

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
Laboratory Accreditation Procedures and Revision History

No.	Title	Rev.	Eff. Date	Superseded
1.0	Program Management: Quality Management Plan, Quality Policy Statement, Operational Standards, Organization, Key Personnel, and Internal Quality Assurance Audits	2	10 Feb 12	Rev. 1
1.1	Definitions and Acronyms	1	10 Feb 12	Rev. 0
1.2	Technical Advisory Group	1	10 Feb 12	Rev. 0
1.3	Fields of Accreditation	2	10 Feb 12	Rev. 1
1.4	Accreditation Application	1	10 Feb 12	Rev. 0
2.0	Scheduling Audits	4	2 Apr 12	Rev. 3
2.1	Auditor Qualification	3	10 Feb 12	Rev. 2
2.2	Laboratory Accreditation Audits	2	10 Feb 12	Rev. 1
3.1	Receipt and Administrative Review of Accreditation Applications	1	10 Feb 12	Rev. 0
3.2	Technical Review of Applications for Primary Accreditation	1	10 Feb 12	Rev. 0
3.3	Review of Applications for Secondary Accreditation	1	10 Feb 12	Rev. 0
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5.1	Confidential Business and National Security Information	1	10 Feb 12	Rev. 0
5.2	Evaluation of Changes in a Laboratory's Key Accreditation Criteria	1	10 Feb 12	Rev. 0
5.3	Receipt and Evaluation of Proficiency Test Samples	1	10 Feb 12	Rev. 0
5.4	Reports of Potential Non-conformances and Potentially Illegal Laboratory Practices	1	10 Feb 12	Rev. 0
6.0	Suspension and Revocation	1	10 Feb 12	Rev. 0
6.1	Voluntary Reduction or Withdrawal of Accreditation	1	10 Feb 12	Rev. 0
7.0	Document and Records Management	2	10 Feb 12	Rev. 1
7.1	Laboratory Accreditation Procedures	1	10 Feb 12	Rev. 0

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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

Effective Date: 10 February 2012
Approval:

Revision: 2
Supersedes: Revision 1

Program Manager

Quality Assurance Specialist

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.

The Quality Assurance Specialist is responsible for monitoring the accreditation program's quality system and its implementation.

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 (OPP’s) concerning professional guidelines and general workplace policies; 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 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 Field Operations Support Division Director, Deputy Director for the Office of Compliance and Enforcement, and the Texas Commission on Environmental Quality’s Executive Director and Deputy Executive Director 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, Field Operations Support Division,

Laboratory and Quality Assurance Section. The agency's organizational arrangements are shown at www.tceq.state.tx.us/about/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.

Key personnel for the laboratory accreditation program shall include the Program Manager and the Laboratory Accreditation Team 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.

With the concurrence of the Program Manager, the Quality Assurance Specialist may reduce the frequency of internal audits if the program demonstrates acceptable performance during on-site evaluations.

Internal audits should normally be conducted annually. The frequency of internal audits may be reduced to every three years if the program demonstrates acceptable performance during on-site evaluations.

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, OPP's 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. The frequency of audits may be reduced if the audit results and other evidence demonstrate the quality system has been effectively implemented and has proven stability.

3.8 Nonconformances and Preventive Actions

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

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;
- define or redefine policies, goals and objectives.

The review should normally be conducted annually.

4.0 DOCUMENTS AND RECORDS

OPP's 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:

- Management review records, including actions taken.

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.

Figure 1
LABORATORY ACCREDITATION PROGRAM AND KEY PERSONNEL

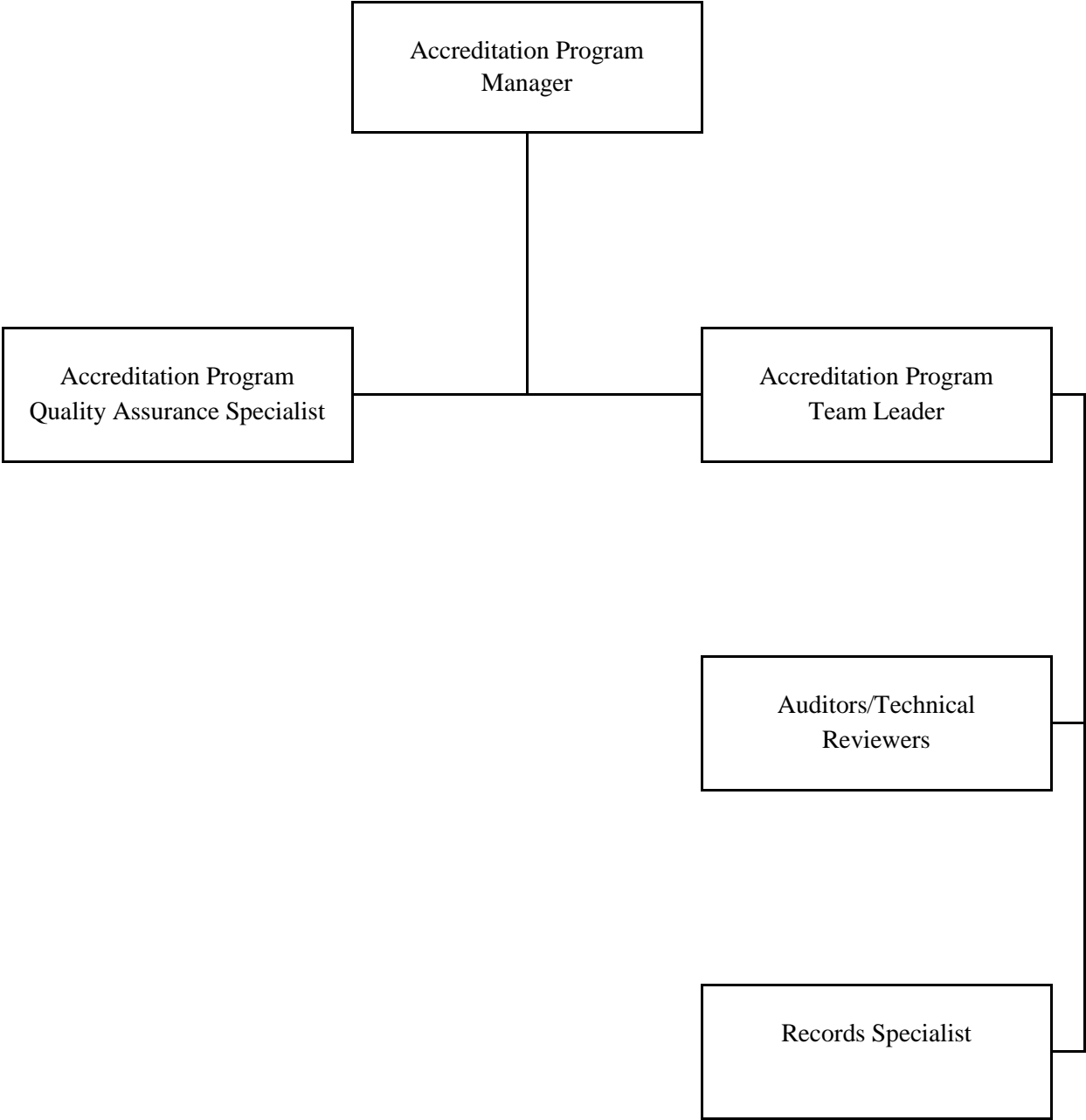


Figure 2
Example Personnel Commitment Form

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

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 1.1

TERMS AND DEFINITIONS

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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

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

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.

American National Standards Institute (ANSI): A non-profit organization that provides accreditation to voluntary consensus standards developing organizations in the United States and coordinates the development of American National Standards with international standards.

Analyte: A constituent for which an environmental sample is analyzed.

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

Appeal: A request by a laboratory for reconsideration of any adverse decision made by the accreditation body related to the laboratory's desired accreditation status.

Audit: The formal process used by an accrediting body to measure the performance, effectiveness, and conformity of a laboratory to the standards for accreditation. An audit may include a physical inspection of a laboratory and its operations. Generally, an audit is a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are effectively implemented and are suitable to achieve objectives.

Audit Bases: Generally, audit bases are statutes, rules, codes, standards, policies, procedures, prior audit results, nonconformance reports, corrective actions, and other requirements and specifications to which audited items and activities are compared.

Audit Checklist: A document that lists items and activities to be audited, questions to be asked, and includes forms to be used during an audit.

Audit Objective: The purpose of an audit.

Audit Plan: A document that identifies the auditee, audit scope, audit objective, schedule, members of an audit team, and other information relating to an audit.

Audit Sample: The items and activities selected for purposes of an audit.

Audit Scope: The organizations, items, activities, audit bases, and time period that will be audited.

Audit Test: A comparison of objective evidence and audit bases.

Auditee: The entity being audited.

Auditor: A person qualified to perform audits.

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.

Complaint: An expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, concerning the activities of the accreditation body or an accredited laboratory.

Confidential Business Information: Any document or record provided by a laboratory in the course of applying for or maintaining accreditation that is labeled as “Confidential Business Information,” “Trade Secret,” or similar phrase.

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.

Division Director: A functional title that refers to the Field Operations Support Division Director.

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

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

Finding: An audit conclusion that identifies a condition having a significant effect on an item or activity and is normally accompanied by specific observations. A finding may be positive or negative.

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.

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.

Laboratory Accreditation Audit: The process used to measure the performance, effectiveness, and conformity of an environmental laboratory to the standards for accreditation. An audit 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.

Lead Auditor/Lead Auditor: A person qualified to organize and direct audits.

Matrix: Sample type, including drinking water, non-potable water, solid and chemical materials, air and emissions, and biologic tissue.

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

Mobile Laboratory: A laboratory capable of being moved from one site to another site.

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.

Nonconformance: 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 audit that is supported by objective evidence.

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

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.

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

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.

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

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

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.

Written Request: Correspondence, electronic mail, and facsimile.

4.0 DOCUMENTS AND RECORDS

No documents or records are produced by this procedure.

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 1.2

TECHNICAL ADVISORY GROUP

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

1.0 PURPOSE AND SCOPE

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

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 web site for advisory group information;
- providing the advisory group's internet address to Agency Communications 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 Deputy 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 Office of Public Assistance, Office of Public Interest Counsel, and Small Business and Local Government Assistance Division for review and comment. These organizations shall have one week to provide comments.

Upon approval by the Deputy 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 Field Operations Support 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 Agency Communications 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.

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 1.3

FIELDS OF ACCREDITATION

Effective Date: 10 February 2012
Approval:

Revision: 2
Supersedes: Revision 1

Program Manager

Quality Assurance Specialist

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, maintaining, and revising fields of accreditation and changes to 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 Program Manager shall maintain a listing of 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.

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 and 30 days notice on the agency's internet site or the date identified in the notice on the agency's internet site, whichever is later.

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.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 1.4

ACCREDITATION APPLICATION

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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, including applications for initial accreditation, applications to renew or modify accreditation, and applications to reinstate suspended applications (Figure 1).

3.1 Application

At a minimum, application forms 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;

- certification of compliance by laboratory management;
- fees;
- laboratory FAX number;
- laboratory identification number(s);
- unique vehicle identification number(s) for mobile laboratory(ies)
- personnel qualifications worksheets for key personnel; 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.



TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
Environmental Laboratory Accreditation Program
PO Box 13087, MC-165
Austin, TX 78711-3087



Application for Environmental Laboratory Accreditation

Pages 14-15 contain instructions for completing and returning the application.

Please enter, type, or print in ink all entries except for signatures.

TRADE SECRETS NOTIFICATION (CONFIDENTIAL BUSINESS INFORMATION)

Unless specifically designated and labeled as such, information contained in this application and the documents submitted with it are not considered trade secrets and may be released without review by the Commission in accordance with the Texas Public Information (Open Records) Act.

1. Type of Application:

- checkbox New checkbox Renewal checkbox Amendment

- checkbox Primary Accreditation checkbox Secondary Accreditation checkbox Primary and Secondary Accreditation

Date: _____

2. Laboratory Information:

a. Legal Name of Laboratory:

b. Mailing Address:

Designated Mail Recipient (Name and Title): _____

Street _____

City _____ State _____ County _____ Zip + 4 _____

c. Laboratory Physical Location (If different than Mailing Address):

Street _____

City _____ State _____ County _____ Zip + 4 _____

d. Billing Address (If different than Mailing Address):

Billing Recipient (Name and Title): _____

Street _____

City _____ State _____ County _____ Zip + 4 _____

e. Telephone Number: _____

f. FAX Number: _____

g. U. S. Environmental Protection Agency (EPA) Laboratory Number: _____

h. TNI/NELAP Laboratory ID Number: _____

3. Laboratory Type:

Check all that apply.

- | | |
|--|---|
| <input type="checkbox"/> Commercial | <input type="checkbox"/> Public Water System |
| <input type="checkbox"/> Federal | <input type="checkbox"/> Public Wastewater System |
| <input type="checkbox"/> Hospital or Health Care | <input type="checkbox"/> Industrial (industry with discharge permits) |
| <input type="checkbox"/> State Agency | <input type="checkbox"/> River Authority |
| <input type="checkbox"/> Academic Institute | <input type="checkbox"/> Other _____ |

Mobile Lab(s) Yes No

Unique Vehicle Identification Information:

Vehicle Make	Model	Vehicle Identification Number	License Number	State of Registration

4. Key Personnel:

a. Owner:

Name _____
Street _____
City _____ State _____ County _____ Zip + 4 _____
Telephone Number _____ E-mail Address _____

b. Laboratory Manager (However named):

Name _____
Telephone Number _____ E-mail Address _____

c. Technical Manager (However named):

Name _____
Telephone Number _____ E-mail Address _____

d. Quality Manager (However named):

Name _____
Telephone Number _____ E-mail Address _____

e. Laboratory Contact Person:

Name _____ Title _____
Telephone Number _____ E-mail Address _____

Other Key Personnel (for example, other Technical Managers):

f. Title _____
Name _____
Telephone Number _____ E-mail Address _____

g. Title _____
Name _____
Telephone Number _____ E-mail Address _____

Use multiples copies of this page if necessary. Complete a Personnel Qualifications Worksheet (page 9) for the Technical Manager(s) and Quality Manager.

5. Laboratory Days and Hours of Operation:

(For example; Monday - Friday, 8 am - 5 pm. Please include Time Zone information)

6. Primary Accreditation Body Information (Secondary Accreditation Only):

(If other than the State of Texas – Enclose copies of the lab’s current Certificate(s) and Scope(s) of Accreditation)

7. Fields of Accreditation:

Download and complete the Fields of Accreditation document. Check all fields for which the lab is seeking to accreditate. Enclose the document with the application package.

http://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/tceq20132a.pdf

(If you cannot access the Fields of Accreditation document, contact us at (512) 239–3754 for paper copies.)

8. Annual Accreditation Fee:

a. Administrative Fee:

1. Enter **\$500** for laboratories seeking primary accreditation;
2. Enter **\$250** for laboratories seeking **ONLY** secondary accreditation; **OR**
3. Enter **\$250** to add one or more Fields of Accreditation to an existing accreditation.

\$

b. Category Fee:

1. For each category (a-p), enter an X in the **Matrix** blocks (1-5) that apply to your lab. Add the Matrices checked and enter the result in the corresponding row of the **Number of Matrices** column (6). Multiply this number by the associated **Annual Fee per Matrix** (7) and enter the result in the **Lab Fees** column (8).
2. Add the totals from all the boxes the **Lab Fees** column (8) and enter the result in the **Category Fee** box (q).

CATEGORIES	MATRIX					FEES		
	Air (1)	Biologic Tissue (2)	Drinking Water (3)	Non- potable Water (4)	Solids & Chemicals (5)	Number of Matrices (6)	Annual Fee per Matrix (7)	Lab Fees (8)
(a.) Microbiology	NA	NA					\$255	
(b.) Radiochemistry							\$510	
(c.) Metals		NA					\$385	
(d.) Metals – Biologic Tissue only	NA		NA	NA	NA		\$510	
(e.) General Chemistry							\$510	
(f.) Disinfection By-products	NA	NA		NA	NA		\$255	
(g.) Volatile Organic Compounds by GC/MS		NA					\$255	
(h.) Volatile Organic Compounds by GC/MS – Biologic Tissue only	NA		NA	NA	NA		\$385	
(i.) Semivolatile Organic Compounds by GC/MS							\$385	
(j.1) Organic Compounds by GC using detection other than MS (including TCEQ Method 1005)							\$510	
(j.2) TPH by TCEQ Method 1005 ONLY	NA	NA	NA				\$255	
(k.) Organic Compounds by HPLC							\$510	
(l.) Polychlorinated Dibenzo-p-dioxins and Dibenzofurans							\$385	
(m.) Asbestos & Airborne Fibers by Microscopy	NA	NA		NA	NA		\$385	
(n.) Aquatic Toxicity	NA	NA	NA				\$510	
(o.) Waste Characteristics	NA	NA	NA				\$255	
(p.) Particulate Matter		NA	NA	NA	NA		\$255	
(q.)							Category Fee =	\$

c. Total Fee:

Add the Administrative fee selected to the result entered in (q) above to determine your **Total Fee:**

\$

Accreditation fees must be paid by check or money order made payable to the Texas Commission on Environmental Quality.

Out of state laboratories shall also pay reasonable travel costs associated with conducting an on-site assessment. TCEQ will contact you prior to assessing these costs.

NOTE: TCEQ will not process your application until all fees have been received. All fees associated with accreditation are nonrefundable. Contact us to verify fee calculations prior to sending any monies. Our phone number is (512) 239-3754. You may also e-mail us at:

labprgms@tceq.texas.gov

9. Completion and Quality Manual, Operating Procedures (Primary Accreditation Only):

- a. Fill out the attached Completion (p. 8) and Quality Manual & Policies and Procedures checklists (pp. 10 – 13).

NOTE: TCEQ will not process your application if the Completion and Quality Manual, Policies and Procedures checklists are not filled out completely and enclosed with the application.

- b. Enclose copies of your laboratory Quality Manual and all technical and non-technical Standard Operating Procedures (SOPs).

NOTE: TCEQ will not process your application if the Quality Manual and SOPs are not enclosed with the application.

10. Proficiency Testing (PT) Provider(s) (Primary Accreditation Only):

Have your provider mail PT sample results to:

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

For initial accreditation, two PT samples must have been successfully analyzed for each field of accreditation. The analysis date of the PT samples for an accreditation FoPT shall be no more than eighteen (18) months prior to the application date for accreditation, with the analysis date of the most recent PT sample for an accreditation FoPT having been no more than six (6) months prior to the application date for accreditation. There shall be at least fifteen (15) calendar days between the analysis dates of successive PT samples for the accreditation FoPT.

NOTE: TCEQ will not process your application until all PT sample results are received.

11. Certification of Compliance:

This application must be signed and dated by laboratory management to attest the validity of the application information.

- a) I understand and acknowledge that the laboratory is required to be continually in compliance with all the provisions set forth in Title 30 Texas Administrative Code (TAC), Chapter 25, Subchapters A and B, and with the TNI NELAP standards, and is subject to the enforcement and penalty provisions of the Texas Commission on Environmental Quality (TCEQ) accrediting authority.
- b) I hereby certify that I am authorized to sign this application on behalf of the applicant/owner and that there are no misrepresentations in my answers to the questions on this application.

Legal Name of Laboratory: _____

Owner/Authorized Agent

Laboratory Manager

Title

Title

Printed Name

Printed Name

Signature

Signature

Date

Date

Lead Technical Manager

Quality Manager

Title

Title

Printed Name

Printed Name

Signature

Signature

Date

Date

Technical Manager/Other

Technical Manager/Other

Title

Title

Printed Name

Printed Name

Signature

Signature

Date

Date

Use additional sheets if necessary.

<p style="text-align: center;">Completion Checklist</p> <p style="text-align: center;"><i>(Gray shaded areas for TCEQ use only.)</i></p>		For TCEQ use Only		
		YES	NO	N/A
<input type="checkbox"/>	The form is completely filled out, signed, and dated			
<input type="checkbox"/>	Personnel Qualification Worksheets have been included for all required personnel <input type="checkbox"/> Laboratory Manager (However named) <input type="checkbox"/> Technical Manager (However named) <input type="checkbox"/> Quality Manager (However named) <input type="checkbox"/> Other Technical Manager(s) and Key Personnel			
<input type="checkbox"/>	Completed Fields of Accreditation document is included			
<input type="checkbox"/>	Proper fees are enclosed			
<input type="checkbox"/>	Completed Quality Manual, Policies and Procedures checklists are enclosed (Primary Accreditation Only)			
<input type="checkbox"/>	A copy of the Quality Manual is enclosed (Primary Accreditation Only)			
<input type="checkbox"/>	Copies of technical and non-technical SOPs are enclosed (Primary Accreditation Only)			
<input type="checkbox"/>	PT results have been forwarded by the provider(s) to TCEQ			
<input type="checkbox"/>	The Certification of Compliance has been signed and dated by: <input type="checkbox"/> Laboratory Owner or Authorized Agent <input type="checkbox"/> Laboratory Manager <input type="checkbox"/> Technical Manager(s) <input type="checkbox"/> Quality Manager			

Include this checklist with the application package.

Personnel Qualifications Worksheet

a. Laboratory Name _____

b. Person's Name: _____

c. Job Title: _____

3. Discipline(s):

- Chemical analysis Microbiology Radiochemistry
- Microscopy Quality Assurance Other

4. Education:

Month/Year From – to	College/ University	Location	Major	Degree	Year Compl.	Sem. Cred. Hrs. per discipline

5. Technical Training:

Month/Year From – To	Technical Trade or Service School	Location	Subject	Certificate	Year Completed

6. Relevant Experience:

Month/Year From – To	Name and Address of Employer	Job Title

7. Treatment Plant Operator's Certificate:

Grade	Specialty	Expiration Date	Issuing Organization/Authority

Please attach a copy of the certificate

If relevant, describe any additional experience on a separate sheet of paper. Be sure to identify by name the individuals, laboratories, and positions listed.

QUALITY MANUAL, POLICIES AND PROCEDURES CHECKLISTS

(Gray shaded areas for TCEQ use only.)

Laboratory Name: _____ TNI Laboratory ID (if known): _____ TCEQ Assessor Checklist Reviewer (Initials/Date): _____	Citations taken: TNI Standard, EL 2009, Volume 1, Module 2 Effective date 7/1/2011
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QUALITY MANUAL CHECKLIST

Please indicate, by section number and/or page number, where the following elements are found in the submitted Laboratory Quality Manual.

Mandatory Quality Elements & TNI Reference	Laboratory Reference	Document Compliant			Comments & Corrective Actions
		Y	N	N/A	
4.2.8.3 The quality manual shall contain					
a) Document title					
b) Laboratory's full name and address					
c) Name, address (if different from above), and telephone number of individual(s) responsible for the laboratory					
d) Identification of all major organizational units covered by the quality manual and effective date of the version					
e) Identification of the laboratory's approved signatories					
f) Signed and dated concurrence (with appropriate names and titles) of all responsible parties including quality manager(s), technical manager(s), and the agent who's in charge of all laboratory activities (such as the lab director or lab manager)					
g) Objectives of the quality system and contain, or reference, the laboratory's policies and procedures					
h) Laboratory's official quality policy statement, including quality system objectives and management's commitment to ethical lab practices and to upholding the requirements of the standard					
i) Table of contents and applicable lists of references, glossaries, and appendices					
4.2.6 Roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the standard					
4.2.8.4 The quality manual shall contain or reference:					
a) All maintenance, calibration, and verification procedures used by the laboratory in conducting tests					
b) Major equipment and reference measurement standards used, as well as facilities and services used by the laboratory					
c) Verification practices (e.g. inter-laboratory comparisons, proficiency testing programs, use of reference materials, and internal QC schemes)					
d) Procedures for reporting analytical results					
e) Organization and management structure, its place in any parent organization, and relevant organizational charts					
f) Procedures to ensure records are retained; procedures for control and maintenance of documentation through a document control system that clearly indicates time periods during which procedures or documents are in force					
g) Job descriptions of key staff and reference to job descriptions of other lab staff					
h) Procedures for achieving traceability of measurements					

Mandatory Quality Elements & TNI Reference	Laboratory Reference	Document Compliant			Comments & Corrective Actions
		Y	N	N/A	
i) List of all test methods under which the lab performs accredited testing					
j) Procedures for reviewing new work and ascertaining appropriateness of facilities and resources prior to commencing new work					
k) Procedures for handling samples					
l) Procedures followed for feedback and corrective action when testing discrepancies are detected or when departures to documented policies and procedures occur					
m) Policy for permitting departures from documented policies and procedures or from standard specifications					
n) Procedures for dealing with complaints					
o) Procedures for protecting confidentiality (including national security concerns) and proprietary rights					
p) Procedures for audits and data review					
q) Procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training					
r) Policy addressing the use of unique electronic signatures, where applicable					

POLICIES AND PROCEDURES CHECKLIST

Please indicate, by document, section number and/or page number, where the following elements are found in the laboratory's documentation.

Mandatory Quality Elements & TNI Reference	Laboratory Reference	Document Compliant			Comments & Corrective Actions
		Y	N	N/A	
In addition to the mandatory quality elements listed above, the following elements also require documentation in policies, procedures, and/or the quality manual.					
4.2.1-2	The laboratory shall establish, implement, and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel. The quality policy statement shall be issued under the authority of top management and shall include at least the following:				
a)	Lab Management's commitment good professional practice and to the quality of its testing and calibration in servicing its customers				
b)	Management's statement of the lab's standard of service				
c)	Purpose of the management system related to quality				
d)	Requirement that all personnel concerned with testing and calibration activities within the lab familiarize themselves with the quality documentation and implement the policies and procedures in their work				
e)	Lab management's commitment to comply with the standard and to continually improve the effectiveness of the management system				
4.1.5.c	Policies and procedures to ensure protection of customers' confidential information and proprietary rights, including procedures for protecting electronic storage and transmission of results				
4.1.5.d	Policies and procedures to avoid involvement in activities that would diminish confidence in the laboratory's competence, impartiality, judgment, or operational integrity				
4.1.5.e	Relationship between management, technical operations, support services, and quality system				
4.2.8.1	Procedures for establishing and maintaining data integrity, including training, documentation, and monitoring				
4.2.8.5	SOPs that accurately reflect all phases of current lab activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods				
4.6.1	Procedures for selection and purchasing of services and supplies; procedures for purchase, reception, and storage of reagents and consumables				
4.13.1.1	Procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records				
4.13.1.4	Procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records				
4.13.3.h	Plan to ensure that records are maintained or transferred according to clients' instructions in the event the laboratory transfers ownership or goes out of business				
4.14.1.5	Procedures addressing internal audits, findings, and corrective actions that ensure these actions are completed within the agreed time frame				
4.15.1	Procedures for conducting a review of the laboratory's management system and testing and/or calibration activities by laboratory's top management				
5.4.7.2.b	Procedures for protecting the data, including integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing				
5.5.6	Program for safe handling, transport, storage, use, and planned maintenance of measurement equipment				

Mandatory Quality Elements & TNI Reference	Laboratory Reference	Document Compliant			Comments & Corrective Actions
		Y	N	N/A	
5.5.11 Procedures to ensure where calibration gives rise to a set of correction factors that copies (e.g. in computer software, for thermometers) are correctly updated					
5.6.3.1 Program and procedure for the calibration of the laboratory's reference standards					
5.6.3.4 Procedures for safe handling, transport, storage, and use of reference standards and reference materials					
5.6.4 Procedures for purchasing, receiving, and storing materials used in technical operations of the laboratory					
5.7.1, Sampling plan & procedures, if applicable, availability of plan at the sampling location 5.7.3 Procedures for recording relevant data and operations relating to sampling					
5.7.1 Procedures and appropriate techniques for obtaining representative subsamples as part of the test method					
5.8.1 Procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of samples					
5.8.4 Procedures to avoid deterioration, contamination, or damage to samples during storage, handling, preparation, and testing					
5.8.5.a System for uniquely identifying samples to be tested, including samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates					
5.8.6.a-e Written sample acceptance policy					
5.8.6.f-g Procedures followed when samples who signs of damage, contamination or inadequate preservation; and qualification of data					
5.8.9.c Procedures for disposal of samples, digestates, leachates, extracts, and other sample prep products					
5.9.1 Quality control procedures for monitoring the validity of environmental tests and calibrations undertaken					
5.9.3.a Written protocols to monitor quality controls					
5.9.3.c Procedures for development of quality control acceptance/rejection criteria					

Instructions

(Do not return the instruction pages with the application package)

If you have questions about the Texas Environmental Laboratory Accreditation Program, contact us at (512) 239-3754

You may also e-mail us at: labprgms@tceq.texas.gov

- Item 1:**
Type of Application
- Check whether this is a new application or an amendment of an existing accreditation.
 - Check whether this application is for Primary, Secondary, or both Primary and Secondary Accreditation.
- Item 2:**
Laboratory Information
- a. Enter the legal name of the laboratory. This name will appear on the laboratory's certificate and on all official correspondence.
 - b. Enter the laboratory's mailing address. Note that the TCEQ verifies address information using the nine-digit Zip Code format.
 - c. Enter the laboratory's physical address if it differs from the mailing address.
 - d. As in "c," enter the billing address if it differs from the mailing address.
 - e. Enter the Telephone number with area code.
 - f. Enter the Fax number with area code.
 - g. Enter your EPA Laboratory Number. If you have any questions on this matter, contact us at (512) 239-3754 and we will assist you.
 - h. Enter your TNI/NELAP Laboratory Number. If you have any questions on this matter, contact us at (512) 239-3754 and we will assist you.
- Item 3:**
Laboratory Type
- Check the section(s) that best describes your laboratory.
- If you have mobile lab(s), check the appropriate box and enter the required information for each vehicle.
- Item 4:**
Key Personnel
- a. Enter the owner's contact information.
 - b. Enter the name, phone number (with area code), and e-mail address of the Laboratory Manager.
 - c. Enter the name, phone number (with area code), and e-mail address of the Technical Manager.
 - d. Enter the name, phone number (with area code), and e-mail address of the Quality Manager.
 - e. Enter the name, phone number (with area code), and e-mail address of the laboratory's contact person.
 - f-g. Enter contact information on other key personnel (such as technical manager) pertinent to the application.
 - Complete a Personnel Qualifications Worksheet (p. 9) for the Laboratory's Technical Manager(s) and Quality Manager.
- Item 5:**
Laboratory days and hours of Operations
- Enter the lab's normal business hours as well as the time zone in which it operates.
- Item 6:**
Primary Accreditation Authority
- Secondary Accreditation only.
 - Enter the lab's primary accreditation body or bodies and certificate number(s).
 - Enclose copies of the lab's certificate(s) and Fields of Accreditation with the application package.
- Item 7:**
Fields of Accreditation Requested
- For initial accreditation. Download and complete the required Fields of Accreditation document. Check all fields for which the lab is seeking accreditation. Include the document with the application package.
 - When adding Fields of Accreditation to an existing accreditation. Download and complete the Fields of Accreditation document (only check those additions you wish to make).
- Item 8:**
Annual Accreditation Fee
- a. Enter the proper **Administrative Fee** based on the type of accreditation you are seeking.
 - b. For each category (a-p), enter an X in the **Matrix** blocks (1-5) that apply to your lab. Add the Matrices checked and enter the result in the corresponding row of the **Number of Matrices** column (6). Multiply the resulting number by the associated **Annual Fee per Matrix** (7) and enter the result in the **Lab Fees** column (8). Add the totals from all the boxes in the **Lab Fees** column (8) and enter the result in the **Total Category Fee** box (q).
 - c. Add the amounts you entered in 8a and 8b to figure your **Total Fee** amount.
- Item 9:**
Quality Manual & Standard Operating Procedures
- Primary Accreditation only.
 - a. Complete the attached Quality Manual, Policies and Procedures Checklists
 - b. Enclose copies of your laboratory Quality Manual and all technical and non-technical SOPs.
- Item 10:**
PT Provider(s)
- Primary Accreditation only.
 - Have PT Provider(s) forward PT sample results to TCEQ.
- Item 11:**
Certification of Compliance
- The owner/authorized agent of the Laboratory as well as the Laboratory Manager, Technical Manager(s) and Quality Manager must sign and date the required compliance statement (p. 7). Use additional sheets if necessary.

Mail the application and supporting documents to:

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

Our physical address for overnight deliveries is:

Laboratory Accreditation Program
Texas Commission on Environmental Quality
12100 Park 35 Circle, Building B, MC-165
Austin, Texas 78753

Individuals are entitled to request and review their personal information that the agency gathers on its forms. They may also have any errors in their information corrected. To review such information, contact us at (512) 239-3754.

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 2.0

SCHEDULING AUDITS

Effective Date: 2 April 2012
Approval:

Revision: 4
Supersedes: Revision 3

Program Manager

Quality Assurance Specialist

1.0 PURPOSE AND SCOPE

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

2.0 RESPONSIBILITIES

The Program Manager or designee is responsible for:

- preparing, revising, and maintaining a schedule of audits and
- approving the audit schedule.

3.0 PROCEDURES

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

- laboratories applying for initial accreditation are audited within six months of submitting a complete application;
- accredited laboratories are audited at least once every two years, plus or minus six months;
- laboratories granted interim accreditation are audited during the term of the interim accreditation;
- in cases where prior audit deficiencies are of such severity as to possibly warrant downgrading the laboratory's accreditation status, any follow-up audits 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 audit, a laboratory's capability and quality are audited in a timely manner;
- the program has adequate resources to perform the audits as required;
- complaints about accredited laboratories requiring an audit are investigated in a timely manner; and
- appeals about denials, suspensions, or revocations requiring an audit are addressed in a timely manner.

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

3.1 Audit Schedule

The Program Manager or designee shall prepare a schedule of planned audits and perform a review to ensure the program has sufficient resources to conduct the scheduled audits in a timely manner. At a minimum, the schedule shall include the name of the auditee and the month or calendar quarter of the audit.

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

3.2 Approval

The Program Manager or Team Leader shall approve the audit schedule before implementation.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include the audit schedule.

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.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 2.1

AUDITOR QUALIFICATION

Effective Date: 10 February 2012
Approval:

Revision: 3
Supersedes: Revision 2

Program Manager

Quality Assurance Specialist

1.0 PURPOSE AND SCOPE

This procedure describes requirements for the qualification of laboratory auditors.

2.0 RESPONSIBILITIES

Auditors 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 auditors 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 auditors and lead auditors;
- monitoring auditor performance;
- ensuring auditors and lead auditors are familiar with accreditation procedures, criteria, and any other regulations;
- verifying auditors and lead auditors have undergone required training;
- ensuring auditors and lead auditors have a thorough knowledge of relevant audit methods; and

- ensuring auditors and lead auditors 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 Auditors

An auditor 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 auditor must also successfully complete a training program that includes:

- completion of an approved course in auditing quality systems, such as a basic auditor 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 auditor will assess, including attainment of a passing score on the written examination for each course;
- for auditors with documented experience auditing environmental laboratories, participation in at least one on-site audit under the supervision and observation of a qualified auditor;
- for auditors with no documented experience auditing environmental laboratories participating in at least two on-site audits under the supervision and observation of a qualified auditor; and
- formal approval by the Program Manager to perform unsupervised audits based in part on the documented supervising auditor's conclusions.

An auditor 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 auditor 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.

The Program Manager 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 Safe Drinking Water Act meet accreditation program requirements

Participation in audits includes participation in the planning, on-site, reporting, and closure activities described in LAP 2.2, *Laboratory Accreditation Audits*.

Auditors that 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 are exempt from the requirement to undergo training with a qualified lead auditor unless other requirements (e.g., drinking water delegation agreement) mandate specific or additional technical training.

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

Auditors 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, auditors must successfully demonstrate their knowledge, skills, and abilities relating to these areas through effective participation in the planning, on-site, reporting, and closure activities described in LAP 2.2, *Laboratory Accreditation Audits*. Auditors 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 Group 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 auditor qualification and the individual is capable of performing effectively as an auditor, 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 auditor has demonstrated competence to assess by completing a Laboratory Auditor Qualification Record (Figure 1).

For auditors-in-training, a tabular listing, spreadsheet, or other record that includes the supervising qualified auditor's evaluation of the individual's ability to perform unsupervised audits may be attached to the Laboratory Auditor Qualification Record in lieu of completing section entitled, "Audit Participation." This initial auditor 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 may waive, amend, or adjust qualification requirements as necessary to assure effective implementation of the accreditation program.

3.3 Initial Qualification of Lead Auditors

At a minimum, a lead auditor must have the education and experience, and successfully complete the training of an auditor 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; or combinations of these.

The Program Manager or designee shall verify that an individual's training and experience conform to the preceding minimum requirements for initial lead auditor qualification and the individual is capable of performing effectively as a lead auditor, i.e., effectively performing the activities of a lead auditor 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 auditor has demonstrated competence to audit, by completing a Laboratory Auditor Qualification Record (Figure 1). This initial lead auditor 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 may waive, amend, or adjust qualification requirements as necessary to assure effective implementation of the accreditation program.

3.4 Ongoing Auditor Qualification and Maintenance of Proficiency

Auditors are expected to maintain proficiency on an on-going basis. Refresher training will be provided as available and as deemed necessary by the Program Manager to ensure auditors are aware of changes to accreditation standards and/or approved analytical methodology and to enhance and improve audit skills. Initially, the refresher training is conceptualized as follows:

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

- current developments.

Therefore, at a minimum, auditors 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 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 auditor qualification and the individual continues to be capable of performing effectively as an auditor, i.e., effectively performing the activities described in LAP 2.2, *Laboratory Accreditation Audits*. This verification will be based on monitoring, such as by 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 auditor performance. Each auditor will be observed on-site on a regular basis (normally every three years) unless there is sufficient supporting evidence that the auditor is continuing to perform competently.

The Program Manager or designee shall document the verification and ongoing auditor qualification by completing a Laboratory Auditor Qualification Record (Figure 1). This ongoing auditor 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).

3.5 Ongoing Lead Auditor Qualification and Maintenance of Proficiency

Lead auditors shall maintain their proficiency by successfully completing refresher training for auditors 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 auditor qualification and the individual continues to be capable of performing effectively as a lead auditor, i.e., effectively organizing and performing the activities of a lead auditor described in LAP 2.2, *Laboratory Accreditation Audits*. This verification will be based on monitoring, such as by 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 auditor performance. Each auditor will be observed on-site on a regular basis (normally every three years) unless there is sufficient supporting evidence that the auditor is continuing to perform competently.

The Program Manager or designee shall document the verification and ongoing lead auditor qualification by completing a Laboratory Auditor Qualification Record (Figure 1). This ongoing lead auditor 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 may waive, amend, or adjust qualification requirements as necessary to assure effective implementation of the accreditation program.

3.6 Standards of Conduct

Auditors and lead auditors 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 auditors.

3.7 Conflict of Interest

As soon as possible and before participating in any audit, an auditor must disclose any present or former relationships, associations, or investments that might reasonably influence or appear to influence the auditor's judgment, discretion, or impartiality. The disclosure shall be made in writing to the Program Manager. Failure to provide this information will make the proposed auditor ineligible to participate in the audit program.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- auditor qualification forms and any attachments, e.g. work experience, supervising auditor observations, and results of monitoring;
- auditor qualification, commitment, and conflict of interest form(s); and
- equivalent records for contracted individual external auditors and experts, including the position 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.

Figure 1
Example Laboratory Auditor Qualification Record

RECORD OF AUDITOR QUALIFICATION					
Name:			Title:		
Organization:					
Mailing Address:					
City:		State:		Zip Code:	
Education					
Degree	Field of Study	University/College		Date	
Auditor/Lead Auditor 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 Auditor 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			
Audit Participation (<i>auditor-in-training only</i>)					
Auditee				Date	
Evaluation					
Date:					
Approval Initials:					

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

- I meet the education and training relating to the qualification of laboratory accreditation auditors 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 Auditor-in-Training/Auditor Observation Form

Auditor-in-Training/Auditor:

Supervising Auditor/Observer:

Auditee:

Audit Date(s):

Audit Participation (*check one*)

- Direct Observation: The auditor-in-training/auditor performed the audit in its entirety under observation.
- Limited Observation: The auditor-in-training/auditor performed parts of the audit under observation and other parts independently.

Conclusions

In my judgment, the auditor-in-training/auditor: (*check one*)

- Demonstrated knowledge of accreditation procedures and criteria and other related requirements; a thorough knowledge of relevant audit methods; the ability to communicate effectively, both in writing and orally; and appropriate personal attributes and is capable of performing independent audits.
- Is not capable of performing independent audits and should participate in additional supervised audits.

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

Supervising Auditor/Observer

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 2.2

LABORATORY ACCREDITATION AUDITS

Effective Date: 10 February 2012
Approval:

Revision: 2
Supersedes: Revision 1

Program Manager

Quality Assurance Specialist

1.0 PURPOSE AND SCOPE

This procedure describes requirements for conducting audits relating to the accreditation of environmental laboratories.

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 lead auditors;
- familiarizing themselves with audit plans, checklists, reference documents, tests, 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;
- 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 and the audit;
- suspending an audit, if necessary;

- forwarding audit reports to auditees; and
- forwarding technical review documents and completed audit records to the Program Manager or designee.

The Team Leader 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 or 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 sufficient 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.

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, 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, including 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

Generally, 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 – Program standards, including changes to program standards;
30 TAC Chapter 25, Subchapters A and B;
Rules, test methods, procedures, and requirements relating to a laboratory's application for accreditation, including participation in and results of proficiency testing; and

Items and Activities – Accreditation application, facilities, personnel, documents, records, data, analyses, and operations for the scope of accreditation for which a laboratory seeks accreditation, including the items and activities identified in the standards for accreditation.

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, at a minimum, include the following additional items and activities:

Audit Bases – 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 so as to accomplish the audit objective(s).

3.1.4 Audit Schedule

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

(NOTE: A number of factors can affect audit schedules: the number of individuals on an audit team; the number and complexity of the organizations, items, documents, records, and activities being audited; holidays; prior commitments; the availability of key personnel; access to facilities; and 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.)

The lead auditor shall to the extent possible determine the number of items of objective evidence to be tested during an audit. The lead auditor shall identify a number of samples for a recently completed or on-going project to evaluate as part of the scope of any audit. Sample sizes ranging from two to seven are normally appropriate, i.e., provide confidence levels of 75 per cent to more than 99 per cent, respectively.

(NOTE: It may be impractical to measure an entire population of evidence. Moreover, the size of a population of evidence may not be known before an audit or limited by a laboratory's operations, e.g., number of documents and personnel.)

3.1.6 Audit Plan

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

- 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 disclosure (Figure 1);
- audit appraisal form (Figure 2);
- procedures concerning confidential business information and confidentiality notice (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.

3.1.7 Audit Checklist

The lead auditor shall prepare a written audit checklist to be used for each audit. The lead auditor shall use an approved checklist, if available. 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.

(NOTE: Procedural checklists should be considered when an audit will assess compliance or complex technical activities or verify steps in a process. Procedural checklists are also useful for relatively inexperienced auditors.)

The lead auditor may designate auditors and technical specialists to prepare portions of the audit checklist.

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.

An audit notification must include an audit notification letter or memorandum, a copy of the audit plan, copies of audit checklists to be used, 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.

(NOTE: Copyright restrictions may prevent distribution of audit checklists.)

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

Generally, unannounced audits should rarely occur. 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, accreditation application, assigned tasks, and relevant audit samples and tests.

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;
- confirm roles and responsibilities of key personnel and staff;
- review 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;
- review 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.

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 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 and photograph 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: Concurrent work at two or more locations should be avoided. 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.

Where a laboratory seeks accreditation for two or more test methods for a technology, the audit team shall verify these elements for at least one method.

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.

Where a laboratory seeks accreditation for two or more test methods for a technology, the audit team shall verify these elements for at least one method.

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 course of 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 audit 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.

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 normally 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, should collect completed audit checklists from audit team members before the exit meeting and 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 suspend an audit and instruct the audit team to leave an auditee's facility if the:

- 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. The lead auditor may assign members of the audit team to prepare portions of an audit 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;
- audit scope and objectives;

- summary of any audit findings, an overall audit of the laboratory's operations, quality assurance program, and the 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;
- 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).

The audit report may include comments intended to improve the efficiency or effectiveness of the auditee's quality assurance program.

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 lead auditor and Team Leader or designee shall approve audit reports prior to distribution.

3.3.3 Distribution of Audit Reports

The lead auditor 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 national laboratory accreditation database or the public until audit findings and corrective actions 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 the:

- systems, methods, results, documents, records, and reports to be corrected;
- specific corrective action(s) taken or planned to prevent recurrence;
- timetable for completing each correction and corrective action;
- information concerning the resolution of all negative findings; and

- means to be used 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.

3.4 Evaluation of Corrective Action Plans

Within 30 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.

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. If an auditee fails to submit a revised corrective action plan within 30 days, the lead auditor 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 lead auditor shall also advise the auditee in writing that the laboratory failed the audit.

3.5 Audit Closure

The lead auditor shall assemble and turn over audit records to the Team Leader or designee responsible for the technical review of a laboratory's application for accreditation. The lead auditor shall turn over audit records within 30 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 submits audit records to the Team Leader or designee.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include the following:

- audit notification correspondence ;
- audit plans;
- completed audit checklists;
- audit reports;
- corrective action plans; and
- corrective action plan acceptance and rejection 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 five years following the end of the fiscal year in which they were produced.

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 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
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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 3.1

RECEIPT AND ADMINISTRATIVE REVIEW OF ACCREDITATION APPLICATIONS

Effective Date: 10 February 2012
Approval:

Revision: 1
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Program Manager

Quality Assurance Specialist

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;
- advising laboratories of administrative deficiencies in accreditation applications; and
- forwarding checklists and applications to the Team Leader or designee.

3.0 PROCEDURES

The Records Specialist or designee shall receive accreditation applications and initiate reviews in the order applications are received.

Within 15 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).

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

If an accreditation application is not complete, the Records Specialist or designee shall advise the laboratory in writing 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. All deficiencies should normally be corrected within 90 days of receiving the application.

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

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include:

- 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.

Figure 1
Example Application Review Checklist

Completion Checklist <i>(Gray shaded areas for TCEQ use only.)</i>		For TCEQ use		
		YES	NO	N/A
<input type="checkbox"/>	The form is completely filled out, signed, and dated			
<input type="checkbox"/>	Personnel Qualification Worksheets have been included for all required personnel <input type="checkbox"/> Laboratory Manager (However named) <input type="checkbox"/> Technical Manager (However named) <input type="checkbox"/> Quality Manager (However named) <input type="checkbox"/> Other Technical Manager(s) and Key Personnel			
<input type="checkbox"/>	Completed Fields of Accreditation document is included			
<input type="checkbox"/>	Proper fees are enclosed			
<input type="checkbox"/>	Completed Quality Manual, Policies and Procedures checklists are enclosed (Primary Accreditation Only)			
<input type="checkbox"/>	A copy of the Quality Manual is enclosed (Primary Accreditation Only)			
<input type="checkbox"/>	Copies of technical and non-technical SOPs are enclosed (Primary Accreditation Only)			
<input type="checkbox"/>	PT results have been forwarded by the provider(s) to TCEQ			
<input type="checkbox"/>	The Certification of Compliance has been signed and dated by: <input type="checkbox"/> Laboratory Owner or Authorized Agent <input type="checkbox"/> Laboratory Manager <input type="checkbox"/> Technical Manager(s) <input type="checkbox"/> Quality Manager			

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 3.2

TECHNICAL REVIEW OF APPLICATIONS FOR PRIMARY ACCREDITATION

Effective Date: 10 February 2012
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Program Manager

Quality Assurance Specialist

1.0 PURPOSE AND SCOPE

This procedure describes requirements for reviewing applications for primary accreditation.

2.0 RESPONSIBILITIES

The Team 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; and
- advising the Program Manager of significant nonconformances.

The Team Leader is responsible for extending review periods as necessary in order to receive additional information from laboratories.

3.0 PROCEDURES

3.1 Technical Review Not Requiring a Laboratory Audit

The Program Manager 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. 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 or designee shall complete a review of the application within 45 days of receiving an administratively complete application from the Records Specialist or designee. The 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 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;
- 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 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 or designee shall document the results of the review by completing the applicable portions of the accreditation audit checklist(s) (Figure 1) and forwarding the checklist(s) and accreditation application and supporting documents to the Program Manager for final action.

The Team Leader shall advise the Program Manager as soon as practicable of any significant non conformances, 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 or designee shall complete a technical review of the application within 45 days of receiving an administratively complete application from the Records Specialist or designee. The Team Leader or designee may extend the review period as necessary in order to receive additional documents, records, and other information from a laboratory.

The Team 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;
- 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 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 or designee shall document the results of the review by completing the applicable portions of the accreditation audit checklist(s) (Figure 1).

(NOTE: The Team Leader or designee shall leave blank any items on the checklist that cannot be assessed from the accreditation application and supporting documents but would be assessed as part of a laboratory audit, e.g., calibration records, additional personnel training and qualification records.)

The Team Leader or designee shall forward the checklist and accreditation application and supporting documents to the lead auditor if the technical review indicates a laboratory's operations and quality system conform to the standards for accreditation.

The Team Leader or designee shall forward the checklist and accreditation application and supporting documents to the Program Manager if the technical review demonstrates a laboratory's operations and quality system do not conform to the standards for accreditation. The Program Manager shall determine whether an audit will be conducted. If an audit will not be conducted, the Program Manager 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.

3.3 Final Technical Review Involving a Laboratory Audit

Within 30 days of receiving the accreditation audit checklist, accreditation application, supporting documents, and audit documents from the lead auditor, the Team Leader or designee shall review the results of the audit, including documents and records provided by a laboratory in response to an audit report, and complete the technical review of a laboratory's application for primary accreditation.

The Team Leader or designee shall complete any remaining items on the accreditation audit checklist and forward all documents and records associated with an application for accreditation to the Program Manager for final action according to Laboratory Accreditation Procedure 3.4, Final Action on Accreditation Applications.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include accreditation audit 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.

Figure 1 Example Accreditation Audit Checklist

Laboratory Name: _____ TEXAS NELAP Assessor/Date: _____
 Document/Revision: _____ Interviewees: _____

ID	Citation	Does the laboratory comply with this section?	Response			Comments
			Yes	No	N/A	
1077	V1M4 1.6.2	Initial DOC				
1078	V1M4 1.6.2	An initial DOC shall be conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period.				
1079	V1M4 1.6.2.1	The laboratory shall document each initial DOC in a manner such that the following information is readily available for each affected employee:				
1080	V1M4 1.6.2.1 a)	analyst(s) involved in preparation and/or analysis;				
1081	V1M4 1.6.2.1 b)	matrix;				
1082	V1M4 1.6.2.1 c)	analyte(s), class of analyte(s), or measured parameter(s);				
1083	V1M4 1.6.2.1 d)	identification of method(s) performed;				
1084	V1M4 1.6.2.1 e)	identification of laboratory-specific SOP used for analysis, including revision number;				
1085	V1M4 1.6.2.1 f)	date(s) of analysis; and				
1086	V1M4 1.6.2.1 g)	summary of analyses, including information outlined in Section 1.6.2.2.c.				
1087	V1M4 1.6.2.2	If the method or regulation does not specify an initial DOC, the following procedure is acceptable. It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.				
1088	V1M4 1.6.2.2 a)	The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) sufficient to prepare four (4) aliquots at the concentration specified, or if unspecified, to a concentration of one (1) to four (4) times the limit of quantitation.				
1089	V1M4 1.6.2.2 b)	At least four (4) aliquots shall be prepared and analyzed according to the method(s) either concurrently or over a period of days.				

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 3.3

REVIEW OF APPLICATIONS FOR SECONDARY ACCREDITATION

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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 accreditation body or NELAP;
- information provided orally by an employee or designee of the accreditation body; or
- combinations 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.

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.

**TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 3.4**

FINAL ACTION ON ACCREDITATION APPLICATIONS

Effective Date: 10 February 2012
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Revision: 1
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Program Manager

Quality Assurance Specialist

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 Program Manager 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 shall without undue delay issue 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.

If, after six months of the date on which a complete application for accreditation was received, a laboratory audit has not been scheduled, the Program Manager may issue an interim accreditation for up to 12 months to a laboratory that otherwise meets the standards for accreditation.

(NOTE: Primary accreditations should normally be issued within nine months of the date on which a laboratory's completed accreditation application was received by the Records Specialist.)

The Program Manager shall issue secondary accreditation to an out-of-state 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 a 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 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;
- NELAP 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 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 photocopies 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.



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: 11/1/2011
Expiration Date: 10/31/2012
NELAP Standards: EL-V1-2009 and EL-V2-2009

**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 Suspended Particulates, Total	AB TX	Analyte ID 10221	Method 40 CFR 50 App B
Method 40 CFR 50 App G			
Analyte Lead	AB TX	Analyte ID 1075	Method 40 CFR 50 App G

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 4.1

NATIONAL LABORATORY ACCREDITATION DATABASE

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Program Manager

Quality Assurance Specialist

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 reports for the national laboratory accreditation database.

3.0 PROCEDURES

Until staff can put information into the national database directly, the Records Specialist or designee shall provide NELAP with information for the national laboratory accreditation database every two weeks. Unless otherwise requested by the NELAP, the Records Specialist or designee shall provide the following information for any laboratory the Texas Commission on Environmental Quality accredits or whose accreditation status changes:

- name, address, and telephone number of the laboratory;
- accreditation status, e.g., primary/secondary 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 also advise NELAP if there are no changes to report.

Unless otherwise requested by NELAP, the Records Specialist or designee shall normally provide the information for the national laboratory accreditation database by electronic mail, facsimile, or postal mail during the first and third weeks of each month. Once direct access is available, the Records Specialist will put information directly into the national laboratory accreditation database.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include reports submitted for the national laboratory accreditation database.

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.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 4.2

NOTIFICATION OF ACCREDITATION PROGRAM CHANGES

Effective Date: 10 February 2012
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Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

1.0 PURPOSE AND SCOPE

This procedure describes requirements for notifying NELAP, if applicable, of changes in the laboratory accreditation program.

2.0 RESPONSIBILITIES

The Program Manager or designee is responsible for notifying and providing information and documentation to NELAP, if applicable.

3.0 PROCEDURES

The Program Manager or designee shall notify NELAP, if applicable in writing of any changes concerning the Texas Commission on Environmental Quality's:

- authority to accredit laboratories as stated in the statutes, regulations, and promulgating instructions establishing and governing the laboratory accreditation program;
- organizational structure for laboratory accreditation, including key personnel;
- rules, regulations, policies, guidance documents, and procedures affecting program operations;
- mailing address, office location, telephone number(s), facsimile number(s), and electronic mail address(es) for the accreditation program; and
- contractual arrangements for accreditation activities, including contractor personnel and activities related to granting, maintaining, suspending, or revoking laboratory accreditations.

The Program Manager or designee shall notify NELAP within 30 calendar days of a change. If NELAP requests further information or documentation concerning changes in the accreditation program to verify the changes do not place that program in violation of NELAP standards, the Program Manager or designee shall provide the information or documentation to NELAP within 30 days of receiving the request.

The Program Manager may notify NELAP of minor changes to laboratory accreditation procedures as part of the agency's application for renewal of accreditation body status.

The Program Manager or designee shall give due notice of changes to requirements for accreditation. The notice may be in the form of a public notice, e.g., Texas Register notice of proposed rule changes,

a posting on the program's web site, e.g., changes to available fields of accreditation, or other forms of notification. The Program Manager shall consider views expressed by interested parties before deciding on the precise form and effective date of the changes.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include notifications of accreditation changes and information and documentation provided to NELAP and posted to the accreditation program website.

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.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 5.1

CONFIDENTIAL BUSINESS AND NATIONAL SECURITY INFORMATION

Effective Date: 10 February 2012
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Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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 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 & Open Records 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 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; 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 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.

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 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.

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 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; 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 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.

**TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 5.2**

**EVALUATION OF CHANGES IN A LABORATORY'S
KEY ACCREDITATION CRITERIA**

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Program Manager

Quality Assurance Specialist

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 of significant changes relevant to its accreditation, in any aspect of its status or operation as specified in the standards for accreditation without delay.

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

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

3.0 PROCEDURES

The Records Specialist or designee shall receive notifications of significant changes relevant to a laboratory's accreditation.

Within seven 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 Team Leader or designee.

The Team Leader 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 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 Team Leader or designee shall forward a copy of the correspondence to the Records Specialist or designee within seven 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.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 5.3

RECEIPT AND EVALUATION OF PROFICIENCY TEST SAMPLES

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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.

The Team Leader or designee is responsible for:

- evaluating proficiency test results and determining whether laboratories continue to meet proficiency test standards for accreditation;
- advising the Program Manager of laboratories that do not successfully complete the required number of proficiency test studies; and
- determining whether or not to accept proficiency test sample results that do not meet quality control requirements.

The Program Manager is responsible for:

- 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;
- determining and advising laboratories affected by nonconforming proficiency test results whether the laboratories should wait until the next regularly scheduled test round to analyze another proficiency test sample or obtain and analyze a supplemental proficiency test sample; and
- initiating action to 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, e.g., investigations and corrective actions concerning failed proficiency test studies.

The Records Specialist or designee shall forward proficiency test results and other documents relating to proficiency tests to the Team Leader or designee for evaluation.

Within 60 days of receiving proficiency test results for a laboratory, the Team Leader or designee shall evaluate the results and determine whether the laboratory continues to meet proficiency test standards for accreditation. The evaluation shall consider whether or not a laboratory:

- successfully, i.e., is evaluated as acceptable by the proficiency test sample provider, completes the required number proficiency test studies at the required intervals, for each field of accreditation;
- secures proficiency test study samples from an approved provider as part of study that complies with the standards for accreditation;
- manages, analyzes, and reports the proficiency test samples in the same manner as environmental samples;
- returns proficiency test results to the provider on or before the closing dates of the proficiency test studies and within the timeframes specified in the standards for accreditation, e.g., analysis date that is no more than 18 months prior to the application date for accreditation, with the most recent analysis date having been no more than six months prior to the application date for accreditation, at least fifteen (15) calendar days between the analysis dates; and
- complies with requirements concerning the transfer of proficiency test samples and communication of sample results.

(NOTE: Laboratories may analyze and report multiple method specific results for the same analytes from one proficiency test sample. 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.)

(NOTE: 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 on adhering to the required intervals for proficiency tests.

(NOTE: 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 analysis dates of these supplemental studies must be at least 15 calendar days apart. For supplemental studies, laboratories report results for all analytes for which they are demonstrating corrective action.)

3.2 Failed Proficiency Tests

As part of the evaluation, the Team Leader or designee shall advise the Program Manager 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;
- does not successfully participate in the proficiency test program as required by the standards; or
- submits results for test samples that were generated by another laboratory.

Within 15 days of being advised of a laboratory that does not successfully complete the required number of proficiency test studies at the required intervals, the Program Manager shall initiate action to suspend the laboratory's accreditation for each affected field of accreditation.

Within 15 days of being advised of a laboratory that, after being suspended due to failure of proficiency test samples, a laboratory's analysis of the next proficiency test sample results in three consecutively failed proficiency tests, the Program Manager shall initiate action to revoke the laboratory's accreditation for each affected field 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 Team Leader 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 shall first contact the 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. The Program Manager may also advise affected laboratories to wait until the next regularly scheduled test round and analyze another proficiency test sample for the affected field(s) of accreditation or obtain and analyze a supplemental proficiency test sample, and repeat the test.

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, including whether nonconforming laboratories shall wait until the next regularly scheduled test round or obtain and analyze a supplemental proficiency test sample; and
- documents and records concerning the initiation of suspension and 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 10 years following the end of the fiscal year in which they were produced.

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 5.4

REPORTS OF POTENTIAL NONCONFORMANCES AND POTENTIALLY ILLEGAL LABORATORY PRACTICES

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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 concerning potentially illegal laboratory activities.

3.0 PROCEDURES

3.1 Potential Laboratory and Program Non-conformances

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 nonconformances 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 may not require contact information.

The Program Manager or designee shall review and investigate potential nonconformances as soon as possible. Where appropriate, the Program Manager or designee shall ensure a complaint concerning a laboratory is first addressed by the laboratory. Where practical, e.g., the complainant provides contact information, the Program Manager or designee will respond to the complainant.

Reports from secondary accreditation bodies concerning potential non-conformances 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. 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.

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.

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 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 may 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 and summaries of potential nonconformances and
- responses and actions taken concerning potential nonconformances.

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.

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TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 6.0

SUSPENSION AND REVOCATION

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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 is responsible for:

- initiating action to suspend or revoke laboratory accreditations 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;
- requesting the return of accreditation certificates and lists of fields of accreditation from laboratories whose accreditation change as a result of suspensions or revocations; and
- forwarding revised accreditation certificates and lists of fields of accreditation to laboratories whose accreditation is suspended or revoked in part or whose accreditation is reinstated.

3.0 PROCEDURES

3.1 Suspensions

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

Note: 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 the on-site audit that the public interest, safety or welfare imperatively requires emergency action.

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

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

The Program Manager 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 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 the next regular update of the national laboratory accreditation database.

3.2 Revocations

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

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 the next regular update of the national laboratory accreditation database. The Records Specialist 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 shall take follow-up action when required.

3.4 Certificates

Within seven days of a suspension or revocation, the Records Specialist 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.

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**TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 6.1**

VOLUNTARY REDUCTION OR WITHDRAWAL OF ACCREDITATION

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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.

3.0 PROCEDURES

The Records Specialist or designee shall receive and process any written request to withdraw from the laboratory accreditation program that is signed 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 signed by the laboratory's owner or authorized agent.

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

If a laboratory withdraws from the laboratory accreditation program in part, the Records Specialist or designee shall request return of the laboratory's accreditation certificate and list of fields of accreditation and prepare a new accreditation certificate and list of fields of accreditation within 15 days. The Records Specialist or designee shall forward a new accreditation certificate and list of fields of accreditation upon receipt of the prior accreditation certificate and list of fields of accreditation.

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 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.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

LABORATORY ACCREDITATION PROCEDURE 7.0

DOCUMENT AND RECORDS MANAGEMENT

Effective Date: 10 February 2012
Approval:

Revision: 2
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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 is responsible for:

- approving 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 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;
- labeling and filing documents and records; and
- maintaining up-to-date lists of documents and records in laboratory accreditation files.

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 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 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, the Records Specialist 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, the Records Specialist 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:

- 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.

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
LABORATORY ACCREDITATION PROCEDURE 7.1

LABORATORY ACCREDITATION PROCEDURES

Effective Date: 10 February 2012
Approval:

Revision: 1
Supersedes: Revision 0

Program Manager

Quality Assurance Specialist

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 is responsible for ensuring laboratory accreditation procedures are prepared, approved, implemented, periodically reviewed, revised as necessary, and are available to laboratory accreditation staff.

The Quality Assurance Specialist is responsible for concurring with laboratory accreditation procedures and changes to laboratory accreditation procedures.

The Records Specialist or designee is responsible for:

- maintaining laboratory accreditation procedures;
- incorporating changes to procedures in revised procedures;
- 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 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 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 as necessary text, training, qualifications, references, figures, and tables;
- a listing of the documents and records produced by the procedure and the retention period for the records; 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 Records Specialist or designee shall distribute laboratory accreditation procedures electronically in read-only form to laboratory accreditation staff.

3.2 Changes to Laboratory Accreditation Procedures

Changes to laboratory accreditation procedures shall be approved and documented prior to implementation. At a minimum, changes to laboratory accreditation procedures shall include:

- the number and title of the affected procedure;
- an effective date and new revision number;
- approval and concurrence signatures of the Program Manager and Quality Assurance Specialist; respectively, and
- revised procedures, records, and retention periods as necessary.

Upon approval by the Program Manager and Quality Assurance Specialist, the Records Specialist or designee shall distribute changes to laboratory accreditation procedures electronically in read-only form to laboratory accreditation staff. The Records Specialist or designee shall also notify other interested parties.

4.0 DOCUMENTS AND RECORDS

Documents and records produced by this procedure include laboratory accreditation procedures and revisions to procedures.

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.

Figure 1
Example Format for Laboratory Accreditation Procedures

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY LABORATORY ACCREDITATION PROCEDURE [No.]	
[TITLE]	
Effective Date: Approval:	Revision: Supersedes:
<hr/> Program Manager	<hr/> Quality Assurance Specialist
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

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