		
4. Did the SOPs meet the requirements found in the 2009 TNI Standard V1M2 4.2.8.5?		
5. Did the SOPs appear to meet the requirements in the reference methods and/or regulations? *Note: If allowable deviations from the reference method (e.g., those described in 40 CFR 136.6) are documented appropriately, check "YES."*		
6. Did the SOPs appear to be technically sound and were they free of major typographical errors or ambiguous language that could affect the quality of testing?		

Is the application complete from a technical perspective? YES ☐ NO ☐

If not, were documents, records, or corrections requested? YES ☐ NO ☐

Date Requested: _____

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 3.3

REVIEW OF APPLICATIONS FOR SECONDARY ACCREDITATION

Issue Date: 3/15/19 Revision: 3

Effective Date: 3/29/19 Supersedes: Revision 2

Ken Lancaster 3/15/19
Program Manager Date

Sharon Coleman 3/15/2019
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for reviewing administratively complete applications for secondary laboratory accreditation.

2.0 RESPONSIBILITIES

The Records Specialist or designee is responsible for:

- determining whether a laboratory's primary accreditation includes the fields of accreditation checked in the accreditation application;
- verifying fees received from a laboratory equal the amount due;
- notifying the laboratory of any deficiencies preventing application processing; and
- recommending action on an application for secondary accreditation.

3.0 PROCEDURES

The Records Specialist or designee shall review each application for secondary accreditation and verify a laboratory's primary accreditation includes the fields of accreditation for which the laboratory is requesting secondary accreditation by comparing the fields of accreditation checked in the accreditation application with objective evidence provided by the primary accreditation body. Objective evidence provided by a primary accreditation body may include:

- a copy of an accreditation certificate, including fields of accreditation;
- correspondence;
- information maintained on a public internet site maintained by the primary accreditation body or TNI;
- information provided orally by an employee or designee of the primary accreditation body; or
- a combination of these.

The Records Specialist or designee shall verify fees received from a laboratory equal the amount due by calculating the fee according to the current fee schedule and comparing that amount to the amount received from the laboratory.

The Records Specialist or designee shall notify the laboratory of any deficiencies preventing processing of the application. All deficiencies should normally be corrected within three months of receiving the

application. If an application still has deficiencies after six months, or if there has been no action by the laboratory to correct deficiencies for three months, the application may be forwarded to the Program Manager for formal denial action.

The Records Specialist or designee shall forward the application for secondary accreditation to the Program Manager or designee for final action according to Laboratory Accreditation Procedure 3.4, Final Action on Accreditation Applications, within 15 days of the date on which a complete application was received.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include objective evidence confirming a laboratory's primary accreditation and fields of accreditation.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 2/10/12
Revision 2, Effective date: 3/15/17

Revisions to this document:

- Changed the external organization that maintains accreditation information from NELAP to TNI to reflect current naming convention. *Section 3.0*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 3.4

FINAL ACTION ON ACCREDITATION APPLICATIONS

Issue Date: 3/12/21 Revision: 3

Effective Date: 3/15/21 Supersedes: Revision 2

Ken Lancaster 3/12/21
Program Manager Date

Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for final actions on applications for accreditation, including awarding primary and secondary accreditations and denying accreditations.

2.0 RESPONSIBILITIES

The Program Manager or designee is responsible for:

- awarding primary, secondary, and interim accreditations; and
- denying applications for accreditation for insufficiency or for cause.

The Records Specialist or designee is responsible for providing certificates and lists of fields of accreditation to accredited laboratories.

3.0 PROCEDURES

3.1 Accreditations

The Program Manager or designee shall, without undue delay, authorize the issue of primary accreditation to a laboratory if the laboratory meets the standards for accreditation (30 TAC Section 25.9, Standards for Environmental Testing Laboratory Accreditation), including successful completion of an audit (30 TAC 25.18, Environmental Testing Laboratory Assessments) and successful participation in required proficiency tests. The Program Manager shall not issue primary accreditation if the laboratory does not meet the standards for accreditation.

NOTE: The audit may have been conducted by another NELAP-approved accrediting body.

The Program Manager may issue an interim accreditation for up to 12 months to a laboratory that appears to meet the standards for accreditation if, after six months from the date on which a complete application for accreditation was received, a laboratory assessment has not been scheduled or if it appears likely a laboratory assessment will not be scheduled within six months.

The Program Manager or designee shall authorize the issue of secondary accreditation to a laboratory within 30 days of the date on which a complete application was received if the laboratory's primary accreditation includes the fields of accreditation checked in the completed accreditation application and fees received from the laboratory equal the amount due according to the current fee schedule. The Program Manager shall not issue secondary accreditation if the laboratory does not meet the standards for accreditation.

3.2 Certificate and Fields of Accreditation List

In granting accreditation, the Program Manager or designee shall provide a laboratory with a certificate (Figure 1) that includes:

- the name and insignia of the accreditation body;
- the name and address of the laboratory and all premises covered by the accreditation;
- a statement of conformity and a reference to the standard(s), including issue or revision;
- a statement that continued accreditation depends on successful participation in the accreditation program;
- a statement urging customers to verify the laboratory's accreditation status;
- a certificate number (the unique accreditation number of the laboratory);
- authorized signature;
- term of accreditation (effective date and expiration date); and
- NELAP/TNI insignia.

The Program Manager or designee shall also provide the laboratory with a listing of the fields of accreditation (Figure 2) that includes, at a minimum:

- the name and insignia of the accreditation body;
- fields of accreditation for which the laboratory is receiving accreditation;
- the primary accreditation body for each field of accreditation;
- the laboratory's name and address;
- a certificate number;
- term of accreditation ("Issue Date and Expiration Date");
- NELAP/TNI insignia; and
- page numbers and total number of pages.

The certificate and fields of accreditation list shall be considered official documents.

3.3 Denial of Accreditations

The Program Manager shall, without undue delay, deny an initial or renewal application for insufficiency and for cause. Reasons to deny an application are specified in 30 TAC Section 25.32(a).

The Program Manager shall notify a laboratory in writing of the agency's intent to deny an accreditation application in part or in total and advise the applicant of the opportunity to file a motion to overturn according to 30 TAC Section 50.139, relating to Motion to Overturn Executive Director's Decision, and take follow-up action when required.

If a laboratory is not successful in correcting deficiencies as required by the standards for accreditation and the laboratory's application is denied, the laboratory must wait a minimum of six months before reapplying for accreditation.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- records documenting accreditations awarded to laboratories, including copies of the certificates and lists of fields of accreditation issued to laboratories; and
- correspondence and records concerning accreditation denials and recommendations of denial.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective Date: 6/01/05
Revision 1, Effective Date: 2/10/12
Revision 2, Effective Date: 3/15/17

The following revisions were made to this document:

- Figure 1 was updated to reference the 2016 Standard in lieu of the 2009 Standard.

Figure 1
Example Accreditation Certificate

Texas Commission on Environmental Quality

NELAP-Recognized Laboratory Accreditation is hereby awarded to

Blank Environmental Laboratory, Inc. - Anytown

3 Main Street
Anytown, TX 78711

for demonstrating conformance with Texas Water Code Chapter 5, Subchapter R, Title 30 Texas Administrative Code Chapter 25, and the Standards for Accreditation Adopted by the National Environmental Laboratory Accreditation Program.

The laboratory's scope of accreditation includes the fields of accreditation that accompany this certificate. Continued accreditation depends upon successful ongoing participation in the program. The Texas Commission on Environmental Quality urges customers to verify the laboratory's locations and current accreditation status for particular methods and analyses. (See www.tceq.texas.gov/goto/lab.)

Certificate Number: T104700000-YR-Seq#
Effective Date: 11/1/2020
Expiration Date: 10/31/2021
NELAP Standards: EL-V1-2016 and EL-V2-2016

Executive Director Texas Commission on Environmental Quality

Figure 2
Example List of Laboratory Fields of Accreditation

Texas Commission on Environmental Quality

NELAP - Recognized Laboratory Fields of Accreditation

Blank Environmental Laboratory, Inc. - Anytown
3 Main St
Anytown, TX 78711

Certificate: T104700000-11-2
Expiration Date: 11/01/2011
Issue Date: 10/31/2012

These fields of accreditation supercede all previous fields. The Texas Commission on Environmental Quality urges customers to verify the laboratory's current accreditation status for particular methods and analyses.

Matrix: *Air*

Method 40 CFR 50 App B			
Analyte	**AB**	**Analyte ID**	**Method**
Suspended Particulates, Total	TX	10221	40 CFR 50 App B

Method 40 CFR 50 App G			
Analyte	**AB**	**Analyte ID**	**Method**
Lead	TX	1075	40 CFR 50 App G

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 4.1

NATIONAL LABORATORY ACCREDITATION DATABASE

Issue Date: 3/15/19 Revision: 4

Effective Date 3/29/19 Supersedes: Revision 3

Ken Lancaster 3/15/19
Program Manager Date

Marvel Columbus 3/15/2019
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for preparing and submitting information for the national laboratory accreditation database.

2.0 RESPONSIBILITIES

The Records Specialist or designee is responsible for preparing and submitting information to the national laboratory accreditation database.

3.0 PROCEDURES

The Records Specialist or designee shall provide the following information for laboratories which the Texas Commission on Environmental Quality (TCEQ) serves as the primary accreditation body or whose primary accreditation status through the TCEQ changes:

- name, address, and telephone number of the laboratory;
- accreditation status, e.g., primary accreditation, scope of accreditation;
- changes in accreditation status, e.g., additional fields, withdrawal; and
- other information required by the standards for accreditation.

The Records Specialist or designee shall electronically submit updated scopes of accreditation for the laboratories discussed above to the national database at least monthly. All other information listed above will be added to or updated on the national database as the information becomes available.

3.1 Updating Information in The NELAC Institute Laboratory Accreditation Management System

The procedure for accessing and updating information in The NELAC Institute Laboratory Accreditation Management System (TNI LAMS) is as follows.

- Navigate to "https://lams.nelac-institute.org/" or search "TNI LAMS" in Google and click on the TNI LAMS link.
- Click on "AB Login."
- Enter your login credentials.

The procedure to add or update general laboratory information is as follows.

- Click on the "Labs" link.
- Click on the "Add a Lab" link to add a laboratory or click on the desired laboratory and click on the "Edit" button.
- Update respective information.
- Click on the "Save" button.

The procedure to electronically submit updated scopes of accreditation for all laboratories discussed above is as follows.

- Click on the "Uploads/Downloads" link.
- Under the "Information Type" dropdown menu, select "LAB FoAs."
- Select box "Check here to remove all of your FOAs from LAMS prior to processing your upload file."
- Click on the "Select File" button.
- When the pop-up screen appears , select the "NdbFOA.CSV" file and click on the "Open" button.
- Back in LAMS, click on the "Process File" button.
- Allow the process to work without interruption (this may take a while).

3.2 Creating Scopes of Accreditation File from AB Manager

The procedure for generating an updated Scopes of Accreditation .CSV file is as follows.

- Make sure there is a folder with the path name "C:\PT_Files." This folder is where the .CSV file will appear once generated. If one does not exist, contact the Records Specialist to have the necessary folder and files installed.
- Open the "AB Manager" Microsoft Access database.
- Under the "Welcome" tab, click on the "Tables/Reports" button.
- In the "Tables and Reports" window, click on the "NationalDatabase" link.
- In the "National Database Functions" window, click on the "Export FOA" button. Allow the process to work without interruption.
- When the process is complete, a notification window will pop up and state: "National Database file created. The file is called NdbFOA.CSV located in C:\PT_Files."

4.0 DOCUMENTS AND RECORDS

None. The national database (TNI LAMS) maintains information concerning uploads, including user, upload date, and upload type (laboratory or FOA). The national database administrator can provide reports documenting uploads if necessary.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 2/10/12
Revision 2, Effective date: 10/24/12
Revision 3, Effective date: 03/15/17

Revisions to this document:

- Added procedures on how to upload information to LAMS and updated links to reflect current practice using LAMS version 2.0. *Section 3.1*
- Added a procedure for contacting the Records Specialist to install necessary folders and files to clarify the process for generating updated scopes of accreditation. *Section 3.2*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 5.1

CONFIDENTIAL BUSINESS AND NATIONAL SECURITY INFORMATION

Issue Date: 3/15/19 Revision: 3

Effective Date: 3/29/19 Supersedes: Revision 2

Ken Lancaster 3/15/19
Program Manager Date

Sharon Coleman 3/15/2019
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for identifying and maintaining documents and records claimed by a laboratory as confidential business or national security information.

2.0 RESPONSIBILITIES

Laboratories are responsible for:

- identifying documents and records claimed as confidential business information and
- responding to questions concerning claims of confidential business information.

Laboratories operated by Federal agencies, departments, or contractors are responsible for identifying documents and records claimed as national security information.

Laboratory accreditation staff are responsible for:

- safeguarding documents and records claimed as confidential business information and
- not releasing documents and records claimed as confidential business information to the public except as provided by applicable laws, rules, and procedures.

Lead auditors are responsible for:

- including information concerning confidential business information in audit plans and
- ensuring confidential business and national security information has been stricken from audit reports before the reports are released.

The Program Manager or designee is responsible for:

- contacting laboratories regarding questions associated with claims of confidential business information, if necessary, and
- notifying laboratory directors of decisions regarding the disposition of claims of confidential business information.

3.0 PROCEDURES

3.1 Confidential Business Information

A laboratory may claim any document or record provided in the course of applying for or maintaining accreditation as confidential business information by labeling the document or record as "Confidential Business Information," "Trade Secret," or similar phrase.

Laboratory accreditation staff shall safeguard documents and records claimed as confidential business information and may not disclose or provide copies of documents or records claimed as confidential business information to the public except as provided in:

- Texas Government Code Chapter 552;
- OPP 6.18.01, Requests For Public Information: Policy Introduction;
- OPP 6.18.02, Requests For Public Information: How to Respond to a Request for Public Information;
- OPP 13.02.01, Records Management: Policy Introduction;
- Guide for Administrative Procedures (GAP) Manual, Chapter 3C, Public Information Act Request Procedures; and
- Texas Commission on Environmental Quality open records requests procedures for divisions, regions, and offices.

In the event the Texas Commission on Environmental Quality questions a claim that a document or record is confidential business information, the Program Manager or designee shall contact the affected laboratory and allow the laboratory 21 calendar days to:

- provide justification for the claim of confidential business information;
- remove the claim of confidential business information;
- resolve the issue in a manner agreeable to both the laboratory and the accreditation body;
- engage legal assistance;
- appeal the action according to the standards for accreditation; or
- withdraw the laboratory's accreditation application for the field of accreditation associated with the confidential business information.

The Program Manager or designee shall notify a laboratory's director of all decisions regarding acceptance or denial of a claim of confidential business information within the time frames established by applicable state laws and agency procedures. If no time frames are specified, the Program Manager or designee shall notify a laboratory's director of a decision regarding the acceptance or denial of a claim of confidential business information within 30 calendar days of receiving the laboratory's response to the question regarding the claim. In no instance shall the Texas Commission on Environmental Quality declassify information claimed as confidential business information without notifying the affected laboratory.

Lead auditors shall include information concerning confidential business information (Figure 1) in audit plans and shall ensure all confidential business information has been stricken from audit reports before the reports are released.

In the event of a conflict between standards and Texas statutes or agency rules and procedures, laboratory accreditation staff shall ensure their activities conform to requirements contained in Texas statutes and agency rules and procedures. The Program Manager or designee shall contact TNI and attempt to resolve the conflict.

3.2 National Security Information

A laboratory operated by a federal agency, department, or contractor may claim any document or record or information contained in any document or record associated with an application for or maintenance of accreditation as national security information by informing the agency in writing that the information is controlled for national security reasons and may not be released to the public.

Laboratory accreditation staff shall not receive, use, or disclose documents or records claimed as national security information or information contained in documents or records claimed as national security information without written approval from the cognizant federal agency, department, or contractor and the Program Manager.

In the event of a conflict between standards and a claim of national security information, laboratory accreditation staff shall ensure their activities conform to requirements contained in this procedure.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include documents, records, and correspondence relating to claims, questions, and decisions regarding confidential business and national security information.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 06/01/2005
Revision 1, Effective date: 02/10/2012

The following revisions were made to this document:

- Revised the contact person in the event of conflicts between state laws and the standard regarding confidential business information from the standards for accreditation director to TNI to reflect current practice. *Section 3.1 and Figure 1*

Figure 1
CONFIDENTIAL BUSINESS INFORMATION

A laboratory may claim any document or record provided to the Texas Commission on Environmental Quality in the course of applying for or maintaining accreditation as confidential business information by labeling the document or record as "Confidential Business Information," "Trade Secret," or similar phrase.

Laboratory accreditation staff will safeguard documents and records claimed as confidential business information and will not disclose or provide copies of documents or records claimed as confidential business information to the public except as provided in Texas Government Code Chapter 552.

In the event the Texas Commission on Environmental Quality questions a claim that a document or record is confidential business information, agency staff will contact the affected laboratory and allow the laboratory 21 calendar days to:

- provide justification for the claim of confidential business information;
- remove the claim of confidential business information;
- resolve the issue in a manner agreeable to both the laboratory and the agency;
- engage legal assistance;
- appeal the action according to the standards for accreditation; or
- withdraw the laboratory's accreditation application for the field of accreditation associated with the confidential business information.

The Texas Commission on Environmental Quality will notify the laboratory's director of all decisions regarding the acceptance or denial of a claim of confidential business information within the time frames established by applicable state laws and agency procedures. If no time frames are specified, the agency will notify the laboratory's director of a decision regarding the acceptance or denial of a claim of confidential business information within 30 calendar days of receiving the laboratory's response to the question regarding the claim. In no instance will the Texas Commission on Environmental Quality declassify information claimed as confidential business information without notifying the affected laboratory.

In the event of a conflict between standards for accreditation and Texas statutes or agency rules and procedures, laboratory accreditation staff shall ensure their activities conform to requirements contained in Texas statutes and agency rules and procedures. The Program Manager or designee shall contact TNI and attempt to resolve the conflict.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 5.2

EVALUATION OF CHANGES IN A LABORATORY'S KEY ACCREDITATION CRITERIA

Issue Date: 3/1/17 Revision: 2

Effective Date: 3/15/17 Supersedes: Revision 1

Ken Lancaster 2/24/17
Program Manager Date

Sharon Coleman 2/24/2017
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for receiving and evaluating significant changes relevant to a laboratory's accreditation.

2.0 RESPONSIBILITIES

Laboratories are responsible for notifying the program, without delay, of significant changes relevant to their accreditation, in any aspect of their status or operation as specified in the standards for accreditation.

The Records Specialist or designee is responsible for receiving and filing notifications and evaluations of significant changes relevant to a laboratory's accreditation.

The Program Manager or designee is responsible for evaluating significant changes relevant to a laboratory's accreditation and advising laboratories of the results of the evaluations.

The Work Group Lead or designee is responsible for updating the audit schedule, if necessary, based on changes to a laboratory's accreditation.

3.0 PROCEDURES

The Records Specialist or designee shall receive notifications of significant changes relevant to a laboratory's accreditation. Examples of significant changes include, but are not limited to the following:

- changes in laboratory ownership or management (including technical or quality manager changes);
- changes in laboratory location(s);

- desired addition or removal of parameters from the laboratory's scope of accreditation; or
- events that interrupt the laboratory's ability to analyze samples (e.g. technical manager's extended absence, building fire, or natural disaster).

Within seven calendar days of receiving notification of significant changes relevant to a laboratory's accreditation, the Records Specialist or designee shall file the notification in the appropriate laboratory accreditation file and forward a copy to the Work Group Lead or designee so that they may alter the audit schedule if necessary based on the new information. The Work Group Lead or designee does not need notification of changes in laboratory ownership or management.

The Program Manager or designee shall evaluate significant changes relevant to a laboratory's accreditation and determine whether:

- the changes could alter or impair a laboratory's capability and quality; and
- an audit is needed to verify a laboratory's capability or quality.

The Program Manager, Team Leader, or designee shall advise the laboratory in writing if an audit will be scheduled to verify a laboratory's capability or quality.

The Program Manager, Team Leader, or designee shall forward a copy of the correspondence to the Records Specialist or designee within seven calendar days of mailing the evaluation.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- notifications received from laboratories of significant changes relevant to their accreditation; and
- correspondence concerning changes in key accreditation criteria sent to laboratories.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 2/10/12

Revisions to this document:

- Added an "Issue Date" to allow time for staff to read and understand LAP before implementation. *Approval section*
- Added Work Group Lead responsibilities to reflect current practices. *Section 2.0*
- Changed the responsibility of evaluating significant changes from Team Leader to Program Manager to reflect current practices. *Sections 2.0 and 3.0*
- Added examples of significant changes relevant to a laboratory's accreditation to provide additional information to users of this document; added criteria for when the Work Group Lead does not need to be notified of a change to reflect current practices; added Program Manager to the list of people who notify the laboratory and provide records to the Records Specialist to add more flexibility; and added "calendar" to "days" to provide clarity. *Section 3.0*
- Added a revision history section to improve documentation of previous revisions of this LAP and to document changes made to this revision. *Section 5.0*

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 5.3

RECEIPT AND EVALUATION OF PROFICIENCY TEST SAMPLES

Effective Date: 02/05/2024 Revision: 7

Supersedes: Revision 6

	02/01/2024		02/02/2024
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements concerning the receipt and evaluation of proficiency test sample results associated with the ongoing maintenance of laboratory accreditations.

2.0 RESPONSIBILITIES

The Records Specialist or designee is responsible for:

- receiving and forwarding proficiency test sample results and other documents relating to proficiency tests;
- evaluating proficiency test results and determining whether laboratories continue to meet proficiency test standards for accreditation;
- periodically reviewing records to ensure laboratories are performing required PT studies; and
- notifying laboratories and the Program Manager or designee whenever a laboratory is out of compliance.

The Program Manager or designee is responsible for:

- determining whether or not to accept proficiency test sample results that do not meet quality control requirements;
- contacting proficiency test sample providers concerning samples that do not meet quality control requirements and attempting to resolve the issue(s) associated with the samples;
- referring concerns as necessary to a proficiency test sample provider's accreditation body; and
- initiating action to deny, suspend, or revoke the accreditation of laboratories that do not meet proficiency test requirements.

3.0 PROCEDURES

3.1 Receipt and Evaluation

The Records Specialist or designee shall receive proficiency test results and other documents relating to proficiency tests.

Within 60 calendar days of receiving proficiency test results for a laboratory, the Records Specialist or designee shall evaluate the results and determine whether the laboratory continues to meet proficiency test standards for accreditation. The evaluation shall consider whether a laboratory:

- successfully (i.e., is evaluated as acceptable by the proficiency test sample provider) completes the required number of proficiency test studies at the required intervals, for each field of accreditation;
    - "Acceptable" PT study scores from a PT Provider do not automatically result in a successful evaluation of a PT study by an AB. For example, failure to report an analytical method or reporting of an incorrect method, failure to provide the PT Provider with a release of results to the AB before the close of the study, failure to report results to the PT Provider before the closing date, failure to handle PT study samples in the same manner as routine environmental samples, etc. may be cause for an unsuccessful evaluation by an AB.
    - If a laboratory has a transcriptional error when entering the method code to the PT provider database and the PT provider will correct the method code, then we may accept the results. For the result to be accepted, the laboratory will need to initiate contact with the PT provider and provide to TCEQ the following documentation: the data package from the PT, the original information submitted to the PT provider, and the corrected PT provider information with the passing result documented. The results to the PT provider must have been completed within the required interval for the laboratory.
- secures proficiency test study samples from an approved provider as part of study that complies with the standards for accreditation; and
- returns proficiency test results to the provider on or before the closing dates of the proficiency test studies and within the time frames specified in the standards for initial accreditation.
    - These timeframes are as follows: The two (2) PT studies must be performed no more than eighteen (18) months prior to obtaining initial accreditation, with the closing date of the most recent successful PT study for an FoPT being no more than six (6) months prior to the application for initial accreditation. The opening date of the second study must be at least seven (7) calendar days after the closing date of the first study. This includes directing the PT provider, on or before the closing date of the study, to report the PT study performance results directly to the laboratory's primary AB. Failure to direct the PT provider to submit the results to the AB, on or before the closing date of the study, constitutes a PT failure.

The Records Specialist or designee shall periodically review laboratory PT data to ensure laboratories are not missing any required PTs and performing required PTs within the time frames specified in the continued accreditation clauses.

The Records Specialist or designee shall notify the laboratory if it fails to meet proficiency test standards for accreditation. Notification will include the matrix, parameter, and number of successful PT results needed to be in compliance.

Except for drinking water analytes referenced in 40 CFR 141, a laboratory may analyze and report multiple method-specific results for the same analytes from one proficiency test sample. However, if a laboratory reports more than one method per technology per study for a field of test, an unacceptable result by any method would be considered a failed study for that technology.

A laboratory may withdraw from a proficiency test study for an analyte(s) or for the entire study if the laboratory notifies both the sample provider and the Texas Commission on Environmental Quality before

the closing date of the study. This does not exempt the laboratory from successfully completing the required number of proficiency test studies or adhering to the required intervals for proficiency tests.

A laboratory may participate in supplemental proficiency test studies when the laboratory fails a proficiency test study and wishes to re-establish its history of successful performance. The laboratory must notify the test provider that the proficiency sample is to be used for corrective action and the opening date of PT study samples for a particular field of accreditation must be at least seven (7) calendar days after the closing date of a PT study for the same field of accreditation.

3.2 Failed Proficiency Tests

As part of the evaluation, the Records Specialist or designee shall advise the Team Leader or designee of any laboratory that:

- does not successfully complete the required number of proficiency test studies at the required intervals, i.e., judged not acceptable by the proficiency test sample provider because of an unacceptable result, not being reported in a timely manner, not being reported, or other criteria in the standards for accreditation; or
- submits results for test samples that were generated by another laboratory.

The Program Manager shall be notified by the Records Specialist or designee if action is to be taken against the laboratory. Subject to applicable laws, regulations, and due process requirements, the Program Manager shall initiate action to deny, suspend, or revoke the laboratory's accreditation for each affected field of accreditation. The laboratory may also resolve failed proficiency tests through a voluntary withdrawal of affected fields of accreditation.

3.3 Proficiency Test Samples Not Meeting Requirements

There may be occasions when a proficiency test sample provider shipped one or more samples that do not meet quality control requirements contained in the standards and the provider has not notified affected laboratories or accrediting authorities in a timely manner. Upon review of summary data or other relevant documentation, the Program Manager or designee may choose not to accept proficiency test results for the analyte(s)/matrices to support the accreditation status of the laboratories.

Before rejecting the results, the Program Manager or designee shall first contact the proficiency test sample provider and attempt to resolve the issue(s) associated with the samples. The Program Manager may refer the issues associated with the proficiency test samples to the proficiency test provider's accreditation body.

If the Program Manager or designee discovers that a proficiency test sample provider suggested or directed a laboratory to purchase QC standards specifically designed for a given proficiency test sample or the proficiency test sample provider gave the laboratory instructions beyond those specified in the standards for accreditation, the Program Manager or designee shall report these findings to the proficiency test sample provider accrediting body.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- proficiency test sample results;
- investigations and corrective actions concerning failed proficiency test studies;

- correspondence concerning proficiency test samples; and
- documents and records concerning the initiation of denial, suspension, or revocation actions.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of ten years past the term of accreditation.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 2/10/12
Revision 2, Effective date: 10/24/12
Revision 3, Effective date: 3/15/17
Revision 4, Effective date: 3/14/19
Revision 5, Effective date: 1/31/20
Revision 6, Effective date: 1/31/22

The following revisions were made to this document:

- Updated language to reflect potential acceptance of transcriptional errors for method codes of PTs.
- Updated the document retention time period.
- Removed the issued date.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 5.4

REPORTS OF POTENTIAL NONCONFORMANCES AND POTENTIALLY ILLEGAL LABORATORY PRACTICES

Issue Date: 3/11/19 Revision: 3

Effective Date: 3/14/19 Supersedes: Revision 2

Ken Lancaster 3/11/19
Program Manager Date

Sharon R. Coleman 3/11/2019
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for addressing reports of potential nonconformances. Potential nonconformances include complaints and potentially illegal laboratory practices.

2.0 RESPONSIBILITIES

Laboratory accreditation staff are responsible for advising the Program Manager or designee of potential nonconformances, including complaints and potentially illegal activities.

The Program Manager or designee is responsible for:

- reviewing, investigating, determining the validity of, and responding to reports of potential nonconformances;
- notifying primary accrediting authorities of potential laboratory nonconformances; and
- forwarding information to necessary parties concerning potentially illegal laboratory activities.

3.0 PROCEDURES

3. 1 Potential Laboratory and Program Nonconformances

Laboratory accreditation staff shall advise the Program Manager or designee of potential laboratory and program nonconformances as soon as possible by forwarding copies of written reports they receive and summaries of potential nonconformance information received by telephone or identified in the course of work.

Laboratory accreditation staff may ask an individual making a report for contact information, e.g., name, telephone number, but shall not require contact information.

The Program Manager or designee shall review and investigate potential nonconformances as soon as possible. The TCEQ LAP Complaint Tracking Form must be completed on complaints concerning the program. An example of the form is shown in Figure 1. The Laboratory Complaint Tracking Form must be completed on complaints concerning laboratories with primary accreditation from TCEQ. An example of the form is shown in Figure 2. The Program Manager or designee shall ensure the following:

- the validity of the complaint is determined
- where appropriate, a complaint concerning a laboratory is first addressed by the laboratory;
- any reports of potentially illegal laboratory activities are forwarded to the Texas Commission on Environmental Quality's Environmental Crimes Unit;
- appropriate actions are taken and their effectiveness assessed;
- all complaints and actions taken are recorded; and
- where practical, e.g., the complainant provides contact information, respond to the complainant.

3.1.1 Laboratories with Primary Accreditation from the Texas Commission on Environmental Quality

Reports from secondary accreditation bodies concerning potential nonconformances at laboratories holding primary accreditations from the Texas Commission on Environmental Quality shall be addressed according to the standards for accreditation (30 TAC Section 25.9, Standards for Environmental Testing Laboratory Accreditation).

The Program Manager or designee shall respond to the affected secondary accreditation body in writing as soon as possible. The response shall include:

- initial findings concerning the reported nonconformance(s);
- a description of actions to be taken; and
- a schedule for implementing further actions, if necessary.

3.1.2 Laboratories with Secondary Accreditation from the Texas Commission on Environmental Quality

Reports of potential nonconformances at laboratories holding primary accreditations from other accreditation bodies shall be addressed according to the standards for accreditation (30 TAC Section 25.9, Standards for Environmental Testing Laboratory Accreditation).

The Program Manager or designee shall notify the primary accreditation body in writing as soon as possible and no later than two days after receiving a report of a potential nonconformance. The notification shall identify the laboratory, potential nonconformance(s), and relevant accreditation standards.

The Program Manager shall provide a copy of the notification to the laboratory if no administrative or judicial action is contemplated by the Texas Commission on Environmental Quality. The Program Manager may not provide a copy of the notification to the laboratory if an administrative or judicial action is contemplated by the agency.

The Program Manager may not take any final action concerning a pending application for secondary accreditation until the potential nonconformance(s) has been resolved.

A laboratory holding a secondary accreditation from the Texas Commission on Environmental Quality shall maintain its current accreditation status until the potential nonconformance(s) has been resolved.

If the primary accreditation body does not take timely and appropriate action concerning a report of potential nonconformance(s), the Program Manager may notify NELAP.

3.1.3 Proficiency Test Sample Providers

A nonconformance involving proficiency test samples that do not meet quality control requirements contained in the standards and failure by the proficiency test sample provider to notify affected laboratories and accrediting authorities in a timely manner shall be addressed according to the standards for accreditation (30 TAC Section 25.9, Standards for Environmental Testing Laboratory Accreditation).

After notifying the proficiency test sample provider, the Program Manager may submit a written complaint to the provider's accreditation body. In submitting the complaint, the Program Manager shall follow all procedures for filing complaints specified by the accreditation body.

3.2 Potentially Illegal Laboratory Practices

Laboratory accreditation staff shall advise the Program Manager or designee of reports concerning potentially illegal laboratory practices as soon as possible and no later than two days after receiving information pertaining to potential illegal practices by forwarding copies of written reports they receive or summaries of potentially illegal activities received by telephone or identified in the course of work.

Laboratory accreditation staff may ask an individual making a report for contact information, e.g., name, telephone number, but shall not require contact information.

The Program Manager or designee shall forward all reports concerning potentially illegal laboratory practices to the Texas Commission on Environmental Quality's Environmental Crimes Unit Manager or designee as soon as possible and no later than two days after receiving a report concerning potentially illegal laboratory practices.

Other than performing normal accreditation activities, laboratory accreditation staff shall take no further action relating to reports of potentially illegal laboratory practices.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- reports of potential nonconformances;
- reports of potential illegal laboratory practices.
- Completed TCEQ LAP Complaint Tracking Form
- Completed Laboratory Complaint Tracking Form

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 06/01/2005
Revision 1, Effective date: 02/10/2012
Revision 2, Effective date: 03/15/2017

The following revisions were made to this document:

- Added requirement to complete the TCEQ LAP Complaint Tracking Form and the Laboratory Complaint Tracking Form to ensure all requirements in the TNI Standard concerning complaints are met. In addition, added language from the TNI Standard to clarify requirements for dealing with complaints. *Section 3.1*

- Added the new complaint tracking forms and removed summary reports from the list of documents and records produced due to the addition of the new complaint tracking forms. *Section 4.0*

Figure 1
Example TCEQ LAP Complaint Tracking Form

TCEQ LAP Complaint Tracking Form

Date Complaint Received: _____

Name of Complainant: _____ ☐ Anonymous

Complaint assigned to: _____

1. Did complainant provide contact information? ☐ Yes ☐ No

2. Was an investigation of the complaint conducted? ☐ Yes ☐ No

3. Were the results of the investigation documented? ☐ Yes ☐ No

4. Are corrective actions necessary? ☐ Yes ☐ No

   If yes, are the actions documented in the *Results of Investigation/Conclusions* section? ☐ Yes ☐ No ☐ NA

   If yes, are the means to document effectiveness documented in the *Results of Investigation/Conclusions* section? ☐ Yes ☐ No ☐ NA

5. Was a response provided to the complainant after the investigation? ☐ Yes ☐ No ☐ NA

   What was the date of the response? _____

6. Is there a file for the complaint with all applicable documentation? ☐ Yes ☐ No

Checked & completed by: _____ Date: _____

Details of Complaint:

Summary of Investigation:

Results of Investigation/Conclusions:

Figure 2
Example Laboratory Complaint Tracking Form

Laboratory Complaint Tracking Form

Date Complaint Received: _____

Name of Laboratory: _____

Name of Complainant: _____ ☐ Anonymous

Complaint assigned to: _____

1. Did complainant provide contact information? ☐ Yes ☐ No

2. Are there potential illegal laboratory practices? ☐ Yes ☐ No

   If yes, was complaint forwarded to TCEQ Environmental Crimes Unit? ☐ Yes ☐ No ☐ NA

   If yes, what was the date of forwarding? _____

   If yes, no other action from TCEQ LAP will be taken.

3. Has complainant contacted the laboratory? ☐ Yes ☐ No

   If no, was complainant instructed to contact laboratory? ☐ Yes ☐ No ☐ NA

   If no, what was the date of the instruction? _____

   If no, no other action from TCEQ LAP will be taken.

4. Was an investigation of the complaint conducted? ☐ Yes ☐ No ☐ NA

5. Were the results of the investigation documented (including any actions taken)? ☐ Yes ☐ No ☐ NA

6. Was a response provided to the complainant after the investigation? ☐ Yes ☐ No ☐ NA

   What was the date of the response? _____

7. Is there a file for the complaint with all applicable documentation? ☐ Yes ☐ No

Checked & completed by: _____ Date: _____

Details of Complaint:

Summary of Investigation:

Results of Investigation/Conclusions:

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 6.0

SUSPENSION AND REVOCATION

Issue Date: 03/03/23 Revision: 4

Effective Date: 03/03/23 Supersedes: Revision 3

	03/03/23		03/03/2023
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements concerning the suspension and revocation of laboratory accreditations, reinstatement of suspended accreditations, and appeals of suspensions and revocations.

2.0 RESPONSIBILITIES

The Program Manager or designee is responsible for:

- initiating action to suspend or revoke laboratory accreditations;
- requesting the return of accreditation certificates and lists of fields of accreditation from laboratories whose accreditations change as a result of suspensions or revocations; and
- reinstating suspended accreditations.

The Records Specialist or designee is responsible for:

- including changes in a laboratory's accreditation status resulting from a suspension or revocation in the next regular update of the national laboratory accreditation database; and
- forwarding revised accreditation certificates and lists of fields of accreditation to laboratories whose accreditations are suspended or revoked in part or whose accreditations are reinstated.

3.0 PROCEDURES

3.1 Suspensions

The Program Manager or designee may initiate action to suspend a laboratory's accreditation according to 30 TAC Chapter 80, Contested Case Hearings. Reasons to suspend a laboratory's accreditation, in whole or in part, are specified in 30 TAC Section 25.34, Suspension of Accreditation.

Failing to comply with minimum performance and quality assurance standards includes but is not limited to:

- incorrect references to the accreditation body's NELAP accreditation;
- misleading use of the laboratory's NELAP accreditation status and/or unauthorized use of the NELAP logo is found in catalogs, advertisements, business solicitations, proposals, quotations, laboratory analytical reports or other material;
- failing to provide a corrective action report concerning a failed proficiency test within 30 days of request; and
- findings during an on-site audit that require emergency action due to public interest, safety or welfare.

The Program Manager or designee may initiate action to suspend a laboratory's accreditation within 15 days of learning that grounds for suspension likely exist.

Note: The Texas Commission on Environmental Quality does not generally take action to suspend a laboratory's accreditation due to the time allowances for the process of suspension and appeal. Instead, a laboratory's request for renewal of accreditation will be denied at the time of renewal. In general, denial at the time of renewal is the quickest process to address a laboratory's failure to comply with minimum performance and quality assurance standards.

The Records Specialist or designee shall include changes in a laboratory's accreditation status resulting from a suspension in program files and in the next regular update of the national laboratory accreditation database.

The Program Manager or designee shall reinstate a suspended accreditation if a laboratory meets all requirements imposed by the Texas Commission on Environmental Quality according to 30 TAC Section 25.34, Suspension of Accreditation, including ensuring the laboratory meets all requirements for continued accreditation. The Program Manager or designee shall initiate any action to reinstate an accreditation so as to ensure a laboratory is accredited on the date for reinstatement established in a suspension order.

The Records Specialist or designee shall include changes in a laboratory's accreditation status resulting from the reinstatement of a suspended accreditation in program files and in the next regular update of the national laboratory accreditation database.

3.2 Revocations

The Program Manager or designee shall initiate action to revoke a laboratory's accreditation according to 30 TAC Chapter 80, Contested Case Hearings. Reasons to revoke a laboratory's accreditation, in whole or in part, are listed in 30 TAC Section 25.32, Denial of Accreditation Application and Revocation of Accreditation.

The Program Manager or designee may initiate any action to revoke a laboratory's accreditation within 15 days of learning that grounds for revocation likely exist.

Note: The Texas Commission on Environmental Quality does not generally take action to revoke a laboratory's accreditation due to the time allowances for the process of revocation and appeal. Instead, a

laboratory's request for renewal of accreditation will be denied at the time of renewal. In general, denial at the time of renewal is the quickest process to address a laboratory's failure to comply with minimum performance and quality assurance standards.

The Records Specialist or designee shall include changes in a laboratory's accreditation status resulting from a revocation in program files maintained by the agency and in the next regular update of the national laboratory accreditation database. The Records Specialist or designee shall also notify any known secondary accreditation bodies of a laboratory's revocation.

3.3 Appeals of Suspensions and Revocations

Laboratories may appeal proposed suspensions and revocations. Appeals shall be made and occur according to 30 TAC Chapter 80, Contested Case Hearings. The Program Manager or designee shall take follow-up action when required.

3.4 Certificates

Within seven days of a suspension or revocation, the Program Manager or designee shall request in writing that the affected laboratory return its current accreditation certificate and list of fields of accreditation and that the affected laboratory discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results, or other materials that contain reference to its past accreditation status and/or display the NELAP logo.

Within 15 days of a suspension or, if applicable, revocation, or upon receiving the current certificate and list of fields of accreditation, whichever is later, the Records Specialist or designee shall forward an up-to-date accreditation certificate and list of fields of accreditation to a laboratory whose accreditation is suspended or revoked in part.

The Records Specialist or designee shall forward an up-to-date accreditation certificate and list of fields of accreditation to a laboratory whose suspended accreditation has been reinstated. The Records Specialist designee shall forward the accreditation certificate and list of fields of accreditation so as to ensure a laboratory receives the documents on or before the date for reinstatement established in a suspension order.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- records initiating suspensions and revocations;
- copies of suspension and revocation orders;
- correspondence requesting return of certificates and lists of fields of accreditation;
- records reinstating suspended accreditations; and
- records reflecting changes in the accreditation status of laboratories resulting from suspensions, revocations, and reinstatement of suspended accreditations.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 06/01/05

Revision 1, Effective date: 02/10/12
Revision 2, Effective date: 03/15/17
Revision 3, Effective date: 03/03/21

The following revisions were made to this document:

- Only grammatical revisions were made to the document.
- Added clarifying language. *Section 2.0*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 6.1

VOLUNTARY REDUCTION OR WITHDRAWAL OF ACCREDITATION

Issue Date: Revision: 4
Effective Date: Supersedes: Revision 3

Ken Lancaster 3/29/21
Program Manager Date

3/29/2021
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure describes requirements for receiving and processing requests from laboratories to withdraw, in whole or in part, from the laboratory accreditation program.

2.0 RESPONSIBILITIES

The Records Specialist or designee is responsible for receiving and processing requests to withdraw from the laboratory accreditation program.

The Program Manager or designee is responsible for approving effective dates for requests to surrender accreditations that are not immediately effective and requesting the return of the laboratory's accreditation certificate and list of fields of accreditation.

3.0 PROCEDURES

The Records Specialist or designee shall receive and process any written (traditional or electronic) request to withdraw from the laboratory accreditation program submitted by a laboratory's owner or authorized agent.

Upon receiving a request to withdraw from the laboratory accreditation program, the Records Specialist or designee shall:

- determine the fields of accreditation a laboratory wishes to surrender and
- verify the request was made by the laboratory's recognized owner or authorized agent.

If a laboratory withdraws from the laboratory accreditation program in whole, the Program Manager or designee shall request return of the laboratory's accreditation certificate and list of fields of accreditation. The Records Specialist or designee shall confirm withdrawal of accreditation in writing within 30 calendar days from verification of withdrawal.

If a laboratory withdraws from the laboratory accreditation program in part, the Program Manager or designee shall request return of the laboratory's accreditation certificate and list of fields of accreditation. The Records Specialist or designee shall prepare a new accreditation certificate and list of fields of accreditation and forward to the laboratory within 15 calendar days from verification of withdrawal.

Requests to withdraw from the laboratory accreditation program shall be effective immediately unless another date is requested by a laboratory and approved by the Program Manager or designee.

The Records Specialist or designee may destroy accreditation certificates and lists of fields of accreditation returned by laboratories.

The Records Specialist or designee shall include changes in accreditation status resulting from requests to withdraw from the laboratory accreditation program in program files and in the next regular update of the national laboratory accreditation database.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- correspondence received from laboratories requesting withdrawal from the laboratory accreditation program;
- correspondence sent to laboratories confirming complete withdrawal from the laboratory accreditation program;
- any accreditation certificates and lists of fields of accreditation returned by laboratories; and
- records reflecting revised accreditations issued to laboratories in response to requests to withdraw in part from the laboratory accreditation program.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 Revision History

Revision 0, Effective Date: 6/1/05
Revision 1, Effective Date: 2/10/12
Revision 2, Effective Date: 3/15/17
Revision 3, Effective Date: 3/29/19

Revisions to this document:

- The revisions section in Revision 3 stated that the requirement to wait until receipt of the prior certificate before issuing a new certificate was removed. Although intended, the text was not removed in the final copy of revision 3. The noted text was removed in this revision.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 7.0

DOCUMENT AND RECORDS MANAGEMENT

Issue Date: 3/1/17 Revision: 3

Effective Date: 3/15/17 Supersedes: Revision 2

Ken Lancaster 2/24/17
Program Manager Date

Shara Coleman 2/24/2017
Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE

This procedure provides requirements for organizing, controlling, and maintaining laboratory accreditation documents and records.

2.0 RESPONSIBILITIES

Laboratory accreditation staff are responsible for forwarding documents and records to the Records Specialist or designee.

The Program Manager or designee is responsible for:

- approving laboratory accreditation procedures (LAPs) that identify and provide retention schedule(s) for documents and records associated with the laboratory accreditation program and
- concurring with the form in which laboratory accreditation staff submit documents and records.

The Records Specialist or designee is responsible for:

- preparing the laboratory accreditation records index;
- specifying, with the concurrence of the Program Manager, the form in which laboratory accreditation staff submit documents and records;
- ensuring documents are controlled; and
- labeling and filing documents and records.

3.0 PROCEDURES

3.1 Document and Record Retention

Laboratory accreditation documents and records and their associated retention periods are specified in section four of each laboratory accreditation procedure, *Documents and Records*. These documents and records shall be retained for the period specified in section four of the LAPs.

3.2 Laboratory Accreditation Records Index

The Records Specialist or designee shall prepare and maintain an index of laboratory accreditation documents and records. The index shall include the documents and records identified in laboratory accreditation procedures. The index shall include sufficient detail so the Records Specialist or designee may file, maintain, and retrieve document and record types and individual documents and records.

The Records Specialist or designee shall review and revise the index as necessary.

3.3 Submission of Documents and Records

Laboratory accreditation personnel shall forward completed documents and records to the Records Specialist or designee as required in laboratory accreditation procedures. The Records Specialist or designee shall return incomplete or illegible documents and records for completion or correction.

With the concurrence of the Program Manager or designee, the Records Specialist or designee may specify the form in which laboratory accreditation personnel submit the documents and records.

3.4 Receipt, Acceptance, and Labeling of Documents and Records

Within one week of receiving a document or record, the Records Specialist or designee shall file documents and records received from laboratory accreditation personnel in the laboratory accreditation program files. Documents and records shall be labeled according to the laboratory accreditation records index.

3.5 Control of Documents and Records

With the concurrence of the Program Manager or designee, the Records Specialist or designee shall establish procedures concerning access to and distribution of documents and records according to the agency's Records Management Manual.

The Records Specialist shall:

- ensure changes and current revision status of documents are identified;
- ensure relevant versions of applicable documents are available to accreditation staff, contractors, and laboratories; and
- prevent the unintended use of obsolete documents and suitably identify obsolete documents that are retained.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include the laboratory accreditation document and records index.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 0, Effective date: 6/1/05
Revision 1, Effective date: 11/1/08
Revision 2, Effective date: 2/10/12

The following revisions were made to this document:

- Added an issue date to allow time for staff to read and understand LAP before implementation. *Approval section*
- Added "and designee" designation to Program Manager and Records Specialist to increase flexibility. *Throughout document*
- Added requirement for the Records Specialist to control documents to capture the procedures documented in Section 3.5. Removed the requirement that the Records Specialist maintain an up to date list of documents and records in laboratory accreditation files because this is not a requirement of the standard. *Section 2.0*
- Added a Revision History section to improve documentation of previous revisions of this LAP and to document changes made to this revision. *Section 5.0*

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 7.1

LABORATORY ACCREDITATION PROCEDURES

Issue Date: 3/15/19
Effective Date: 3/29/19

Revision: 3
Supersedes: Revision 2

Program Manager Date: 3/15/19

Quality Assurance Specialist Date: 3/15/2019

1.0 PURPOSE AND SCOPE

This procedure describes the format and content of procedures issued by the laboratory accreditation program.

2.0 RESPONSIBILITIES

The Program Manager or designee is responsible for ensuring laboratory accreditation procedures are prepared, approved, implemented, periodically reviewed, revised as necessary, and available to laboratory accreditation staff.

The Quality Assurance Specialist is responsible for concurring with laboratory accreditation procedures and changes to laboratory accreditation procedures.

The Team Leader or designee is responsible for:

- maintaining laboratory accreditation procedures;
- incorporating changes to procedures in revised procedures; and
- making the procedures available to laboratory accreditation staff and contractors.

Laboratory accreditation staff and contractors are responsible for understanding, implementing, and adhering to laboratory accreditation procedures as they pertain to their job responsibilities.

3.0 PROCEDURES

The Program Manager or designee shall ensure laboratory accreditation procedures required by the standards for accreditation are prepared, implemented, maintained, and available as necessary to laboratory accreditation staff.

3.1 New Laboratory Accreditation Procedures

Laboratory accreditation procedures shall be approved and documented prior to implementation. At a minimum, each laboratory accreditation procedure shall contain:

- a unique title and procedure number;

- an issue date, effective date, and revision number;
- approval and concurrence signatures of the Program Manager and Quality Assurance Specialist, respectively;
- a summary of the purpose and scope of the procedure;
- summaries of individual responsibilities;
- procedures, including training, qualifications, references, figures, and tables, as necessary;
- a listing of the documents and records produced by the procedure and the retention period for the records;
- a revision history that documents previous revision numbers and their effective dates and a brief description of the revisions made, including the sections where the changes were made; and
- other information as necessary, e.g. checklists, forms, and flowcharts.

Figure 1 is an example of the format for laboratory accreditation procedures.

Upon approval by the Program Manager and Quality Assurance Specialist, the Team Leader or designee shall distribute laboratory accreditation procedures electronically in read-only form to laboratory accreditation staff. Laboratory accreditation staff will read the new laboratory accreditation procedure and will sign a statement that they have read, understood, and will follow the procedures identified in the laboratory accreditation procedure.

Figure 2 is an example of the statement that laboratory accreditation staff will sign.

3.2 Changes to Laboratory Accreditation Procedures

Changes to laboratory accreditation procedures shall be approved and documented prior to implementation. Laboratory accreditation procedures will be reviewed at least every two years and will be revised as necessary. At a minimum, changes to laboratory accreditation procedures shall include:

- the number and title of the affected procedure;
- an issue date, effective date, new revision number, and the number that it supersedes;
- approval and concurrence signatures of the Program Manager and Quality Assurance Specialist; respectively;
- revised procedures, records, and retention periods as necessary; and
- a revision history.

Upon approval by the Program Manager and Quality Assurance Specialist, the Team Leader or designee shall distribute changes to laboratory accreditation procedures electronically in read-only form to laboratory accreditation staff. Laboratory accreditation staff will read the revised laboratory accreditation procedure and will sign a statement that they have read, understood, and will follow the procedures identified in the laboratory accreditation procedure. The Team Leader or designee shall also notify other interested parties.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include laboratory accreditation procedures, revisions to procedures, and signed statements from laboratory accreditation staff.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of 10 years following the end of the fiscal year in which they were produced.

5.0 Revision History

Revision 1, Effective date: 2/10/2012
Revision 2, Effective Date: 3/15/2017

The following revisions were made to this document:

- Only grammatical revisions were made to the document.

Figure 1
Example Format for Laboratory Accreditation Procedures

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE [No.]

[TITLE]

Issue Date:
Effective Date:

Revision:
Supersedes:

Program Manager Date

Quality Assurance Specialist Date

1.0 PURPOSE AND SCOPE
2.0 RESPONSIBILITIES
3.0 PROCEDURES
3.1 [Individual Procedures]
3.1.1 [Sub-Paragraphs]
4.0 DOCUMENTS AND RECORDS
5.0 REVISION HISTORY

Figure 2
Example SOP statement

I have read the following laboratory accreditation procedures:

Number	Title	Revision Number	Effective Date

I understand the procedures and agree to follow the procedures identified in the laboratory accreditation procedures. I will obtain documented approval from the Program Manager prior to deviating from any procedure documented in the laboratory accreditation procedures.

_____ _____

Signature Date

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 7.2

RECORDS SPECIALIST PROCEDURES

Issue Date: 10/27/2023 Revision: 2

Effective Date: 11/01/2023 Supersedes: 1

	10/27/2023		
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This procedure describes duties performed by the records specialist that are not specified in other Laboratory Accreditation Procedures.

2.0 RESPONSIBILITIES

The Program Manager is responsible for identifying, approving, and revising fields of accreditation and changes to fields of accreditation. In addition, the program manager is responsible for approving refunds for laboratories.

The program manager and team leader are responsible for resolving issues relating to non-payment by laboratories.

The Records Specialist is responsible for performing the accreditation record activities listed below.

3.0 PROCEDURES

3.1 Notifying the public and responding to public requests for information

3.1.1 Labprgms mailbox

The records specialist or designee shall check the Labprgms mailbox at least once per workday. Technical questions in the mailbox are forwarded to an assessor for response. For responses taking more than three workdays to complete, an e-mail shall be sent to the originator explaining the delay and indicating an expected time for the response to be sent. In the absence of the records specialist, the backup records specialist(s) maintains access to the labprgms mailbox.

Questions that are not within the purview of the laboratory accreditation section shall be forwarded to the External Relations Division (ac@tceq.texas.gov) for routing to the appropriate section. Reassignment of the labprgms mailbox proxy is handled through the Publishing Section of the External Relations Division.

3.1.2 Private water or well water testing

Inquiries from the public about private water testing or private well water testing occur frequently.

- If the caller inquires about water testing for private purposes, the response is that any laboratory may be used. However, any testing must be conducted by a NELAP-accredited laboratory for a public drinking water system or submitted to the commission.
    - Phone calls for either instance is generally followed by an email providing helpful links and accreditation information. Refer to the Guidance for LAP 7.2 for the location of draft email shells.

3.1.3 GovDelivery notifications

When a laboratory is first accredited or loses accreditation for all analyte/method/matrix combinations, a mass e-mail notification shall be sent via the GovDelivery update system. A copy of each notification is retained. Refer to the Guidance for LAP 7.2 for the location of the retained mass e-mails. GovDelivery access is maintained by both the records specialist and backup records specialist(s). Changes in GovDelivery access can be made through a Computer Access Request Form (CARF) located on Sharenet. The Environmental Assistance Division is responsible for implementing the changes.

3.2 Billing

3.2.1 Monthly renewal billing for all laboratories

The records specialist or designee shall prepare invoices (i.e., billing statements) and send them out three months prior to the laboratory's renewal date.

The billing information for each lab and the amount due is obtained from the Billing/Invoice tab on AB Manager. AB Manager will create the of the billing statements to send to the laboratory.

Laboratories shall be notified by email approximately fifteen days prior to the expiration date of their accreditation if a paid billing receipt has not been received by the TCEQ. If payment is not received at least four days prior to expiration, a second email notification is sent. A communication from the *Master e-mails* folder may be used.

If a paid billing receipt has not arrived by the first of the month, a third email is sent to the laboratory indicating that their accreditation will not be renewed (per Texas Administrative Code) without payment. Refer to the Guidance for LAP 7.2 for the location of the invoices and corresponding letters.

Paid billing receipts should be filed as per the records retention schedule (item #111).

3.2.2 Assessment billing for out of state labs

Out of state laboratories with primary accreditation in Texas are billed to recover assessment fees incurred in the prior fiscal year. Once all out of state assessment payments have been approved for payment, the records specialist or designee prepares invoices for those laboratories. The invoices are generated using the assessment cost incurred by the agency. Payment is due within 90 days. If a laboratory fails to pay by the due date, the laboratory is contacted to resolve the situation. If the issue cannot be resolved, the issue is escalated to the team leader and program manager. Refer to the Guidance for LAP 7.2 for the location of where the invoices are retained.

3.2.3 Checks arriving at the laboratory accreditation section

If a check is sent directly to the laboratory accreditation section, photocopy the check, and send the original to the cashier's office (third floor, Bldg. A) as soon as reasonably possible. If a billing statement did not accompany the check, photocopy the first page of the application, and record the account type (*Environmental Lab Accreditation – ELA*) and the laboratory's number on the photocopied application. Checks are considered *Sensitive Personal Information* (OPP 19-10), and the photocopy should be destroyed once the paid billing receipt has been received.

Environmental Lab Accreditation – ELA is not set up to receive credit card payments.

3.2.4 Refunds

For duplicate payments or overpayments, a *Request for Refund* form (*TCEQ-00422*) shall be prepared for the program manager's approval and signature. Once the program manager has approved the form, it should be forwarded to the *Reconciliation and Reporting* Team of the Financial Administration Division. Once the refund form has been forwarded, all laboratory inquiries concerning payment should be directed to the *Reconciliation and Reporting* Team. Refer to the Guidance for LAP 7.2 for the location of the refunds.

3.3 Records Retention

Records, paper or electronic, will be maintained for five years past the term of accreditation. Throughout the calendar year, these records will be segregated for destruction. Once all such records have been removed from the files, a *Records Disposition Request* form (*TCEQ-10519*) should be prepared. The procedures for the destruction of records as detailed in the TCEQ *Records Management Manual* shall be followed. A hard copy of the completed *Records Disposition Request* should be filed with the *Records of Disposition* (retention schedule item #03). The Records Disposition Form is routed through management and the Division Records Specialist. Once all signatures have been received, the form is filed, and the records are destroyed.

3.4 AB Manager Monthly Maintenance (Desktop Version)

After all renewals for the previous month have been finalized, monthly maintenance of AB Manager should be performed.

- Coordinate with staff to ensure the AB Manager program is not in use.
- Open "Run Macro" and then click on "ArchivePT". Wait for that macro to complete its run.
- Run "Compact & Repair Database". Wait for that function to complete its run.
- Notify staff they can resume use of AB Manager.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include the following:

- Correspondence in response to inquiries and billing/payment issues
- Laboratory accreditation document and records index updates
- Copies of GovDelivery notifications
- Invoices and paid billing receipts
- Completed request for refund forms
- Completed Records Disposition Request and Records of Disposition forms.

Unless otherwise required by law, rule, records retention schedule, grant, or contractual agreement, the Program Manager or designee shall maintain documents and records produced by this procedure for a minimum of ten years following the end of the fiscal year in which they were produced.

5.0 REVISION HISTORY

Revision 2, Effective Date: 10/30/2023

The following revisions were made to this document:

- Modified language to reflect updated procedures.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

GUIDANCE FOR LABORATORY ACCREDITATION PROCEDURE 7.2

LOCATIONS OF FILES

Issue Date: 10/27/2023 Revision: 0

Effective Date: 11/01/2023 Supersedes: 0

	10/27/2023		
Program Manager	Date	Quality Assurance Specialist	Date

1.0 PURPOSE AND SCOPE

This guidance document aids the records specialist and back-up records specialist for locations on the local hard drive.

2.0 RESPONSIBILITIES

The Records Specialist is responsible for updating locations if they are moved from the current location on the local hard drive.

3.0 PROCEDURES

3.1 Notifying the public and responding to public requests for information

3.1.1 Labprgms mailbox

Not applicable

3.1.2 Private water or well water testing

Draft email shells are in H:\CSD\QA\AQA\NELAP Laboratories\Master e-mails.

3.1.3 GovDelivery notifications

Retained GovDelivery notifications are in H:\CSD\QA\AQA\NELAP Laboratories\GovDelivery mass e-mails\GovDelivery mass e-mails.

3.2 Billing

3.2.1 Monthly renewal billing for all laboratories

Retained renewal invoices are in H:\CSD\QA\AQA\NELAP Laboratories\Lab Accreditation Fees\Invoices. Place in the applicable fiscal year's invoice folder and the appropriate month.

3.2.2 Assessment billing for out of state labs

Retained invoices for out of state laboratories are in H:\CSD\QA\AQA\NELAP Laboratories\Lab Accreditation Fees\Out of State travel cost receipts.

3.2.3 Checks arriving at the laboratory accreditation section

Not applicable

3.2.4 Refunds

Retained refunds are in H:\CSD\QA\AQA\NELAP Laboratories\Lab Accreditation Fees\Refunds

3.3 Records Purge

Not applicable

3.4 AB Manager Monthly Maintenance (Desktop Version)

Not applicable