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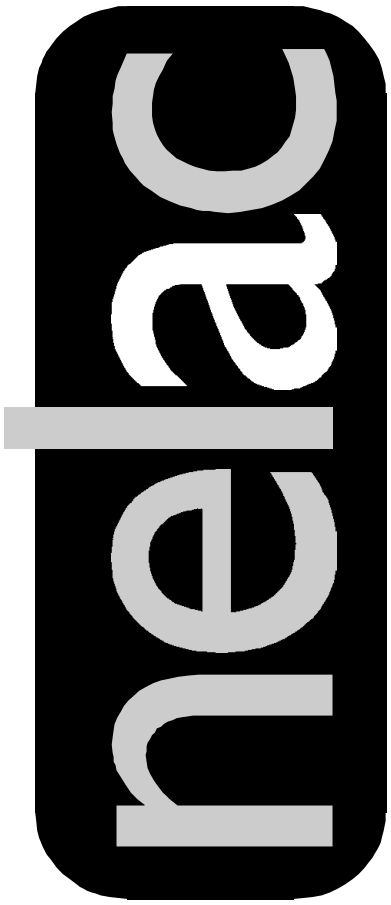
NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

Constitution, Bylaws, and Standards

Approved July 1999

National Environmental Laboratory **Accreditation** Conference



PROGRAM POLICY AND STRUCTURE

July 1, 1999

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1.0 PROGRAM POLICY AND STRUCTURE

Chapter One provides an overview of the history, purpose and objectives of the National Environmental Laboratory Accreditation Conference (NELAC). The organizational structure and function of NELAC, and the roles of the various participants, form the major portion of this chapter. In addition, the Constitution and Bylaws, and the content of the five chapters which follow are briefly described. Together, these six chapters and related appendices constitute the NELAC standards.

1.1 INTRODUCTION

1.1.1 Overview of NELAC

This association shall be known as the "National Environmental Laboratory Accreditation Conference" (NELAC) and is sponsored by the United States Environmental Protection Agency (EPA) as a voluntary association of State and federal officials. The purpose of the organization is to foster the generation of environmental laboratory data of known and documented quality in a cost-effective manner through the development of nationally accepted standards for environmental laboratory accreditation. NELAC encompasses all fields of testing associated with compliance with EPA regulations. The program will be administered by State and federal accrediting authorities in a uniform, consistent fashion nationwide.

1.1.2 History

NELAC is the result of a joint effort by EPA, other federal agencies, the States, and the private sector that began in 1990 when EPA's Environmental Monitoring Management Council (EMMC) established an internal work group to consider the feasibility and advisability of a national environmental laboratory accreditation program. The work group concluded that EPA should consult with representatives of all stakeholders, by establishing a federal advisory committee. As a result, the Committee on National Accreditation of Environmental Laboratories (CNAEL) was chartered in 1991 under the Federal Advisory Committee Act. In its final report to EMMC, CNAEL recommended that a national program for environmental laboratory accreditation be established. In response to the CNAEL recommendations, EPA and State representatives formed the State/EPA Focus Group that developed a proposed framework for NELAC, modeled after the National Conference on Weights and Measures. The Focus Group prepared a draft Constitution, Bylaws and standards, which were published in the Federal Register in December 1994. NELAC was established on February 16, 1995 by State and federal officials with the adoption of an interim Constitution and Bylaws.

NELAC was established as a standards-setting body, only, to support a National Environmental Laboratory Accreditation Program (NELAP). The goal of NELAP is to foster cooperation among the current accreditation activities of different States or other governmental agencies. NELAP seeks to unify the existing State and federal agency standards, at minimum cost to the States, federal agencies and accredited laboratories.

1.1.3 Summary of the NELAC Standards

The NELAC uniform standards are contained in this chapter and the following five chapters and related appendices.

Chapter 2 contains the criteria for the proficiency testing (PT) program. Laboratory participation in PT programs fulfills one part of the quality assessment requirements of NELAC. The PT programs

in which a laboratory must participate to become accredited are defined as well as the criteria for samples, PT providers, and acceptance limits.

Chapter 3 describes the essential elements that are to be included in an on-site assessment and the requirements for an accrediting authority conducting on-site assessments. The qualifications and requirements for assessors are described as well as the program elements to ensure uniform and consistent implementation of the NELAC standards.

Chapter 4 describes the accreditation process the laboratory must follow to be recognized as a NELAC laboratory. The chapter defines the period of accreditation, and the process for maintaining, awarding and revoking accreditation.

Chapter 5 and the related appendices contain the elements of the laboratory quality system. The section provides detail concerning quality assurance/quality control requirements so that all accrediting authorities will evaluate laboratories consistently and uniformly.

Chapter 6 defines the process and operating requirements established by NELAC for an accrediting authority to become nationally recognized. It provides the policies and criteria that an accrediting authority must meet to apply for and maintain recognition.

The Glossary, which is contained as Appendix A to Chapter 1, contains the definition of terms which are used throughout the standards to assure the consistency of their use and interpretation.

1.1.4 General Application of NELAC Standards

These standards are for use by accrediting authorities and others concerned with the competence of environmental laboratories and other organizations directly involved and interested in the standardization of environmental measurements. Note that any reference to NELAP approval or NELAC accreditation means that the accrediting authority or laboratory meets the requirements in the NELAC standards, and is not an endorsement by EPA.

As described in more detail in Chapter 4, an accredited organization may use the NELAC logo on general literature. It is the ethical responsibility of an accredited organization to describe its accredited status in a manner that does not imply accreditation in areas that are outside its actual Scope of Accreditation. When soliciting business or reporting test results, an accredited organization must distinguish between those tests that fall within its scope of accreditation and those that do not.

1.1.5 Application of NELAC Standards to Small Laboratory Operations

All laboratory operations subject to NELAC standards are expected to generate data of known and documented quality and maintain the quality systems required to generate quality data. However, NELAP recognizes that some laboratory operations have some unique characteristics that differentiate them from other operations. The NELAC standards have addressed these issues by allowing some flexibility in meeting the requirements for personnel (Section 5.4.2, Section 5.6) and their credentials (Section 4.1.1).

1.2 OBJECTIVES

The objectives of NELAC, as specified in Article II of the Constitution, are: to provide a national forum for the discussion of all questions related to standards for environmental laboratory accreditation; to provide a mechanism to establish policy and coordinate activities within NELAC; to develop a consensus on uniform standards for laboratory accreditation, and encourage and

promote uniform standards of quality for assessment and accreditation; and to foster cooperation among environmental laboratory accrediting authorities and regulatory officials.

1.3 ELEMENTS

Functional elements of the objectives are:

a) To develop and improve the standards for qualifying as an accredited laboratory, for qualifying as an accrediting authority, and for uniformly implementing the national accreditation program. The standards address the accreditation process; on-site laboratory assessments to review the quality systems; assessor training; proficiency testing; and oversight of accrediting authorities for uniform interpretation of the standards.

b) To designate the States, Territories and Possessions of the United States (hereinafter referred to as States) and federal agencies as the accrediting authorities. These authorities may be the assessor bodies, or may use third parties as assessor bodies to carry out in part or in whole the assessment functions. As accrediting authorities, the States and the federal agencies shall grant accreditation and ensure compliance with NELAC laboratory standards and criteria.

c) To provide for reciprocity among the States and the federal agencies by assuring the consistent application of the national standards. Oversight by NELAP assures uniformity among the various accrediting authorities. The Accrediting Authority Review Board (AARB) provides a balanced review of the program.

d) To develop model language for legislation and regulations which can be adopted by the State legislatures and accrediting authorities.

e) To incorporate, to the extent applicable, ISO 25, ISO 43, and ISO 58.

1.4 PURPOSE AND SCOPE OF NELAC

1.4.1 Purpose

NELAC shall be a standards-setting body. NELAC shall, through the process described in the Constitution and Bylaws, develop, adopt and publish uniform consensus performance standards on which the national accreditation program shall be based. These standards will be adopted by NELAC at its annual meeting. These uniform standards shall include, but are not limited to, quality systems, proficiency testing, audit programs, and other key elements as established by the Standing Committees of NELAC. It is not the purpose of NELAC to function as an assessor body, oversee or approve assessor bodies, or administer any of the main elements of the accreditation program, other than the development and adoption of standards.

1.4.2 Scope

1.4.2.1 Scope of NELAC

The scope of NELAC shall encompass the necessary scientific testing to serve the needs of the States, United States Environmental Protection Agency (EPA), and other federal agencies involved in the generation and use of environmental data, where such generation or use is mandated by EPA statutes and pursuant regulations. Laboratories are encouraged to use the NELAC standards for all other tests.

1.4.2.2 Applicable EPA Statutes

Applicable EPA statutes include the Clean Air Act (CAA); the Comprehensive Environmental Response Compensation and Liability Act (CERCLA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Federal Water Pollution Control Act (Clean Water Act; CWA); the Resource Conservation and Recovery Act (RCRA); the Safe Drinking Water Act (SDWA); and the Toxic Substances Control Act (TSCA). The standards shall also include provisions to permit special requirements or fields of testing promulgated by any of the accrediting authorities.

1.4.2.3 Exemptions

The NELAC standards apply to all EPA-mandated testing, except as provided below:

a) laboratory analyses associated with FIFRA (40 CFR Part 160) good laboratory practices (GLP), for testing performed for studies that support applications for research or marketing permits for pesticide products regulated by EPA under FIFRA.

b) laboratory analyses associated with TSCA (40 CFR Part 792) good laboratory practices (GLP), for studies relating to health effects, environmental effects and chemical fate testing as directed under Section 4 and Section 5 of TSCA.

c) State governmental laboratories when conducting analyses such as pesticide formulation, efficacy and residue testing to support FIFRA compliance and enforcement activities under pesticide cooperative agreement grants.

d) governmental laboratories engaged solely in the analysis of forensic evidence.

1.4.2.4 No Restriction on Legal Actions

The standards shall not be implemented or administered in a way which limits the ability of local, State or federal agencies to investigate and prosecute enforcement cases. Specifically, when engaged in the collection and analysis of forensic evidence to support litigation, those agencies may use any procedure that is appropriate given the nature of the investigation, subject only to the bounds of sound scientific practice.

1.5 ROLES AND RESPONSIBILITIES OF THE FEDERAL GOVERNMENT, THE STATES, AND OTHER PARTIES

1.5.1 EPA

EPA shall provide staff support to NELAC as provided for in the Bylaws and agreed to by EPA. EPA shall assist NELAC by publishing all proposed and final standards .

EPA also participates in joint activities with other federal and State agencies, as described below.

1.5.1.1 National Environmental Laboratory Accreditation Program

EPA shall establish and administer the National Environmental Laboratory Accreditation Program (NELAP), and shall staff an office to oversee the implementation of NELAC standards. The purpose of this oversight is to ensure a high degree of standardization and coordination among the different accrediting authorities.

NELAP performs the following functions in support of NELAC:

a) evaluating and approving the implementation of NELAC standards by accrediting authorities;

b) establishing and maintaining a national database on environmental laboratories which contains information on the status of accrediting authorities, current status of NELAC accredited laboratories, and status of providers of proficiency test samples;

c) where conflict of interest may occur in an accrediting authority, accrediting that authority's principal laboratory if requested. See Chapter 6, section 6.2.2 d) and e);

d) accrediting EPA laboratories;

e) reporting to NELAC on the evaluation of the conformance of State and federal accreditation program activities to NELAC standards;

f) reporting to NELAC on results of evaluations of proficiency testing sample providers and assessor training programs; and

g) approving supplemental accreditation requirements proposed by accrediting authorities (see Section 1.8.2).

1.5.2 States and Federal Agencies as Accrediting Authorities

In order to be considered a NELAP approved accrediting authority, the individual State or federal program must adopt the NELAC standards, utilize assessors trained according to the requirements of NELAC, and be evaluated by the EPA oversight office as being an agency whose accreditation and assessment program meet all of the requirements of NELAC. Failure in any one of these areas would preclude a State or federal program from being recognized by NELAP.

1.5.2.1 Federal Agencies

To operate as accrediting authorities, or to obtain NELAC accreditation for their environmental monitoring laboratories, federal agencies shall conform to the NELAC standards.

1.5.2.2 States

The authority of the States to adopt the NELAC standards is manifest in the authority granted to their administrative agencies by State legislatures. State governments shall be the principal accrediting authorities.

1.5.2.3 Accrediting Authorities

An accrediting authority can be either a) any federal department/agency with responsibility for operating mandated environmental monitoring programs which require laboratory testing, or b) any State which requires laboratory testing in conformance with at least one of the EPA programs listed within the scope of NELAC (see Section 1.4.2). If a State chooses not to adopt the NELAC standards, laboratories in that State may obtain accreditation from any other accrediting authority.

A primary accrediting authority is one which ensures directly that the laboratory is in conformance with the NELAC standards. A secondary accrediting authority is one which, through reciprocity, recognizes the accreditation of a primary accrediting authority.

1.5.2.3.1 Responsibilities of Primary Accrediting Authorities

Once a State or federal department/agency has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of NELAC, it will be a primary accrediting authority, and it will have full responsibility for:

a) using the NELAC standards as the basis for assessing the qualifications of laboratories applying for initial or continuing NELAC accreditation;

b) ensuring conformance by the laboratories it accredits with the national standards established by NELAC;

c) granting interim and/or full accreditation to applicant laboratory organizations through the review and approval of applications, performance of on-site assessments, evaluation of results on proficiency testing samples, and enforcement of all applicable laws and rules relating to accreditation; and

d) submitting the names and appropriate accreditation material to EPA for inclusion in the national laboratory database.

Federal laboratories within a State may be accredited by the State accrediting authority or by a federal accrediting authority. A State accrediting authority is the primary accrediting authority for all non-federal NELAP accredited laboratories in that State. However, if the State accrediting authority does not grant NELAP accreditation for testing in conformance with a particular field of testing (see section 1.8), laboratories may obtain primary accreditation for that particular field of testing from any other accrediting authority.

In addition, a primary accrediting authority may delegate assessment activities to a third party (assessor body). If any of these assessment activities are delegated to a third party, the accrediting authority maintains responsibility for ensuring compliance with the standards established by NELAC.

1.5.2.3.2 Responsibilities of Secondary Accrediting Authorities

A secondary accrediting authority must be approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of NELAC for a secondary accrediting authority.

A secondary accrediting authority may require laboratories to submit an application, may issue certificates of accreditation, and will exercise its legal authority for enforcement of all applicable laws and rules. However, it must recognize the laboratory accreditations through reciprocity, and must not replicate any of the assessment functions, of a primary accrediting authority.

1.5.2.3.3 Accreditation Fees

Accrediting authorities may adopt and impose laboratory accreditation fees.

1.5.3 Reciprocity

Reciprocity means that an accrediting authority will recognize and accept the accreditation status of a laboratory issued by another NELAP accrediting authority. This principle of reciprocity is an element of the national accreditation standard to which all accrediting authorities are held. In recognizing the accreditation status of a laboratory through reciprocity, the accrediting authority assumes the responsibilities of a secondary accrediting authority as stated in Section 1.5.2.3.2. A

State, in the role of a secondary accrediting authority, which has a law or decision resulting from a legal action, the legal effect of which precludes that State from granting any accreditation to a particular laboratory, is not required to accept the accreditation of this laboratory.

Reciprocity among the environmental laboratory accreditation authorities is necessary to the success of a national program. The essential ingredient of reciprocity is uniformity from one accrediting authority to another. The mechanisms to assure this uniformity (e.g., uniform national performance standards, thorough and consistent inspections, and comparable decisions on accreditation status when deficiencies are uncovered) are necessary to ensure that reciprocity is equitable.

1.5.4 Joint Federal and State Roles

NELAC shall be the joint responsibility of EPA, the States, and the other federal agencies. As provided in the following section on the structure of NELAC and in the NELAC Bylaws, EPA, the States, and the other federal agencies share responsibilities of governance, analysis and establishment of policy and NELAC technical standards.

1.5.5 Assessor Bodies

An assessor body, operating under written agreement with an accrediting authority, may perform specified functions of the assessment process. These functions may include: the review of the laboratories' documentation regarding facilities, personnel, use of approved methods, and quality assurance procedures; and conduct of on-site assessments, including review of performance in the analysis of proficiency test samples. The assessor body reports to the accrediting authority under which it is operating. The assessor body will provide full documentation to the accrediting authority. Only the accrediting authority may determine if a laboratory has met the NELAC standards, may issue certificates of accreditation, may make any decisions on the granting and withdrawal of a laboratory's accreditation status, and may take responsibility for the accreditation process.

1.5.6 Other Parties

All other interested parties including, but not limited to, the laboratory industry, clients of the laboratory industry, environmental or other public interest groups, private industry, third party assessors, and the general public, may participate in NELAC. In this role, these other parties may bring technical and policy issues to the attention of NELAC, its Board of Directors, or its committees and subcommittees. It is anticipated that these issues shall be brought to NELAC in the form of reports, presentations, discussion material, or other forms of documentation for presentation at the NELAC annual, interim, or committee/subcommittee meetings.

1.6 STRUCTURE OF NELAC

The structure of NELAC is shown in Figure 1-1. NELAC is composed of a Board of Directors, a House of Representatives, a House of Delegates, Contributors, and a number of committees. There are nine elected officials of NELAC: the Chair; the Chair-Elect; the immediate Past Chair; and six members at large. The Standing Committees and Administrative Committees are appointed by the Chair. The activities of the Standing and Administrative Committees are overseen by the Board of Directors.

NELAC will meet twice a year: an annual meeting at which final action is taken on all issues, and an interim meeting about six months prior to the annual meeting at which time committees meet to receive, consider and deliberate on issues, propose and draft standards or policies for adoption at the annual meeting.

NELAC shall also consider advice and comment provided by the Environmental Laboratory Advisory Board (ELAB) chartered under the Federal Advisory Committee Act and the Accrediting Authority Review Board (AARB).

1.6.1 The Board of Directors

The Board of Directors consists of the NELAC Chair, the Chair-Elect, immediate Past Chair, six members elected at large from the active membership (to serve 3-year staggered terms), a NELAC Director, and an Executive Secretary. The NELAP Director is the ex officio Director of NELAC. The Executive Secretary is an EPA employee.

The Board of Directors serves as a policy and coordinating body in matters of national and international significance and makes interim policy decisions when necessary between annual meetings. The Board of Directors has the overall responsibility and authority for the supervisory, administrative and procedural duties associated with NELAC. The Board of Directors will charge the committees with issues they must address or take under consideration. Comments on the standards should be directed to the committees through their respective chairs.

1.6.2 The Environmental Laboratory Advisory Board

The Environmental Laboratory Advisory Board (ELAB), chartered under the Federal Advisory Committee Act, consists of members appointed by EPA and composed of a balance of non-State, non-federal representatives, from the environmental laboratory community, and chaired by an ELAB member. The ELAB advises EPA and NELAC on matters affecting the interests of the regulated laboratories and other interested parties. The recommendations of the ELAB shall be presented to the Chairs of the standing committees, the Board of Directors and to the EPA.

1.6.3 The Accrediting Authority Review Board

The Accrediting Authority Review Board (AARB) is composed of five representatives from EPA, other federal agencies, and the States. The AARB shall include one member from EPA and at least two members from the States. The AARB annually selects one of its members to serve as its chair. All members are appointed by the NELAC Director following consultation with the Board of Directors. Each member shall serve five years with one member appointed annually. The AARB has the responsibility to monitor EPA to assure that EPA is following the NELAC standards for approving the accrediting authorities, to serve as an appeal board for accrediting authorities that have been denied NELAP recognition or have had such recognition revoked (see Chapter 6), and to review issues referred by the NELAP Director, which may include matters raised by entities other than the accrediting authorities. In all cases, the final decision remains with the NELAP Director. The AARB will report on its activities to the Board of Directors at each annual meeting.

1.6.4 The Participants

The participants consist of two groups, i.e., Voting Members and Contributors.

Membership is limited to officials who are in the employ of the Government of the United States and the States, and who are actively engaged in environmental programs or accreditation of environmental laboratories. State and federal participants being compensated by the private sector to inspect environmental laboratories or as consultants are considered to have a conflict of interest and are ineligible for Voting Membership but may participate as Contributors. The Voting Member may vote and is eligible to serve on all committees and the Board of Directors. At the annual meeting the Voting Members are divided into a House of Representatives and a House of Delegates.

The House of Representatives is composed of one officially designated representative from each State, one representative from each of eight EPA Assistant/Associate Administrators, and one representative from each EPA Region. Each other cabinet level federal department or independent agency (as defined in the Constitution) with environmental laboratory accreditation, certification or evaluation activities may appoint one official to the House of Representatives.

The House of Delegates is composed of all other State and federal environmental officials. The size of the House of Delegates is not limited.

Contributors are all other interested parties and groups. They include, but are not limited to, laboratory personnel, industry representatives, environmental groups, the general public, laboratory associations, industry associations, accreditation associations and retired Voting Members. The Contributors may not vote, but can make presentations, comments or input at all stages of the standards and procedures making process, and do have the ability to enter the substantive debate on the floor of the meeting as it occurs. Contributors are eligible to serve as non-voting participants on all committees.

1.6.4.1 Participation of the Voting Members and Contributors

Contributors, as well as Voting Members, have the right to appear before the standing committees as they consider proposed standards and procedures related to the national accreditation program and to debate the substantive issues before NELAC as such discussion occurs during the meeting. Appearance before the committees will be in accordance with procedures approved by the Board of Directors and Voting Membership.

1.6.5 The Committees

Two types of committee are associated with NELAC: Standing Committees and Administrative Committees. Each committee has five Voting Members including the chair and five Contributors who may not vote. Except for the Nominating Committee, the Voting Members of each committee annually select a chair from one of its Voting Members. All committees report to NELAC through the Board of Directors. Following each annual meeting, the Board of Directors will make available an updated roster of the Board of Directors, NELAC officers and committee participants and chairs.

New Standing Committees:

The Board of Directors shall establish a new standing committee if the following conditions exist:

An ad hoc group appointed by a NELAC Chair has been studying an issue which is likely to require continuing attention by NELAC; the ad hoc group has reached a consensus and is ready to develop standards; once the standards are implemented, they are likely to need evaluation and revision in the future; no NELAC committee exists to deal with the issue; the topic is of broad scope and has impact on a significant portion of the laboratory community; the Program Policy and Structure Committee has reviewed the proposal and has recommended that the new standing committee be created; and the NELAC Voting Members have approved the creation of the committee.

1.6.5.1 The Standing Committees

The participants of each committee serve for five years, with one Voting Member and one Contributor being appointed each year. There are eight Standing Committees:

- Program Policy and Structure Committee
- Accrediting Authority Committee

- Quality Systems Committee
- Proficiency Testing Committee
- On-site Assessment Committee
- Accreditation Process Committee
- Regulatory Coordination Committee
- Field Activities Committee

The Standing Committees shall receive input regarding standards and test procedures, then process this input into resolutions which shall be put before the Voting Membership at the annual meeting. These resolutions will be made available not less than 45 calendar days prior to the annual meeting. All resolutions shall be presented to the Voting Membership at the annual meeting for discussion and ballot. The committees may also receive input via comments and presentations at the interim and annual meetings. The committees shall draft resolutions which shall be made available not later than 30 calendar days prior to either the interim or annual meetings. The committees shall prepare and arrange agenda items for interim meetings and annual meetings to be made available 30 calendar days prior to the meeting.

1.6.5.1.1 Program Policy and Structure Committee

This committee generates the Constitution and Bylaws of NELAC, and interprets the intent and meaning of the Constitution and Bylaws, presents amendments, proposes changes in organizational structure, and defines roles and responsibilities as appropriate, for approval of the Voting Membership. This committee develops modifications to the scope, structure, and requirements to the tiers and fields of testing.

1.6.5.1.2 Accrediting Authority Committee

This committee develops the standards for use by EPA to oversee compliance by State and federal accrediting authorities with NELAC standards. This committee considers matters concerning implementation of reciprocity among accrediting authorities.

1.6.5.1.3 Quality Systems Committee

This committee develops and keeps current uniform standards for quality systems in testing operations. The elements of the quality system include organizational structure, responsibilities, procedures, processes and resources (e.g., facilities, staff, equipment) for implementing quality management in testing operations.

1.6.5.1.4 Proficiency Testing Committee

This committee develops standards for the proficiency testing samples, develops criteria for selection of the providers of the samples, and develops and updates protocols for the use of proficiency test samples and data in the accreditation of laboratories.

1.6.5.1.5 On-Site Assessment Committee

This committee generates procedures for the on-site assessments, and publishes standard check-lists based on these procedures. This committee also establishes the frequency of inspection, and the minimum education, experience, and training requirements of the assessors.

1.6.5.1.6 Accreditation Process Committee

This committee generates and develops procedures for the administrative aspects of the accreditation process of environmental laboratories, for use by the accrediting authorities, including the requirements for accreditation, procedures for changes in accreditation status, roles and responsibilities of laboratories, and appeal processes.

1.6.5.1.7 Regulatory Coordination Committee

This committee provides the Standing Committees with current information on regulations and laws that impact laboratory testing and accreditation. The Regulatory Coordination Committee is also responsible for the development of model language for state legislation and regulations that reflect the findings and actions of NELAC.

1.6.5.1.8 Field Activities Committee

This committee develops and maintains uniform standards for field measurement and sampling, and coordinates the development of these standards with other standing committees.

1.6.5.2 The Administrative Committees

Administrative Committees have varying terms. The duties are outlined below. The term of service shall be three years; two Voting Members and two Contributors will be appointed each of two years and one Voting Member and one Contributor the third year, except for the Nominating Committee (see below).

1.6.5.2.1 Nominating Committee

The chair is the NELAC Past Chair. Four Voting Members and five Contributors shall be appointed annually to serve one year. This committee presents nominees for all elective offices at the annual meeting. The names of these nominees shall appear in the report of the Nominating Committee and be published in the meeting announcement.

1.6.5.2.2 Membership and Outreach Committee

This committee initiates membership invitations, publicizes NELAC to prospective participants, coordinates and resolves participants' concerns, establishes credentialing criteria and resolves credentialing conflicts of Voting Members.

This committee solicits and develops informational materials to promote understanding and appreciation of the importance of the NELAC objectives.

This committee promotes a spirit of cooperation and timely dialogue between NELAC and other organizations and federal agencies.

1.7 CONDUCT OF CONFERENCE BUSINESS

1.7.1 The Generation of Standards

The process for the generation and adoption of standards by a State accrediting authority is shown in Figure 1-2. The standards for the accreditation of laboratories begin with recommendations made within or to the committees. Committees shall propose standards in the form of resolutions on which the Voting Membership shall vote. Standards proposed by the committees are publicized on the

NELAC electronic bulletin board by EPA not later than 45 calendar days prior to the date of the meeting at which they will be considered.

Proposed amendments from the floor to specific standards and proposals offered by the committee for adoption by NELAC shall be allowed in the manner described in the Constitution and Bylaws. Amendments to the report describing committee activities over the year will not be allowed without the concurrence of the chair of the subject committee and the concurrence of the Chair of NELAC.

1.7.2 Meetings

1.7.2.1 Annual Meeting

An annual meeting of NELAC shall be held to conduct business including, but not limited to, election of officers, consideration of issues for presentation to the membership for voting, receiving reports from committees, task groups, or other sources, and conducting other business of NELAC. All final action on resolutions or proposals shall take place at the annual meeting.

The Board of Directors shall determine the place and dates for the annual meeting, and shall publish this information on the NELAC electronic bulletin board at least 90 calendar days prior to the annual meeting.

A completed registration for the annual meeting shall serve as the application for participation as Voting Member or Contributor. The registration form must be completed by all potential participants, whether or not attending the annual meeting. Prior to the annual meeting, the Executive Secretary shall certify the names of the Voting Members and their alternates of the House of Representatives to the Board of Directors. The Nominating Committee shall present, to the Board of Directors, nominees for all elective offices for the annual meeting. The names and qualifications of the nominees shall be published in the annual meeting announcement.

The following deadlines will apply in preparing and submitting material for the annual meeting:

a) Sixty calendar days prior to the date of the annual meeting, each of the standing committees shall present to the Board of Directors a summary of the issues and matters considered by the committees over the course of the year. This report shall discuss all matters which the committee considered since its last report, including how the committee disposed of the issues it considered. The report shall also contain draft standards for consideration by NELAC.

b) Committees shall prepare and arrange agenda items and resolutions for the annual meeting. These, and other resolutions received by the Board of Directors will be made available not less than 45 calendar days prior to the meeting.

c) Standards proposed by the committees for consideration at the annual meeting shall be publicized on the electronic bulletin board not less than 45 calendar days prior to the annual meeting.

As soon as possible, but no later than 90 calendar days after the annual meeting, the Board of Directors shall make available an updated roster of the Board of Directors, NELAC officers, committee members and chairs, and minutes and findings of the meeting to the participants. EPA shall publish the revised standards as soon as possible, but no later than 90 calendar days after the annual meeting. Changes in organization and/or procedures of NELAC proposed at the annual meeting shall not be acted upon until the annual meeting following the annual meeting at which proposed.

1.7.2.2 Interim Meeting

The interim meeting, at which time committees meet to receive, consider and debate issues, and propose and draft standards or policies for the annual meeting, shall be scheduled at least six months prior to the annual meeting.

The Board of Directors shall determine the place and dates for the interim meeting, and shall publish this information on the NELAC electronic bulletin board at least 90 calendar days prior to the interim meeting.

Committees shall prepare and arrange agenda items for the interim meeting. The agenda shall be approved by the Board of Directors and will be made available not less than 30 calendar days prior to the date of the meeting.

Conclusions and findings of the interim meeting shall be provided to the participants not later than 90 calendar days following the interim meeting.

1.7.2.3 Special Meetings

The NELAC Chair is authorized to call a meeting of the Board of Directors at any time deemed necessary by the Chair to be in the best interests of NELAC. Announcements of the meetings and meeting summaries or reports shall be made available to the participants.

1.7.2.4 Committee Meetings

Committees of NELAC are authorized to hold meetings at times other than the annual or interim meeting. Announcements of the meetings and meeting summaries or reports shall be made available to the participants.

1.8 ORGANIZATION OF THE ACCREDITATION REQUIREMENTS

1.8.1 Scope of Accreditation

Laboratories must meet all relevant EPA program requirements, including quality assurance/quality control, use of specified methods, and other criteria.

The accreditation requirements shall be based on the tiered approach shown in Figure 1-3. Laboratories must meet the general requirements found in Chapter 5, and the specific quality control requirements for the type of testing being performed, as found in Appendix D of Chapter 5. Accreditation then will be granted for compliance with the relevant EPA program, the methods used by the laboratory, and for individual analytes determined by a particular method; e.g., a laboratory determining lead in drinking water, in compliance with the Safe Drinking water Act, by both inductively-coupled plasma mass spectrometry and graphite furnace atomic absorption spectrometry would be accredited for lead by both methods. Loss of accreditation for an analyte would not automatically result in loss of accreditation for all other analytes accredited under the method, provided the laboratory remained proficient in the determination of the other analytes.

The following example shows the tiered approach applied to a laboratory seeking accreditation in hazardous waste organic testing under the auspices of RCRA. The laboratory must meet all the requirements listed in general laboratory (NELAC Chapter 5), chemistry (NELAC Chapter 5, Appendix D.1), the RCRA regulations (40CFR261), and the method(s) used (e.g., SW846 5030/8240). In all cases, a NELAC accredited laboratory must be accredited for the specific method it uses. In some cases the regulations mandate the method to be used (e.g., 40CFR261 specifies

SW846 Method 1311, TCLP). In other cases the regulations provide guidance for the methods which can be used (e.g., 40CFR264, Appendix IX, suggests applicable methods). Finally, in some situations the regulations provide no guidance as to the methods to be used (e.g., 40CFR268 lists analytes required to be measured, with no guidance on methods). In those cases where the test method is not mandated by regulation, the laboratory must be accredited for the specific method used, as documented in the laboratory's SOP (see Chapter 5). This method must meet the relevant start-up, calibration, and on-going validation and QC requirements specified in Chapter 5. The tiered approach allows for the incorporation of performance based measurement systems (PBMS) by substituting PBMS for the specified analytical methods when allowed under EPA regulations.

The tiered approach eliminates redundancy by allowing for the incorporation of new methods or new instrumentation without the laboratories repeatedly demonstrating the basic requirements. This structure defines the scope of accreditation for inclusion on the laboratory accreditation certificate. The on-site assessment, proficiency testing evaluation, and data assessments are the processes for assessing the capabilities of the laboratories within the tiered structure. These processes, defined in Chapters 2 and 3, do not necessarily evaluate all tiers within the tiered structure; e.g., proficiency testing examines the determination of individual analytes in specific matrix types, and is not method-specific. However, they are comprehensive enough to assure the accrediting authority that a system is in place that produces data of known and documented quality.

The procedure and conditions for interim accreditation are described in Chapter 4.

1.8.2 Supplemental Accreditation Requirements

In addition, a category of supplemental accreditation requirements is designated for additional methods or analytes required by an accrediting authority. Supplemental accreditation requirements shall be reserved for methods or analytes that are not required under any of the EPA programs that are part of NELAC, and shall not be used to modify any NELAC standards for analytes or methods. Any supplemental accreditation requirements essential to meet the specific needs of an accrediting authority would be added at the method-specific or analyte level, and must be approved by NELAP and made available to all NELAC participants. Exceptions to this requirement may be necessary (e.g., national security concerns) and will be processed as waivers by the AARB.

1.8.3 General Laboratory Requirements

The general requirements are applicable to all laboratory applicants regardless of their size, volume of business, or field of testing. The organizational structure, or procedures used by applicant laboratory organizations to meet these general requirements may differ as a function of size or scope of testing of an organization. Under the tiered approach the general requirements shall include the elements outlined in Chapter 5.

The following applicable requirements are presented in Chapter 5 (Quality Systems): Organization and Management (5.4); Quality System - Establishment, Audits, Essential Quality Controls and Data verification (5.5); Personnel (5.6); Physical Facilities - Accommodation and Environment (5.7); Equipment and Reference Materials (5.8); Measurement Traceability and Calibration (5.9); Test Methods and Standard Operating Procedures (5.10); Sample Handling, Sample Acceptance Policy and Sample Receipt (5.11); Records (5.12); Laboratory Report Format and Contents (5.13); Subcontracting Analytical Samples (5.14); Outside Support Services and Supplies (5.15); and Complaints (5.16).

1.8.4 General Field Sampling Requirements

(To be developed)

1.8.5 Chemistry Requirements

The following applicable requirements are presented in Section D.1 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative Controls (D.1.1); Analytical Variability/Reproducibility (D.1.2); Method Evaluation (D.1.3); Sensitivity (D.1.4); Data Reduction (D.1.5); Quality of Standards and Reagents (D.1.6); Selectivity (D.1.7); and Constant and Consistent Test Conditions (D.1.8).

1.8.6 Whole Effluent Toxicity Requirements

The following applicable requirements are presented in Section D.2 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative Controls (D.2.1); Variability and/or Reproducibility (D.2.2); Accuracy (D.2.3); Test Sensitivity (D.2.4); Selection of Appropriate Statistical Analysis Methods (D.2.5); Selection and Use of Reagents and Standards (D.2.6); Selectivity (D.2.7); and Constant and Consistent Test Conditions (D.2.8).

1.8.7 Microbiology Requirements

The following applicable requirements are presented in Section D.3 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative Controls (D.3.1); Test Variability/Reproducibility (D.3.2); Method Evaluation (D.3.3); Test Performance (D.3.4); Data Reduction (D.3.5); Quality of Standards, Reagents and Media (D.3.6); Selectivity (D.3.7); and Constant and Consistent Test Conditions (D.3.8).

1.8.8 Radiochemistry Requirements

The following applicable requirements are presented in Section D.4 of Appendix D of Chapter 5 (Quality Systems); Negative Controls (D.4.1); Positive Controls (D.4.2); Test Variability/Reproducibility (D.4.3); Other Quality Control Measures (D.4.4); Method Evaluation (D.4.5); Radiation Measurement System Calibration (D.4.6); Method Detection Limits (D.4.7); Data Reduction (D.4.8); Quality of Standards and Reagents (D.4.9); and Constant and Consistent Test Conditions (D.4.10).

1.8.9 Microscopy Requirements

(To be developed)

1.8.10 Field Activities Requirements

(To be developed)

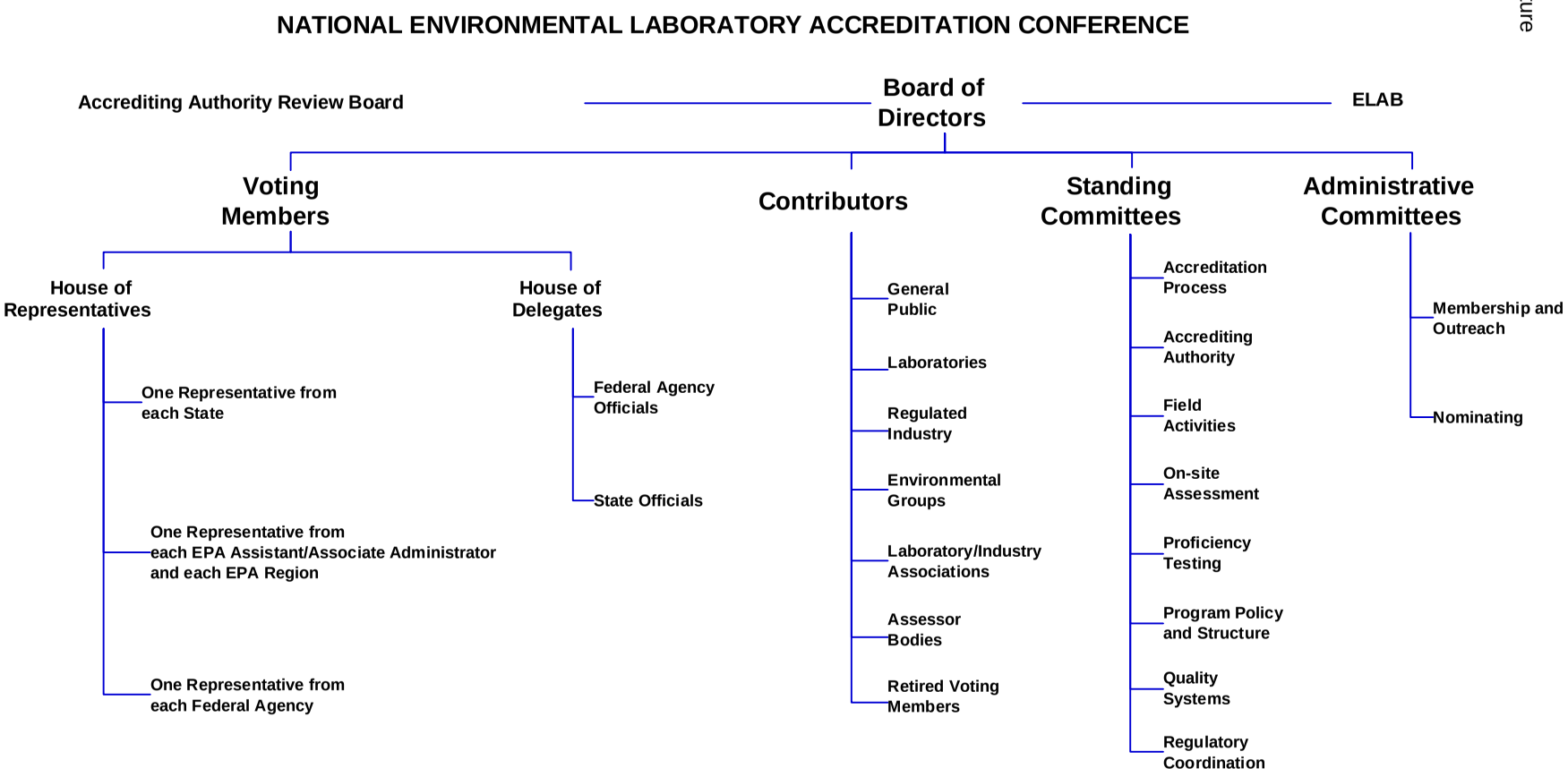


Figure 1-1. NELAC Structure

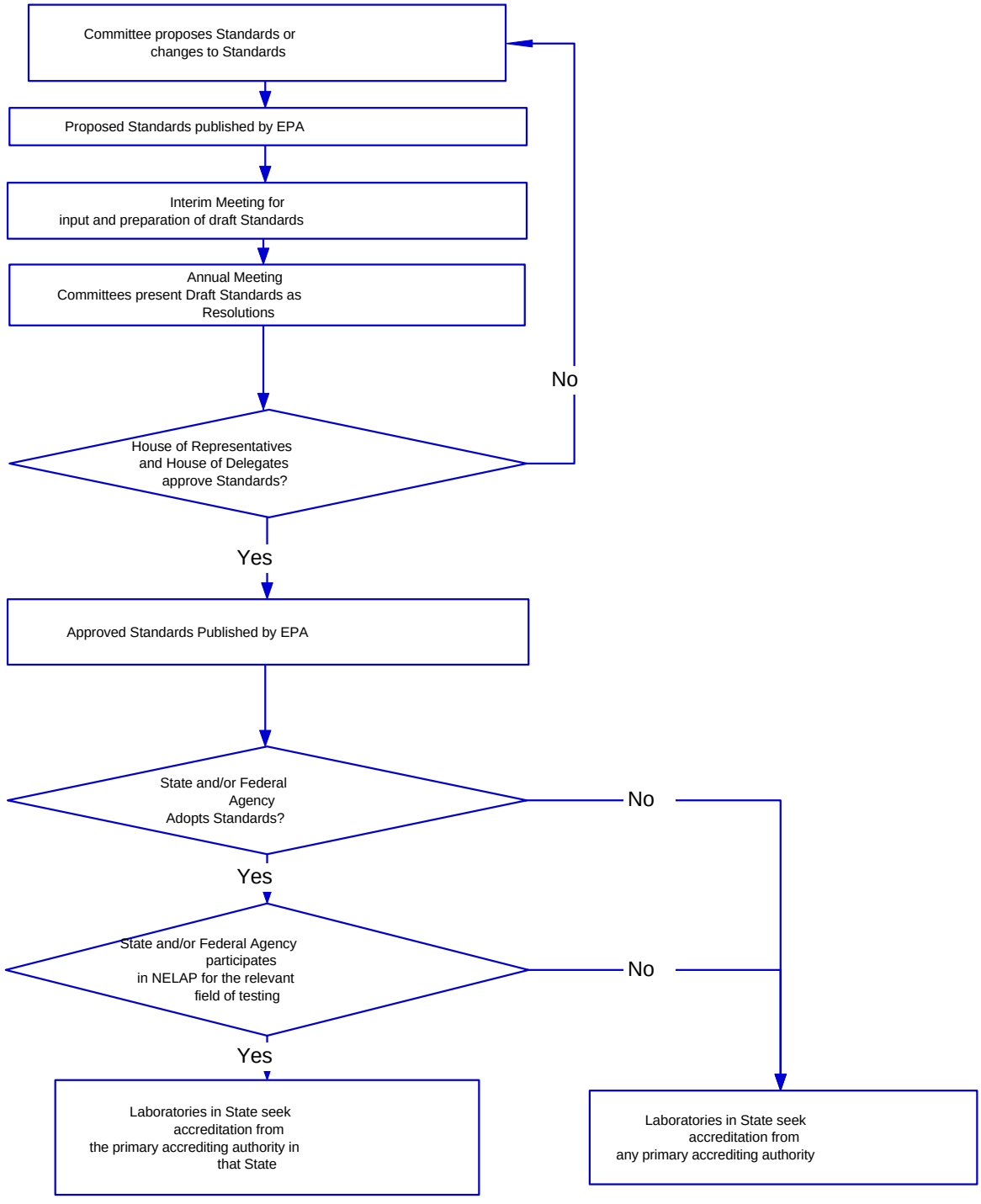
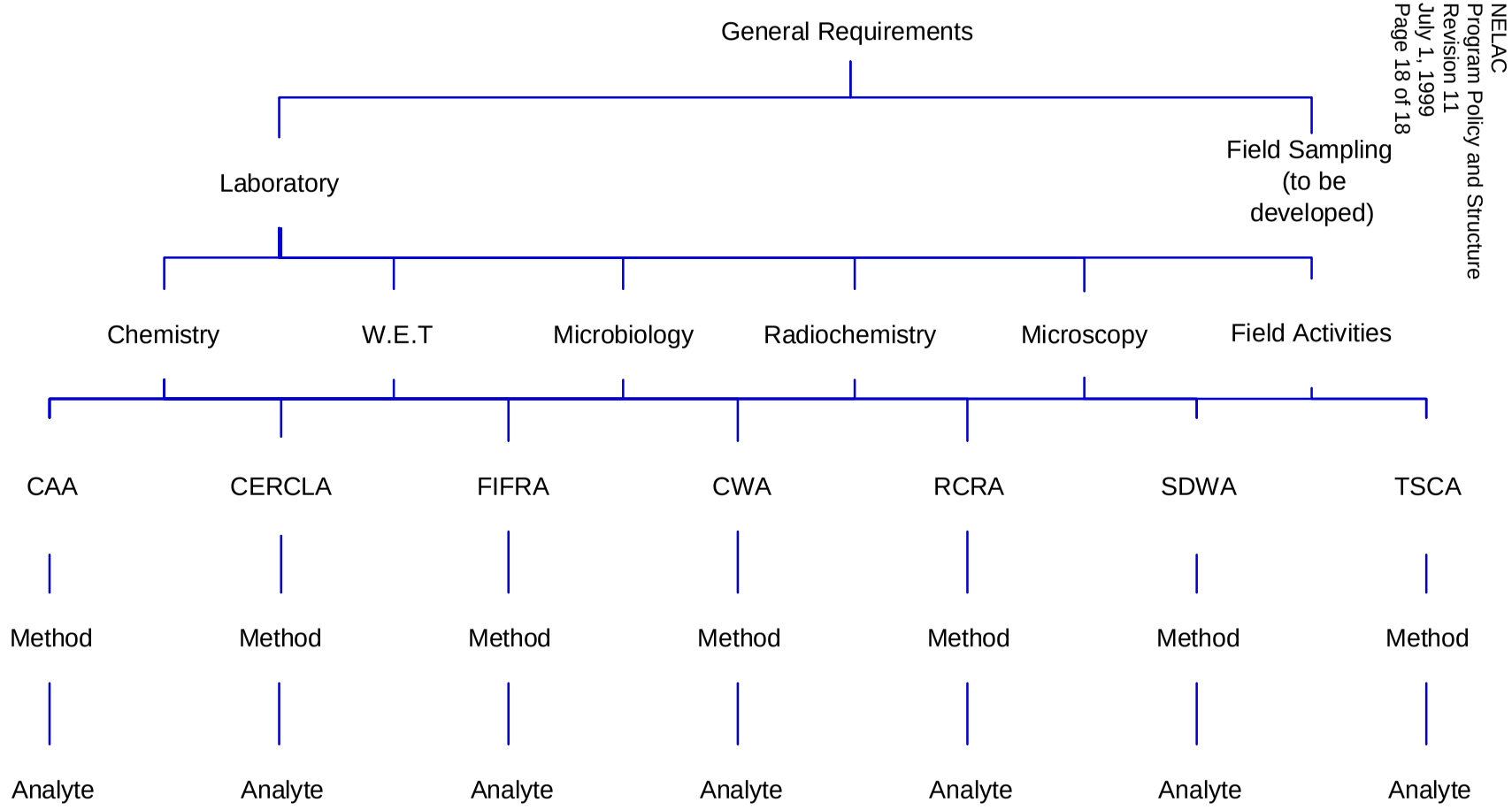


Figure 1-2. Flowchart for Standards Development and Implementation



This figure will be reviewed at a later date to accomodate the unique characteristics of field sampling, pending development of applicable standards by the appropriate NELAC committee.

Figure 1-3 NELAC Tiered Scope of Accreditation

PROGRAM POLICY AND STRUCTURE
APPENDIX A

GLOSSARY

GLOSSARY

Acceptance Criteria: specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

Accrediting Authority: the Territorial, State, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (NELAC)[1.5.2.3]

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

Analytical Detection Limit: the smallest amount of an analyte that can be distinguished in a sample by a given measurement procedure throughout a given (e.g., 0.95) confidence interval. (applicable only to radiochemistry)

Assessor Body: the organization that actually executes the accreditation process, i.e., receives and reviews accreditation applications, reviews QA documents, reviews proficiency testing results, performs on-site assessments, etc., whether EPA, the State, or contracted private party. (NELAC)

Accrediting Authority Review Board (AARB): five representatives from the Territories, States, EPA, and/or other federal agencies, appointed by the NELAP Director, in consultation with the NELAC Board of Directors, for the purpose of reviewing the processes and procedures used by EPA to approve accrediting authorities in accordance with NELAC standards. (NELAC)[1.6.3]

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

Applicant Laboratory or **Applicant**: the laboratory or organization applying for NELAP accreditation. (NELAC)

Assessment: the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of NELAC). (NELAC)

Assessment Criteria: the measures established by NELAC and applied in establishing the extent to which an applicant is in conformance with NELAC requirements. (NELAC)

Assessment Team: the group of people authorized to perform the on-site inspection and proficiency testing data evaluation required to establish whether an applicant meets the criteria for NELAP accreditation. (NELAC)

Assessor: one who performs on-site assessments of accrediting authorities and laboratories' capability and capacity for meeting NELAC requirements by examining the records and other physical evidence for each one of the tests for which accreditation has been requested. (NELAC)

Audit: a systematic evaluation to determine the conformance to quantitative *and qualitative* specifications of some operational function or activity. (EPA-QAD)

Batch: environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 environmental samples of the same NELAC-defined matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. (NELAC Quality Systems Committee)

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

Blind Sample: a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

Calibration: to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

Calibration Curve: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

Calibration Method: a defined technical procedure for performing a calibration. (NELAC)

Calibration Standard: a substance or reference material used to calibrate an instrument. (QAMS)

Certified Reference Material (CRM): a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

Chain of Custody: an unbroken trail of accountability that ensures the physical security of samples and includes the signatures of all who handle the samples. (NELAC)[5.12.4]

Clean Air Act: the enabling legislation in 42 U.S.C. 7401 *et seq.*, Public Law 91-604, 84 Stat. 1676 Pub. L. 95-95, 91 Stat., 685 and Pub. L. 95-190, 91 Stat., 1399, as amended, empowering EPA to promulgate air quality standards, monitor and to enforce them. (NELAC)

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/Superfund): the enabling legislation in 42 U.S.C. 9601-9675 *et seq*., as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9601*et seq.*, to eliminate the health and environmental threats posed by hazardous waste sites. (NELAC)

Compromised Samples: those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions compromised samples are not analyzed. If emergency situations require analysis, the results must be appropriately qualified. (NELAC)

Confidential Business Information (CBI): information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. NELAC and its representatives agree to safeguarding identified CBI and to maintain all information identified as such in full confidentiality.

Confirmation: verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

Second column confirmation
Alternate wavelength
Derivatization
Mass spectral interpretation
Alternative detectors or
Additional cleanup procedures.
(NELAC)

Conformance: an affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)

Contributor: a participant in NELAC who is not a Voting Member. Contributors include representatives of laboratories, manufacturers, industry, business, consumers, academia, laboratory associations, laboratory accreditation associations, counties, municipalities, and other political subdivisions, other federal officials not engaged in environmental activities, and other persons who are interested in the objectives and activities of NELAC. (NELAC)[Art III, Const]

Corrective Action: the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit: a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria). (NELAC)

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

Deficiency: an unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)

Delegate: any environmental official of the States or the Federal government not sitting in the House of Representatives, who is eligible to vote in the House of Delegates. (NELAC)

Demonstration of Capability: a procedure to establish the ability of the analyst to generate acceptable accuracy. (NELAC)

Denial: to refuse to accredit in total or in part a laboratory applying for initial accreditation or resubmission of initial application. (NELAC)[4.4.1]

Detection Limit: the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence. See Method Detection Limit. (NELAC)

Document Control: the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

Duplicate Analyses: the analyses or measurements of the variable of interest performed identically on two sub-samples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

Environmental Detection Limit (EDL): the smallest level at which a radionuclide in an environmental medium can be unambiguously distinguished for a given confidence interval using a particular combination of sampling and measurement procedures, sample size, analytical detection limit, and processing procedure. The EDL shall be specified for the 0.95 or greater confidence interval. The EDL shall be established initially and verified annually for each test method and sample matrix. (NELAC Radioanalysis Subcommittee)

Environmental Laboratory Advisory Board (ELAB): a Federal Advisory Committee, with members appointed by EPA and composed of a balance of non-state, non-federal representatives, from the environmental laboratory community, and chaired by an ELAB member. (NELAC)[1.6.2]

Environmental Monitoring Management Council (EMMC): an EPA Committee consisting of EPA managers and scientists, organized into a Policy Council, a Steering Group, *ad hoc* Panels, and work groups addressing specific objectives, established to address EPA-wide monitoring issues. (NELAC)

Equipment Blank: a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA): the enabling legislation under 7 U.S.C. 135 *et seq.,* as amended, that empowers the EPA to register insecticides, fungicides, and rodenticides. (NELAC)

Federal Water Pollution Control Act (Clean Water Act, CWA): the enabling legislation under 33 U.S.C. 1251 *et seq.*, Public Law 92-50086 Stat. 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance. (NELAC)

Field Blank: blank prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)

Field of Testing: NELAC's approach to accrediting laboratories by program, method and analyte. Laboratories requesting accreditation for a program-method-analyte combination or for an up-dated/improved method are required submit to only that portion of the accreditation process not previously addressed (see NELAC, section 1.9ff). (NELAC)

Finding: an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition. (NELAC)

Holding Times (Maximum Allowable Holding Times) the maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)

Inspection: an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic. (ANSI/ASQC E4-1994)

Interdependent Analytes: analytes analyzed using methods in which the ability to correctly identify and quantitate a series of analytes is indicative of the laboratory's ability to correctly determine the presence or absence of similar analytes. (NELAC)[2.C5.1]

Interim Accreditation: temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment which has been delayed for reasons beyond the control of the laboratory. (NELAC)

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

Instrument Blank: a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Laboratory: a defined facility performing environmental analyses in a controlled and scientific manner. (NELAC)

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes from a source independent of the calibration standards or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC)

Laboratory Duplicate: aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

Limit of Detection (LOD): the lowest concentration level that can be determined by a single analysis and with a defined level of confidence to be statistically different from a blank. (Analytical Chemistry, 55, p.2217, December 1983, modified) See also Method Detection Limit.

Manager (however named): the individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual. (NELAC)

Matrix: the component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with <15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges and other matrices with >15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device. (NELAC)

Matrix Spike (spiked sample or fortified sample): a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent

estimate of Target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS)

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

May: denotes permitted action, but not required action. (NELAC)

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

Method Detection Limit: the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B)

Must: denotes a requirement that must be met. (Random House College Dictionary)

National Accreditation Database: the publicly accessible database listing the accreditation status of all laboratories participating in NELAP. (NELAC)

National Institute of Standards and Technology (NIST): an agency of the US Department of Commerce's Technology Administration that is working with EPA, States, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested States can be accredited by NIST to provide NIST-traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater. (NIST)

National Environmental Laboratory Accreditation Conference (NELAC): a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

National Environmental Laboratory Accreditation Program (NELAP): the overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

National Voluntary Laboratory Accreditation Program (NVLAP): a program administered by NIST that is used by providers of proficiency testing to gain accreditation for all compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples. (NELAC)

Negative Control: measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (NELAC)

NELAC Standards: the plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the National Environmental Laboratory Accreditation Conference. (NELAC)

NELAP Recognition: the determination by the NELAP Director that an accrediting authority meets the requirements of the NELAP and is authorized to grant NELAP accreditation to laboratories. (NELAC)

Non-interdependent Analytes: analytes that are analyzed using methods in which the ability to correctly identify and quantitate a series of analytes in a sample is not indicative of the laboratory's ability to correctly identify and quantitate similar analytes. (NELAC)[2.C.5.2]

Objective Evidence: any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measures, or tests that can be verified. (ASQC)

Performance Audit: the routine comparison of independently obtained *qualitative and* quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

Performance Based Measurement System (PBMS): a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate test methods to meet those needs in a cost-effective manner. (NELAC)

Positive Control: measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (NELAC)

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

Preservation: refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. (NELAC)

Primary Accrediting Authority: the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting NELAC accreditation for a specified field of testing. (NELAC)[1.5.2.3]

PT Fields of Testing: NELAC's approach to offering proficiency testing by regulatory or environmental program, matrix type, and analyte. (NELAC)

Proficiency Testing: a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC)[2.1]

Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor (PTOB/PTPA): an organization with technical expertise, administrative capacity and financial

resources sufficient to implement and operate a national program of PT provider evaluation and oversight that meets the responsibilities and requirements established by NELAC standards. (NELAC)

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

Proficiency Testing Study Provider: any person, private party, or government entity that meets stringent criteria to produce and distribute NELAC PT samples, evaluate study results against published performance criteria and report the results to the laboratories, primary accrediting authorities, PTOB/PTPA, and NELAP. (NELAC)

Proficiency Test Sample (PT): a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

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

Pure Reagent Water: shall be water (defined by national or international standard) in which no target analytes or interferences are detected as required by the analytical method. (NELAC)

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance [Project] Plan (QAPP): a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

Quality Control Sample: an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (EPA-QAD)

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

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 quality in its work processes, products

(items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ASQC E-41994)

Quantitation Limits: the maximum or minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be quantified with the confidence level required by the data user. (NELAC)

Range: the difference between the minimum and the maximum of a set of values. (EPA-QAD)

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted. (EPA-QAD)

Reagent Blank (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Reciprocity: the mutual agreement of two or more parties (i.e., States) to accept each other's findings regarding the ability of environmental testing laboratories in meeting NELAC standards. (NELAC)[1.5.3]

Record Retention: The systematic collection, indexing and storing of documented information under secure conditions. (EPA-QAD)

Recognition: the determination that an accrediting authority meets the requirements of the NELAP and is authorized to grant NELAP accreditation to laboratories. (NELAC)

Reference Material: a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30-2.1)

Reference Method: a method of known and documented accuracy and precision issued by an organization recognized as competent to do so. (NELAC)

Reference Standard: a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.08)

Reference Toxicant: the toxicant used in performing toxicity tests to indicate the sensitivity of a test organism and to demonstrate the laboratory's ability to perform the test correctly and obtain consistent results (see Chapter 5, Appendix D, section 2.1f). (NELAC)

Replicate Analyses: the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (NELAC)

Requirement:. denotes a mandatory specification; often designated by the term “shall”. (NELAC)

Resource Conservation and Recovery Act (RCRA): the enabling legislation under 42 USC 321 *et seq.* (1976), that gives EPA the authority to control hazardous waste from the “cradle-to-grave”, including its generation, transportation, treatment, storage, and disposal. (NELAC)

Resume: the summary (usually written) of an individual’s relevant technical and management experience, including training. (NELAC)

Revocation: the total or partial withdrawal of a laboratory’s accreditation by the accrediting authority. (NELAC)[4.4.3]

Safe Drinking Water Act (SDWA): the enabling legislation, 42 USC 300f *et seq.* (1974), (Public Law 93-523), that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations. (NELAC)

Sample Duplicate: two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis. (EPA-QAD)

Secondary Accrediting Authority: the Territorial, State or federal agency that grants NELAC accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accrediting Authority. See also **Reciprocity** and **Primary Accrediting Authority**. (NELAC)[1.5.2.3]

Selectivity: (Analytical chemistry) the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. (EPA-QAD)

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

Shall: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (ANSI)

Should: denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (ANSI)

Spike: a known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes. (NELAC)

Standard: the document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies. (ASQC)

Standard Operating Procedures (SOPs): a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

Standardized Reference Material (SRM): a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD)

Supervisor (however named): the individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses. (NELAC)

Surrogate: a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (QAMS)

Suspension: temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six months, to allow the laboratory time to correct deficiencies or area of non-compliance with the NELAC standards. (NELAC)[4.4.2]

Systems Audit (also Technical Systems Audit): a thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

Technical Director: individual(s) who has overall responsibility for the technical operation of the environmental testing laboratory. (NELAC)

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2-12.1, amended)

Test Method: an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP. (NELAC)

Testing Laboratory: a laboratory that performs tests. (ISO/IEC Guide 2-12.4)

Test Sensitivity/Power: the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis (see Chapter 5, Appendix D, section 2.4.a). (NELAC)

Tolerance Chart: A chart in which the plotted quality control data is assessed via a tolerance level (e.g. +/- 10% of a mean) based on the precision level judged acceptable to meet overall quality/data use requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma) (applies to radiobioassay laboratories). (ANSI)

Toxic Substances Control Act (TSCA): the enabling legislation in 15 USC 2601 *et seq.*, (1976), that provides for testing, regulating, and screening all chemicals produced or imported into the United States for possible toxic effects prior to commercial manufacture. (NELAC)

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

United States Environmental Protection Agency (EPA): the federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e., the air, water, and land) upon which human life depends. (US-EPA)

Validation: the process of substantiating specified performance criteria. (EPA-QAD)

Verification: confirmation by examination and provision of evidence that specified requirements have been met. (NELAC)

NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

Voting Member: officials in the employ of the Government of the United States, and the States, the Territories, the Possessions of the United States, or the District of Columbia and who are actively engaged in environmental regulatory programs or accreditation of environmental laboratories. (NELAC)

Work Cell: a well-defined group of analysts that together perform the method analysis. The members of the group and their specific functions within the work cell must be fully documented. (NELAC)

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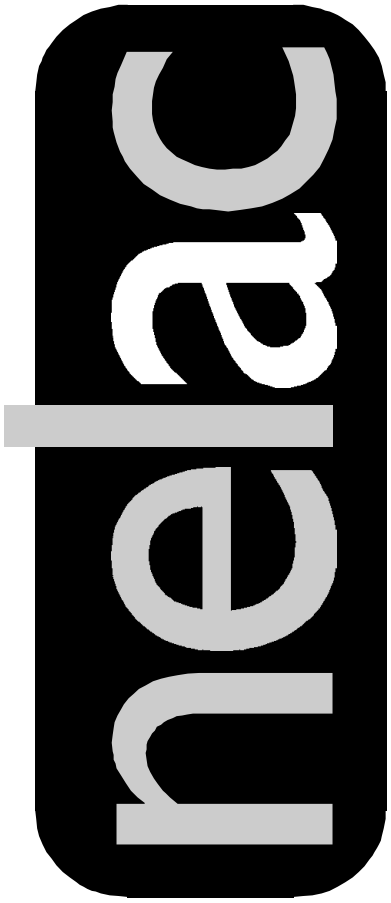

PROFICIENCY TESTING

July 1, 1999

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PROFICIENCY TESTING

2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

Until such time as the National Institute of Standards and Technology (NIST) has accredited proficiency testing (PT) Providers, laboratories shall obtain PT samples for purposes of NELAC accreditation, from a PT Provider that has submitted application to NIST for approval and that has submitted to the laboratory written attestation that it complies with NIST Handbook 150, NIST Handbook 150-19, and EPA's National Standards for Water Proficiency Testing Criteria Document (dated December 1998 or later). Following implementation of the NIST National Voluntary Laboratory Accreditation Program (NVLAP) for Providers of Proficiency Testing, and before a Proficiency Test Provider distributes PT samples to laboratories for the purpose of the laboratories obtaining or maintaining NELAP accreditation, the provider shall first obtain NVLAP accreditation for all compounds/matrices for which NIST accreditation is available, and for which the provider intends to provide NELAC PT samples.

For all other programs and compounds for which NIST/NVLAP accreditation is not available, a provider of PT samples for NELAC accreditation must be accredited by an American National Standards Institute/Registrar Accreditation Board (ANSI/RAB)-accredited registrar or equivalent Proficiency Test Provider Accreditor (PTPA) or provided evidence to the laboratory of applying to an ANSI/RAB-accredited registrar or equivalent Proficiency Testing Oversight Body (PTOB)/PTPA for the compounds/matrices offered. The PT Provider must also produce samples for these matrices that comply with all criteria published by the NELAC Standing Committee on Proficiency Testing.

For fields of testing for which PT samples are not available from either a NELAP PTOB/PTPA (e.g., NIST) or an ANSI/RAB-accredited registrar or equivalent PT Provider, a Primary Accrediting Authority may accept PT results from non-accredited PT Providers. In these cases, the Secondary Accrediting Authority shall accept the decision of the Primary Accrediting Authority.

2.1 INTRODUCTION, SCOPE, AND APPLICABILITY

This chapter and the associated appendices define the major participating organizations and components of the NELAC PT Program. In addition to complying with the requirements of this chapter, any person, private party or government entity seeking to participate as a NELAP-designated PTOB/PTPA-approved PT Provider shall also comply with the requirements of the applicable Appendices A (PT Provider Approval Criteria), B (PT Sample Design and Acceptance Guidelines), C (Proficiency Testing Acceptance Criteria), D (Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor), E (Microbiology), and F (Environmental Toxicology). The criteria set forth in these standards shall be used by laboratories and PT Providers for the purposes of obtaining or maintaining NELAP accreditation or NELAP approval.

In addition to complying with the requirements of this chapter and appendices, any entity seeking to participate as a NELAP-designated PTOB/PTPA-approved PT Provider shall also comply with all applicable requirements of "National Standards for Water Proficiency Testing Studies, Criteria Document", U.S. Environmental Protection Agency or other NELAC documents that define analytes, analyte numbers, concentrations, and acceptance criteria as required in Section C.1.1.2.

Proficiency testing (PT) is defined for the purpose of this chapter as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. PT is not the sole criterion for determining accreditation status. Additional essential elements of the overall NELAP accreditation process, including the on-site assessment, are discussed in other chapters of the NELAC standards.

The PT program is intended to cover all types of federal and State environmental analyses. However, the body of the PT standard applies primarily to chemistry.

The major components of the NELAC PT program include:

a) multiple PT Providers who shall meet stringent criteria to become approved by a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA), as described in Section 2.3 and Appendix A;

b) specific requirements for the design of PT samples and studies, to ensure that all samples provide a consistent, fair and known challenge to laboratories seeking accreditation from a NELAP-approved Accrediting Authority, as described in Section 2.3 and Appendix B;

c) specifically defined acceptable/not acceptable criteria for evaluating PT sample results, as described in Section 2.3 and Appendix C;

d) initial approval and ongoing oversight of PT Providers by a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA), Section 2.3 and Appendix D;

e) specific requirements for laboratories participating in PTOB/PTPA-approved PT programs, as described in Sections 2.4, 2.5, and 2.7; and,

f) oversight of all PT program activities by the PTOB(s)/PTPA(s), as described in Section 2.2.2.

2.1.1 Purpose

The PT program incorporates several practical purposes, which include:

a) the production and supply of test samples that are procedure-sensitive; that is, the samples challenge the critical components of each analytical procedure, ranging from initial sample preparation to final data analysis;

b) the production and supply of test samples that are as similar to real-world samples as is reasonably possible; it is further expected that the PT samples shall be representative of materials analyzed for environmental regulatory programs, agencies, and communities;

c) a program which is affordable by all participants;

d) the yielding of PT data that are technically defensible on the basis of the type and quality of the samples provided; and,

e) the preparation of samples such that the identification and quantitation of analytes in the samples pose equivalent difficulty and challenge regardless of the manner in which the samples are designed and manufactured by the PT Providers, e.g., samples prepared for analysis by a drinking water or wastewater method would pose equal challenge whether prepared as whole volume or as a concentrate in ampules.

2.1.2 Goals

The PT program incorporates several practical goals, which include:

a) the generation of data at a quality level required by environmental and regulatory programs;

b) the generation of data, at a minimum, comparable in quality to that of currently certified and/or accredited laboratories; and

c) the improvement of the overall performance of laboratories over time.

2.1.3 PT Fields of Testing

The PT program is organized by PT fields of testing. The following elements collectively define PT fields of testing:

a) regulatory or environmental program, as listed in Chapter 1,

b) matrix type (e.g., gas, aqueous liquid, nonaqueous liquid, solid), and

c) analyte.

2.2 MAJOR PT GROUPS AND THEIR RESPONSIBILITIES

The PT program structure incorporates five major groups with separate and distinct roles and responsibilities. The groups are NELAC, the PTOB/PTPA, the PT Providers, the testing laboratories, and the Primary Accrediting Authorities (AA). The lines of interaction among these groups are shown in Figure 2-1.

2.2.1 Proficiency Testing Study Providers

The PT Providers shall produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to the laboratories, the respective Primary Accrediting Authorities, the appropriate PTOB/PTPA, and NELAP. The PT Provider shall meet the requirements of Appendix A, manufacture samples that meet the requirements of Appendix B, and score sample results in accordance with the requirements of Appendix C.

2.2.2 Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA)

The PTOB/PTPA establishes and implements a program to accredit PT Providers and to monitor accredited providers to ensure that their studies and practices meet all applicable standards. The PTOB/PTPA shall meet the requirements of Appendix D. Organizations meeting the requirements of this standard and its appendices, as determined by the NELAC Standing Committee on Proficiency Testing, may be nominated by the committee to NELAP to be designated as a PTOB/PTPA. NELAP may approve or disapprove the designation of an organization as a PTOB/PTPA. The committee may also recommend to NELAP that a PTOB/PTPA's designation be withdrawn for failing to meet the criteria in this standard and appendices.

2.2.3 Laboratories

Laboratories that seek to obtain or maintain accreditation shall perform analyses of PT samples for each PT field of testing as defined in Section 2.1.3. PT samples shall be obtained from NELAP designated PTOB/PTPA-approved PT Providers. The laboratory shall obtain PT samples from any so approved PT Provider. The results of the analyses shall be submitted to the PT Provider for scoring.

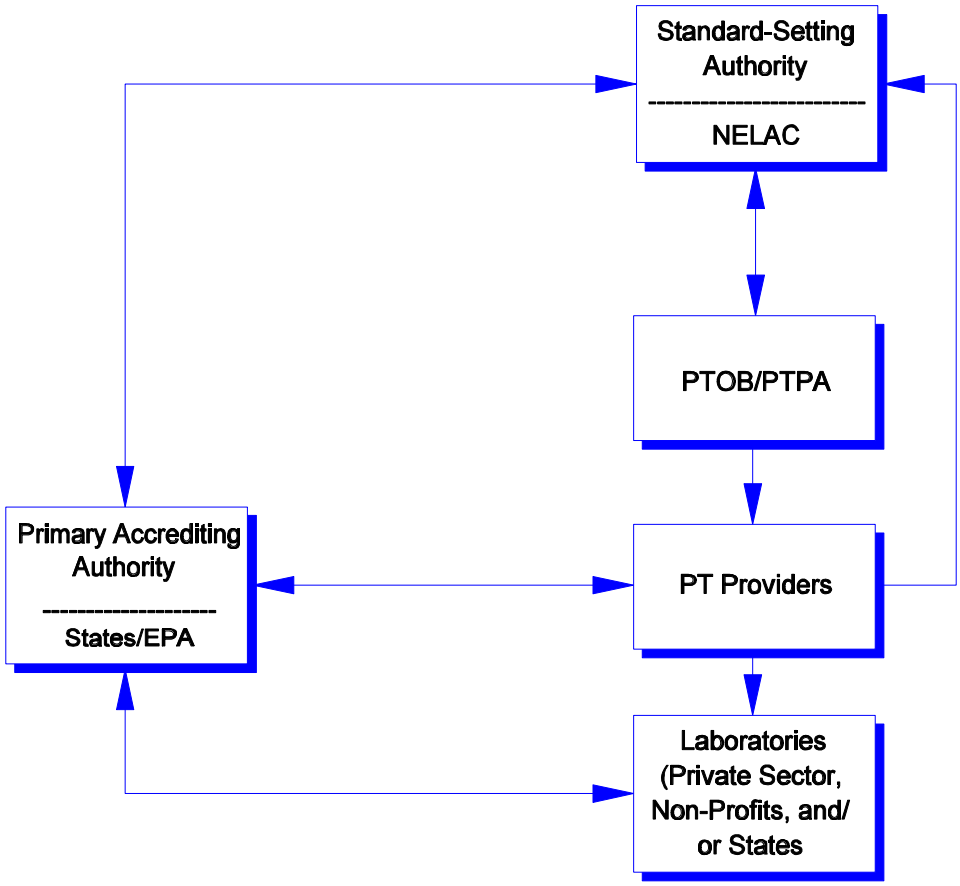

Figure 2-1. NELAP Proficiency Testing

2.2.4 Accrediting Authorities (AA)

The Primary Accrediting Authorities shall make all decisions regarding a laboratory's accreditation status. They are responsible for taking action to make these determinations including ensuring that laboratories seeking or holding their accreditations have participated in the PT program. Accrediting authorities shall accept for the purposes of initial and continuing accreditation, PT results from any NELAP-designated PTOB/PTPA-approved PT Provider that meets the requirements of this standard.

2.3 REQUIREMENTS FOR PT PROVIDERS

This section and associated Appendix A describe the criteria that all PT Providers shall meet in order to be approved by the PTOB/PTPA as PT Providers. A PTOB/PTPA shall grant approval to PT Providers on a field-of-testing basis, as described in Section 2.1.3.

2.3.1 On-Site Inspection of PT Providers

A PTOB/PTPA shall conduct an on-site inspection of any organization seeking to participate as a PT Provider, as described in Appendix D. The PTOB/PTPA shall determine whether the provider meets the applicable requirements described in this chapter and Appendices A, B, and C. Approval

of a PT Provider shall be the responsibility of a PTOB/PTPA. A PTOB/PTPA shall conduct ongoing oversight of the PT Providers as necessary to ensure conformance with all applicable standards.

2.3.2 Sample Requirements and Design

This section and associated Appendix B describe PT sample design and acceptance criteria. The matrices of all PT samples shall, to the extent possible, resemble the matrices for which the laboratory seeks to obtain or maintain accreditation. Samples may not be reused in any subsequent NELAC PT study.

2.3.2.1 Sample Analytes

The PT Provider shall prepare each sample lot such that the prepared concentration of each analyte in each lot is unique. The required group of analytes covering each PT field of testing shall be determined by the NELAC Standing Committee on Proficiency Testing and shall be evaluated and updated, as necessary.

2.3.2.2 PT Provider Sample Testing

The PT Provider shall design, manufacture, and test the samples for homogeneity, stability, and verification of assigned values as required by Appendix B. This testing shall verify that the quality of all samples is acceptable for use in each PT field of testing.

2.3.3 PT Study Data Analysis

This section and associated Appendix C describe the criteria to be used by PT Providers when scoring and evaluating NELAC PT sample results.

2.3.3.1 Data Acceptance Criteria

PT Providers shall use the data acceptance criteria described in Appendix C to evaluate laboratories' PT data to ensure a laboratory's performance shall be judged fairly and consistently.

2.3.4 Generation of Study Reports

Each PT Provider shall evaluate the data and issue a report within 21 calendar days of the close of each study.

2.3.5 Provider Conflict of Interest

Each PT Provider shall certify that it is free of any organizational conflict of interest. A PT Provider shall never split a sample lot and offer these samples for sale as known-value check samples before the unknown samples are used in a PT study. In addition, each PT Provider shall follow procedures and have systems in place that maintain confidentiality and security of all assigned values through the closing date of each study. All records shall be retained for a period of five years.

2.3.6 Disapproval of PT Providers

A PT Provider's approval may be subjected to revocation per the procedures outlined in Appendix A, Section A.9.2.

2.3.7 PTOB/PTPA Listing of PT Providers

PTOBs/PTPAs shall maintain a list of approved PT Providers. PTOBs/PTPAs shall evaluate, update, and publish this list as specified in Appendix D.

2.4 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

2.4.1 Required Level of Participation

To be accredited initially and to maintain accreditation, a laboratory shall participate in two single-blind, single-concentration PT studies, where available, per year for each PT field of testing for which it seeks or wants to maintain accreditation. Laboratories must obtain PT samples from a PTOB/PTPA-approved PT Provider. Each laboratory shall participate in at least two PT studies for each PT field of testing per year unless a different frequency for a given program is defined in the appendices. Section 2.5 describes the time period in which a laboratory shall analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.6 and 2.7 of this chapter.

2.4.2 Requesting Accreditation

At the time each laboratory applies for accreditation, it shall notify the Primary Accrediting Authority which field(s) of testing it chooses to become accredited for and shall participate in the appropriate PT studies. For all fields of testing, including those for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of Chapter Five of the NELAC standards.

2.4.3 Reporting Results

Each laboratory shall authorize the PT Provider to release all accreditation and remediation results and acceptable/not acceptable status directly to the Primary Accrediting Authority, NELAP and the PTOB/PTPA, in addition to the laboratory.

2.5 REQUIREMENTS FOR LABORATORY TESTING OF PT STUDY SAMPLES

The samples shall be analyzed and the results returned to the PT Provider no later than 45 calendar days from the scheduled study shipment date. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

2.5.1 Restrictions on Exchanging Information

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

a) A laboratory shall not send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it seeks accreditation, or is accredited;

b) A laboratory shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation, or is accredited;

c) Laboratory management or staff shall not communicate with any individual at another laboratory (including intracompany communication) concerning the PT sample; and

d) Laboratory management or staff shall not attempt to obtain the assigned value of any PT sample from their PT Provider.

2.5.2 Maintenance of Records

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the assessors of the Primary Accrediting Authority during on-site audits of the laboratory.

2.6 EVALUATION OF PROFICIENCY TESTING RESULTS

PT Providers shall evaluate results from all PT studies using NELAC-mandated acceptance criteria described in Appendix C. The NELAC Standing Committee on Proficiency Testing shall provide, and update as necessary, the data acceptance criteria that all PT Providers shall use for all PT studies. Each result shall be scored on an acceptable/not acceptable basis. The PT Provider shall provide the participant laboratories and the Primary Accrediting Authority a report showing at a minimum the laboratory's reported value, the assigned value, the acceptance range, the acceptable/not acceptable status, and the method for each analyte reported by the laboratory. This report shall be sent no later than 21 calendar days from the study closing date. Upon request by either the Primary Accrediting Authorities or laboratories, the PT Provider shall make available a report listing the total number of participating laboratories and the number of laboratories scoring not acceptable for each analyte. The PT Providers shall not disclose specific laboratory results or evaluations to any other parties without the written release of the laboratory.

2.7 PT CRITERIA FOR LABORATORY ACCREDITATION

2.7.1 Result Categories

The criteria described in this section apply individually to each PT field of testing, as defined by the laboratory seeking to obtain or maintain accreditation in its accreditation request. These criteria apply only to the PT portion of the overall accreditation standard, and the Primary Accrediting Authority shall consider PT results along with the other elements of the NELAC standards when determining a laboratory's accreditation status. The Primary Accrediting Authority ultimately makes all decisions regarding the accreditation status of the laboratory. There are two PT result categories: "acceptable" and "not acceptable."

2.7.2 Initial and Continuing Accreditation

A laboratory seeking to obtain or maintain accreditation shall successfully complete two PT studies for each requested PT field of testing within the most recent three rounds attempted. Successful performance is described in Appendix C. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each PT field of testing and maintain a history of at least two acceptable PT studies for each PT field of testing out of the most recent three. For initial accreditation or supplemental testing, the PT studies shall be at least 30 calendar days apart. For continuing accreditation, completion dates of successive proficiency rounds for a given PT field of

testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study.

2.7.3 Supplemental Studies

A laboratory may elect to participate in PT studies more frequently than required by the semiannual schedule. This may be desirable, for example, when a laboratory first applies for accreditation or when a laboratory fails a study and wishes to quickly re-establish its history of successful performance. These additional studies are not distinguished from the routinely scheduled studies; that is, they shall be reported and are counted and scored the same way and shall be at least 30 calendar days apart.

2.7.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to the Primary Accrediting Authority both the investigation and the action taken. If a laboratory fails two out of the three most recent studies for a given PT field of testing, its performance is considered unacceptable under the NELAC PT standard for that field. The laboratory shall then meet the requirements of initial accreditation as described in Section 2.7.2 - Initial and Continuing Accreditation.

2.7.5 Second Failed Study

The PT Provider reports laboratory PT performance results to the Primary Accrediting Authority at the same time that it reports the results to the laboratory. If a laboratory fails a second study out of the most recent three, as described in Section 2.7.4, the Primary Accrediting Authority shall take action, pursuant to Chapter Four, within 60 calendar days to determine the accreditation status of all methods for the unacceptable analyte(s) for that program and matrix.

2.7.6 Scheduling of PT Studies

A Primary Accrediting Authority may specify which months that laboratories within its authority are required to participate in NELAC PT programs. If the Primary Accrediting Authority chooses to specify the months, then it shall adhere to the required semiannual schedule. If the Primary Accrediting Authority does not specify the months, then the laboratory shall determine the semiannual schedule.

2.7.7 Withdrawal from PT Studies

A laboratory may withdraw from a PT study for an analyte(s) or for the entire study if the laboratory notifies both the PT Provider and the Primary Accrediting Authority before the closing date of the PT study. This does not exempt the laboratory from participating in the semiannual schedule.

2.7.8 Process for Handling Questionable PT Samples

There may be occasions in which the PT Provider has shipped one or more samples for NELAP accreditation which do not meet the quality control requirements of Appendix B, and the provider has not in a timely manner notified all affected laboratories or Accrediting Authorities as described in Section A.10 of this standard. In this case, an AA, upon review of summary data or other relevant documentation, may choose not to use the results of the analyte(s)/matrices to support the accreditation status of the laboratories. In order to justify not using the results, the AA shall first contact the PT Provider and attempt to resolve the situation. If after notifying the PT Provider, the AA still chooses to pursue a complaint against the provider, the AA shall submit a written complaint

to the Accrediting Authority Review Board (AARB). The AARB shall evaluate the complaint. If the complaint is determined to be valid, then the AA shall submit the written complaint to the PTOB/PTPA which initially accredited the provider for the particular analyte(s) and matrices. The AA shall follow all procedures for filing complaints as specified by the PTOB/PTPA. The AA may determine that the affected laboratories shall either wait until the next regularly scheduled PT testing round to analyze another PT for the analyte(s)/matrices, or may require the labs to obtain and analyze a supplemental sample, and repeat the test.

PROFICIENCY TESTING
APPENDIX A

PT PROVIDER APPROVAL CRITERIA

Appendix A - PT PROVIDER APPROVAL CRITERIA

A.0 SCOPE

This appendix describes the responsibilities and requirements a proficiency testing (PT) provider shall meet in order to be a Proficiency Testing Oversight Body (PTOB) /Proficiency Test Provider Accreditor (PTPA) Approved PT Provider. In order for a PT Provider to participate in the NELAC PT program, a provider shall be approved by a PTOB/PTPA. The criteria provided below are designated to ensure the integrity and technical excellence of the NELAC PT program while allowing all qualified providers to participate in the program.

A.1 APPROVAL PROCESS

The process for approval of a PT Provider includes a biennial on-site inspection by a PTOB/PTPA to ensure that the technical criteria of this appendix are being met. At the discretion of the PTOB/PTPA, the PT Provider may be requested to confirm their ability to perform analyses within the required limits through participation in a proficiency testing program operated by the PTOB/PTPA, or through the analysis of unknown samples provided by the PTOB/PTPA. Providers are also required to submit the results of PT programs operated for NELAC to the PTOB/PTPA for review and evaluation. The PT Provider agrees to accept the findings and decisions of the PTOB/PTPA as final.

A.2 QUALITY SYSTEM REQUIREMENTS

The manufacturing quality system used by the PT Provider shall meet the requirements of both International Organization for Standardization (ISO) 9001 for the design, production, testing, and distribution of performance evaluation samples and the requirements of ISO Guide 34, Quality System Guidelines for the Production of Reference Materials. The design and operation of the PT Provider's proficiency testing program shall meet the requirements of ISO Guide 43, Proficiency Testing by Interlaboratory Comparisons. The testing facilities used to support the verification, homogeneity, and stability testing required in Appendix B of this document shall meet the requirements of both ISO Guide 25, General Requirements for the Competency of Testing and Calibration Laboratories and Chapter Five, Quality Systems, of the NELAC standards. The ability to meet the ISO 9001 quality system requirement may be fulfilled through registration of the PT Provider's quality system to American National Standards Institute (ANSI) standards by a Registrar Accreditation Board (RAB)-accredited registrar. However, a biennial on-site inspection by the PTOB/PTPA demonstrating continuing conformance is required.

A.3 PROVIDER FACILITIES AND PERSONNEL

Each provider is required to have systems in place to produce, test, distribute, and provide data analysis and reporting functions for any series of samples for which they are requesting approval. Similarly, the provider shall have in place sufficient technical staff, instrumentation, and computer capabilities as may be required by the PTOB/PTPA to support the production, distribution, analysis, data collection, data analysis, and reporting functions of the samples. No portion of the production, testing, distribution, data collection, data analysis, nor data reporting functions may be outside the control of the PT Provider for any particular study, since it is essential that the confidentiality of the samples be maintained throughout the PT study. For the purposes of this requirement "control" can mean ownership or that the subcontracted service is performed under an agreement which specifically ensures the ability of the provider to access and restrict the distribution of information related to these services. Any subcontracted services shall be assessed by a PTOB/PTPA and meet the same criteria as the PT Provider.

A.4 SAMPLE FORMULATION REVIEW

The PT Provider shall demonstrate to the PTOB/PTPA, by the submission of appropriate data, that the sample formulation for which the PT Provider is seeking approval shall permit participating laboratories to generate results that fall within the sample acceptance ranges established by the NELAC Standing Committee on Proficiency Testing and meet the criteria of the "National Standards for Water Proficiency Testing Studies, Criteria Document" (USEPA).

A.4.1 Release of Information

In support of the requirement in Section A.4.0, PTOBs/PTPAs shall treat all sample formulation information submitted to them for review as the proprietary information of the PT Provider submitting the information. Such formulation information shall not be released by a PTOB/PTPA without the prior written consent of the PT Provider.

A.5 PROVIDER CONFLICT-OF-INTEREST REQUIREMENTS

PT Providers seeking approval shall document to the satisfaction of the PTOB/PTPA that they do not have a conflict of interest with any laboratory seeking, or having, NELAP accreditation. PT Providers shall notify the PTOB/PTPA of any actual or potential organizational conflicts of interest, including but not limited to:

a) Any financial interest in a laboratory seeking, or having, NELAP accreditation;

b) The sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, NELAP accreditation.

The PT Provider is also required to inform all internal and contract personnel who perform work on NELAC PT samples of their obligation to report personal and organizational conflicts of interest to the PTOB/PTPA. The provider shall have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of NELAC PT programs. If an actual or potential organizational conflict of interest is identified during performance of work in support of NELAC PT programs, the PT Provider shall immediately make a full disclosure to the PTOB/PTPA. The disclosure shall include a description of any action which the provider has taken or proposes to take, after consultation with the PTOB/PTPA, to avoid, mitigate or neutralize the actual or potential conflict of interest. The PTOB/PTPA may reevaluate a PT Provider's approval status as a result of unresolved conflict of interest situations. Any conflict of interest disputes between the PT Provider and the PTOB/PTPA may be appealed to NELAP for a final determination.

A.5.1 Ban on Distribution of Samples

PT Providers shall not sell, distribute, or provide samples used in the NELAC PT program prior to the conclusion of the study for which they were designed. Providers shall not sell, distribute, or provide samples of identical formulation and concentration to those samples which it is currently using in a NELAC study.

A.6 CONFIDENTIALITY OF PT STUDY DATA

The PT Provider shall demonstrate to the PTOB/PTPA that it has systems in place to ensure that the confidentiality of data associated with NELAC PT samples and programs are not compromised.

PT Providers shall not release the assigned value of any sample currently being used in a NELAC PT study prior to the conclusion of the study.

A.7 DATA REVIEW AND EVALUATION

The NELAP designated PTOB/PTPA shall review the data from every PT Provider's studies to ensure that acceptance limits used to evaluate laboratories are consistent with national standards as established by NELAC. The PTOB/PTPA shall also evaluate the performance of the PT Providers by monitoring, and reporting, to both the providers and the NELAC Standing Committee on Proficiency Testing the pass/fail rates of all providers on all samples tested. A PTOB/PTPA is required to investigate any PT Provider whose pass/fail rate is statistically different from the national average.

A.8 COMPLAINTS & CORRECTIVE ACTION

Written complaints received by the PT Provider regarding technical or procedural aspects of the studies they conduct shall be submitted to the PTOB/PTPA within 30 calendar days of receiving the complaint. The PT Provider shall resolve the complaint to the satisfaction of the PTOB/PTPA. The PTOB/PTPA is the sole judge of the adequacy of the corrective action taken by the PT Provider. The PTOB/PTPA shall provide NELAP with an annual summary of all PT Provider complaints received during the prior year.

A.9 LOSS OF PROVIDER APPROVAL

PT Providers who fail to meet the requirements of these standards may be subject to loss of their approval as a NELAC PT Provider. Providers may lose approval to provide individual sample sets based upon review of PT study data by a PTOB/PTPA as required in Appendix A, Section A.7. Similarly, PT Providers who fail to meet the requirements of Appendix A, Sections A.2 through A.6, on a continuous basis may lose their approval as a PTOB/PTPA-approved PT Provider for all samples.

A.9.1 Periodic Review of PT Providers

A PTOB/PTPA may at any time, review the performance of any approved PT Provider against these standards. Based upon this review, the PTOB/PTPA may decide that the approval status of a PT Provider be revoked, adjusted, limited, or otherwise changed based upon failure to meet one or more of the specified requirements.

A.9.2 Revocation of Approval

Should a PTOB/PTPA propose to revoke or suspend a provider's approval for failure to meet the requirements of these standards, the PTOB/PTPA shall inform the provider of the reasons for the proposed revocation or suspension and the procedures for appeal of such a decision. The due process rights of the provider shall be protected during any revocation or suspension proceedings. The final decision on the revocation or suspension of a provider's approval to supply PT samples for the NELAP accreditation resides with the Director of NELAP. If the provider loses PTOB/PTPA approval it shall lose NELAP approval to supply samples for the NELAC PT program.

A.10 NOTIFICATION OF SAMPLE INTEGRITY

The provider is responsible for notifying all laboratories and Primary Accrediting Authorities when a particular analyte was determined not to meet the requirements of Appendix B or is deemed of unacceptable quality for NELAC purposes, within 30 calendar days of the study closing date.

PROFICIENCY TESTING
APPENDIX B

PT SAMPLE DESIGN
& ACCEPTANCE GUIDELINES

Appendix B - PT SAMPLE DESIGN & ACCEPTANCE GUIDELINES

B.0 INTRODUCTION

An integral element of the NELAC PT program standards is the assurance of PT samples which are of high quality, well documented, homogeneous, and stable. To meet the goals of NELAC, the PT samples used in the program shall also provide all laboratories with samples which offer a consistent challenge. All PT samples shall meet all applicable specifications of these standards.

B.1 SAMPLE FORMULATION APPROVAL

The PT Provider shall demonstrate the adequacy of sample formulation to the satisfaction of the PTOB/PTPA. The criteria for formulation adequacy are that the sample shall provide equivalent challenge to the laboratories under test as similar samples for the same parameters as other providers, and that the sample shall exhibit laboratory acceptance rates, measured as provider percentage pass/fail performance, consistent with other samples used in the program for the same parameters.

B.1.1 Adequacy of the Sample Formulation

The testing and verification protocol required to establish sample equivalency shall be agreed to by both the PT Provider and the PTOB/PTPA on a case-by-case basis. It is the responsibility of the PT Provider to demonstrate the adequacy of sample formulation to the satisfaction of the PTOB/PTPA.

B.1.2 PT Sample Composition for Water Matrices

PT Providers may choose to leave one or more specific analyte(s) out of PT samples, yet may still include those analyte(s) in the PT study to be counted and scored with the present analytes. The guidelines in this section apply only to PT samples that contain analytes and matrices listed in the following NIST program designations: water supply (WS) regulated volatiles, WS unregulated volatiles, WS pesticides, WS herbicides, water pollution (WP) haloaromatics/halocarbons, and WP pesticides. Analytes from different USEPA test program designations may not be combined. The value assigned to these unspiked analytes would be zero. A PT Provider may choose not to include analytes; however, a minimum number of analytes shall be present in every PT sample. The PT Provider shall prepare samples according to the following criteria:

a) PT samples that are to be scored for one to ten analytes must include all of these analytes.

b) PT samples that are to be scored for ten to twenty analytes must include at least ten of these analytes or 80% of the total, whichever number is greater.

c) PT samples that are to be scored for more than twenty analytes must include at least sixteen of these analytes, or 60% of the total analytes, whichever number is greater.

d) If following (b) or (c) above and a percentage of the total number of analytes in the sample is a fraction, the fraction shall be rounded up to the next whole number. For example: 16 analytes × 0.80 = 12.8 = 13 analytes in sample.

e) PT Providers shall use a random selection process to determine which parameters will be assigned zero values within any given PT sample.

All other PT samples must contain all the analytes of interest within the concentration ranges as required by this standard.

B.2 VERIFICATION OF ASSIGNED VALUE

All PT samples used for obtaining or maintaining NELAP accreditation shall be analyzed by the PT Provider prior to shipment to the laboratories to ensure suitability for use in the program. The assigned value of the sample shall be used to establish acceptance criteria, and it shall be verified by analysis. PT Providers shall verify the assigned value by direct analysis against National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM), if a suitable NIST SRM is available for use. If a NIST SRM is not available then verification shall be performed against an independently prepared calibration material. An independently prepared calibrant is one prepared from a separate raw material source, or one prepared and documented by a source external to the provider.

B.2.1 Relative Standard Deviation of Verification Analysis

The method used by the PT Provider for verification analysis shall have a relative standard deviation of not more than 50% of the relative standard deviation predicted at the assigned value by the laboratory acceptance criteria being used by NELAC for each parameter. The relative standard deviation of the provider's verification method shall be established by a method validation study, and the suitability for use shall be approved by the NELAP designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA).

B.2.2 Quality Control Check of the Assigned Value

The assigned value for every parameter in all PT samples shall be verified by analysis. The assigned value of the analyte is verified if the mean of the verification analyses is within 1.5 standard deviations, as calculated as described in Sections C.1.1.1 or C.1.1.2, of either a) the assigned value if an unbiased verification method is used or b) the mean value for the analyte as calculated in Sections C.1.1.1 or C.1.1.2 if a biased method is used. The standard deviation of the verification analyses also shall be less than one standard deviation as calculated in Sections C.1.1.1 or C.1.1.2. For analytes that are evaluated using fixed percentages as defined in Section C.1.1.1, standard deviations are calculated by assuming that the fixed percentage is equal to two standard deviations.

B.3 HOMOGENEITY TESTING

PT sample homogeneity is essential to ensuring that all laboratories are treated fairly. Therefore, the purpose of the homogeneity testing procedure is to establish at the 95% confidence level that all samples distributed to the laboratories have the same assigned value for every parameter to be evaluated. Homogeneity testing is required on all PT samples prior to sample shipment to the laboratories.

B.3.1 Homogeneity Testing Procedure

The homogeneity of the samples shall be established using a generally accepted statistical procedure. The procedure selected by the PT Provider shall be capable of evaluating the relative consistency of each analyte across the production run, and shall be performed on the final packaged samples. The procedure shall establish at the 95% confidence level that the assigned value is consistent across the production run. Samples, or parameters, which fail to pass the homogeneity testing criteria cannot be used in the NELAC PT program to evaluate laboratories.

B.3.2 Suitable Homogeneity Testing Procedures

A suitable homogeneity testing procedure shall be capable of comparing the between sample to within sample standard deviation across the PT Provider's packaging run, and shall ensure comparability with 95% confidence. Suitable homogeneity testing procedures are available in both ISO Guide 35 for the Certification of Reference Materials and in the ISO Reference Material Committee (REMCO)-Association of Official Analytical Chemists (AOAC) Harmonized Protocol for the Proficiency Testing of Analytical Laboratories. However, the homogeneity testing procedure used by the PT Provider shall be approved for use by the PTOB/PTPA.

B.4 STABILITY TESTING

The samples used in the NELAC PT program shall be verified as stable for the period of each study. Therefore, the stability of all samples and parameters shall be established by the PT Provider following the close of data submission from the laboratories. The samples are considered stable for the period of the study if the mean analytical value as determined after the study for each parameter falls within the 95% Confidence Interval calculated for the prior to shipment verification testing used to establish the assigned value. The testing procedure used for stability testing shall be approved for use by the PTOB/PTPA.

B.5 DATA REPORTING BY PT PROVIDERS

The results of sample assigned value verification, homogeneity, and stability testing shall be available to the participating laboratories. All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis shall be provided to any laboratory participating in the program upon request after the close of the study. Providers shall supply PT data to the Primary Accrediting Authorities, as per Section 2.6, in a format acceptable to the Primary Accrediting Authority.

B.5.1 Verification and Homogeneity Reports

The data developed by the PT Provider in support of verification and homogeneity testing shall be supplied in summary format to the PTOB/PTPA in an electronic format to be determined by the PTOB/PTPA. Verification and homogeneity data shall be supplied to the PTOB/PTPA prior to sample distribution to the laboratories.

B.5.2 Laboratory Data and Stability Reports

All summary data from the laboratories and the results of stability testing shall be provided to the PTOB/PTPA in an electronic format to be determined by the PTOB/PTPA within 30 calendar days of the close of the study.

PROFICIENCY TESTING
APPENDIX C

PT ACCEPTANCE CRITERIA
AND
PT PASS/FAIL CRITERIA

Appendix C - PT ACCEPTANCE CRITERIA AND PT PASS/FAIL CRITERIA

C.0 PURPOSE, SCOPE, AND APPLICABILITY

This appendix defines the criteria to be used by any entity which seeks to participate as a NELAP-designated PTOB/PTPA-approved Proficiency Test Provider for scoring the results obtained from the analyses of samples in any NELAC PT study. The PT Providers shall submit all laboratories' performance rating(s) to the Primary Accrediting Authority, as described in Chapter Two of the NELAC standards, to be used as a tool for determining a laboratory's accreditation status. PT acceptance limits and pass/fail criteria are established on a program-matrix-analyte basis.

C.1 ANALYTE ACCEPTANCE LIMITS

Acceptance limits are established for each analyte as described in this appendix.

C.1.1 Analyte Acceptance Limit Categories

Acceptance limits are separated into two categories. Results for analytes with acceptance limits determined as described in Sections C.1.1.1 and C.1.1.2 shall be used in the determination of a laboratory's PT program-matrix-analyte pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section C.1.1.3 shall not be used as part of the program-matrix-analyte acceptable/not acceptable evaluation.

C.1.1.1 Drinking Water, Waste Water, and Ambient Water Analytes with USEPA Established Acceptance Limits

PT Providers shall utilize the proficiency test acceptance limits that have been established by USEPA in the "National Standards for Water Proficiency Testing, Criteria Document" where they apply. The "National Standards for Water Proficiency Testing, Criteria Document" is incorporated into this appendix by reference.

C.1.1.2 Analytes with Acceptance Limits Established by the NELAC Standing Committee on Proficiency Testing

For analytes not included in the "National Standards for Water Proficiency Testing, Criteria Document," Proficiency Test providers shall use acceptance limits established by the NELAC Standing Committee on Proficiency Testing and shall be made available to PTOB/PTPA-approved PT Providers by the PT Committee Chair or the Director of NELAP. Data from sources such as the USEPA Proficiency Evaluation (PE) studies, interlaboratory results from professional organizations such as ASTM, other Proficiency Test Providers, commercial and non-profit organizations, shall be used to establish the evaluation criteria. All evaluation criteria shall be approved by the NELAC Standing Committee on Proficiency Testing prior to use by a PTOB/PTPA-approved PT Provider.

C.1.1.3 Experimental Data: Analytes without Promulgated Acceptance Limits or Established Regression Equations

For those analytes not included in categories C.1.1.1 or C.1.1.2, e.g., newly regulated analytes, or analytes in a matrix that have not been fully evaluated in interlaboratory studies, NELAC acceptance limits shall be established only after interlaboratory data has been collected for a minimum of one year unless the NELAC Standing Committee on Proficiency Testing determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as "experimental data". The NELAC Standing Committee on Proficiency Testing

shall derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected. The laboratory shall receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

C.2 ACCEPTABLE PT RESULTS FOR CHEMICAL ANALYTES IN POTABLE WATER AND NON-POTABLE WATER PT SAMPLES

A laboratory's PT analyte result is acceptable when it falls within the regulatory promulgated acceptance limits (Section C.1.1.1). For Section C.1.1.2 analytes, PT Providers shall use the PT sample's verified assigned value and said regression equations to determine the mean and standard deviation. Acceptance limits shall be set at the mean ± two standard deviations for potable water analytes and the mean ± three standard deviations for non-potable water analytes. A result is acceptable when it falls within these derived acceptance limits.

C.3 NOT ACCEPTABLE PT RESULTS FOR POTABLE WATER AND NON-POTABLE WATER PT SAMPLES

A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

a) the result falls outside the acceptance limits;

b) the laboratory reports a result for an analyte not present in the PT sample (i.e., a false positive); or,

c) the laboratory does not withdraw from a study as described in Section 2.7.7, and fails to submit its results to the PT Provider on or before the deadline for the PT study.

C.4 ADDITIONAL REQUIREMENTS FOR PT PROVIDERS

PT Providers shall examine all data sets for bimodal distribution and/or situations where results from a given method have disproportionally large failure rates or reporting anomalies to the Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor. All proficiency test data are to be submitted to the PTOB/PTPA in the format specified by the PTOB/PTPA and shall be reviewed annually by the NELAC Standing Committee for Proficiency Testing for the purpose of revising existing and establishing new evaluation criteria.

C.4.1 Additional Matrix/Analyte Groups

Additional matrices and/or analytes may be added to the NELAC PT fields of testing at the request of any Accrediting Authority, USEPA program office, or PTOB / PTPA-approved PT Provider. The request for the addition of an analyte must include at a minimum ten sets of interlaboratory data on the analyte in the particular matrix. Each data set must contain a minimum of twenty valid data points. The NELAC Standing Committee on Proficiency Testing shall review the data and develop an initial set of laboratory acceptance limits based upon the needs of the Accrediting Authorities, USEPA, and the laboratories. Laboratory acceptance limits developed by the PT Committee on any new matrix/analyte combinations shall be reviewed annually by the PT Committee. The purpose of this annual review is to ensure that the limits represent the actual capabilities of the laboratories.

PROFICIENCY TESTING
APPENDIX D

PROFICIENCY TESTING OVERSIGHT BODY/ PROFICIENCY TEST PROVIDER ACCREDITOR

Appendix D - PROFICIENCY TESTING OVERSIGHT BODY/ PROFICIENCY TEST PROVIDER ACCREDITOR

D.0 PURPOSE, SCOPE, AND APPLICABILITY

This appendix defines the qualifications, scope of responsibilities and requirements for a NELAP designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) as defined in Section 2.2.2 of the NELAC document. In addition to complying with the requirements of this appendix, a PTOB/PTPA, for this oversight function, shall comply with the applicable requirements described in Chapter 2 and associated Appendices A (PT Provider Acceptance Criteria), B (PT Sample Design and Acceptance Guidelines), and C (Criteria for Setting PT Data Acceptance Limits).

D.1 TECHNICAL AND ADMINISTRATIVE QUALIFICATIONS

An organization shall demonstrate to the NELAC Standing Committee on Proficiency Testing by the submission of a current Statement of Qualifications that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider evaluation and oversight. In the event that the organization is not a nationally or internationally recognized authority, the NELAC Standing Committee on Proficiency Testing reserves the right to request further documentation detailing the organization's qualifications. The organization shall meet the following general requirements:

a) Demonstrate the capability to manage and evaluate complex environmental reference materials in a variety of matrices;

b) Demonstrate expertise in statistical applications as related to large interlaboratory performance evaluation programs;

c) Demonstrate the capability to conduct on-site audits of PT Providers;

d) Demonstrate the capability to conduct technical reviews of Initial Applications;

e) Demonstrate a knowledge and understanding of the ISO guides 9001, 34, 43, and Chapter Two of the NELAC standards including Appendices A, B, and C.

D.2 PTOB/PTPA RESPONSIBILITIES REGARDING INITIAL ASSESSMENT OF PT PROVIDERS

PTOB/PTPA responsibilities are described in this section. The primary responsibility of a PTOB/PTPA is the oversight and ongoing monitoring and evaluation of the PT Providers. The oversight activities of a PTOB/PTPA shall be designed to ensure that the PT Provider meets the requirements specified in Chapter Two and Appendices A, B and C. Any variations from these requirements shall be approved by the NELAC Standing Committee on Proficiency Testing prior to a body being approved as a NELAC PTOB/PTPA. All activities described herein shall be conducted by a PTOB/PTPA.

D.2.1 Development of Standard Operating Procedures and Forms

PTOBs/PTPAs shall develop the Standard Operating Procedures (SOPs) necessary to conduct the PT Provider evaluation process. These documents shall be based upon the requirements of Chapter Two of the NELAC standards and the associated Appendices A, B, and C. The NELAC

Standing Committee on Proficiency Testing has the authority to review and approve, as necessary, the SOPs developed by a PTOB/PTPA.

D.2.1.1 SOP(s) for the Assessment Process

The PTOB/PTPA shall develop and implement SOP(s) including but not limited to: the initial application submittal and review process, on-site inspection, submittal of final reports to NELAP, the procedures for determining that a PT Provider's approval be revoked, the procedures for appealing approval determinations, and any other procedures deemed necessary by NELAC.

D.2.1.2 Initial Application

A PTOB/PTPA shall develop the initial application process to be submitted by PT Providers applying for approval as PT Providers of NELAC samples. The application shall include questions regarding the qualifications of the organization seeking approval. In addition to completing the initial application process, a PTOB/PTPA shall require that the PT Provider submit copies of its current ISO 9001 registration certificate or any other documents which detail the quality systems required by the provisions of Chapter Two and associated appendices.

D.2.1.3 SOP(s) for On-Site Inspections and Checklist(s)

A PTOB/PTPA shall develop SOP(s) for conducting consistent, effective, on-site inspections of PT Providers. The SOP shall include policies which describe the circumstances for conducting any additional inspections, and circumstances for determining whether on-site inspections shall be announced or unannounced. A PTOB/PTPA shall develop standard, consistent checklist(s) to be used during any and all inspections of PT Providers.

D.2.2 Initial Application Review and On-site Inspections

A PTOB/PTPA shall follow the procedures described in this section for the review of applications and on-site inspections of any candidate PT Provider.

a) A PTOB/PTPA shall review the initial application documents, described in D.2.1.2, for compliance with the PT Provider qualifications described in Appendix A and other applicable documents.

b) A PTOB/PTPA shall review the sample designs used by the PT Provider for compliance with Appendix B and other applicable documents.

c) A PTOB/PTPA shall review the PT analyte and sample scoring procedures used by the PT Provider for compliance with Appendix C and other applicable documents.

d) Following the review of the Initial Application and associated documents, a PTOB/PTPA shall conduct an on-site inspection of the PT Provider. The PT Provider shall be provided with checklist(s) to be used during the inspection as part of the initial application process.

e) Following the inspection, a PTOB/PTPA shall conduct an exit meeting with the PT Provider, which shall include discussion of deficiencies and discrepancies found; however, a PTOB/PTPA may further revise the findings after the closing of the exit meeting, if necessary.

The inspection shall include, at a minimum:

1) Review of the quality system for adherence to the requirements of Appendices A, B and C;

2) Review of staff qualifications and technical expertise necessary to produce acceptable proficiency testing samples;

3) Review of the sample manufacturing and verification procedures to ensure that the requirements of Appendices A and B are met;

4) Review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for PT Providers and confidentiality of sample values; and,

5) Review of data reporting systems to ensure that the requirements of Appendix C are met within the time periods specified in Chapter Two.

f) A PTOB/PTPA shall send a draft report to the PT Provider after the completion date of the inspection. A PTOB/PTPA shall allow the PT Provider to review and comment on the draft if the PT Provider finds any discrepancies and determines that revisions are necessary. A PTOB/PTPA shall then submit a final inspection report to the PT Provider after the completion of the on-site inspection. The final report may only contain discrepancies and findings identified during the on-site inspection or discussed during the exit briefing.

g) A PTOB/PTPA shall allow the provider to submit their response to the report. In order for the provider's response to be considered acceptable, a PTOB/PTPA shall require that it include a description of corrective actions necessary to meet the criteria of Chapter Two, and Appendices A, B, and C.

D.3 PTOB/PTPA RESPONSIBILITIES REGARDING APPROVAL OF PT PROVIDERS

A PTOB/PTPA shall utilize the appropriate final report and associated documents submitted by the PT Provider to grant or deny approval to that provider.

D.4 PTOB/PTPA RESPONSIBILITIES FOR ONGOING OVERSIGHT OF PT PROVIDERS

A PTOB/PTPA shall conduct ongoing oversight of all approved PT Providers. The oversight shall include at a minimum:

a) the use of referee laboratories to verify the concentrations of analytes in randomly selected PT Provider samples;

b) the statistical monitoring of PT Provider's study data to detect occurrences which indicate samples of unacceptable quality, i.e., failure rates that exceed expected norms, analyte standard deviations that exceed expected intervals, and analyte mean recoveries which are significantly above or below historical trends. The ongoing monitoring criteria to be used by a PTOB/PTPA shall be developed by NELAC.

c) biennial on-site inspections of the PT Provider review and monitoring of critical operational parameters of the PT Provider, i.e., change in senior management, sale of the company.

d) on-site inspections of the PT Provider for cause.

Based upon the results of its ongoing oversight, the PTOB/PTPA may determine that the provider's approval status be reevaluated.

D.5 DEVELOPMENT AND MAINTENANCE OF A COMPREHENSIVE PT DATABASE

A comprehensive PT database shall be developed and maintained by the PTOB(s)/PTPA(s) in conjunction with NELAC.

D.6 COMPLAINTS AND CORRECTIVE ACTION

A PTOB/PTPA shall evaluate all complaints that it receives regarding either approved or candidate PT Providers. If the PTOB/PTPA determines that a complaint warrants investigation, the PTOB/PTPA shall notify the provider of the complaint. The PT Provider is required to resolve the complaint to the satisfaction of the PTOB/PTPA. A PTOB/PTPA shall provide to the NELAC Standing Committee on Proficiency Testing a summary of all PT Provider complaints received the previous year.

D.7 LIST OF APPROVED PT PROVIDERS

A PTOB/PTPA shall maintain a list of approved PT Providers. The list shall be maintained on a continuing basis on an electronic bulletin board or similar means and shall be readily available to laboratories seeking NELAP accreditation, State Accrediting Authorities and other interested parties. PT Providers shall agree to abide by the provisions of NELAC regarding the advertising and marketing use of the designation, "NELAP-designated PTOB/PTPA Approved Proficiency Test Provider".

D.8 SPONSORSHIP OF ANNUAL *NELAC PROFICIENCY TESTING CAUCUS*

The PTOB(s)/PTPA(s) shall, in conjunction with NELAC, sponsor an annual *NELAC Proficiency Testing Caucus*. The *Caucus* shall, if possible, be held in conjunction with the annual NELAC meeting. The purpose of the *Caucus* is to provide a forum for PT Providers, Accrediting Authorities, laboratories, federal agencies, and other interested parties to exchange information regarding the PT study results of the previous year. The *Caucus* shall include technical presentations and open discussions on means to improve the proficiency testing aspect of NELAC with a continuing goal of improving the quality of environmental data generated by the NELAC accredited laboratories.

D.9 PTOB/PTPA ETHICS

This section describes the overall ethics and standards of conduct that shall be adhered to for a PTOB/PTPA to implement and administer a successful PT Provider oversight program. A PTOB/PTPA shall serve as an impartial body designed to objectively evaluate information about PT Providers and use this information to make sound determinations regarding providers' approval status. A PTOB/PTPA shall be able to certify to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of Appendix D. A PTOB/PTPA shall remain unbiased in evaluating information gathered and received including inspection reports, referee sample results, complaints, and any other information obtained regarding a PT Provider. The PTOB/PTPA shall evaluate all information gathered and received about a provider related to providing NELAC PT samples, and determine which information is relevant to the approval status of a provider, and provide that information to NELAP, the Primary Accrediting Authorities, the laboratories, and the public as appropriate.

D.10 CONFIDENTIALITY

A portion of the information provided to a PTOB/PTPA by the PT Provider in the course of its inspection and oversight activities shall be proprietary in nature. A PTOB/PTPA shall agree to maintain the confidentiality of proprietary information provided to it by the PT Provider.

PROFICIENCY TESTING
APPENDIX E

MICROBIOLOGY

Appendix E - MICROBIOLOGY

E.0 PURPOSE

This appendix outlines the requirements for microbiological proficiency testing under the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA). Microbiological testing for other USEPA programs shall be added as required. Semi-annual proficiency testing is required per the schedule contained in Section 2.4.

E.1 SAMPLES

E.1.1 SDWA Samples

PT Providers shall present samples either as full volume samples or preparations easily reconstituted to full volume samples. For the SDWA, there shall be ten 100+ ml. samples (as presented or after reconstitution) for the qualitative determination (Presence/Absence) of total coliform and fecal coliform (or *E. coli*). Sample sets which are provided to the laboratories shall contain bacteria that produce the following:

- Verification as total and fecal coliforms (E. coli).
- Verification as total coliforms, but not as fecal coliforms.
- Bacterial contaminates which shall not verify as total or fecal coliforms.

Furthermore, each set shall contain the following samples:

- One to four samples containing an aerogenic strain of Escherichia coli for total and fecal coliform positive results using all USEPA approved methods.
- One to four samples containing Enterobacter sp. or other microorganisms ensuring a total coliform positive and fecal coliform negative result using all USEPA approved methods.
- One to four samples containing Pseudomonas sp. or other microorganisms ensuring a total and fecal coliform negative result using all USEPA approved methods.
- One to four blank samples.
- Optionally, one sample for the quantitative determination of Heterotrophic Plate Count.

Sample sets for qualitative analysis shall be randomly composed of samples that are Total coliform absent, Total coliform only present and Fecal coliform (E. coli) present.

E.1.2 CWA Samples

For the CWA, one sample shall be provided for the quantitative determination of Total coliform or Fecal coliform. Providers may require laboratories to analyze samples during a fixed time period after sample shipment or at any time during the testing period which shall not exceed the time limit set in Chapter Two.

E.2 SAMPLE PREPARATION AND QUALITY CONTROL

Proficiency test sample providers shall select bacterial strains and *holding media* that produce the appropriate biochemical reactions for *all* approved analytical methods. This shall be documented by analyses performed by the provider prior to sample shipment. The provider shall also

demonstrate that the samples are stable by analysis of a randomly selected set either after the study closing date or in the case of a study with a fixed testing period, on the last working day of the testing period.

E.3 SCORING

E.3.1 Qualitative Analyses, *SDWA Samples*

Participating laboratory results shall be considered Acceptable or Unacceptable when compared to the known presence or absence of total coliform or fecal coliform (or *E. coli*) bacteria. Passing shall be considered as nine out of ten samples having acceptable results, and no false negatives reported.

E.3.2 Quantitative Analyses

Quantitative result data sets shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Most Probable Number data shall be transformed to logs prior to statistical analysis. Acceptable results are those that are within the 99% confidence limits as set by the mean, standard deviation and set size *(n)* for their respective data set.

E.3.2.1 Requirement for Quantitative Data Set Size

Each PT Provider's microbiological data set shall be comprised of at least 20 valid data points for each method evaluated. Sample sets of less than 20 data points may be used only with the approval of the PTOB/PTPA.

PROFICIENCY TESTING
APPENDIX F

ENVIRONMENTAL TOXICOLOGY

Appendix F - ENVIRONMENTAL TOXICOLOGY

F.0 Whole Effluent Toxicity (WET) PT PROGRAM: INTERIM STANDARDS

Prior to NIST accreditation of PT Providers for Environmental Toxicology methods, laboratories seeking WET accreditation shall be assessed through on-site audit and evaluation of EPA Discharge Monitoring Report - Quality Assurance (DMR-QA) test results. During this interim period, a failed DMR-QA endpoint shall require: 1) a formal response to the Accrediting Authority (AA) with an explanation of probable cause for the endpoint failure and description of corrective actions to be taken (where appropriate) and 2) a decision by the AA to accept the response or require additional on-site audits. There shall be no loss of accreditation based solely on PT results during this interim period.

If a laboratory fails a WET PT endpoint, the laboratory is required to successfully complete a remedial study. A remedial study must be conducted, at least 30 calendar days from the previous PT study, until two acceptable results are obtained. The AA may conduct additional onsite audits as necessary. The default for the WET PT program is accreditation without PT samples.

F.1 PURPOSE, SCOPE, AND APPLICABILITY

This appendix defines the criteria applying the proficiency testing (PT) program to the following environmental toxicology programs: 1) whole effluent toxicity, 2) sediment toxicity, and 3) soils toxicity.

F.2 RATIONALE

Accreditation for environmental toxicology testing laboratories shall be based on Proficiency Testing and on-site audits, the latter including but not limited to an evaluation of personnel qualifications, facility acceptability, quality system and standard operating procedures, status of data/reports generated and routine standard toxicant testing. Proficiency Testing provides a snapshot of the laboratory's capability; however, due to the number of variables inherent to environmental toxicology testing it cannot carry the same weight as PT samples for chemical analytes. PT samples shall be comprised of unknown concentrations of EPA's historical reference toxicant materials. Every effort shall be made by the PTOB/PTPA working together with the providers to reduce the number of variables in each method (i.e., organism age, etc.) while following the routine language of the EPA protocols.

F.3 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAMS

F.3.1 Required Level of Participation

Laboratories seeking accreditation for environmental toxicology shall participate in at least one PT study per year for each method code as designated (method code includes matrix, organism, exposure system, and endpoint).

F.3.2 Requirements for Laboratory Testing of PT Study Samples

a) Analyze within 30 calendar days of sample receipt; report results within 30 calendar days of completion.

b) Samples shall be analyzed in the same manner as routine samples within the limits of the method code – as close to "real world" testing as possible.

F.4 PT CRITERIA FOR LABORATORY ACCREDITATION

F.4.1 Initial and Continuing Accreditation

Laboratories which seek to obtain or maintain accreditation for environmental toxicology shall successfully complete at least one PT sample per year for a given field of testing (i.e., not more than 12 months apart) and at least 30 calendar days apart (i.e., participation in a second round or remedial study may not occur within 30 calendar days of the first or failed study). Failure to meet the annual schedule shall be regarded as a failed study. Results other than acceptable/not acceptable may apply.

F.5 FIELDS OF TESTING

The environmental toxicology PT program shall be organized by fields of testing based on method [including matrix, test organism, and exposure system and endpoint(s)]. Laboratories may choose to participate in one or more PT fields of testing, or portions thereof.

F.5.1 Whole Effluent Toxicity (WET) Method Codes

Method codes shall reflect the EPA DMR-QA study codes for the current study year.

F.5.2 Test Conditions for Sediment Toxicity (Solid Phase)

The following table describes the test conditions to be followed for sediment toxicity testing:

Test Organism	Test Conditions	Method Code
Freshwater amphipod	10-d, static, renewal, synthetic MHW	TBS[1]
Midge larvae	10-d, static, renewal, synthetic MHW	TBS
Saltwater amphipod	10-d, static, non-renewal, synthetic SW @ 20 ‰	TBS
Polychaete worm	10-d, static, non-renewal, synthetic SW @ 28 ‰	TBS
[1] TBS = To Be Specified		

F.5.2.1 Sediment Toxicity PT Samples

Accreditation for whole sediment toxicity methods shall be based solely on the on-site audit until further notice.

F.5.3 Test Conditions for Soil Toxicity

The following table describes the test conditions to be followed for soil toxicity testing:

Test Organism	Test Conditions	Method Code
Eisenia foetida survival test	14-d static, non-renewal, 24L:0D	TBS[1]
Lettuce (Lactuca sativa) seed germination test	120-h static, non-renewal, 16L:8D	TBS
Lettuce (Lactuca sativa) root elongation test	120-h static, non-renewal, 0L:24D	TBS
[1] TBS = to be specified		

F.5.3.1 Soil Toxicity PT Samples

Accreditation for soil toxicity methods shall be based solely on the on-site audit until further notice.

National Environmental
Laboratory **Accreditation**
Conference

ON-SITE ASSESSMENT

July 1, 1999

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3.0 ON-SITE ASSESSMENT

3.1 INTRODUCTION

The on-site assessment is an integral and requisite part of a laboratory accreditation program and will be one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team will collect and evaluate information and make observations which will be used to judge the laboratory's conformance with established accreditation standards.

It is essential that the on-site assessment conducted by any accrediting authority in the United States wishing to be recognized by the National Environmental Laboratory Accreditation Program be conducted in a uniform, consistent manner. Reasons for fostering this consistency include a need to assure the base quality of data coming from the laboratories; to allow more confident comparison of results generated by different laboratories; to facilitate reciprocity; and for the laboratory community to accept the accreditation standards.

This section describes the essential elements that are to be included in any acceptable on-site assessment and the qualifications and requirements for assessors.

The responsibility for promulgating and enforcing occupational safety and health standards rests with the U.S. Department of Labor. While it is not within the scope of the assessment team to evaluate all health and safety regulations, any obviously unsafe condition(s) observed should be described to the appropriate laboratory official and reported to the accrediting authority. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with any applicable health and safety regulations.

3.2 ON-SITE ASSESSMENT PERSONNEL

3.2.1 Basic Qualifications

A laboratory assessor may work for a Federal, State, or a third party assessor body. An assessor must be an experienced professional and hold at least a Bachelor’s degree in a basic science, or have equivalent education and experience in laboratory assessment or related fields.

Each assessor also must have satisfactorily completed an approved assessor training program. All assessors must take annual update/refresher training as specified by the NELAC.

Each new candidate assessor must undergo training with a qualified assessor during four or more actual assessments until judged proficient by the accrediting authority. Assessors employed by accrediting authorities (either directly or as a third party) when the authority is granted NELAP recognition (see section 6.7) are exempt from the requirement to undergo training with a qualified assessor during four or more actual on-site assessments, provided they have previously conducted four assessments and been judged proficient by the accrediting authority. Assessors employed by accrediting authorities on the date that the first Accrediting Authority is granted NELAP recognition must meet the NELAC-specified basic training course requirements within two years after the first NELAC-specified basic training course is offered and the applicable technical training course requirements within four years after the first NELAC-specified technical training course is offered.

In addition, the assessors must:

a) Be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;

b) Have a thorough knowledge of the relevant assessment methods and assessment documents;

c) Be thoroughly familiar with the various forms of records described in Section 3.5.3 - Records review;

d) Be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;

e) Be technically knowledgeable and 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; and,

f) Be able to communicate effectively, both orally and in writing.

3.2.2 Assessor Qualification

Before an assessor can conduct on-site assessments, the individual must be qualified by an accrediting authority. Each assessor must sign a statement before conducting an assessment certifying that no conflict of interest exists and provide any supporting information as required by the accrediting authority. Failure to provide this information will make the proposed assessor ineligible to participate in the assessment program.

3.2.3 Training

The National Environmental Laboratory Accreditation Conference (NELAC) specifies the minimum level of education and training for assessors, including refresher/update training. The NELAC also develops standards for training requirements. The assessor training program will be implemented by either accrediting authorities, assessor bodies, or other entities. All assessor training programs, must meet the NELAC standards.

The purpose of the basic assessor training course is to familiarize the assessor with the NELAC standards and the skills and techniques associated with auditing. The assessor training program is defined as follows:

NELAC Basic Assessor Training Course

DAY 1

- Basic Auditing Techniques and Skills

DAY 2

- NELAC Overview (Chapter 1 NELAC Standards)
- Accrediting Authority (Chapter 6)
- Accreditation Process (Chapter 4)
- Proficiency Testing (Chapter 2)

DAY 3

- Quality Systems (Chapter 5)

DAY 4

- On-Site Assessment (Chapter 3)

DAY 5

- Course Summary
- Written Examination

NOTE: Until such time as the NELAC has developed the training program for laboratory assessors, each accrediting authority shall approve the training for each of its assessors (federal, State and/or third party).

When the NELAC has approved the assessor training program standards, accrediting authorities, assessor bodies, or other entities may petition for approval of various formal training programs that address auditing skills which may meet the NELAC standards (Day 1). It is the intent of this chapter to allow those assessors that produce evidence of successful completion of an approved alternative training course concerning auditing to be exempt from the analogous NELAC training (Day 1). The specific training associated with the NELAC standards (Days 2 - 5) is required and must be successfully completed. All assessor candidates must pass the written examination (Day 5).

In addition to the basic NELAC assessor training, each assessor must successfully complete additional technical training in up to seven (7) separate analytical disciplines. Each assessor may pursue recognition in one or more analytical disciplines according to individual wants or needs.

The purpose of the technical training courses is to ensure consistency of knowledge and techniques among the NELAC assessors. The technical courses assume a level of basic knowledge of the course subject and will, therefore, concentrate on the elements of the technology or methods which are key to properly assure laboratory competency to deliver data of known and documented quality. The technical training program will consist of the following courses:

NELAC Technical Training Courses for Assessors

COURSES

1. Microbiology (2.5 days)
   - Bacteriology
   - Viruses/Parasites
   - Microscopic Particulate Analysis (MPA)

2. Biological (2.5 days)
   - Aquatic Toxicity Testing
   - Freshwater/Marine/Estuarine Fish
   - Freshwater/Marine/Estuarine
   - Icthyoplankton
   - Macrophytes
   - Periphyton
   - Phytoplankton
   - Zooplankton
   - Biomass
   - Chlorophyll a (Spectrophotometric and Fluorometric)

3. Inorganic - Nonmetals/Misc (2.5 days)
   - Spectrophotometric
   - Titrimetric
   - Potentiometric
   - Colorimetric
   - TOC/TOX
   - Residue/Solids
   - COD/BOD
   - IR
   - IC

4. Inorganic - Metals (2.5 days)
   - FAA
   - GFAA
   - ICP
   - ICP/MS
   - Sample Preparation (Digestion/TCLP/etc.)

NELAC Technical Training Courses for Assessors (cont'd)

5. Organics (5 days)
   - Sample Preparation
   - HPLC
   - GC
   - GC/MS
   - Instrument Software

6. Asbestos (2.5 days)
   - Bulk
   - Air
   - Water/TEM (Day 1. Assessors not requiring TEM could begin course on second day)

7. Radiochemistry (2.5 days)

The purpose for requiring refresher/update training for all assessors is to ensure that the assessors are aware of changes to the standards and/or approved analytical methodology as they occur and to enhance and improve skills associated with auditing. Initially, the refresher/update training is conceptualized as follows:

NELAC Refresher/Update Training for Assessors

Day 1
- Changes to the NELAC Standards and the Resulting Checklist Changes
- Technical Changes Associated with Approved Methodology and the Resulting Checklist Changes
- Auditing Skills and Techniques
- Current Developments

3.3 FREQUENCY AND TYPES OF ON-SITE ASSESSMENTS

3.3.1 Frequency

Accrediting authorities must require a comprehensive on-site assessment of each facility that is accredited at least every two years. Assessments may be conducted more frequently for cause, at the option of the accrediting authority.

3.3.2 Follow-up Assessments

In addition to routine assessments, assessors may need to conduct follow-up assessments at laboratories where a deficiency was identified by the previous assessment. These assessments may be, but are not necessarily limited to, determining whether a laboratory has corrected its deficiency(ies), or determining the merit of a formal appeal from the laboratory. When deficiencies are of such severity as to possibly warrant the downgrading of a laboratory's accreditation status, any follow-up assessment that is planned or conducted should be completed and reported within thirty (30) calendar days after the receipt of the laboratory's plan of corrective action.

Nothing in this section should be construed as requiring an accrediting authority to reassess a facility prior to taking a regulatory or administrative action affecting the status of the facility's accreditation. Nothing in this section should be construed as limiting in any way the accrediting authorities ability to revoke or otherwise limit a laboratory's accreditation upon the identification of such deficiencies as to warrant such action.

3.3.3 Changes in Laboratory Capabilities

The accrediting authority may also deem necessary an assessment when a major change occurs at a laboratory in personnel, equipment, or in a laboratory's location that might alter or impair analytical capability and quality.

3.3.4 Announced and Unannounced Visits

The accrediting authority, at its discretion, may conduct either unannounced or announced on-site assessments. The accrediting authority is not required to provide advance notice of an assessment.

To the maximum extent practical, accrediting authorities, when necessary, shall work with Federal departments/agencies/contractors to obtain government security clearances for their assessors as far in advance as possible. Federal departments/agencies/contractors shall facilitate expeditious attainment of the necessary clearances.

3.4 PRE-ASSESSMENT PROCEDURES

3.4.1 Assessment Planning

A good assessment begins with planning, which should commence well before the assessment team visits the laboratory. Planning is the means by which the lead assessor identifies all the required activities to be completed during the assessment process. Planning includes conducting a thorough review of NELAP and/or State records pertaining to the laboratory to be inspected. This may save time because familiarity with the operation, history, and compliance status of the laboratory increases the efficiency and focus of an on-site visit.

Pre-assessment activities include: deciding the scope of the assessment; reviewing NELAP/State information; providing advance notification of the assessment to the laboratory, when appropriate; obtaining any security clearances which may be necessary; coordinating the assessment team; and gathering assessment documents. Section 3.4.5 discusses Confidential Business Information (CBI) issues.

3.4.2 Scope of the Assessment

The first step in the assessment planning process is deciding what type of assessment will be conducted. The assessment may be a general one to determine the capability of the laboratory to perform environmental testing or a specific examination of a certain area of testing. The assessment must include both an appraisal of the laboratory's operations and a review of the appropriate records. The assessment for a field of testing must cover all of the tests for which the laboratory seeks accreditation.

3.4.2.1 Laboratory Assessments

A laboratory assessment must review the ability of the lab to conduct environmental testing. The examination of the systems, processes and procedures of the laboratory should give a general sense of its past and present capabilities to perform work of known and documented quality. During

a laboratory assessment, the assessment team may identify a number of samples or a recently completed or on-going project and evaluate to what extent the tests are being conducted according to NELAC standards.

3.4.2.2 Records Review

The purpose of a records review is to determine whether the testing laboratory has maintained necessary documentation of data and other information to technically substantiate reports previously issued. During a records review, the assessment team will conduct an overall audit of data and will compare data with submitted reports to determine whether the data were collected, generated, and reported following the NELAC standards.

3.4.3 Information Collection and Review

Prior to initiating an on-site assessment, the assessment team shall make determinations as to which laboratory records they wish to review prior to the actual site visit. These records, from the files of the accrediting authority, the national laboratory accreditation database, or the laboratory itself may include, but are not limited to:

a) Copies of previous assessment reports and proficiency testing sample results;

b) General laboratory information such as laboratory submitted self-assessment forms, SOPs and Quality Assurance Plan(s);

c) Official laboratory communications and associated records with appropriate accrediting authority staff;

d) Available documents from recipients of reports from the laboratory;

e) The laboratory's application for accreditation;

f) The existing program regulations and special requirements that apply to the areas for which accreditation is sought (i.e. security clearances, radioactive exposure protocols, etc.); and,

g) The most recently approved analytical methods for the tests for which the laboratory has requested accreditation.

3.4.4 Assessment Documents

Documents necessary for the assessment and which may need to be provided to the laboratory management or staff should be assembled before the assessment, whenever possible. The lead assessor should obtain copies of the required assessment forms, including the appropriate checklist(s) as documented in the NELAC Assessor Training Manual. Other types of documents that may be required include:

- Assessment Confidentiality Notice;
- Conflict of Interest Form;
- Assessor Credentials;
- Assessment Assignment(s);
- Assessment Notification Letter;
- Attendance Sheet(s) (opening and closing conference); and,
- Assessment Appraisal Form.

In addition, the lead assessor should be able to provide information about how to obtain copies of documents and materials associated with an assessment from the accrediting authority.

3.4.5 Confidential Business Information (CBI) Considerations

During on-site assessments, on-site assessors may come into possession of information claimed as business confidential. The EPA regulations for handling confidential business information are detailed in Title 40, Code of Federal Regulations, Part 2, Subpart B and will be followed in NELAP related matters. Subpart B defines a business confidentiality claim as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment."

NELAC standards must, consistent with 40 CFR Part 2, protect Confidential Business Information (CBI) from disclosure. For this information to be adequately protected, certain actions are required, by NELAP, on-site assessors and the laboratory. The lead assessor must provide a NELAP assessment confidentiality notice to the responsible laboratory official at the beginning of the assessment. This notice informs laboratory officials of their right to claim any portion of the information requested during the assessment data as CBI. NELAP personnel, assessors and other users of said information must have CBI training. The assessors should be familiar with the procedures for asserting a CBI claim and handling information which contain the information claimed as CBI. The lead assessor must take custody of all CBI information before leaving the laboratory, and must maintain them in custody, using all proper procedures and safeguards, until they can be received by the accrediting authority, who must also treat such information as CBI, until an official determination has been made in accordance with federal and State laws.

Certain actions are required of the responsible laboratory official when claiming information as business confidential. The laboratory representative must place on (or attach to) the information at the time it is submitted to the assessor, a cover sheet, stamped or typed legend, or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Allegedly confidential portions of otherwise non-confidential information should be clearly identified by the business, and may be submitted separately to facilitate identification and handling by the assessor. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. If the information claimed as business confidential suggests the need for further action, the information may be forwarded to the appropriate agency which may take further action outside the scope of the accreditation process, to obtain the client's identity. If the information claimed as business confidential suggests the need for further enforcement action, the accrediting authority is responsible for ensuring that all CBI issues are handled in accordance with NELAC standards.

If a business confidentiality claim is received after the on-site assessment by the accrediting authority, the authority should make such efforts as are administratively practical to associate the late claim with copies of the previously submitted information in its files. However the accrediting authority cannot assure that such efforts will be effective in light of the possibility of prior disclosure or dissemination of the information.

It is not the responsibility of the on-site assessor to make any determination with respect to the validity of a confidential business information claim; this responsibility rests with the accrediting authority. The assessor must maintain custody of CBI-claimed information collected during the assessment until they are delivered to an authorized official of the accrediting authority. CBI-claimed information may be the intellectual property of the laboratory. Therefore, all CBI-claimed information must be held in a secure manner throughout the holding period of assessment records and may not be reproduced or distributed inconsistent with 40 CFR Part 2. If the accrediting

authority questions the claim that certain information is CBI, the host laboratory must be contacted and given twenty-one (21) calendar days to:

(1) provide justification of their claim to CBI,

(2) remove the claim of CBI,

(3) resolve the issue in a manner agreeable to both the laboratory and the accrediting authority,

(4) engage legal assistance,

(5) appeal the action to NELAP, or

(6) withdraw their NELAC accreditation application for the field of testing associated with the CBI information.

In no instance may the accrediting authority declassify CBI-claimed information without notification of the laboratory. If the responsible laboratory official does not consent to declassification of the CBI-claimed information, the laboratory may pursue any or all of the above stated actions.

3.4.6 National Security Considerations

Assessors performing assessments at facilities owned and/or operated by Federal departments/agencies/contractors may need security clearances, appropriate badging, and/or a security briefing before proceeding with the on-site assessment. Assessors shall be informed in writing of any information, including analytical data, that is controlled for national security reasons and cannot be released to the public.

3.5 ASSESSMENT PROCEDURES

3.5.1 Length of Assessment

The length of an on-site assessment will depend upon a number of factors such as the number of tests for which a laboratory desires accreditation, the number of assessors available, the size of the laboratory, the number of problems encountered during the assessment, and the cooperativeness of the laboratory staff. The assessor body should assign an adequate number of assessors to complete the assessment within a reasonable period of time. Assessors must strike a balance between thoroughness and practicality, but in all cases must determine to what effect the laboratories' operations meet NELAC standards.

3.5.2 Opening Conference

Arrival at the facility should normally occur during established working hours. The responsible laboratory official(s) should be located as soon as the assessment team arrives on the premises.

A laboratory's refusal to admit the assessment team for an assessment will result in an automatic failure of the laboratory to receive accreditation or loss of an existing accreditation by the laboratory, unless there are extenuating circumstances that are accepted and documented by the accreditation authority. The team leader must notify the accrediting authority as soon as possible after refusal of entry.

An opening conference must be conducted and shall address the following topics:

a) the purpose of the assessment;

b) the identification of the assessment team;

c) the tests that will be examined;

d) any pertinent records and operating procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing the assessment team with the necessary documentation;

e) the roles and responsibilities of key managers and staff in the laboratory;

f) the procedures related to Confidential Business Information;

g) any special safety procedures that the laboratory may think necessary for the protection of the assessment team while in certain parts of the facility (under no circumstance is an assessment team required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an inspection to gain access to the facility);

h) the standards that will be used by the assessors in judging the adequacy of the laboratory operation;

i) confirmation of the tentative time for the exit conference;

j) provision of the assessment appraisal form to the responsible laboratory official (to be submitted to NELAP and the accrediting authority); and

k) discussion of any questions the laboratory may have about the assessment process.

3.5.3 On-site Laboratory Records Review and Collection

Records will be reviewed by assessment team members for accuracy, completeness and the use of proper methodology for each test and analyte to be evaluated.

A minimum record set that must be examined as part of a accreditation assessment includes;

a) application for accreditation from the laboratory;

b) previous assessment results and reports including proficiency testing results;

c) laboratory management structure and chains of responsibility (e.g. organizational charts);

d) qualifications statements of all key staff involved in the analysis or reporting of results for which accreditation has been requested and a matching of the staff qualifications with the statements submitted with the applications;

e) quality assurance plan(s) for the laboratory;

f) standard operating procedures and methodologies for each parameter for which accreditation is sought;

g) maintenance and calibration records of laboratory equipment and instrumentation;

h) procedures for the make-up and calibration of stock solutions and standard reagents;

i) origins, purities, assays and expiration dates of primary standards, analytical reagents and standard reference materials;

j) records associated with method-specific QA\QC requirements;

k) the specific records associated with the initial method validation study in the laboratory which must be examined in detail with the historical calibration data;

l) records associated with the methods used to estimate precision and accuracy in general for specific analyses;

m) sample receipt and handling documentation;

n) proficiency testing sample receipt and handling procedures;

o) information about the proficiency testing providers;

p) records of any internal audits conducted or corrective actions taken by the laboratory itself; and

q) documentation of the laboratory's annual and/or ongoing management review.

The laboratory must mark all confidential information. The lead assessor must handle it as required by appropriate laws and regulations. All other information for all aspects of application, assessment and accreditation of laboratories is considered public information. If the laboratory requests that information other than noted above is confidential, the information should be treated as confidential until a ruling can be made by the accrediting authority.

3.5.4 Staff Interviews

As an element of the assessment process, the assessment team should evaluate an analysis regimen by requesting that the analyst normally conducting the procedure give a step-by-step description of exactly what is done and what equipment and supplies are needed to complete the regimen. Any deficiencies shall be noted and discussed with the analyst. The deficiencies will also be discussed in the closing conference.

The assessment team members shall have the authority to conduct interviews with any/all staff**.** Calculations, data transfers, calibration procedures, quality control/assurance practices, adherence to SOPs and report preparation shall be assessed for each test with the appropriate analyst(s).

3.5.5 Closing Conference

The assessment team must meet with representative(s) of the laboratory following the assessment for an informal debriefing and discussion of findings with the possible exception of any issues of improper and/or potentially illegal activity which may be the subject of further action. It should be noted that the assessment team in no way limits its ability to identify additional problem areas in the final report should it become necessary.

In the event the laboratory disagrees with the findings of the assessor(s), and the team leader adheres to the original findings, the deficiencies with which the laboratory takes exception shall be

documented by the team leader and included in the report to the accreditation authority for consideration. The accrediting authority will make the final determination as to the validity of the contested elements.

The assessment team should inform the laboratory representative(s) that an assessment report encompassing all relevant information concerning the ability of the applicant laboratory to comply with the accreditation requirements is forthcoming.

3.5.6 Follow-up and Reporting Procedures

The accrediting authority or its authorized third party must present an assessment report to the laboratory within thirty (30) calendar days of the assessment. The laboratory will have thirty (30) calendar days from the date of receipt of the report to provide a plan of corrective action to the accrediting authority (Chapter 4, Section 4.1.3). An exception to these deadlines may be necessary in those circumstances where a possible enforcement investigation or other action has been initiated.

3.5.7 Assessment Closure

After reviewing the assessor's report(s) and any completed corrective action(s) reported by the laboratory, the accrediting authority will make the determination of the accreditation status for a laboratory.

If the deficiencies listed are substantial or numerous, an additional on-site assessment may be conducted before a final decision for accreditation can be made.

3.6 STANDARDS FOR ASSESSMENT

3.6.1 Assessor Training Manual

The NELAC Assessor Training Manual is available on the NELAC Bulletin Board and will be provided at all NELAC assessor training courses. The manual will be used when assessors take the NELAC required training (Section 3.2.3) and will serve as a reference for on-site assessment personnel.

The manual for on-site assessors shall include guidance for evaluating the following items:

a) Size, appearance, and adequacy of the laboratory facility;

b) Organization and management of the laboratory;

c) Qualifications and experience of laboratory personnel;

d) Receipt, tracking and handling of samples;

e) Listing/inventory, condition, and performance of laboratory instrumentation and equipment;

f) Source, traceability and preparation of calibration/verification standards;

g) Test methods (including the adequacy of the laboratory’s standard operating procedures as well as confirmation of the analyst’s adherence to SOPs, and the analyst’s proficiency with the described task);

h) Data reduction procedures, including an examination of raw data and confirmation that final reported results are derived from raw data and original observations; and,

i) Quality assurance/quality control procedures, including adherence to the laboratory's quality assurance plan and adequacy of the plan.

3.6.2 Assessor's Role

When performing an on-site laboratory assessment, the assessor must appraise each of the areas listed in Section 3.6.1 and perform a thorough assessment of the records for each of the tests for which accreditation has been requested.

The on-site assessor should use a variety of tools in the assessment process. The experience of the assessor, his/her observations, interviews with laboratory staff, and examination of SOPs, raw data, and the laboratory's documentation all play important roles in the assessment. The accreditation of a particular laboratory will depend to a large extent on the assessment team's findings and recommendations. Much of the on-site assessment will depend upon the assessor's observations of existing conditions. The recommendation not to accredit a laboratory, or to change a laboratory's accreditation status, must be based on factual information and not upon subjective evaluations. Therefore, it is crucial that the on-site assessor have a clear understanding of the laboratory's procedures and policies and that the assessor document any deficiencies in the report of the on-site assessment.

The assessment team must use specific documentation in its reporting of deficiencies. The assessor should discuss any deficiencies with the laboratory's management at the exit conference.

During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information should be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team should present such information to the accrediting authority for appropriate action(s). These issues, at the discretion of the accrediting authority, may or may not be subjects or issues of the closing conference. However, the assessor should continue to gather the information necessary to complete the accreditation assessment.

3.6.3 Checklists

Standardized checklists, as documented in the NELAP Assessor Training Manual, must be used for the on-site assessment. The use of checklists does not replace the need for assessor observations and staff interviews, but is another tool which assists in conducting a thorough and efficient assessment. A checklist is not a substitute for assessor training and experience.

3.6.4 Assessment Standards

The areas to be evaluated in an on-site assessment shall include:

a) Size, appearance, and adequacy of the laboratory facility;

b) Organization and management of the laboratory;

c) Qualifications and experience of laboratory personnel;

d) Receipt, tracking and handling of samples;

e) Quantity, condition, and performance of laboratory instrumentation and equipment;

f) Preparation and traceability of calibration standards;

g) Test methods (Including the adequacy of the laboratory's standard operating procedures as well as confirmation of the analyst(s) adherence to SOPs, and the analyst(s) proficiency with the described task);

h) Data reduction procedures, including an examination of raw data and confirmation that final reported results can be traced to the raw data/original observations; and,

i) Quality assurance/quality control procedures, including adherence to the laboratory's quality assurance plan(s) and adequacy of the plan(s).

These areas must be evaluated against the standards detailed in Chapter 5, Quality Systems, of the NELAC Standards and the appropriate method references. Additional information on the process for evaluating these areas can be found in the Assessor Training Manual.

3.7 DOCUMENTATION OF ON-SITE ASSESSMENT

3.7.1 Checklists

The checklists used by the assessors during the assessment shall become a part of the permanent file kept by the accrediting authority for each laboratory.

3.7.2 Report Format

The final site visit report shall be written to contain a description of the adequacy of the laboratory as it relates to the assessment standards in Section 3.6.4. Assessment reports should be generated in a narrative format. Deficiencies must be addressed at a minimum. Documentation of existing conditions at the laboratory should be included in each report to serve as a baseline for future contacts with the facility.

Assessment reports will contain:

a) Identification of the organization assessed (name and address),

b) Date of the assessment,

c) Identification and affiliation of each assessment team member,

d) Identification of participants in the assessment process,

e) Statement of the objective of the assessment,

f) Summary,

g) Assessment findings (deficiencies) and requirements, and,

h) Comments and recommendations.

The Findings and Requirements Section must be referenced to the NELAC standards so that both the finding (deficiency) is understood and the specific requirement is outlined. The team leader shall

assure that the results within the final report conform to established standards for the evaluated parameters.

The Comments and Recommendations Section can be used to convey recommendations aimed at helping the laboratory improve.

3.7.3 Distribution

The accrediting authority shall be recognized as having the responsibility for the distribution of the assessment reports. The assessment team leader shall compile, edit and submit the final report to the accrediting authority.

3.7.4 Release of Report

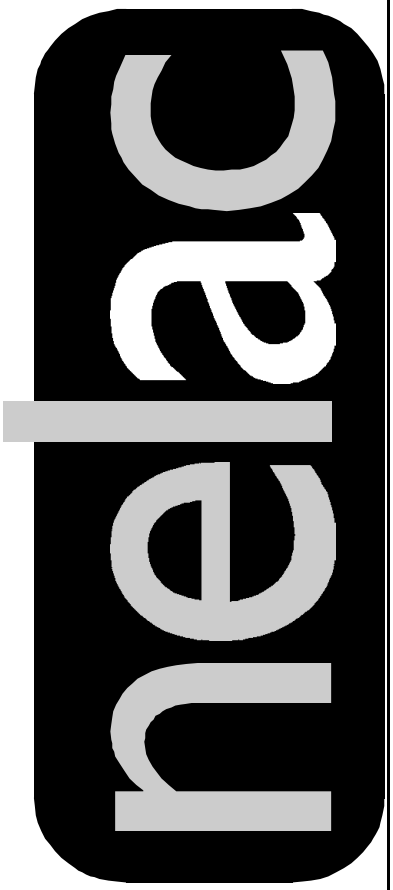
On-site assessment reports should be released initially by the accrediting authority only. The reports will be released to the responsible laboratory official(s). The assessment report shall not be released to the National Accreditation Database and the public until findings of the assessment and the corrective actions have been finalized, all Confidential Business Information and information related to national security has been stricken from the report in accordance with prescribed procedures, and the report has been provided to the laboratory (Section 4.1.3).

In accordance with the Freedom of Information requirements, any documentation adjudged to be proprietary, financial and/or trade information, or relevant to an ongoing enforcement investigation, will be considered exempt from release to the public.

3.7. 5 Record Retention Time

Copies of all assessment reports, checklists, and laboratory responses must be retained by the assessors and the accrediting authority for a period of at least ten (10) years, or longer if required by specific State or Federal regulations.

National Environmental Laboratory **Accreditation** Conference



ACCREDITATION PROCESS

July 1, 1999

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ACCREDITATION PROCESS

4.0 ACCREDITATION PROCESS

(NB. MANY OF THE STANDARDS AND ELEMENTS LISTED IN THIS CHAPTER ARE REFLECTIVE OF STANDARDS SET FORTH IN CHAPTERS DEALING WITH DETAILED EXPLANATIONS OF THESE ELEMENTS. THEREFORE, IT IS ANTICIPATED THAT SOME OF THE DETAILS MAY CHANGE AS THE DISCUSSIONS AND CONCLUSIONS IN THESE CHAPTERS CHANGE.)

4.1 COMPONENTS OF ACCREDITATION

The components of accreditation include review of personnel qualifications, on-site assessment proficiency testing and quality assurance/quality control standards. These criteria must be fulfilled for accreditation. The components and criteria are herein described. Details of some of the requirements described below will be found in other sections of these Standards.

4.1.1 Personnel Qualifications

Persons who do not meet the education credential requirements but possess the requisite experience of Section 4.1.1.1 of the NELAC standards and are the technical director(s) on the date that the laboratory becomes subject to these NELAC Standards and obtains accreditation shall qualify as technical director(s) for the same field(s) of testing of that laboratory or any other NELAC-accredited laboratory.

4.1.1.1 Definition, Technical Director(s)

The technical director(s) means a full-time member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory procedures and reporting of results. The title of such person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager. A laboratory may appoint one or more technical directors for the appropriate fields of testing for which they are seeking accreditation. His/her name must appear in the national database. This person's duties shall include, but not be limited to, monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data; ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and providing educational direction to laboratory staff. An individual shall not be the technical director(s) of more than one accredited environmental laboratory without authorization from the primary Accrediting Authority. Circumstances to be considered in the decision to grant such authorization shall include, but not be limited to, the extent to which operating hours of the laboratories to be directed overlap, adequacy of supervision in each laboratory, and the availability of environmental laboratory services in the area served. The technical director(s) who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical director(s) to temporarily perform this function. If this absence exceeds 65 consecutive calendar days, the primary accrediting authority shall be notified in writing.

Qualifications of the technical director(s) .

a) Any technical director of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelors degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least 24 college semester credit hours in chemistry and at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

b) Any technical director of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two years of equivalent and successful college education, with a minimum of 16 college semester credit hours in chemistry. In addition, such a person shall have at least two years of experience performing such analysis.

c) Any technical director of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelors degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of 16 college semester credit hours in general microbiology and biology and at least two years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.

   A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four college semester credit hours in general microbiology may be the technical director(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform and standard plate count. Two years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one year of experience in environmental analysis.

d) Any technical director of an accredited environmental laboratory engaged in radiological analysis shall be a person with a bachelor’s degree in chemistry, physics or engineering with 24 college semester credit hours of chemistry with two or more years of experience in the radiological analysis of environmental samples. A masters or doctoral degree in one of the above disciplines may be substituted for one year experience.

e) The technical director(s) of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:

   i) For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of courses in the use of the instrument, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

   ii) For procedures requiring the use of a polarized light microscope, an associate's degree or two years of college study, successful completion of formal coursework in polarized light microscopy, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

   iii) For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate's degree or two years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one year of experience, under supervision, in the use of the instrument.

f) Any technical director of an accredited environmental laboratory engaged in the examination of radon in air shall have at least an associate’s degree or two years of college and one year of experience in radiation measurements, including at least one year of experience in the measurement of radon and/or radon progeny.

4.1.1.2 Personnel Qualification Clarifications and Exceptions

a) Notwithstanding any other provision of this section, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements serving as the director of the accredited laboratory devoted exclusively to the examination of environmental samples taken within such facility. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit.

b) A full-time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision in environmental analysis shall be deemed to meet the requirements for serving as the director of an accredited laboratory devoted exclusively to the examination of environmental samples taken within such facility for the scope of that facility's regulatory permit.

4.1.2 On-site Assessments

On-site assessments are a requirement of the Accreditation Process and a summary of the process requirements are described. Refer to On-site Assessment (Chapter Three) for additional information regarding frequency, procedures, criteria, scheduling and documentation of on-site assessments. On-site assessments shall be of two types: announced and unannounced. The on-site assessment of each accredited laboratory must be performed a minimum of one time per two years. On-site assessments may be conducted more frequently for cause or at the option of the primary accrediting authority. Situations which might trigger more frequent on-site assessments include, review of a previously deficient on-site assessment, poor performance on a proficiency testing (PT) sample, change in other accreditation elements, or other information concerning the capabilities or practices of the accredited laboratory. The on-site assessment ensures that the environmental laboratory is in compliance with NELAC standards.

The responsibility and accountability for meeting the NELAC standards are the responsibility of the primary accrediting authority. The primary accrediting authority has the responsibility for conducting on-site assessments for national accreditation based on the following factors:

a) Individual sites are subject to the same application process, assessments and other requirements as environmental laboratories. Any remote laboratory sites are considered separate sites and subject to separate on-site assessments, again provided that the analysis or any portion of the analysis takes place at that site.

b) A mobile laboratory, which is configured with equipment to perform analyses, whether associated with a fixed-based laboratory or not, is considered an environmental laboratory and will require separate accreditation. This accreditation will remain with the mobile laboratory and be site independent; moving the configured mobile laboratory to a different site will not require a new or separate accreditation.

c) The assessment may consist of all of the fields of testing and/or methods for which the laboratory wants to obtain accreditation.

d) The number of assessors conducting the on-site assessment should be appropriate for the laboratory's scope and testing.

e) The on-site assessment should be conducted during normal working hours.

Laboratories shall be furnished with a report documenting any deficiencies found by the assessor. This report shall be known as an assessment report.

4.1.3 Corrective Action Reports In Response to On-Site Assessment

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

a) The primary accrediting authority shall present an assessment report to the laboratory within 30 calendar days of the on-site assessment.

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

c) The primary accrediting authority shall respond to the action noted in the corrective action report within 30 calendar days of receipt.

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

e) If the corrective action report is not acceptable to the primary accrediting authority after the second submittal, the laboratory shall have accreditation revoked pursuant to Section 4.4.3 for all or any portion of its scope of accreditation for any or all of a field of testing, a method, or analyte within a field of testing.

f) All information included and documented in an assessment report and the corrective action report are considered to be public information and are to be released pursuant to Chapter Three, Section 3.7.4.

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

h) Proprietary data, Confidential Business Information and classified national security information will be excluded from all public records.

4.1.4 Proficiency Testing Samples

A critical component of laboratory assessments is the analysis of PT samples. Refer to Proficiency Testing (Chapter Two) for additional information. PT samples are used and evaluated in the accreditation process as follows:

a) Each laboratory seeking accreditation must receive, and analyze initial PT samples from a NELAP approved PT study provider for each field of testing (program-matrix-analyte) in which it is requesting accreditation.

b) Unless otherwise specified by the proficiency testing standard, each laboratory seeking or maintaining accreditation shall be required to perform analysis of one PT sample twice per year in each field of testing (program-matrix-analyte) for which it has applied for accreditation or for which it is currently accredited.

c) The laboratory shall be informed of its score on the PT samples by the primary accrediting authority or the NELAP approved PT provider within 21 calendar days from the closing date of submission. The results of all of the PT sample tests including "pass" or "fail" shall be part of the public record. The result of passing or failing a PT sample shall apply to all accredited methods within the matrix for which a laboratory employs for an analyte.

d) When a laboratory initially requests accreditation, it must successfully analyze two sets of PT samples, the analyses to be performed 30 calendar days apart. Each set shall contain one sample for each requested field of testing (program-matrix-analyte). When a laboratory has been granted accreditation status, it must maintain a history of at least two passing results out of the most recent three for each field of testing (program-matrix-analyte).

e) The results of the PT sample analyses shall be considered by the primary accrediting authority, in determining whether accreditation should be granted, denied, revoked, or suspended pursuant to this Chapter, for a field of testing (program-matrix-analyte) or an analyte within a field of testing (program-method-analyte).

4.1.5 Accountability for Analytical Standards

Elements in NELAP that shall ensure consistency and promote the use of quality assurance/quality control procedures to generate quality data for regulatory purposes are:

a) In accordance with Chapter Five, each laboratory seeking or maintaining NELAP accreditation shall have a named quality assurance officer or a person designated as accountable for data quality.

b) NELAC requires that each laboratory seeking or maintaining NELAP accreditation have a developed and maintained Quality Assurance Manual on-site, as required in Chapter Five. The primary accrediting authority may request the manual prior to the on-site assessment.

c) The primary accrediting authority shall consider that the accountability for negligence and the falsification of data shall rest upon the analyst, the laboratory management and the company.

4.1.6 Fee Process for National Accreditation

Refer to Policy and Structure, Chapter One, for specific information on funding of this program (Section 1.5.2.3.3).

Where required, and if applicable, the level and timing of fee payments shall be established by the primary accrediting authority (ies) to which the laboratory is applying for accreditation. Additional fees on the laboratory may be levied by other secondary accrediting authorities with which the laboratory chooses to seek accreditation.

4.1.7 Application

The NELAP encompasses a standardized set of elements in each application for accreditation that shall be reported to and recorded in the national database. The application package includes any specific State regulatory requirements that are essential for accreditation within an individual State.

An accrediting authority participating in NELAC shall include in its application form the following:

a) Legal name of laboratory,
b) Laboratory mailing address,

c) Billing address (if different from b),
d) Name of owner,
e) Address of owner,
f) Location (full address) of laboratory,
g) Name and phone number of technical director(s),however named, and the lead technical director (if applicable),
h) Name and phone number of Quality Assurance Officer,
i) Name and phone number of laboratory contact person,
j) Laboratory hours of operation,
k) Primary Accrediting Authority,
l) Fields of Testing for which the laboratory is requesting accreditation,
m) Methods employed including analytes,
n) Description of laboratory type (for example),
   - Commercial
   - Federal
   - Hospital or health care
   - State
   - Academic Institutes
   - Public water system
   - Public wastewater system
   - Industrial (an industry with discharge permits)
   - Mobile
   - Other (Describe)_____
o) Certification of compliance by laboratory management (*vide infra*: 4.1.9),
p) Fee enclosed (if applicable),
q) Description of geographical location,
r) FAX number,
s) Lab identification number, and,
t) Quality Manual

A laboratory seeking renewal of accreditation shall follow the process outlined by the accrediting authority by which they are currently accredited.

4.1.8 Change of Ownership and/or Location of Laboratory

Accreditation may be transferred when the legal status or ownership of an accredited laboratory changes without affecting its staff, equipment, and organization. The primary accrediting authority may charge a transfer fee and may conduct an on-site assessment to verify affects of such changes on laboratory performance.

The following conditions apply to the change in ownership and/or the change in location of a laboratory that has national accreditation.

a) Any change in ownership and/or location of an accredited laboratory must be reported in writing to the primary accrediting authority and entered into the national database by the primary accrediting authority.

b) Such a change in ownership and/or location shall not necessarily require reaccreditation or reapplication in any or all of the categories in which the laboratory is currently accredited.

c) Change in ownership and/or location may require an on-site assessment with the elements of the assessment being determined by the assessor.

d) Any change in ownership must assure historical traceability of the laboratory accreditation number(s).

e) For a change in ownership, the following conditions must be in effect:

1. The previous (transferring) owner must agree in writing, before the transfer of ownership takes place, to be accountable and liable for any analyses, data and reports generated up to the time of legal transfer of ownership; and

2. The buyer (transferee) must agree in writing to be accountable and liable for any analyses, data and reports generated after the legal transfer of ownership occurs.

3. All records and analyses performed pertaining to accreditation must be kept for a minimum of 5 years and are subject to inspection by the accrediting authorities during this period without prior notification to the laboratory. This stipulation is applicable regardless of change in ownership, accountability or liability.

4.1.9 "Certification of Compliance" Statement

The following "Certification of Compliance" statement must accompany the application for laboratory accreditation. It must be signed and dated by both the laboratory management and the quality assurance officer, or other designated person, for that laboratory.

CERTIFICATION BY APPLICANT

The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the (insert the name of the primary accrediting authority) standards and is subject to the enforcement and penalty provisions of that accrediting authority.

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 answer to the questions on this application.

Signature Quality Assurance Officer or other designated individual	Name of Quality Assurance Officer
Print Name of Applicant Laboratory (Legal Name)	Date
Signature Technical Director(s)	Name Technical Director(s)

4.2 PERIOD OF ACCREDITATION

For a laboratory in good standing, the period for accreditation within fields of testing for methods or analytes shall be 12 months and will be considered to be ongoing once a laboratory has been accredited for that field of testing method or analyte within a field of testing. To maintain accreditation the laboratory shall meet the requirements of Section 4.3, Maintaining Accreditation. Failure to meet the requirements delineated in Section 4.3 shall constitute grounds for suspension or revocation of accreditation as specified in Section 4.4. Additionally, failure to pay the required

fees to the primary accrediting authority (ies) within the stipulated deadlines or by the stipulated dates shall result in revocation of accreditation by all the accrediting authorities (primary and secondary) with which the laboratory maintains accreditation. Failure to pay required fees to a secondary accrediting authority shall result in revocation of accreditation by that secondary accrediting authority. This information may be entered into the national database in a timely and effective manner. The NELAP recognizes that different accrediting authorities operate the yearly period with different start times. The individual laboratory being accredited is responsible for tracking an accrediting authority's period of accreditation and is responsible for paying the necessary fees (if applicable) to those accrediting authorities to maintain accreditation.

4.3 MAINTAINING ACCREDITATION

Accreditation remains in effect until revoked by the accrediting authority, withdrawn at the written request of the accredited laboratory, or until expiration of the accreditation period. To maintain accreditation, the accredited laboratory shall complete or comply with Section/elements 4.3.1 to 4.3.3. Failure to complete or comply with these elements shall be cause for suspending or revoking accreditation as specified in Section 4.4 of this Chapter.

4.3.1 Quality Systems

Laboratories seeking accreditation under NELAP must assure consistency and promote the use of quality assurance/quality control procedures. Chapter Five, Quality Systems provides the details concerning quality assurance and quality control requirements for the evaluation of laboratories. The quality assurance policies, which establish essential quality control procedures, are applicable to all environmental laboratories regardless of size, volume of business and fields of testing. Failure to maintain, revise, or replace any of these key components may be cause for suspending or revoking a laboratory's accreditation status, as specified in Section 4.4 of this Chapter.

4.3.2 Notification and Reporting Requirements

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

4.3.3 Record Keeping and Retention

All laboratory records associated with accreditation parameters shall meet the requirements of Chapter Five, Section 5.12 and shall be maintained for a minimum of five years unless otherwise designated for a longer period in another regulation or authority. In the case of data used in litigation, the laboratory is required to store such records for a longer period upon written notification from the accrediting authority.

4.4 DENIAL, SUSPENSION, AND REVOCATION OF ACCREDITATION

4.4.1 Denial

Denial - shall mean to refuse to accredit in total or in part a laboratory applying for initial accreditation or resubmission of initial application.

a) Reasons to deny an initial application shall include:

1) Failure to submit a completed application;

2) Failure of laboratory staff to meet the personnel qualifications of education, training, and experience as required by the NELAC standards;

3) Failure to successfully analyze and report proficiency testing samples as required by the NELAC standards, Chapter Two;

4) Failure to respond to an assessment report from the on-site assessment with a corrective action report within the required 30 calendar days after receipt of the assessment report;

5) Failure to implement the corrective actions detailed in the corrective action report within the time frame as specified by the primary accrediting authority;

6) Failure to pay required fees;

7) Failure to pass required on-site assessment(s) as specified in the NELAC standards, Chapter Three;

8) Misrepresentation of any fact pertinent to receiving or maintaining accreditation; or,

9) Denial of entry during normal business hours for an on-site assessment as required by the NELAC standards, Chapter Three.

b) If the laboratory is not successful in correcting the deficiencies as required by the NELAC standards, the laboratory must wait six months before again reapplying for accreditation.

c) Upon reapplication, the laboratory may again be responsible for all or part of the fees as applicable incurred as part of the initial application for accreditation.

d) No laboratory's accreditation shall be denied without the right to due process.

4.4.2 Suspension

Suspension - shall mean the temporary removal of a laboratory's accreditation for a defined period of time which shall not exceed six months. The purpose of suspension is to allow a laboratory time to correct deficiencies or an area of non-compliance with the NELAC standards.

a) A laboratory's accreditation shall be suspended in total or in part. The laboratory shall retain accreditation for the field of testings, methods and analytes where it continues to meet the requirements of the NELAC standards.

b) Reasons for suspension shall include:

1) If the primary accrediting authority finds during the on-site assessment that the public interest, safety or welfare imperatively requires emergency action;

2) Failure to complete proficiency testing studies and maintain a history of at least two successful proficiency testing studies for each affected accredited field of testing out of the three most recent proficiency testing studies as defined in NELAC, Chapter Two; or,

3) Failure to notify the primary accrediting authority of any changes in key accreditation criteria, as set forth in Section 4.3.2 of this Chapter.

c) A suspended laboratory cannot continue to analyze samples for the affected fields of testing for which it holds accreditation.

d) The laboratory's suspended accreditation status will change to accredited when the laboratory demonstrates to the primary accrediting authority that the laboratory complies with the NELAC standards.

e) A suspended laboratory would not have to reapply for accreditation if the cause/causes for suspension are corrected within six months.

f) If the laboratory fails to correct the causes of suspension within six months after the effective date of the suspension, the primary accrediting authority shall revoke in total or part the laboratory's accreditation.

g) No laboratory's accreditation shall be suspended without the right to due process as set forth by the primary accrediting authority.

4.4.3 Revocation

Revocation - shall mean the in part or total withdrawal of a laboratory's accreditation by the accrediting authority.

a) The accrediting authority shall revoke a laboratory's accreditation, in part or in total for failure to correct the deficiencies as set forth in section 4.1.3 (e) of this Chapter and for failure to correct the reasons for being suspended. The laboratory shall retain accreditation for the fields of testing, methods and analytes where it continues to meet the requirements of the NELAC standards.

b) Reasons for revocation in part or in total include a laboratory's:

   1) Failure to submit an acceptable corrective action report, in response to an assessment report and failure to implement corrective action(s) related to any deficiencies found during a laboratory assessment. The laboratory may submit two corrective action reports within the time limits specified in Section 4.1.3.

   2) After being suspended due to failure of proficiency testing samples, if the laboratory's analysis of the next proficiency testing study results in three consecutively failed proficiency testing studies, the laboratory shall be revoked for each affected accredited field of testing as defined in NELAC Chapter Two.

c) Reasons for total revocation include a laboratory's:

   1) Failure to respond with a corrective action report within the required 30 calendar days;

   2) Failure to participate in the proficiency testing program as required by the NELAC standards, Chapter Two;.

   3) Submittal of proficiency test sample results generated by another laboratory as its own;

   4) Misrepresentation of any material fact pertinent to receiving and maintaining accreditation;

   5) Denial of entry during normal business hours for an on-site assessment as required by the NELAC standards, Chapter Three;

6) Conviction of charges relating to the falsification of any report relating to a laboratory analysis; or,

7) Failure to remit the accreditation fees, if applicable, within the time limit as established by the accrediting authority.

d) After correcting the reason/cause for total revocation, the laboratory may reapply for accreditation.

e) No laboratory's accreditation shall be revoked without the right to due process.

4.4.4 Voluntary Withdrawal

If an environmental laboratory wishes to withdraw from NELAP, in total or in part, it must notify the primary accrediting authority no later than 30 calendar days before the end of the accreditation year.

4.5 INTERIM ACCREDITATION

4.5.1 Interim Accreditation

If a laboratory completes all of the requirements for accreditation except that of an on-site assessment because the accrediting authority is unable to schedule the assessment, the accrediting authority may issue an interim accreditation. Interim accreditation shall allow a laboratory to perform analyses and report results with the same status as an accredited laboratory until the on-site assessment requirements have been completed. Interim accreditation status shall not exceed twelve months. The interim accreditation status is a matter of public record and shall be entered into the national database.

4.5.2 Revocation of Interim Accreditation

Revocation of interim accreditation may be initiated for due cause as described in Section 4.4.3 by order of the primary accrediting authority.

4.6 AWARDING OF ACCREDITATION

When a participating laboratory has met the requirements specified for receiving accreditation, the laboratory shall receive a certificate awarded on behalf of the accrediting authority. The certificate shall be signed by a member of the accrediting authority and shall be considered an official document. It will be transmitted as a sealed and dated (effective date and expiration date) document containing the NELAC insignia. The certificate shall include:

a) name of laboratory,
b) address of the laboratory,
c) fields of testing (program, method, analyte), and,
d) addenda or attachments (these shall be considered to be official documents).

The laboratory must have a certificate for each State or federal department/agency in which it is accredited. Even though a parent laboratory is accredited, the subfacilities (laboratories operating under the same parent organization, analytical procedures, and quality assurance system) are inspected or processed separately and shall be issued their own Certificate of Accreditation. Any subfacilities or remote laboratory sites are considered separate sites and are subject to separate announced and unannounced assessments, provided that the analysis or any portion of the analysis takes place at that site.

The certificate shall explain that continued accredited status depends on successful ongoing participation in the program. The certificate shall urge a customer to verify the laboratory's current accreditation standing within a particular State. The certificate must be returned to the accrediting authority upon loss of accreditation. However, this does not require the return of a certificate which has simply expired (reached the expiration date). If an accredited laboratory changes its scope of accreditation, a new certificate shall be issued which details the laboratory's accreditation(s).

4.6.1 Use of NELAC Accreditation by Accredited Laboratories

An accredited laboratory shall not misrepresent its NELAP accredited fields of testing, methods, analytes, or its NELAP accreditation status on any document. This includes laboratory reports, catalogs, advertising, business solicitations, proposals, quotations or other materials (pursuant to NELAC Chapter Six, Section 8).

4.6.2 Changes in Fields of Testing

An accredited laboratory may approve a laboratory's application to add an analyte or method to its scope of accreditation by performing a data review, without an on-site assessment. An addition to the scope of accreditation via a data review of proficiency testing performance (if available), quality control performance, and written standard operating procedure is at the discretion of the accrediting authority. An addition of a new technology or test method requiring specific equipment may require an on-site assessment.

4.7 ENFORCEMENT

Since NELAC is a standard setting body, it cannot enforce civil or criminal penalties but rather all enforcement actions are taken independently by the accrediting authorities.

The enforcement component of the accrediting authorities should be based on explicit values, or principles, with which all participants concur. The proposed basic principles are:

a) The program should be equitable to all participants.

b) The rules should be well publicized.

c) The program needs of the participating agencies must be upheld.

d) The due process rights of participating laboratories must be protected.

National Environmental Laboratory **Accreditation** Conference

QUALITY SYSTEMS

July 1, 1999

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5.0 QUALITY SYSTEMS

INTRODUCTION

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a Quality Manual and followed to ensure and document the quality of the analytical data. Laboratories seeking accreditation under NELAP must assure implementation of all QA policies and the essential applicable QC procedures specified in this Chapter. The QA policies, which establish essential QC procedures, are applicable to environmental laboratories regardless of size and complexity.

The intent of this Chapter is to provide sufficient detail concerning quality management requirements so that all accrediting authorities evaluate laboratories consistently and uniformly.

NELAC is committed to the use of Performance-based Measurement Systems (PBMS) in environmental testing and provides the foundation for PBMS implementation in these standards. While this standard may not currently satisfy all the anticipated needs of PBMS, NELAC will address future needs within the context of State statutory and regulatory requirements and the finalized EPA implementation plans for PBMS.

Chapter Five is organized according to the structure of ISO/IEC Guide 25, 1990. Where deemed necessary, specific areas within this Chapter may contain more information than specified by ISO/IEC Guide 25.

All items identified in this Chapter shall be available for on-site inspection or data audit.

5.1 SCOPE

a) This Standard sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific environmental tests.

b) This Standard includes additional requirements and information for assessing competence or for determining compliance by the organization or accrediting authority granting the recognition (or approval).

   If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. (See the supplemental accreditation requirements in Section 1.9.2.)

c) This Standard is for use by environmental testing laboratories in the development and implementation of their quality systems. It shall be used by accrediting authorities, in assessing the competence of environmental laboratories.

5.2 REFERENCES

See Appendix A.

5.3 DEFINITIONS

The relevant definitions from ISO/IEC Guide 2, ISO 8402, ANSI/ASQC E-4,1994, the EPA "Glossary of Quality Assurance Terms and Acronyms", and the *International vocabulary of basic and general terms in metrology (VIM*) are applicable, the most relevant being quoted in Appendix A, Glossary, of Chapter One together with further definitions applicable for the purposes of this Standard.

See Appendix A, Glossary, of Chapter One.

5.4 ORGANIZATION AND MANAGEMENT

5.4.1 Legal Definition of Laboratory

The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Standard**.**

5.4.2 Organization

The laboratory shall:

a) have managerial staff with the authority and resources needed to discharge their duties;

b) have processes to ensure that its personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work;

c) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

d) specify and document the responsibility, authority, and interrelationship of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

   Such documentation shall include:

   1) a clear description of the lines of responsibility in the laboratory and shall be proportioned such that adequate supervision is ensured and

   2) job descriptions for all positions.

e) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results;

   The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision to ensure adherence to laboratory procedures and accepted techniques.

f) have a technical director(s) (however named) who has overall responsibility for the technical operation of the environmental testing laboratory;

   The technical director(s) shall certify that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited. Such certification shall be documented.

The technical director(s) shall meet the requirements specified in the Accreditation Process. (see 4.1.1.1)

g) have a quality assurance officer (however named) who has responsibility for the quality system and its implementation;

The quality assurance officer shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical director. Where staffing is limited, the quality assurance officer may also be the technical director or deputy technical director;

The quality assurance officer (and/or his/her designees) shall:

1) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;

2) have functions independent from laboratory operations for which they have quality assurance oversight;

3) be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;

4) have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC;

5) have a general knowledge of the analytical test methods for which data review is performed;

6) arrange for or conduct internal audits on the entire technical operation annually; and,

7) notify laboratory management of deficiencies in the quality system and monitor corrective action.

h) nominate deputies in case of absence of the technical director(s) and/or quality assurance officer;

i) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights (this may not apply to in-house laboratories);

j) when available, participate in interlaboratory comparisons and proficiency testing programs. For purposes of qualifying for and maintaining accreditation, each laboratory shall participate in a proficiency test program as outlined in Chapter Two.

5.5 QUALITY SYSTEM - ESTABLISHMENT, AUDITS, ESSENTIAL QUALITY CONTROLS AND DATA VERIFICATION

5.5.1 Establishment

The laboratory shall establish and maintain a quality system based on the required elements contained in this chapter and appropriate to the type, range and volume of environmental testing activities it undertakes.

a) The elements of this quality system shall be documented in the organization's quality manual.

b) The quality documentation shall be available for use by the laboratory personnel.

c) The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.

d) The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned.

e) The quality manual shall be maintained current under the responsibility of the quality assurance officer.

5.5.2 Quality Manual

The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Standard.

The Quality Manual shall list on the title page: a document title; the laboratory's full name and address; the name, address (if different from above), and telephone number of individual(s) responsible for the laboratory; the name of the quality assurance officer (however named); the identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;

The quality manual and related quality documentation shall also contain:

a) a quality policy statement, including objectives and commitments, by top management;

b) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

c) the relationship between management, technical operations, support services and the quality system;

d) procedures to ensure that all records required under this Chapter are retained, as well as procedures for control and maintenance of documentation through a document control system which ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force;

e) job descriptions of key staff and reference to the job descriptions of other staff;

f) identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual must have the signed and dated concurrence, (with appropriate titles) of all responsible parties including the QA officer(s), technical director(s), and the agent who is in charge of all laboratory activities such as the laboratory director or laboratory manager;

g) the laboratory's procedures for achieving traceability of measurements;

h) a list of all test methods under which the laboratory performs its accredited testing;

i) mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

j) reference to the calibration and/or verification test procedures used;

k) procedures for handling submitted samples;

l) reference to the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;

m) reference to procedures for calibration, verification and maintenance of equipment;

n) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

o) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

p) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;

q) procedures for dealing with complaints;

r) procedures for protecting confidentiality (including national security concerns), and proprietary rights;

s) procedures for audits and data review;

t) processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training;

u) processes/procedures for educating and training personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions;

v) reference to procedures for reporting analytical results; and,

w) a Table of Contents, and applicable lists of references and glossaries, and appendices.

5.5.3 Audits

5.5.3.1 Internal Audits

The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality assurance officer to plan and organize audits as required by a predetermined schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

5.5.3.2 Managerial Review

The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations. The review shall take account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of interlaboratory comparisons or proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions and other relevant factors. The laboratory shall have a procedure for review by management and maintain records of review findings and actions.

5.5.3.3 Audit Review

All audit and review findings and any corrective actions that arise from them shall be documented. The laboratory management shall ensure that these actions are discharged within the agreed time frame.

5.5.3.4 Performance Audits

In addition to periodic audits, the laboratory shall ensure the quality of results provided to clients by implementing checks to monitor the quality of the laboratory's analytical activities. Examples of such checks are:

a) internal quality control procedures using whenever possible statistical techniques; (see 5.5.4 below)

b) participation in proficiency testing or other interlaboratory comparisons (See Chapter Two);

c) use of certified reference materials and/or in-house quality control using secondary reference materials as specified in Section 5.5.4;

d) replicate testings using the same or different test methods;

e) re-testing of retained samples;

f) correlation of results for different parameters of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).

5.5.3.5 Corrective Actions

a) In addition to providing acceptance criteria and specific protocols for corrective actions in the Method Standard Operating Procedures (see 5.10.1.1), the laboratory shall implement general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred. These procedures shall include but are not limited to the following:

1) identify the individual(s) responsible for assessing each QC data type;

2) identify the individual(s) responsible for initiating and/or recommending corrective actions;

3) define how the analyst should treat a data set if the associated QC measurements are unacceptable;

4) specify how out-of-control situations and subsequent corrective actions are to be documented; and,

5) specify procedures for management (including the QA officer) to review corrective action reports.

b) To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data is to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifier(s).

5.5.4 Essential Quality Control Procedures

These general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., chemical, whole effluent toxicity, microbiological, radiological, air) and are further described in Appendix D. The standards for any given test type shall assure that the applicable principles are addressed:

a) All laboratories shall have protocols in place to monitor the following quality controls:

1) Adequate positive and negative controls to monitor tests such as blanks, spikes, reference toxicants;

2) Adequate tests to define the variability and/or repeatability of the laboratory results such as replicates;

3) Measures to assure the accuracy of the test method including sufficient calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

4) Measures to evaluate test method capability, such as detection limits and quantitation limits or range of applicability such as linearity;

5) Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses;

6) Selection and use of reagents and standards of appropriate quality;

7) Measures to assure the selectivity of the test for its intended purpose; and

8) Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.

b) All quality control measures shall be assessed and evaluated on an on-going basis, and quality control acceptance criteria shall be used to determine the usability of the data. (See Appendix D.)

c) The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist. (See 5.11.2, Sample Acceptance Policy.)

d) The quality control protocols specified by the laboratory's method manual (5.10.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D are incorporated into their method manuals.

The essential quality control measures for testing are found in Appendix D of this Chapter.

5.6 PERSONNEL

5.6.1 General Requirements for Laboratory Staff

The laboratory shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

All personnel shall be responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management.

5.6.2 Laboratory Management Responsibilities

In addition to 5.4.2.d, the laboratory management shall be responsible for:

a) Defining the minimal level of qualification, experience and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills such as using a balance, colony counting, aseptic or quantitative techniques shall be considered;

b) Ensuring that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented. (See Appendix C);

Note: In laboratories with specialized “work cells” (a well defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.

c) Ensuring that the training of each member of the technical staff is kept up-to-date (on-going) by the following:

1) Evidence must be on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities.

2) Training courses or workshops on specific equipment, analytical techniques or laboratory procedures shall all be documented.

3) Training courses in ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions. Evidence must also be on file which demonstrates that each employee has read, acknowledged and understood their personal ethical and legal responsibilities including the potential punishments and penalities for improper, unethical or illegal actions.

4) Analyst training shall be considered up to date if an employee training file contains a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:

i. Acceptable performance of a blind sample (single blind to the analyst);

ii. Another demonstration of capability;

iii. Successful analysis of a blind performance sample on a similar test method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5035/8260) would only require documentation for one of the test methods;

iv. At least four consecutive laboratory control samples with acceptable levels of precision and accuracy;

v. If i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable results.

d) Documenting all analytical and operational activities of the laboratory;

e) Supervising all personnel employed by the laboratory;

f) Ensuring that all sample acceptance criteria (Section 5.11) are verified and that samples are logged into the sample tracking system and properly labeled and stored;

g) Documenting the quality of all data reported by the laboratory; and

h) Developing a proactive program for prevention and detection of improper, unethical or illegal actions. Components of this program could include: internal proficiency testing (single and double blind); post-analysis, electronic data and magnetic tape audits; effective reward program to improve employee vigilance and co-monitoring; and separate SOPs identifying appropriate and inappropriate laboratory and instrument manipulation practices.

5.6.3 Records

Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory [see 5.6.2.c], including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.10.2.1 for chemical testing.

5.7 PHYSICAL FACILITIES - ACCOMMODATION AND ENVIRONMENT

5.7.1 Environment

a) Laboratory accommodation, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of tests.

b) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

c) The laboratory shall provide for the effective monitoring, control and recording of environmental conditions as appropriate. Such environmental conditions may include biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels .

d) In instances where monitoring or control of any of the above mentioned items are specified in a test method or by regulation, the laboratory shall meet and document adherence to the laboratory facility requirements.

NOTE: It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of this Standard.

5.7.2 Work Areas

a) There shall be effective separation between neighboring areas when the activities therein are incompatible including culture handling or incubation areas and volatile organic chemicals handling areas.

b) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

c) Adequate measures shall be taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality.

d) Work spaces must be available to ensure an unencumbered work area. Work areas include:

1) access and entryways to the laboratory;
2) sample receipt area(s);
3) sample storage area(s);
4) chemical and waste storage area(s); and,
5) data handling and storage area(s).

5.8 EQUIPMENT AND REFERENCE MATERIALS

a) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests for which accreditation is sought. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Standard are met.

b) All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented.

c) Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

d) Each item of equipment including reference materials shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status.

e) Records shall be maintained of each major item of equipment and all reference materials significant to the tests performed. These records shall include documentation on all routine and non-routine maintenance activities and reference material verifications.

The records shall include:

1) the name of the item of equipment;
2) the manufacturer's name, type identification, and serial number or other unique identification;
3) date received and date placed in service (if available);
4) current location, where appropriate;
5) if available, condition when received (e.g. new, used, reconditioned);
6) copy of the manufacturer's instructions, where available;
7) dates and results of calibrations and/or verifications and date of the next calibration and/or verification;
8) details of maintenance carried out to date and planned for the future; and,
9) history of any damage, malfunction, modification or repair.

5.9 MEASUREMENT TRACEABILITY AND CALIBRATION

5.9.1 General Requirements

All measuring operations and testing equipment having an effect on the accuracy or validity of tests shall be calibrated and/or verified before being put into service and on a continuing basis. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. This includes balances, thermometers and control standards.

5.9.2 Traceability of Calibration

a) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available.

b) Calibration certificates, when available, shall indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory shall maintain records of all such certifications.

c) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis.

5.9.3 Reference Standards

a) Reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards have not been invalidated. Reference standards of measurement shall be calibrated by a body that can provide, where possible, traceability to a national standard of measurement.

b) There shall be a program of calibration and verification for reference standards.

c) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications. Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

5.9.4 Calibration

Calibration requirements are divided into two parts: (1) requirements for analytical support equipment, and 2) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification.

5.9.4.1 Support Equipment

These standards apply to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor/dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. All support equipment shall be:

a) Maintained in proper working order. The records of all repair and maintenance activities including service calls, shall be kept.

b) Calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used or:

   1) The equipment shall be removed from service until repaired; or

   2) The laboratory shall maintain records of established correction factors to correct all measurements.

c) Raw data records shall be retained to document equipment performance.

d) Prior to use on each working day, balances, ovens, refrigerators, freezers, incubators and water baths shall be checked with NIST traceable references (where possible) in the expected use range. Additional monitoring as prescribed by the test method shall be performed for any device that is used in a critical test (such as incubators or water baths). The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

e) Mechanical volumetric dispensing devices (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but must come with a certificate attesting to established accuracy or the accuracy must be initially demonstrated and documented by the laboratory.

f) For chemical tests the temperature, cycle time, and pressure of each run of autoclaves must be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.

g) For biological tests the sterilization temperature, cycle time, sterilization time, and pressure of each run of autoclaves must be documented by the use of appropriate chemical or biological sterilization indicators. Autoclave tape may be used to indicate by color change that a load has been processed, but not to demonstrate completion of an acceptable sterilization cycle. Demonstration of sterilization shall be provided by a continuous temperature recording or with the frequent use of spore strips.

5.9.4.2 Instrument Calibration:

This standard specifies the essential elements that will define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data will be of known quality and be appropriate for a given regulation or decision. This standard does not specify detailed procedural steps ("how to") for calibration, but establishes the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.

Note: In the following sections, initial instrument calibration is directly used for quantitation and continuing instrument calibration verification is used to confirm the continued validity of the initial calibration.

5.9.4.2.1 Initial Instrument Calibration:

The following items are essential elements of initial instrument calibration:

a) The details of the initial instrument calibration procedures including calculations, integrations, and acceptance criteria associated statistics must be included or referenced in the test method SOP.

b) Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor.

c) Sample results must be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification.

d) All initial instrument calibrations must be verified with a standard obtained from a second source and traceable to a national standard, when available.

e) Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient or relative percent difference.

f) Results of samples not bracketed by initial instrument calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the detection limit.

g) If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.

h) Calibration standards must include concentrations at or below the regulatory limit/decision level, if these limits/levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits (See D.1.4 Detection Limits)

i) If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.

5.9.4.2.2 Continuing Instrument Calibration Verification

When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch. The following items are essential elements of continuing instrument calibration verification:

a) The details of the continuing instrument calibration procedure, calculations and associated statistics must be included or referenced in the test method SOP.

b) A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. If an internal standard is used, only one continuing instrument calibration verification must be analyzed per analytical batch.

c) Sufficient raw data records must be retained to permit reconstruction of the continuing instrument calibration verification, e.g., test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor.

d) Criteria for the acceptance of a continuing instrument calibration verification must be established, e.g., relative percent difference.

e) If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration must be performed. If the laboratory has not demonstrated acceptable performance, sample analyses shall not occur until a new initial calibration curve is established and verified. However, sample data associated with an unacceptable calibration verification may be reported as qualified data under the following special conditions:

   i. When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

   ii. When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed

a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

5.10 TEST METHODS AND STANDARD OPERATING PROCEDURES

5.10.1 Methods Documentation

a) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests.

b) All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

5.10.1.1 Standard Operating Procedures (SOPs)

Laboratories shall maintain standard operating procedures that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.

a) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents.

b) The test methods may be copies of published methods as long as any changes in the methods are documented and included in the methods manual (see 5.10.1.2).

c) Copies of all SOPs shall be accessible to all personnel.

d) The SOPs shall be organized .

e) Each SOP shall clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority.

5.10.1.2 Laboratory Method Manual(s)

a) The laboratory shall have and maintain an in-house methods manual(s) for each accredited analyte or test method.

b) This manual may consist of copies of published or referenced test methods or standard operating procedures that have been written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each test method shall include or reference where applicable:

1) identification of the test method;
2) applicable matrix or matrices;
3) detection limit;
4) scope and application, including components to be analyzed;
5) summary of the test method;

6) definitions;
7) interferences;
8) safety;
9) equipment and supplies;
10) reagents and standards;
11) sample collection, preservation, shipment and storage;
12) quality control;
13) calibration and standardization;
14) procedure;
15) calculations;
16) method performance;
17) pollution prevention;
18) data assessment and acceptance criteria for quality control measures;
19) corrective actions for out-of-control data;
20) contingencies for handling out-of-control or unacceptable data;
21) waste management;
22) references; and,
23) any tables, diagrams, flowcharts and validation data.

5.10.2 Test Methods

a) The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample collection, sample handling, transport and storage, sample preparation and sample analysis). The method and procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

1) When the use of specific test methods for a sample analysis are mandated or requested, only those methods shall be used.

2) Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see 5.10.2.1 and Appendix C), and be available to the client and other recipients of the relevant reports.

5.10.2.1 Demonstration of Capability

a) Prior to acceptance and institution of any test method, satisfactory demonstration of method capability is required. (See Appendix C and 5.6.2.b.) In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., water, solids, biological tissue and air. In addition, for analytes which do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples.

b) Thereafter, continuing demonstration of method performance, as per the quality control requirements in Appendix D (such as laboratory control samples) is required.

c) In all cases, the appropriate forms such as the Certification Statement (Appendix C) must be completed and retained by the laboratory to be made available upon request. All associated supporting data necessary to reproduce the analytical results summarized in the Certification Statement must be retained by the laboratory. (See Appendix C for Certification Statement.)

d) A demonstration of capability must be completed each time there is a significant change in instrument type, personnel, or test method.

e) In laboratories with a specialized "work cell(s)" (a group consisting of analysts with specifically defined tasks that together perform the test method), the group as a unit must meet the above criteria and this demonstration of capability must be fully documented.

f) When a work cell(s) is employed, and the members of the cell change, the new employee(s) must work with experienced analyst(s) in the speciality area and this new work cell must demonstrate acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples). Such performance must be documented and the four preparation batches following the change in personnel must not result in the failure of any batch acceptance criteria, e.g., method blank and laboratory control sample, or the demonstration of capability must be repeated. In addition, if the entire work cell is changed/replaced, the work cell must repeat the demonstration of capability (Appendix C).

g) When a work cell(s) is employed the performance of the group must be linked to the training record of the individual members of the work cell (see section 5.6.2).

5.10.3 Sample Aliquots

Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.

5.10.4 Data Verification

Calculations and data transfers shall be subject to appropriate checks.

a) The laboratory shall establish Standard Operating Procedure to ensure that the reported data are free from transcription and calculation errors.

b) The laboratory shall establish a Standard Operating Procedures to ensure that all quality control measures are reviewed, and evaluated before data are reported.

5.10.5 Documentation and Labeling of Standards and Reagents

Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

a) The laboratory shall retain records for all standards including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt,

recommended storage conditions, and an expiration date after which the material shall not be used unless it is verified by the laboratory.

b) Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date.

c) Records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

d) All containers of prepared reagents and standards must bear a unique identifier and expiration date and be linked to the documentation requirements in 5.10.5.c above.

5.10.6 Computers and Electronic Data Related Requirements

Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:

a) all requirements of this Standard (i.e. Chapter Five) are met;

Sections 8.1 through 8.11 of the EPA Document “2185 - Good Automated Laboratory Practices” (1995), shall be adopted as the standard for all laboratories employing microprocessors, computers, as well as laboratories employing Laboratory Information Management Systems.

b) computer software is documented and adequate for use;

c) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

d) computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data; and,

e) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

5.11 SAMPLE HANDLING, SAMPLE ACCEPTANCE POLICY AND SAMPLE RECEIPT

While the laboratory may not have control of field sampling activities, the following are essential to ensure the validity of the laboratory’s data.

5.11.1 Sample Tracking

a) The laboratory shall have a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time. This system shall include identification for all samples, subsamples and subsequent extracts and/or digestates. The laboratory shall assign a unique identification (ID) code to

each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample.

b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned each container.

c) The laboratory ID code shall be placed on the sample container as a durable label.

d) The laboratory ID code shall be entered into the laboratory records (see 5.11.3.d) and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration.

e) In cases where the sample collector and analyst are the same individual or the laboratory preassigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.

5.11.2 Sample Acceptance Policy

The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted. Data from any samples which do not meet the following criteria must be flagged in an unambiguous manner clearly defining the nature and substance of the variation. This sample acceptance policy shall be made available to sample collection personnel and shall include, but is not limited to, the following areas of concern:

a) Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample;

b) Proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;

c) Use of appropriate sample containers;

d) Adherence to specified holding times;

e) Adequate sample volume. Sufficient sample volume must be available to perform the necessary tests; and

f) Procedures to be used when samples which show signs of damage or contamination.

5.11.3 Sample Receipt Protocols

a) Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified in 5.11.2 above shall be checked.

1) All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within +/-2°C of the required temperature or the

method specified range. For samples with a specified temperature of 4°C, samples with a temperature ranging from just above the freezing temperature of water to 6°C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.

2) The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine, prior to or during sample preparation or analysis.

b) The results of all checks shall be recorded.

c) Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, the laboratory should consult the client for further instruction before proceeding. The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory. If the sample does not meet the sample receipt acceptance criteria listed in 5.11.3.a, 5.11.3.b or 5.11.3.c, the laboratory shall either:

a) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or

2) Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.

i. The condition of these samples shall, at a minimum, be noted on the chain of custody or transmittal form and laboratory receipt documents.

ii. The analysis data shall be appropriately "qualified" on the final report.

d) The laboratory shall utilize a permanent chronological record such as a log book or electronic database to document receipt of all sample containers.

1) This sample receipt log shall record the following:

i. Client/Project Name,

ii. Date and time of laboratory receipt,

iii. Unique laboratory ID code (see 5.11.1), and,

iv. Signature or initials of the person making the entries.

2) During the log-in process, the following information must be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable upon request and readily available to

individuals who will process the sample. Note: the placement of the laboratory ID number on the sample container is not considered a permanent record.

i. The field ID code which identifies each container must be linked to the laboratory ID code in the sample receipt log.

ii. The date and time of sample collection must be linked to the sample container and to the date and time of receipt in the laboratory.

iii. The requested analyses (including applicable approved test method numbers) must be linked to the laboratory ID code.

iv. Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

e) All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter shall be retained.

f) A complete chain of custody record (Section 5.12.4), if utilized, shall be maintained.

5.11.4 Storage Conditions

The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary.

a) Samples shall be stored according to the conditions specified by preservation protocols:

1) Samples which require thermal preservation shall be stored under refrigeration which is +/-2° of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable.

2) Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

b) Sample fractions, extracts, leachates and other sample preparation products shall be stored according to 5.11.4.a above or according to specifications in the test method.

c) Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

5.11.5 Sample Disposal

The laboratory shall have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.

5.12 RECORDS

The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. The system shall produce unequivocal, accurate records which document all laboratory activities. The laboratory shall retain on record all original observations, calculations and derived data, calibration records and a copy of the test report for a minimum of five years.

There are two levels of record keeping: 1) sample custody or tracking and 2) legal or evidentiary chain of custody. All essential requirements for sample custody are outlined in Sections 5.12.1, 5.12.2 and 5.12.3. The basic requirements for legal chain of custody (if required or implemented) are specified in Section 5.12.4.

5.12.1 Record Keeping System and Design

The record keeping system must allow historical reconstruction of all laboratory activities that produced the resultant sample analytical data. The history of the sample must be readily understood through the documentation. This shall include interlaboratory transfers of samples and/or extracts.

a) The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

b) All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification shall be documented.

c) The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes.

d) All documentation entries shall be signed or initialed by responsible staff. The reason for the signature or initials shall be clearly indicated in the records such as “sampled by”, “prepared by”, or “reviewed by”).

e) All generated data except those that are generated by automated data collection systems, shall be recorded directly, promptly and legibly in permanent ink.

f) Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction. These criteria also shall apply to electronically maintained records.

g) Refer to 5.10.6 for Computer and Electronic Data.

5.12.2 Records Management and Storage

a) All records (including those pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client. NELAP-related records shall be available to the accrediting authority.

b) All records, including those specified in 5.12.3 and 5.12.4, shall be retained for a minimum of five years from last use. All information necessary for the historical reconstruction of data must be maintained by the laboratory. Records which are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

c) Records that are stored or generated by computers or personal computers shall have hard copy or write-protected backup copies.

d) The laboratory shall establish a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting.

e) Access to archived information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources.

f) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions (see 4.1.8.e) in the event that a laboratory transfers ownership or goes out of business.

5.12.3 Laboratory Sample Tracking

5.12.3.1 Sample Handling

A record of all procedures to which a sample is subjected while in the possession of the laboratory shall be maintained. These shall include but are not limited to all records pertaining to:

a) Sample preservation including appropriateness of sample container and compliance with holding time requirement;

b) Sample identification, receipt, acceptance or rejection and log-in;

c) Sample storage and tracking including shipping receipts, transmittal forms, and internal routing and assignment records;

d) Sample preparation including cleanup and separation protocols, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

e) Sample analysis;

f) Standard and reagent origin, receipt, preparation, and use;

g) Equipment receipt, use, specification, operating conditions and preventative maintenance;

h) Calibration criteria, frequency and acceptance criteria;

i) Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;

j) Method performance criteria including expected quality control requirements;

k) Quality control protocols and assessment;

l) Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

m) All automated sample handling systems; and,

n) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

5.12.3.2 Laboratory Support Activities

In addition to documenting all the above-mentioned activities, the following shall be retained:

a) All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);

b) A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;

c) Copies of final reports;

d) Archived standard operating procedures;

e) Correspondence relating to laboratory activities for a specific project;

f) All corrective action reports, audits and audit responses;

g) Proficiency test results and raw data; and,

h) Data review and cross checking.

5.12.3.3 Analytical Records

The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, shall include:

a) Laboratory sample ID code;

b) Date and time of analysis;

c) Instrumentation identification and instrument operating conditions/parameters (or reference to such data);

d) Analysis type;

e) All manual calculations; and,

f) Analyst's or operator's initials/signature.

5.12.3.4 Administrative Records

The following shall be maintained:

a) Personnel qualifications, experience and training records;

b) Records of demonstration of capability for each analyst; and

c) A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

5.12.4 Legal/Evidentiary Custody

The use of legal chain of custody (COC) protocols may be required by some State or federal programs. In addition to the records listed in 5.12.3 and the performance standards outlined in 5.12.1 and 5.12.2, the following protocols shall be incorporated if legal COC is implemented by the organization.

5.12.4.1 Basic Requirements

The legal chain of custody records shall establish an intact, continuous record of the physical possession, storage and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates. For ease of discussion, the above-mentioned items shall be referred to as samples:

a) A sample is in someone's custody if:

   1) It is in one's actual physical possession;

   2) It is in one's view, after being in one's physical possession;

   3) It is in one's physical possession and then locked up so that no one can tamper with it;

   4) It is kept in a secured area, restricted to authorized personnel only.

b) The COC records shall account for all time periods associated with the samples.

c) The COC records shall identify individuals who physically handled individual samples.

d) In order to simplify record-keeping, the number of people who physically handle the sample should be minimized. A designated sample custodian, who is responsible for receiving, storing and distributing samples is recommended.

e) The COC records are not limited to a single form or document. However, organizations should attempt to limit the number of documents that would be required to establish COC.

f) Legal chain of custody shall begin at the point established by the federal or State oversight program. This may begin at the point that cleaned sample containers are provided by the laboratory or the time sample collection occurs.

g) The COC forms shall remain with the samples during transport or shipment.

h) If shipping containers and/or individual sample containers are submitted with sample custody seals, and any seals are not intact, the lab shall note this on the chain of custody.

i) Mailed packages should be registered with return receipt requested. If packages are sent by common carrier, receipts should be retained as part of the permanent chain-of-custody documentation.

j) Once received by the laboratory, laboratory personnel are responsible for the care and custody of the sample and must be prepared to testify that the sample was in their possession and view or secured in the laboratory at all times from the moment it was received from the custodian until the time that the analyses are completed or the time of sample disposal.

5.12.4.2 Required Information in Custody Records

In addition to the information specified in 5.11.1.a and 5.11.1.b, tracking records shall include, by direct entry or linkage to other records:

a) Time of day and calendar date of each transfer or handling procedure;

b) Signatures of all personnel who physically handle the sample(s);

c) All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting; and

d) Common carrier documents.

5.12.4.3 Controlled Access to Samples

Access to all legal samples and subsamples shall be controlled and documented.

a) A clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside must be designated as a custody room.

b) Where possible, distribution of samples to the analyst performing the analysis must be made by the custodian(s).

c) The laboratory area must be maintained as a secured area, restricted to authorized personnel only.

d) Once the sample analyses are completed, the unused portion of the sample, together with all identifying labels, must be returned to the custodian. The returned tagged sample must be retained in the custody room until permission to destroy the sample is received by the custodian or other authority.

5.12.4.4 Transfer of Samples to Another Party

Transfer of samples, subsamples, digestates or extracts to another party are subject to all of the requirements for legal chain of custody.

5.12.4.5 Sample Disposal

a) If the sample is part of litigation, disposal of the physical sample shall occur only with the concurrence of the affected legal authority, sample data user and/or submitter of the sample.

b) All conditions of disposal and all correspondence between all parties concerning the final disposition of the physical sample shall be recorded and retained.

c) Records shall indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to client), and the name of the individual who performed the task.

5.13 LABORATORY REPORT FORMAT AND CONTENTS

The results of each test, or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively. The results shall normally be reported in a test report and shall include all the information necessary for the interpretation of the test results and all information required by the method used. Some regulatory reporting requirements or formats such as monthly operating reports, may not require all items listed below, however, the laboratory shall provide all the required information to their client for use in preparing such regulatory reports.

a) Except as discussed in 5.13.b, each report to an outside client shall include at least the following information (those prefaced with “where relevant” are not mandatory):

1) a title, e.g., "Test Report", or "Test Certificate", "Certificate of Results" or "Laboratory Results";

2) name and address of laboratory, and location where the test was carried out if different from the address of the laboratory and phone number with name of contact person for questions;

3) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

This requirement may be presented in several ways:

i. The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or

ii. Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (example: 3 of 10, or 1 of 20).

Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.

4) name and address of client, where appropriate and project name if applicable;

5) description and unambiguous identification of the tested sample including the client identification code;

6) identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature;

7) date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 48 hours;

8) identification of the test method used, or unambiguous description of any non-standard method used;

9) if the laboratory collected the sample, reference to sampling procedure;

10) any deviations from (such as failed quality control), additions to or exclusions from the test method (such as environmental conditions), and any non-standard conditions that may have affected the quality of results, and including the use and definitions of data qualifiers;

11) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as μg/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;

12) when required, a statement of the estimated uncertainty of the test result;

13) a signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

14) at the laboratory's discretion, a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory;

15) at the laboratory's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

16) clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc; and,

17) clear identification of numerical results with values outside of quantitation levels.

b) Laboratories that are operated by a facility and whose sole function is to provide data to the facility management for compliance purposes (in-house or captive laboratories) shall have all applicable information specified in 1 through 17 above readily available for review by the accrediting authority. However formal reports detailing the information are not required if:

1) The in-house laboratory is itself responsible for preparing the regulatory reports; or

2) The laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management must ensure that the appropriate report items are in the report to the regulatory authority if such information is required.

c) Where the certificate or report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable accreditation number.

d) After issuance of the report, the laboratory report shall remain unchanged. Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number . . . [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of this Standard.

e) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

f) The laboratory shall ensure that, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Standard are met and that confidentiality is preserved.

g) Laboratories accredited to be in compliance with these standards shall certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not.

5.14 SUBCONTRACTING ANALYTICAL SAMPLES

a) The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

b) Where a laboratory subcontracts any part of the testing covered under NELAP, this work shall be placed with a laboratory accredited under NELAP for the tests to be performed.

c) The laboratory shall retain records demonstrating that the above requirements have been met.

5.15 OUTSIDE SUPPORT SERVICES AND SUPPLIES

a) Where the laboratory procures outside services and supplies, other than those referred to in this Standard, in support of tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.

b) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

c) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.

5.16 COMPLAINTS

The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Standard or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with Section 5.5.3.1. Records of the complaint and subsequent actions shall be maintained.

QUALITY SYSTEMS
APPENDIX A

REFERENCES

Appendix A - REFERENCES

40 CFR Part 136, Appendix A, paragraphs 8.1.1 and 8.2

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ISO Guide 9000: 1994 Quality management and quality assurance standards - Guidelines for selection and use

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Manual of Method for General Bacteriology, Philipp Gerhard et al., American Society for Microbiology, Washington, 1981

Performance Based Measurement System, EPA EMMC Method Panel, PBMS Workgroup, 1996

APPENDIX B

(Reserved)

QUALITY SYSTEMS
APPENDIX C

DEMONSTRATION OF CAPABILITY

Appendix C - DEMONSTRATION OF CAPABILITY

C.1 PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) must be made prior to using any test method, and at any time there is a significant change in instrument type, personnel or test method (see 5.10.2.1).

Note: In laboratories with specialized "work cells" (a well defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.

In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., water, solids, biological tissue and air. However, before any results are reported using this method, actual sample spike results may be used to meet this standard, i.e.,at least four consecutive matrix spikes within the last twelve months. In addition, for analytes which do not lend themselves to spiking, e.g., TSS, the demonstration of capability may be performed using quality control samples.

All demonstrations shall be documented through the use of the form in this appendix.

The following steps, which are adapted from the EPA test methods published in 40 CFR Part 136, Appendix A, shall be performed if required by mandatory test method or regulation. Note: For analytes for which spiking is not an option and for which quality control samples are not readily available, the 40 CFR approach is one way to perform this demonstration. It is the responsibility of the laboratory to document that other approaches to DOC are adequate, this shall be documented in the laboratory's Quality Manual.

a) A quality control sample shall be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

b) The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit.

c) At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

d) Using all of the results, calculate the mean recovery ($\bar{x}$) in the appropriate reporting units (such as μg/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence absence and logarithmic values, the laboratory will assess performance against established and documented criteria.

e) Compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the

parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

f) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to 1) or 2) below.

1) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above.

2) Beginning with c) above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with c).

C.2 CERTIFICATION STATEMENT

The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee (see 5.6.3 and 5.12.3.4.b).

Demonstration of Capability
Certification Statement

Date: Page __of __
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Matrix:
(examples: laboratory pure water, soil, air, solid, biological tissue)
Method number, SOP#, Rev#, and Analyte, or Class of Analytes or Measured Parameters
(examples: barium by 200.7, trace metals by 6010, benzene by 8021, etc.)

We, the undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

_____	_____	_____
Technical Director's Name and Title	Signature	Date
_____	_____	_____
Quality Assurance Officer's Name	Signature	Date

This certification form must be completed each time a demonstration of capability study is completed.

(1) True: Consistent with supporting data.

Accurate: Based on good laboratory practices consistent with sound scientific principles/practices.

Complete: Includes the results of all supporting performance testing.

Self-Explanatory: Data properly labeled and stored so that the results are clear and require no additional explanation.

QUALITY SYSTEMS
APPENDIX D

ESSENTIAL QUALITY CONTROL REQUIREMENTS

Appendix D - ESSENTIAL QUALITY CONTROL REQUIREMENTS

The quality control protocols specified by the laboratory's method manual (5.10.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D are incorporated into their method manuals.

All quality control measures shall be assessed and evaluated on an on-going basis and quality control acceptance criteria shall be used to determine the validity of the data. The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists.

The requirements from the body of Chapter Five, e.g., 5.5.4, apply to all types of testing. The specific manner in which they are implemented is detailed in each of the sections of this Appendix, i.e., chemical testing, W.E.T. testing, microbiology testing, radiochemical testing and air testing.

D.1 CHEMICAL TESTING

D.1.1 Positive and Negative Controls

a) Negative Controls

1) Method Blanks - Shall be performed at a frequency of one per batch of samples per matrix type per sample extraction or preparation method. The results of this analysis shall be one of the QC measures to be used to assess batch acceptance. The source of contamination must be investigated and measures taken to correct, minimize or eliminate the problem if

i) the blank contamination exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated sample batch or

ii) the blank contamination exceeds the concentration present in the samples and is greater than 1/10 of the specified regulatory limit.

Any sample associated with the contaminated blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.

b) Positive Controls

1) Laboratory Control Sample (LCS) - (QC Check Samples) Shall be analyzed at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The results of these samples shall be used to determine batch acceptance. NOTE: the matrix spike (see 2 below) may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.

2) Matrix Spikes (MS) - Shall be performed at a frequency of one in 20 samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as, total suspended solids, total

dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in a matrix spike may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the spike.

3) Surrogates - Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with the sample composition and shall be reported to the client whose sample produced the poor recovery.

4) If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, a representative number (at a minimum 10%) of the listed components may be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

D.1.2 Analytical Variability/Reproducibility

Matrix Spike Duplicates (MSDs) or Laboratory Duplicates - Shall be analyzed at a minimum of 1 in 20 samples per matrix type per sample extraction or preparation method. The laboratory shall document their procedure to select the use of appropriate type of duplicate. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in the duplicates may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the duplicate.

D.1.3 Method Evaluation

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

a) Demonstration of Analytical Capability - (Section 5.10.2.1) shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel, matrix or test method.

b) Calibration - Calibration protocols specified in Section 5.9.4 shall be followed.

c) Proficiency Test Samples - The results of such analyses (5.4.2.j or 5.5.3.4) shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

D.1.4 Detection Limits

The laboratory shall utilize a test method that provides a detection limit that is appropriate and relevant for the intended use of the data. Detection limits shall be determined by the protocol in the

mandated test method or applicable regulation, e.g., MDL. If the protocol for determining detection limits is not specified, the selection of the procedure must reflect instrument limitations and the intended application of the test method.

a) A detection limit study is not required for any component for which spiking solutions or quality control samples are not available such temperature.

b) The detection limit shall be initially determined for the compounds of interest in each test method in a matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the detection limit must be determined in the matrix of interest (see definition of matrix).

c) Detection limits must be determined each time there is a significant change in the test method or instrument type.

d) It is essential that all sample processing steps of the analytical method be included in the determination of the detection limit.

e) All procedures used must be documented. Documentation must include the matrix type. All supporting data must be retained.

f) The laboratory must have established procedures to tie detection limits with quantitation limits.

D.1.5 Data Reduction

The procedures for data reduction, such as use of linear regression, shall be documented.

D.1.6 Quality of Standards and Reagents

a) The source of standards shall comply with 5.9.2.

b) Reagent Quality, Water Quality and Checks:

1) Reagents - In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the test method shall not be used. The labels on the container should be checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information shall be documented.

2) Water - The quality of water sources shall be monitored and documented and shall meet method specified requirements.

D.1.7 Selectivity

a) Absolute retention time and relative retention time aid in the identification of components in chromatographic analyses and to evaluate the effectiveness of a column to separate constituents. The laboratory shall develop and document acceptance criteria for retention time windows.

b) A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. All confirmation shall be documented.

c) The laboratory shall document acceptance criteria for mass spectral tuning.

D.1.8 Constant and Consistent Test Conditions

a) The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

b) Glassware Cleaning - Glassware shall be cleaned to meet the sensitivity of the test method.

Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs.

D.2 WHOLE EFFLUENT TOXICITY TESTING

D.2.1 Positive and Negative Controls

a) Positive Control - Reference Toxicants - Reference toxicant tests indicate the sensitivity of the test organisms being used and demonstrate a laboratory's ability to obtain consistent results with the test method.

1) The laboratory must demonstrate its ability to obtain consistent results with reference toxicants before it performs toxicity tests with effluents for permit compliance purposes.

i. An intralaboratory coefficient of variation (%CV) is not established for each test method. However, a testing laboratory shall maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or ECp) and shall evaluate the intralaboratory variability with a specific reference toxicant for each test method. In addition, a laboratory must produce test results that meet test acceptability criteria (such as greater than 80% survival in the control) as specified in the specific test method.

ii. Intralaboratory precision on an ongoing basis must be determined through the use of reference toxicant tests and plotted in quality control charts. As specified in the test methods, the control charts shall be plotted as point estimate values, such as EC25 for chronic tests and LC 50 for acute tests, over time within a laboratory.

2) The frequency of reference toxicant testing shall comply with the EPA or State permitting authority requirements.

3) The USEPA test methods for EPA/600/4-91-002, EPA/600/4-91-003 and EPA/600/4-90-027F do not currently specify a particular reference toxicant and dilution series, however, if the State or permitting authority identifies a reference toxicant or dilution series for a particular test, the laboratory shall follow the specified requirements.

4) Test Acceptability Criteria (TAC) - The test acceptability criteria (for example, the chronic *Ceriodaphnia* test, requires 80% or greater survival and an average 15 young per female in the controls) as specified in the test method must be achieved for both the reference toxicant and effluent test. The criteria shall be calculated and shall meet the method specified requirements for performing toxicity:

   i. The control population of *Ceriodaphnia* shall contain no more than 20% males.

   ii. An individual test may be conditionally acceptable if temperature, dissolved oxygen, pH and other specified conditions fall outside specifications, depending on the degree of the departure and the objectives of the tests (see test conditions and test acceptability criteria specified for each test method). The acceptability of the test shall depend on the experience and professional judgment of the technical employee and the permitting authority.

b) Negative Control - Control, Brine Control or Dilution Water - The standards for the use, type and frequency of testing are specified by the test methods and by permit and shall be followed.

D.2.2 Variability and/or Reproducibility

Intralaboratory precision shall be determined on an ongoing basis through the use of further reference toxicant tests and related control charts as described in item D.2.1.a above.

D.2.3 Accuracy

This principle is not applicable to Whole Effluent Toxicity.

D.2.4 Test Sensitivity

a) Test sensitivity (or test power) of the tests will depend in part on the number of replicates per concentration, the significance level selected (0.05), and the type of statistical analysis. If the variability remains constant, the sensitivity of the test will increase as the number of replicates is increased. Test sensitivity is the minimum significant difference (MSD) between the control and test concentration that is statistically significant. If the Dunnett's procedure is used, the MSD shall be calculated according to the formula specified by the EPA test method and reported with the test results.

b) Estimate the MSD for non-normal distribution and or heterogenous variances.

c) Point estimates: (LCp, ICp, or ECp) - Confidence intervals shall be reported as a measure of the precision around the point estimate value.

d) The MSD shall be calculated and reported for only chronic endpoints. In addition, the calculated endpoint is typically a lethal concentration of 50% (LC 50), therefore, confidence intervals shall be reported as a measure of the precision around the point estimate value. In order to have sufficient replicates to perform a reliable MSD, such tests shall have a minimum of four replicates per treatment so that either parametric or non parametric tests can be conducted.

D.2.5 Selection of Appropriate Statistical Analysis Methods

a) The methods of data analysis and endpoints will be specified by language in the permit or, if not present in the permit, by the EPA methods manuals for Whole Effluent Toxicity.

b) Dose Response Curves - When required, the data shall be plotted in the form of a curve relating the dose of the chemical to cumulative percentage of test organisms demonstrating a response such as death.

D.2.6 Selection and Use of Reagents and Standards

a) The grade of all reagents used in Whole Effluent Toxicity tests is specified in the test method except the reference standard. All reference standards shall be prepared from chemicals which are analytical reagent grade or better. The preparation of all standards and reference toxicants shall be documented.

b) All standards and reagents associated with chemical measurements, such as dissolved oxygen, pH or specific conductance, shall comply with the standards outlined in Appendix D.1 above.

D.2.7 Selectivity

This principle is not applicable. The selectivity of the test is specified by permit.

D.2.8 Constant and Consistent Test Conditions

a) If closed refrigerator-sized incubators are used, culturing and testing of organisms shall be separated to avoid loss of cultures due to cross-contamination.

b) The laboratory or a contracted outside expert shall positively identify test organisms to species on an annual basis. The taxonomic reference (citation and page(s))and the names(s) of the taxonomic expert(s) must be kept on file at the laboratory.

c) Instruments used for routine measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, and weight shall be calibrated, and/or standardized per manufacturer's instructions and Section D.1. Temperature shall be calibrated per section 5.9.4.2.1 All measurements and calibrations shall be documented.

d) Test temperature shall be maintained as specified in the methods manuals. The average daily temperature of the test solutions must be maintained within 1°C of the selected test temperature, for the duration of the test. The minimum frequency of measurement shall be

once per 24 hour period. The test temperature for continuous flow toxicity tests shall be recorded and monitored continuously.

e) Water used for culturing and testing shall be analyzed for toxic metals and organics annually or whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause, such as contaminated glassware or poor stock, can be identified. The method specified analytes and concentration levels shall be followed.

f) New batches of food used for culturing and testing shall be analyzed for toxic organics and metals. If food combinations or recipes are used, analyses shall be performed on the final product upon the use of new lot of any ingredient. If the concentration of total organic chlorine exceeds 0.15 μg/g wet weight, or the total concentration of organochlorine pesticides plus PCBs exceeds 0.30 μg/g wet weight, or toxic metals exceeds 20 μg/g wet weight, the food must not be used.

g) Test chamber size and test solution volume shall be as specified in the methods manuals.

h) Test organisms shall be fed the quantity and type food specified in the methods manuals. They shall also be fed at the intervals specified in the test methods.

i) Light intensity shall be maintained as specified in the methods manuals. Measurements shall be made and recorded on a yearly basis. Photoperiod shall be maintained as specified in the test methods and shall be documented at least quarterly. For algal tests, the light intensity shall be measured and recorded at the start of each test.

j) At a minimum, during chronic testing DO and pH shall be measured daily in at least one replicate of each concentration. DO may be measured in new solutions prior to organism transfer, in old solutions after organisms transfer, or both.

k) All cultures used for testing shall be maintained as specified in the methods manuals.

l) Age and the age range of the test organisms must be as specified in the manuals.

m) The maximum holding time (lapsed time from sample collection to first use in a test) shall not exceed 36 hours without the permission of the permitting authority.

n) All samples shall be chilled to 4°C during or immediately after collection. They shall be maintained at a temperature range from just above the freezing temperature of water to 6°C and the arrival temperature shall be no greater than 6°C. Samples that are hand delivered to the laboratory immediately after collection (i.e., within 1 hour) may not meet the laboratory temperature acceptance criteria. In these cases, the laboratory may accept the samples if there is evidence (such as arrival on ice) that the chilling process has begun.

o) Organisms obtained from an outside source must be from the same batch.

D.3 MICROBIOLOGY TESTING

These standards apply to laboratories undertaking the examination of materials, products and substances involving microbiological analysis, recovery or testing. The procedures involve the culture media, the test sample and the microbial species being isolated, tested or enumerated.

a) Microbiological testing refers to and includes the detection, isolation, enumeration and identification of microorganisms and their metabolites, as well as sterility testing. It includes assays using microorganisms as part of a detection system and their use for ecological testing.

b) These standards are concerned with the quality of test results and not specifically with health and safety measures. In the performance of microbiological testing, laboratories must be aware of and have SOPs that conform with local, State, and national regulatory policies for the safety and health of personnel.

D.3.1 Positive and Negative Controls

a) Negative Controls

The laboratory shall demonstrate that the cultured samples have not been contaminated through sample handling/preparation or environmental exposure. These controls shall include sterility checks of media, blanks such as filtration blanks, bottle, and buffer blanks.

1) All blanks and uninoculated controls specified by the test method shall be prepared and analyzed at the frequency stated in the method.

2) A minimum of one uninoculated control shall be prepared and analyzed unless the same equipment set is used to prepare multiple samples. In such cases, the laboratory shall prepare a series of blanks using the equipment. At least one beginning and ending control shall be prepared, with additional controls inserted after every 10 samples.

3) Analyze a known negative culture.

b) Positive Controls

Positive controls demonstrate that the medium can support the growth of the test organism, and that the medium produces the specified or expected reaction to the test organism.

1) On a monthly basis each lot of media shall be tested with at least one pure culture of a known positive reaction and shall be included with the sample test batch.

2) If routine culturing is not part of a laboratory's testing and pre-prepared media are routinely used, strict control of the storage conditions and expiration date of media shall be maintained. A positive growth control from a known positive sample shall be run with each lot to ensure that the media support growth.

3) If the laboratory has at least one known positive result of the appropriate organism during the month, a separate positive control is not required.

D.3.2 Test Variability/Reproducibility

a) Duplicates - At least 5% of the suspected positive samples shall be duplicated. In laboratories with more than one analyst, each shall make parallel analyses on at least one positive sample per month.

b) Where possible, participation in, or organization of collaborative trials, proficiency testing, or interlaboratory comparisons, either formal or informal, must be done.

D.3.3 Method Evaluation

a) In order to demonstrate the suitability of a test method for its intended purpose, the laboratory shall demonstrate and document its ability to meet acceptance criteria either specified by the method or by the EPA or State program requirements. Acceptance criteria must meet or exceed these requirements and must demonstrate that the test method provides correct/expected results with respect to specified detection capabilities, selectivity, and reproducibility.

   1) Accepted (official) test methods or commercialized test kits for official test methods, or test methods from recognized national or international standard organizations, may not require a specific validation. Laboratories are required, however, to demonstrate proficiency with the test method prior to first use. This can be achieved by simultaneous, side-by-side analysis by several analysts.

   2) Qualitative microbiological test methods in which the response is expressed in terms of presence/absence, shall be validated by estimating, if possible, the specificity, and reproducibility. The differences due to the matrices must be taken into account when testing different sample types.

   3) The validation of microbiological test methods shall be performed under the same conditions as those for routine sample analysis. This can be achieved by using a combination of naturally contaminated products and spiked products with results that can be statistically analyzed to demonstrate that the test meets its intended purpose.

   4) All validation data shall be recorded and stored at least as long as the test method is in force, or if withdrawn from active use, for at least 5 years past the date of last use.

b) Laboratories shall participate in the Proficiency Test programs (interlaboratory) identified by NELAP (5.4.2.j or 5.5.3.4).

D.3.4 Test Performance

All growth and recovery media must be checked to assure that the target organisms respond in an acceptable and predictable manner (see D.3.1.b).

D.3.5 Data Reduction

a) The calculations, data reduction and statistical interpretations specified by each test method shall be followed.

b) If the test method specifies colony counts, such as membrane filter or colony counting, then the ability of individual analysts to count colonies shall be verified at least once per month, by having two or more analysts count colonies from the same plate.

D.3.6 Quality of Standards, Reagents and Media

The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.

a) Culture media may be prepared in the laboratory from the different chemical ingredients, from commercial dehydrated powders or may be purchased ready to use.

b) Reagents, commercial dehydrated powders and media shall be used within the shelf-life of the product and shall be documented according to 5.10.5. The laboratory shall retain all manufacturer-supplied "quality specification statements" which may contain such information as shelf life of the product, storage conditions, sampling regimen/rate, sterility check including acceptability criteria, performance checks including the organism used, their culture collection reference and acceptability criteria, date of issue of specification, or statements assuring that the relevant product batch meets the product specifications.

c) Distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances shall be used in the preparation of media solutions and buffers. The quality of the water shall be monitored for attributes such as pH, chlorine residual, specific conductance, metals, or heterotrophic plate count at the specified frequency and evaluated according to the stated standards. Records shall be maintained on all activities.

d) Media, solutions and reagents shall be prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method.

e) All laboratory media shall be checked to ensure they support the growth of specific microbial cultures. In addition, selective media shall be checked to ensure they suppress the growth of non-target organisms. Media purchased pre-prepared from the manufacturer shall be checked monthly except when the use and maintenance of pure cultures is not part of laboratory procedures. In preference to using the commonly used streak method, it is better to use a quantitative procedure, where a known (often low) number of relevant organisms are inoculated into the medium under test and the recovery evaluated.

f) Each lot of detergent for laboratory use shall be checked to ensure that residues from the detergent do not inhibit or promote growth of microorganisms, for example with an inhibitory residue test.

D.3.7 Selectivity

a) All confirmation/verification tests specified by the test method shall be performed according to method protocols.

b) In order to demonstrate traceability and selectivity, laboratories shall use reference cultures of microorganisms obtained from a recognized national collection or an organization recognized by the assessor body.

1) Reference cultures may be subcultured once to provide reference stocks. Appropriate purity and biochemical checks shall be made and documented. The reference stocks shall be preserved by a technique which maintains the desired characteristics of the strains. Examples of such methods are freeze-drying, liquid nitrogen storage and deep-freezing methods. Reference stocks shall be used to prepare working stocks for routine work. If reference stocks have been thawed, they must not be re-frozen and re-used.

2) Working stocks shall not be sequentially cultured more than five times except when:

i. it is required by standard test methods, or

ii. laboratories can provide documentary evidence demonstrating that there has been no loss of viability, no changes in biochemical activity and/or no change in morphology.

3) Working stocks shall not be subcultured to replace reference stocks.

4) A scheme for handling reference cultures is included in Figure D.1.

D.3.8 Constant and Consistent Test Conditions

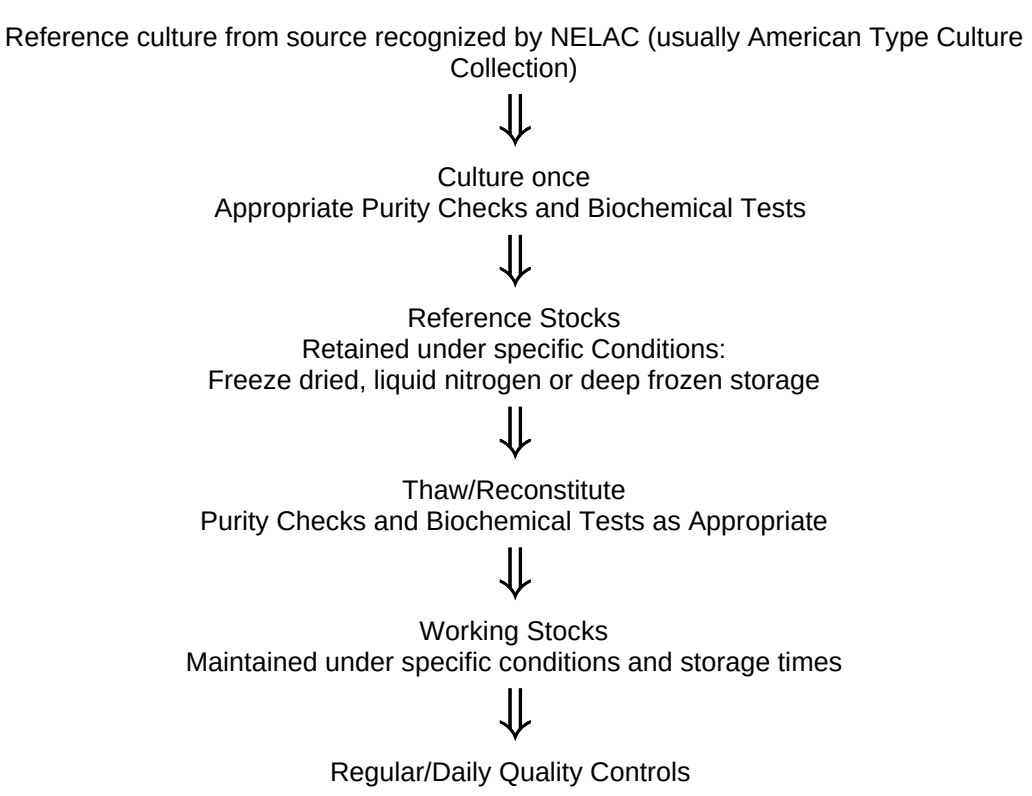
a) The laboratory shall devise an appropriate environmental monitoring program to indicate trends in levels of contamination appropriate to the type of testing being carried out. Acceptable background counts shall be determined and there shall be documented procedures to deal with situations in which these limits are exceeded.

b) Walls, floors, ceilings and work surfaces shall be non-absorbent and easy to clean and disinfect. Wooden surfaces of fixtures and fittings shall be adequately sealed. Measures shall be taken to avoid accumulation of dust by the provision of sufficient storage space by having minimal paperwork in the laboratory and by prohibiting plants and personal possessions from the laboratory work area.

c) Temperature measurement devices

1) Where the accuracy of temperature measurement has a direct effect on the result of the analysis, temperature measuring devices such as liquid-in-glass thermometers, thermocouple, platinum resistance thermometers used in incubators, autoclaves and other equipment shall be the appropriate quality to achieve the specification in the test method. The graduation of the temperature measuring devices must be appropriate for the required accuracy of measurement and they shall be calibrated to national or international standards for temperature (see 5.9.2). Calibration shall be done at least annually.

Figure D-1. USE OF REFERENCE CULTURES (BACTERIA)



2) The stability of temperature, uniformity of temperature distribution and time required to achieve equilibrium conditions in incubators, waterbaths, ovens and temperature controlled rooms shall be established, for example, position, space between and height of stacks of Petri dishes.

d) Autoclaves

1) The performance of each autoclave shall be initially evaluated by establishing its functional properties, for example heat distribution characteristics with respect to typical uses. Autoclaves shall be capable of meeting specified temperature tolerances. Pressure cookers fitted only with a pressure gauge are not recommended for sterilization of media or decontamination of wastes.

2) Records of autoclave operations including temperature and time shall be maintained. This shall be done for every cycle. Acceptance/rejection criteria shall be established and used to evaluate the autoclave efficiency and effectiveness.

e) Volumetric equipment such as automatic dispensers, dispenser/diluters, mechanical hand pipettes and disposal pipettes may all be used in the microbiology laboratory. Regular checks as outlined in Section 5.9.4.2.1 shall be performed and documented.

f) UV Sterilizers

1) Are to be tested quarterly for effectiveness with positives (either reference cultures or positive monitoring samples) and this is to include testing of the power output of the UV bulb.

g) Conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments shall be calibrated according to the method specified requirements (see Appendix D.1). Mechanical timers shall be checked regularly against electronic timing devices to ensure accuracy.

D.4 RADIOCHEMICAL TESTING

These standards apply to laboratories undertaking the examination of environmental samples by radiochemical analysis. These procedures for radiochemical analysis may involve some form of chemical separation followed by detection of the radioactive decay of analyte (or indicative daughters) and tracer isotopes where used. For the purpose of these standards procedures for the determination of radioactive isotopes by mass spectrometry (e.g. ICP-MS or TIMS) or optical (e.g. KPA) techniques are not addressed herein.

D.4.1 Negative Controls

a) Method Blank - Shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the quality control measures to be used to assess batch acceptance. The method blank result shall be assessed against the specific acceptance criteria [see 5.10.1.2.b)18] specified in the laboratory method manual [see 5.10.1.2]. When the specified method blank acceptance criteria is not met the specified corrective action and contingencies [see 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed

method blank acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.13.a)11].

b) In the case of gamma spectrometry where the sample matrix is simply aliquoted into a calibrated counting geometry the method blank shall be of similar counting geometry that is empty or filled to similar volume with ASTM Type II water to partially simulate gamma attenuation due to a sample matrix.

c) There shall be no subtraction of the required method blank [see D.4.1.a)] result from the sample results in the associated preparation or analytical batch. This does not preclude the application of any correction factor (e.g. instrument background, analyte presence in tracer, reagent impurities, peak overlap, calibration blank, etc.) to all analyzed samples, both program/project submitted and internal quality control samples. However, these correction factors shall not depend on the required method blank result in the associated analytical batch.

d) The method blank acceptance criteria [see 5.10.1.2.b)18] shall address the presumed aliquot size on which the method blank result is calculated and the manner in which the method blank result is compared to sample results of differing aliquot size.

D.4.2 Positive Controls

a) Laboratory Control Samples - Shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the quality control measures to be used to assess batch acceptance. The laboratory control sample result shall be assessed against the specific acceptance criteria [see 5.10.1.2.b)18] specified in the laboratory method manual [see 5.10.1.2]. When the specified laboratory control sample acceptance criteria is not met the specified corrective action and contingencies [see 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed laboratory control sample acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.13.a)11].

b) Matrix Spike - Shall be performed at a frequency of one per preparation batch for those methods which do not utilize an internal standard or carrier and for which there is a physical or chemical separation process and where there is sufficient sample to do so. The results of this analysis shall be one of the quality control measures to be used to assess batch acceptance. The matrix spike result shall be assessed against the specific acceptance criteria [see 5.10.1.2.b)18] specified in the laboratory method manual [see 5.10.1.2]. When the specified matrix spike acceptance criteria is not met the specified corrective action and contingencies [see 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed matrix spike acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.13.a)11]. The lack of sufficient sample aliquot size to perform a replicate analysis should be noted in the laboratory report.

c) The activity of the laboratory control sample and matrix spike analyte(s) shall be greater than ten times and less than one hundred times the *a priori* detection limit.

d) The laboratory standards used to prepare the laboratory control sample and matrix spike shall be from a source independent of the laboratory standards used for instrument calibration.

e) Where a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g. isotopic uranium: U-234, -235, and -238), only one of the analyte isotopes need be included in the laboratory control or matrix spike sample at the indicated activity level. However, where more than one analyte isotope is present above the specified activity level each shall be assessed against the specified acceptance criteria.

f) Where gamma spectrometry is used to identify and quantitate more than one analyte isotope, the laboratory control sample and matrix spike shall contain isotopes that represent the low (e.g. americium-241), medium (e.g. cesium-137) and high (e.g. cobalt-60) energy range of the analyzed gamma spectra. As indicated by these examples, the isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.

D.4.3 Test Variability/Reproducibility

a) Replicate - Shall be performed at a frequency of one per preparation batch where there is sufficient sample to do so. The results of this analysis shall be one of the quality control measures to be used to assess batch acceptance. The replicate result shall be assessed against the specific acceptance criteria [see 5.10.1.2.b)18] specified in the laboratory method manual [see 5.10.1.2]. When the specified replicate acceptance criteria is not met the specified corrective action and contingencies [see 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed replicate acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.13.a)11].

D.4.4 Other Quality Control Measures

a) Tracer - For those methods that utilize a tracer (i.e. internal standard) each sample result will have an associated tracer recovery calculated and reported. The tracer recovery for each sample results shall be one of the quality control measures to be used to assess the associated sample result acceptance. The tracer recovery shall be assessed against the specific acceptance criteria [see 5.10.1.2.b)18] specified in the laboratory method manual [see 5.10.1.2]. When the specified tracer recovery acceptance criteria is not met the specified corrective action and contingencies [see 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed tracer recovery acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.13.a)11].

b) Carrier - For those methods that utilize a carrier (i.e., internal standard) each sample will have an associated carrier recovery calculated and reported. The carrier recovery for each sample shall be one of the quality control measures to be used to assess the associated sample result acceptance. The carrier recovery shall be assessed against the specific acceptance criteria [see 5.10.1.2.b)18] specified in the laboratory method manual [see 5.10.1.2]. When the specified carrier recovery acceptance criteria is not met the specified corrective action and contingencies [see 5.10.1.2.a)19 and 20] will be followed. The occurrence of a failed carrier recovery acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.13.a)11].

D.4.5 Method Evaluation

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

a) Demonstration of Capability - (section 5.10.2.1) shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel or method.

b) Proficiency Test Samples - The results of such analysis (5.4.2.j or 5.5.3.4) shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data. The providers of such proficiency test samples should conform to the requirements of ANSI N42.22.

D.4.6 Radiation Measurement System Calibration

Due to the stability and response nature of modern radiation measurement instrumentation, it is not typically necessary to calibrate these systems in the day of use manner done so for some types of chemical measurement instrumentation. As well due to the nature of some radiation measurement instrumentation calibrations, it may not be practical to calibrate in a day of use manner. In addition the calibration of modern radiation measurement instrumentation has significant differences from chemical measurement instrumentation. This section will address those practices that are necessary for proper calibration and those requirements of section 5.9.4.2 (Instrument Calibrations) that are not applicable to some types of radiation measurement instrumentation.

a) Calibration Curves

For those radiochemical methods that may require multiple standards for initial calibration (e.g. gas-proportional counting and liquid scintillation counting), the required number shall be addressed in the laboratory method manual [see 5.10.1.2.13] if not addressed in the method.

b) Calibration Curve Regression

Where linear regression is used to fit standard response or calibration standard results to a calibration curve the correlation coefficient shall be determined. Where non-linear regression is used to fit standard response or calibration standard results to a calibration curve the correlation coefficient should be determined.

c) Calibration Range

The requirements of 5.9.4.2.1.f) are not applicable to the performance of radiochemical methods given the non-correlated event nature of decay counting instrumentation.

d) Calibration Verification

The Laboratory Control Sample may fill the requirements for the performance of an initial calibration and continuing calibration verification standard as specified in sections 5.9.4.2.1 and 5.9.4.2.2. The calibration verification acceptance criteria shall be the same as specified for the Laboratory Control Sample.

e) Background Calibration- Background calibration measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required data quality objectives. These values are subtracted from the total measured activity in the determination of the sample activity.

1) For gamma spectroscopy systems, background calibration measurements shall be performed on at least a monthly basis.

2) For alpha spectroscopy systems, background calibration measurements shall be performed on at least a monthly basis.

3) For gas-proportional and scintillation counters, background calibration measurements shall be performed on a day of use basis.

f) Calibration - Instrument calibration shall be performed with reference standards as defined in section D.4.9.a. The standards shall have the same general characteristics (i.e. geometry, homogeneity, density, etc.) as the associated samples.

g) The frequency of calibration shall be addressed in the laboratory method manual [see 5.10.1.2.13] if not addressed in the method. A specific frequency (e.g. monthly) or observations from the associated control or tolerance chart, as the basis for calibration shall be specified.

D.4.7 Detection Limits

Note: To be addressed in the next Chapter Five revision.

D.4.8 Data Reduction

a) Refer to Section 5.10.6," Computers and Electronic Data Related Requirements," of this document.

b) Method Uncertainties - the laboratory shall have the ability to trace all sources of method uncertainties and their propagation to reported results. The ISO "Guide to the Expression of Uncertainty in Measurement" and/or the NIST Technical Note 1297 on "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results" should be used in this regard.

D.4.9 Quality of Standards and Reagents

a) The quality control program shall establish and maintain provisions for radionuclide standards.

1) Reference standards that are used in a radiochemical laboratory shall be obtained from the National Institute of Standards and Technology (NIST), EPA, or suppliers who participate in supplying NIST standards or NIST traceable radionuclides. Any reference standards purchased outside the United States shall be traceable back to each country's national standards laboratory. Commercial suppliers of reference standards should conform to ANSI N42.22 to assure the quality of their products.

2) Reference standards shall be accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates.

3) Laboratories should consult with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the

certified value. The laboratory shall not use a value other than the decay corrected certified value.

b) All reagents used shall be analytical reagent grade or better.

D.4.10 Constant and Consistent Test Conditions

a) To prevent incorrect analysis results caused by the spread of contamination among samples, the laboratory shall establish and adhere to written procedures to minimize the possibility of cross-contamination between samples.

b) Instrument performance checks - Instrument performance checks using appropriate check sources shall be performed on a regular basis and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the calibration has not changed. The same check source used in the preparation of the tolerance chart or control chart at the time of calibration shall be used in the performance checks of the instrument. The check sources must provide adequate counting statistics for a relatively short count time and the source should be sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel. For alpha and gamma spectroscopy systems, the instrument performance checks shall include checks on the counting efficiency and the relationship between channel number and alpha or gamma ray energy.

1) For gamma spectroscopy systems, the performance checks for efficiency and energy calibration shall be performed on a day of use basis along with performance checks on peak resolution.

2) For alpha spectroscopy systems, the performance check for energy calibration shall be performed on a day of use basis and the performance check for counting efficiency shall be performed on at least a monthly basis.

3) For gas-proportional and scintillation counters, the performance checks for counting efficiency shall be performed on a day of use basis.

D.5 AIR TESTING

Analyses for Air Toxics shall follow the essential quality controls for chemistry outlined in Appendix D.1. For air testing, the blank, laboratory control sample and a desorption efficiency (such as charcoal tubes) shall be used. Matrix spikes and duplicate samples shall be used when feasible.

QUALITY SYSTEMS
APPENDIX E

ADDITIONAL SOURCES OF INFORMATION AND ASSISTANCE

-Non-Mandatory Appendix-

Appendix E - ADDITIONAL SOURCES OF INFORMATION
-Non-Mandatory Appendix-

Additional sources of information are available to assist laboratories in the design and implementation of a quality system. These materials may be found on the NELAC web page at www.epa.gov/ttn/nelac under the topic “Related Information”.

National Environmental Laboratory **Accreditation** Conference

nelac

ACCREDITING AUTHORITY

July 1, 1999

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ACCREDITING AUTHORITY

6.0 ACCREDITING AUTHORITY

6.1 INTRODUCTION

The standards in this Chapter define the process and criteria that will be used by the National Environmental Laboratory Accreditation Program (NELAP) to determine whether accrediting authorities applying for NELAP recognition meet the standards required for such recognition.

Chapter Six is structured so that the requirements of the International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) Guide 58: Calibration and testing laboratory accreditation systems - General requirements for operation and recognition, 1993, are incorporated into the requirements for an accrediting authority to be NELAP-recognized.

Chapter Six addresses most of the requirements of ISO/IEC Guide 58. All NELAP-recognized accrediting authorities are required to administer an environmental laboratory accreditation program that meets the requirements contained in the National Environmental Laboratory Accreditation Conference (NELAC) standards, Chapter Six. Those ISO/IEC Guide 58 requirements not addressed in Chapter Six are addressed in the NELAC standards, Chapters Two through Five. Since Chapter Six requires an accrediting authority to administer an environmental laboratory accreditation program that requires laboratories to meet the standards set forth in the NELAC standards, Chapters Two through Six, all the requirements of ISO/IEC Guide 58 will be met by a NELAP-recognized accrediting authority. In most cases, the ISO/IEC requirements, contained in Chapter Six or elsewhere in the NELAC standards are not direct quotations from the ISO/IEC guidance document.

6.2 GENERAL PROVISIONS

a) In all cases, accrediting authorities are governmental organizations at the territory, State or federal levels.

b) A territorial, State or federal entity shall designate the appropriate agencies or departments as its designated NELAP-recognized accrediting authorities for the fields of testing for which NELAP recognition is being sought.

c) A NELAP-recognized accrediting authority shall not delegate authority for granting, maintaining, suspending or revoking a laboratory's NELAP accreditation to an outside person or body. Portions of the accreditation process may be contracted out when the accrediting authority follows the provisions of subsections 6.3.3.1.2 and 6.3.3.1.3 (b)(3); however, the authority to grant, maintain, suspend or revoke NELAP accreditation must remain with the accrediting authority.

d) The procedures under which a NELAP-recognized accrediting authority operates shall be administered in an impartial and non-discriminatory manner. The accrediting authority also shall require accredited laboratories to maintain impartiality and integrity. An accrediting authority shall have no rules, regulations, procedures or practices that:

    1) restrict the size, large or small, of any laboratory seeking accreditation;

    2) require membership or participation in any laboratory or other professional association;

    3) impose any financial conditions or restrictions for participation in the accreditation program other than the fees authorized by territorial, State or federal law; and,

4) conflict with any territorial, State or federal laws governing discrimination.

e) Accrediting authorities and their contractors shall confine their requirements, assessments and decision making processes for a NELAP accredited laboratory to those matters specifically related to the fields of testing of the NELAP accreditation being sought by a laboratory.

f) If the NELAP insignia is used on general literature such as brochures, letterheads and business cards, a NELAP-recognized accrediting authority shall accompany the display of the NELAP insignia with at least the phrase "NELAP-recognized".

g) Accrediting authorities, within the scope and applicability of their prevailing rules and regulations, shall establish one or more technical committees for assistance in interpretation of requirements and for advising the accrediting authority on the technical matters relating to the operation of its environmental laboratory accreditation program. When such committees are established, the accrediting authority shall have

1) formal rules and structures for the appointment and operation of committees involved in the accreditation process and such committees shall be free from any commercial, financial, and other pressures that might influence decisions, or

2) a structure where committee members are chosen to provide relevant competent technical support and impartiality through a balance of interests where no single interest predominates, and

3) a mechanism for publishing interpretations and recommendations made by these committees.

h) Unless the contrary is clearly indicated, all references in this Chapter to singular nouns include the plural noun, and all references to plural nouns include the singular, for example, “area of responsibility” also includes multiple “areas of responsibility.”

6.2.1 Reciprocity

a) Except as noted in this subsection, NELAP-recognized secondary accrediting authorities shall grant accreditation to laboratories accredited by any other NELAP-recognized primary accrediting authority. Such reciprocal NELAP accreditation shall be granted on a laboratory-by-laboratory basis. The NELAP-recognized secondary accrediting authority shall consider only the current certificate of accreditation issued by the NELAP-recognized primary accrediting authority.

b) When granting reciprocal accreditation to a laboratory, the NELAP-recognized secondary accrediting authority shall:

1) grant reciprocal accreditation for only the fields of testing, methods and analytes for which the laboratory holds current primary NELAP accreditation, and

2) grant reciprocal accreditation and issue certificates, as required in NELAC, Chapter Four, to an applicant laboratory within 30 calendar days of receipt of the laboratory's application.

c) All fees shall be paid by laboratories as required by the NELAP-recognized secondary accrediting authority.

d) Laboratories seeking NELAP accreditation by a NELAP-recognized secondary accrediting authority shall not be required to meet any additional proficiency testing, quality assurance, or on-site assessment requirements for the fields of testing for which the laboratory holds primary NELAP accreditation.

e) If a NELAP-recognized secondary accrediting authority notes any potential nonconformance with the NELAC standards by a laboratory during the initial application process for reciprocal accreditation, or for a laboratory that already has been granted NELAP accreditation through reciprocity, the NELAP-recognized secondary accrediting authority shall immediately notify, in writing, the applicable NELAP-recognized primary accrediting authority and the laboratory. However, the laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated. The notification must cite the applicable sections within the NELAC standards for which nonconformance by the laboratory has been noted.

1) If the alleged nonconformance is noted during the initial application process for reciprocal NELAP accreditation, final action on the application for reciprocal NELAP accreditation shall not be taken until the alleged nonconformance issue has been resolved, or

2) If the alleged nonconformance is noted after reciprocal NELAP accreditation has been granted, the laboratory shall maintain its current NELAP accreditation status until the alleged nonconformance issue has been resolved.

f) Upon receipt of the subsection 6.2.1 (e) notification, the NELAP-recognized primary accrediting authority shall:

1) review and investigate the alleged nonconformance,

2) take appropriate action on the laboratory as set forth by the NELAC standards, including the addition of any change of accreditation status in the National Environmental Laboratory Accreditation Database. All such actions shall be taken in accordance with the laboratory's right to due process as set forth in the NELAC standards, Chapter Four, Accreditation Process,

3) respond to the NELAP-recognized secondary accrediting authority, in writing, with a copy to the NELAP Director, within 20 calendar days of receipt of the subsection 6.2.1 (e) notification providing:

A) an initial report of the findings;

B) a description of the actions to be taken; and,

C) a schedule for implementation of further action on the alleged nonconformance, if necessary.

g) If, in the opinion of the secondary accrediting authority, the primary accrediting authority does not take timely and appropriate action on the complaint, the secondary accrediting authority should notify the NELAP Director of the dispute between the two accrediting authorities regarding proper disposition of the complaint. Within 20 calendar days of receipt of such notification, the NELAP Director shall review the alleged nonconformance and take appropriate action according to the standards set forth in this Chapter.

6.2.2 Where to Apply for NELAP Accreditation

a) Laboratories that are NELAP accredited by an accrediting authority that has lost NELAP recognition may seek NELAP accreditation through any NELAP-recognized accrediting authority. The laboratory's NELAP accreditation shall remain valid throughout its current certificate of accreditation.

b) Except for governmental laboratories as noted in subsection 6.2.2 (d) below, all laboratories seeking NELAP accreditation or renewal of NELAP accreditation must apply for such accreditation through their home State (the State in which the laboratory facility is located) accrediting authority.

c) Laboratories located in a territory or other State that is not NELAP-recognized may seek NELAP accreditation through any NELAP-recognized accrediting authority.

d) Governmental laboratories that are organizational units of the same department or agency in which the accrediting authority is located or have other institutional conflicts of interest shall:

    1) demonstrate by organizational structure that the laboratory's Technical Director and the environmental laboratory accreditation program manager do not report within the same chain-of-command; and

    2) demonstrate by policies and procedures that conflicts-of-interest, actual or potential, do not exist; or,

    3) apply for NELAP accreditation through any other NELAP-recognized accrediting authority.

e) In order that all laboratory applications for NELAP accreditation are treated equally, accrediting authorities shall initiate processing applications for NELAP accreditation in the chronological order that the applications are received.

6.2.3 Documentation Maintained by Accrediting Authorities

a) The accrediting authority shall provide through publication, electronic media or other means a document or documents describing its environmental laboratory accreditation program.

    1) The document or documents shall include the following:

        A) information setting forth the authority of the accrediting authority to grant laboratory accreditations and whether such laboratory accreditation is mandatory or voluntary;

        B) information setting forth the accrediting authority's requirements for an environmental laboratory to become accredited;

        C) information stating the requirements for granting, maintaining, withdrawing, suspending or revoking laboratory accreditation;

        D) information about the laboratory accreditation process;

        E) information on fees charged to applicants and accredited laboratories;

        F) information regarding the rights and duties of accredited laboratories; and,

G) information listing its NELAP accredited laboratories describing the NELAP accreditation granted.

2) The document or documents shall be reviewed annually. A written record of this review must be available for inspection by the NELAP assessment team.

b) When the document or documents reviewed in subsection 6.2.3 (a)(2) above reveals that the accrediting authority's environmental laboratory accreditation program has changed or is otherwise different from the accreditation program described in such documents, the document or documents shall be updated within 30 calendar days of the review.

c) The document or documents described in subsection 6.2.3 (a)(1) above shall be made readily available upon request.

d) The accrediting authority shall have arrangements, consistent with NELAC, Chapter Three, On-Site Assessment to safeguard information claimed by the laboratories as confidential.

6.3 APPLICATION FOR NELAP RECOGNITION

This section describes the process by which accrediting authorities may apply for NELAP recognition and the procedures that NELAP will use to review the applications.

6.3.1 Written Application for NELAP Recognition

a) Each accrediting authority requesting initial NELAP recognition shall complete an application and supply all supporting documentation. Applications can be obtained from the Office of the NELAP Director, USEPA.

b) The application shall request information that is essential for the NELAP to evaluate an accrediting authority's environmental laboratory accreditation program. When documentation is required, copies of the applicable statutes, rules, regulations, policy statements, standard operating procedures, guidance documents, etc. must be submitted along with a clear citation of where the required information is found in the documents. The application will request the following information and documentation from the accrediting authority:

1) the name, mailing address, telephone number, electronic mail address and telefacsimile number of the accrediting authority;

2) the statutes and regulations establishing and governing the accrediting authority's environmental laboratory accreditation program as required in subsection 6.3.3.1 (b) and (c);

3) the policies, guidance documents, promulgating instructions and standard operating procedures governing the operation of the accrediting authority's environmental laboratory accreditation program as set forth in subsection 6.3.3.1;

4) the accrediting authority's arrangements for liability insurance and workman's compensation insurance coverage as required in subsection 6.3.3.1 (d);

5) the requirements governing how the accrediting authority restricts the use of its accreditation by accredited laboratories as required in Section 6.8;

6) the fields of testing for which the accrediting authority is requesting NELAP recognition;

7) the name and title of the primary person responsible for the day-to-day management of the accrediting authority's environmental laboratory accreditation program as required in subsection 6.3.3.1 (h);

8) the names, education and experience levels of the accrediting authority's environmental laboratory accreditation program's management and technical staff as required in subsection 6.3.3.1 (f), (g) and (h);

9) the names and contractual agreements for any external assessment bodies used by the accrediting authority as required in subsection 6.3.3.1.2 and 6.3.3.1.3 (b)(3);

10) the names, areas of responsibility, education and experience levels of all technical and assessment employees of any external assessment bodies used by the accrediting authority as required in subsection 6.3.3.1.2 and 6.3.3.1.3 (b)(3);

11) RESERVED

12) a description of the accrediting authority's environmental laboratory accreditation program quality systems (e.g., a quality systems manual or a quality assurance plan) as required in subsection 6.3.3.1.3;

13) the procedures for the selecting, training, contracting and appointing of the accrediting authority's laboratory assessors as required in subsection 6.3.3.1 (f) and (g);

14) a description of the accrediting authority's conflict-of-interest disclosure program as required in subsection 6.3.3.1 (i);

15) a tabular listing of all laboratories applying for accreditation in the two-year period immediately preceding the date of the application. The table shall set forth the date on which the laboratory's application for accreditation was received by the accrediting authority and the date on which final action on the application was taken.

16) the policies and procedures used by the accrediting authority for establishing and maintaining records on each accredited laboratory and procedures for record access and retention as required in subsection 6.3.3.1.1;

17) the accrediting authority's findings, reports and corrective actions from internal audits conducted in the last two years as required in subsection 6.3.3.1 (j) and 6.3.3.1.3 (b)(4);

18) a certification that the accrediting authority meets the provisions of Section 6.2 of this Chapter;

19) the name and job title of the individual or individuals authorized to sign accreditation certificates; and,

20) the standardized checklist required by subsection 6.3.2 (c)(1) is to be completed by the applicant accrediting authority citing the location in the application or supporting documents where the checklist information is provided.

c) The application must be signed and dated by the highest ranking individual within the department or agency responsible for laboratory accreditation activities for which NELAP recognition is being sought. By signature on the application, this individual must attest to the validity of the information contained within the application and its supporting documents.

d) The accrediting authority shall submit a renewal application to the NELAP every two years to maintain NELAP recognition.

1) The NELAP shall send by certified mail or some other verifiable means to the accrediting authority, no later than 180 calendar days prior to the expiration of the accrediting authority's then-current NELAP recognition an application for renewal of NELAP recognition to the accrediting authority. This notification of renewal shall indicate whether an on-site assessment is due as set forth in subsection 6.4 (a).

2) The accrediting authority must address each requirement of subsection 6.3.1 (b); however, it must submit information and documentation only of changes from the accrediting authority's most recent NELAP-recognized environmental laboratory accreditation program.

3) The accrediting authority must submit the completed renewal application and supporting documents to the NELAP within 30 calendar days of receiving the renewal notification.

6.3.2 Application Completeness Review by NELAP

a) The NELAP is required to provide notices required by this Chapter only to those accrediting authorities who have submitted an initial application for NELAP recognition or who hold NELAP recognition.

b) If the NELAP does not receive a completed renewal application as specified in subsection 6.3.1 (d)(3), the accrediting authority shall be notified in writing. If the accrediting authority does not submit the completed application within 20 calendar days of receipt of this notification from the NELAP, the accrediting authority's NELAP recognition will not be renewed upon expiration of its current NELAP recognition.

c) Following receipt of an initial or a renewal application, the NELAP must complete a review of the application and supporting documents to determine that information and supporting documentation required in subsection 6.3.1 (b) is included with the submittal.

1) The completeness review of the application and supporting documents shall be conducted using a standardized checklist provided by the NELAP as part of the application. The checklist shall be designed to assist the applicant in gathering all the information needed to complete the application and include a place to note the date the completeness review was completed.

2) The NELAP must notify the accrediting authority in writing within 20 calendar days of receiving the application of any additional information needed to complete the application.

3) The accrediting authority must provide any additional information or clarification requested in writing within 20 calendar days of receipt of the 6.3.2 (c)(2) notification.

A) The NELAP may grant extensions to the 20-day time period for up to an additional 20 calendar days if the accrediting authority requests the extension in writing.

B) The NELAP shall notify the accrediting authority in writing when an extension is granted.

4) Written notification to the accrediting authority that an application is complete shall be furnished by the NELAP within seven calendar days of the date of such determination.

6.3.3 Application Technical Review by a NELAP Assessment Team

a) Within 30 calendar days of the determination that the application is complete, the NELAP assessment team as established in subsection 6.9.1 will perform a technical review of the application and its supporting documents and respond in writing to the accrediting authority.

   1) The review shall be conducted in accordance with the NELAP standard operating procedures for application review; and

   2) The review shall be performed by the same NELAP assessment team assigned to conduct the on-site assessment.

   3) In the years when no on-site assessment is required, as provided in subsection 6.4 (a)(2), the NELAP Director shall endeavor to appoint the same NELAP assessment team that conducted the application technical review and on-site assessment for the accrediting authority's immediately preceding application cycle.

   4) The NELAP Director shall appoint a different NELAP assessment team for each succeeding four-year NELAP on-site assessment cycle as set forth in Section 6.4 (a) of this Chapter. New four-year NELAP on-site assessment cycles shall start with each renewal application when an on-site assessment of the accrediting authority is required.

b) The NELAP assessment team will review the application and supporting documents to evaluate whether the accrediting authority's environmental laboratory accreditation program requires its accredited laboratories to meet the standards set forth by the NELAC standards, Chapter Two, Proficiency Testing, Chapter Three, On-Site Assessment, Chapter Four, Accreditation Process and Chapter Five, Quality Systems.

c) Should the NELAP assessment team have questions or need additional application information to determine the accrediting authority's compliance with this Chapter, the NELAP assessment team must seek additional application information and documentation from the accrediting authority.

6.3.3.1 Required Technical Elements of a NELAP-Recognized Accrediting Authority's Program

a) The NELAP assessment team will review the application and supporting documentation to ensure that the accrediting authority's environmental laboratory accreditation program meets the requirements of subsections (b) through (m) below.

b) The accrediting authority shall be a legally identifiable governmental entity.

c) The accrediting authority shall have the authority, rights and responsibilities necessary to carry out an environmental laboratory accreditation program.

d) The accrediting authority shall have the same arrangements to cover liabilities and workman's compensation claims arising from its operations and activities as all other programs, units, divisions, bureaus, etc. in the department or agency in which the accrediting authority is located.

e) The accrediting authority shall have financial stability and the physical and human resources required for the operation of an accrediting authority's laboratory accreditation program. The accrediting authority shall have and make available on request a description of the means by which it receives its financial support. As a benchmark, the accrediting authority shall have the

resources necessary to complete action on a laboratory's application within nine months from the time a completed application is first received from the laboratory. This time period applies as long as all turn-around times for responses to application review, proficiency testing and on-site assessment issues are carried out within the required time limits set forth in the NELAC standards.

f) The accrediting authority shall appoint and maintain records on assessors, including contractual assessors, who meet the education, experience and training requirements set forth in the NELAC standards, Chapter Three, On-site Assessment. Such records shall include:

1) name and address;

2) organization affiliation and position held;

3) educational qualification and professional status;

4) work experience;

5) training applicable to laboratory accreditation;

6) experience in laboratory assessment, together with field of competence; and,

7) date of most recent updating of record.

g) The accrediting authority shall have a system in place to evaluate assessor performance that is consistent with the organizational employee evaluation program and demonstrates compliance with the NELAC standards, Chapter three, On-Site Assessment.

h) The accrediting authority shall identify one individual responsible for day-to-day management of the accrediting authority's environmental laboratory accreditation program. This individual must:

1) be an employee of the accrediting authority, and

2) have the technical expertise necessary to:

A) plan and manage the laboratory accreditation program,

B) coordinate various facets of the laboratory accreditation program with other territory, state and federal accrediting authorities,

C) coordinate development of environmental laboratory accreditation regulations, and,

D) evaluate the technical competence and performance of contractors or employees.

i) The accrediting authority shall have arrangements to ensure that the accrediting authority's management and technical staff are free of any commercial, financial or other pressures that influence the results of the accreditation process and are subject to the same conflict of interest disclosure requirements designed to identify and eliminate potential conflict-of- interest problems as all other programs, units, divisions, bureaus etc. in the department or agency in which the accrediting authority is located.

j) The accrediting authority shall have a documented procedure in place to conduct systematic internal audits annually of the accrediting authority's environmental laboratory accreditation program to verify compliance with the NELAC standards. One element of the annual internal audit shall be to review the effectiveness of the quality systems required in subsection 6.3.3.1.3. When applicable, the accrediting authority shall use the same policies and procedures for internal audits as used by all other programs, units, divisions, bureaus etc. in the department or agency in which the accrediting authority is located.

k) The accrediting authority shall designate the individual specified in subsection 6.3.3.1 (h) or an individual who reports directly to the individual responsible for day-to-day management of the accrediting authority's environmental laboratory accreditation program to take responsibility for the quality system and maintenance of the quality documentation required in subsection 6.3.3.1.3.

l) The accrediting authority shall have established standard operating procedures for dealing with appeals, complaints and disputes arising from denial, suspension or revocation of laboratory accreditation, or from users of the services about the NELAP accredited laboratories or any other matters.

m) The accrediting authority shall require NELAP-accredited laboratories to participate in a proficiency testing program meeting the requirements of the NELAC standards, Chapter Two, Proficiency Testing, Appendix A.

n) The accrediting authority or its contractors shall not offer consultancy or other services which may compromise the objectivity or impartiality of its accreditation process and decisions.

6.3.3.1.1 Records

a) The accrediting authority shall have arrangements to establish and maintain records for each accredited laboratory with respect to all aspects of the laboratory's accreditation process.

b) The accrediting authority shall have a policy and procedure for retaining NELAP accreditation records for a minimum of ten years or a longer period of time if required by contractual obligations or pertinent territorial, State or federal laws and regulations.

c) The accrediting authority shall have a policy and procedures concerning access to records as prescribed by the territorial, State or federal entity in which the accrediting authority resides.

d) The accrediting authority shall have a policy and procedure for updating the NELAP national database with the NELAP-required information specific to the laboratories for which that accrediting authority is the primary or secondary accrediting authority. These updates must occur no less frequently than every two weeks. The schedule for the updates would include submitting a report even if there were no changes to the database.

6.3.3.1.2 Use of Contractors by an Accrediting Authority

a) The accrediting authority shall have arrangements to ensure and require by signed contract or other similar type of binding document that all laboratory accreditation functions performed by a contractor on behalf of the accrediting authority are carried out in compliance with the NELAC standards.

b) When laboratory accreditation functions are contracted out, the accrediting authority shall:

1) take full responsibility for such contracted work,

2) ensure that the contractor and their employees are competent and comply with the applicable provisions of the NELAC standards,

3) ensure that the contractor and their employees comply with the confidentiality requirements of the accrediting authority and NELAC, and,

4) ensure that the contractor and their employees are not directly involved with:

   A) the laboratory seeking NELAP accreditation from the accrediting authority employing the contractor; or

   B) any other affiliation which would compromise impartiality in the NELAP laboratory accreditation process.

6.3.3.1.3 Accrediting Authority's Quality System

a) The accrediting authority shall have a quality system appropriate to the type, range and volume of work performed by the accrediting authority.

b) The quality system shall be documented in a quality manual and associated written quality procedures and shall be made available for use by the staff. The quality manual shall include at least the following:

   1) the quality policy statement, including objectives and commitments, signed by the manager responsible for day-to-day management of the accrediting authority's environmental laboratory accreditation program;

   2) the organizational structure of the accrediting authority's environmental laboratory accreditation program and the responsibilities of individual staff assigned to the structure;

   3) the policies and procedures for acquiring, training, supervising and evaluating the performance of contractors carrying out any part of the accrediting authority's laboratory accreditation program;

   4) the arrangements for annual internal audits, including Quality System reviews, as required in subsection 6.3.3.1 (j);

   5) the system for providing feedback to personnel responsible for the area audited and for taking timely and appropriate corrective actions whenever discrepancies are detected;

   6) the procedures established to address conflict-of-interest questions arising from the NELAC standards as set forth in subsection 6.2.2 (d)(2) and for the accrediting authority's management and technical staff as set forth in subsection 6.3.3.1 (i);

   7) the policies and procedures established to maintain document control for documents required by the NELAC standards;

   8) the policies and procedures to implement the accreditation process; and,

   9) the policies and procedures for dealing with appeals, complaints and disputes by laboratories.

6.3.3.2 Application Technical Review Report

a) The NELAP assessment team will accept an initial application and its supporting documentation for continued processing that contains sufficient information to determine that an accrediting authority meets the requirements of the NELAC standards for designation as a NELAP-recognized accrediting authority. When the NELAP assessment team completes its review of an initial application and notes no deficiencies, the NELAP assessment team will schedule the on-site assessment as set forth in subsection 6.4.1 below.

b) The NELAP assessment team will accept a renewal application and its supporting documentation for continued processing that contains sufficient information to determine that an accrediting authority meets the requirements of the NELAC standards for designation as a NELAP-recognized accrediting authority. When the NELAP assessment team completes its review of a renewal application and denotes no deficiencies, the NELAP assessment team will recommend to the NELAP Director that NELAP recognition be maintained.

c) Except as noted in Section 6.5, the NELAP assessment team will not accept the application for continued processing if it notes deficiencies. The NELAP assessment team will send by certified mail an application technical review report to the accrediting authority. The report will:

   1) identify any specific deficiencies noted during the application technical review,

   2) include references to the specific NELAC standards, and,

   3) provide suggested corrective action.

d) To proceed with the review process, the accrediting authority shall respond with written corrective actions within 30 calendar days of receipt of the NELAP assessment team's subsection 6.3.3.2 (c) notification. The NELAP assessment team will review the corrective actions within 30 calendar days of receipt of the accrediting authority's response. Alternately, the accrediting authority has the option to withdraw all or part of its NELAP recognition request.

   1) If the corrective actions submitted by the accrediting authority do not meet the requirements of this Chapter, the NELAP assessment team will notify the accrediting authority that it must submit additional corrective actions within 20 calendar days of receipt of the NELAP assessment team's response. The NELAP assessment team will review the accrediting authority's second corrective action response within 20 calendar days of receipt.

   2) If the second corrective action response submitted by the accrediting authority does not address satisfactorily all of the application deficiencies, the NELAP assessment team will make no further suggestions to the accrediting authority for correction of application deficiencies.

   3) If application deficiencies still remain after the assessment team's second attempt to resolve those deficiencies, the NELAP assessment team will document those deficiencies which are not resolved and recommend to the NELAP Director that:

      A) the accrediting authority's application for initial NELAP recognition be denied; or

      B) the accrediting authority's NELAP recognition be revoked.

e) If the initial application as submitted contained no deficiencies or if deficiencies were corrected as provided in subsection 6.3.3.2 (d), except those deficiencies requiring legislative or

rulemaking action as set forth in Section 6.5, the NELAP assessment team will schedule the on-site assessment as set forth in subsection 6.4.1 below.

f) If an accrediting authority elects to appeal denial or revocation of NELAP recognition resulting from the Section 6.3.3 application technical review process, an accrediting authority must follow the procedure set forth in Section 6.10 of this Chapter.

g) After review of the renewal NELAP-recognition application and supporting documents, the NELAP assessment team will schedule, when required, an on-site assessment of the accrediting authority's environmental laboratory accreditation program as set forth in Section 6.4 (a) and subsection 6.4.1 (a) below.

6.3.4 Notification of Changes to An Accrediting Authority's Program

a) For all changes in the accrediting authority's environmental laboratory accreditation program listed below, the NELAP Director shall be notified of changes to:

1) the authority to accredit laboratories as stated in the statutes, regulations and promulgating instructions establishing and governing the accrediting authority's environmental laboratory accreditation program,

2) the organizational structure including key personnel,

3) the rules, regulations, policies, guidance documents and standard operating procedures,

4) the mailing address and office location, telephone and telefacsimile numbers and electronic mail address, and,

5) the contractual arrangements, including contractor's personnel, for laboratory accreditation activities contracted out under authority of subsection 6.2 (c).

b) The notification to the NELAP Director shall be made within 30 calendar days of the change taking place in the accrediting authority's environmental laboratory accreditation program.

c) The NELAP Director may request further documentation or conduct on-site assessments to verify that changes in the accrediting authority's NELAP-recognized environmental laboratory accreditation program do not place that program in violation of the NELAC standards.

6.4 ON-SITE ASSESSMENT OF THE ACCREDITING AUTHORITY

a) On-site assessments of an accrediting authority's environmental laboratory accreditation program shall be conducted on a four-year cycle as follows:

1) An initial on-site assessment shall be conducted in conjunction with an accrediting authority's initial application process and every four years thereafter; and,

2) No on-site assessment of an accrediting authority's environmental laboratory accreditation program is required for the two-year renewal application immediately following an application for NELAP recognition where an on-site assessment was conducted.

b) The NELAP assessment team will arrange on-site assessments except as stated in subsection 6.4 (c) below at the mutual convenience of the parties.

c) The NELAP assessment team may make subsequent announced or unannounced on-site assessments of an accrediting authority's environmental laboratory accreditation program whenever such an assessment is necessary to determine the accrediting authority's compliance with the requirements of the NELAC standards.

6.4.1 Scheduling the On-Site Assessments

a) The NELAP assessment team shall contact the accrediting authority to schedule on-site assessments as set forth in Section 6.4 (a) above within 20 calendar days of the date the NELAP assessment team accepts an initial or renewal application.

b) The NELAP assessment team must send to the accrediting authority written confirmation of the logistics required to conduct the on-site assessment. The written confirmation shall include, but is not limited to:

1) on-site assessment date and agenda or schedule of activities,

2) copies of the standardized assessment checklists,

3) the names, titles, affiliations, and on-site assessment responsibilities of the NELAP assessment team members, and,

4) the names and titles of all accrediting authority staff that need to be available during the on-site assessment.

c) All on-site assessments shall be conducted no later than 50 calendar days following approval of the application.

6.4.2 Conducting the On-Site Assessment

a) The purpose of the on-site assessment is to verify compliance with the requirements of the NELAC standards including, but not limited to:

1) determining the accuracy of information contained in the accrediting authority's application and supporting documents;

2) determining whether the accrediting authority's implementation of its environmental laboratory accreditation program conforms with the information and data contained in the application and supporting documents; and,

3) observing, upon recommendation of the NELAP assessment team and the approval of the NELAP Director, an accrediting authority's laboratory assessor(s) conducting an on-site assessment of a laboratory seeking initial or renewal NELAP accreditation. The NELAP assessment team members shall not participate in the laboratory's assessment.

b) When conducting an on-site assessment, the NELAP assessment team shall, at a minimum:

1) review the accrediting authority's record keeping and documentation procedures;

2) conduct interviews with the accrediting authority's management and technical staff;

3) review selected laboratory accreditation cases;

4) review records of laboratory complaints, disputes and appeals; and,

5) review quality assurance and internal audit procedures employed by the accrediting authority.

c) The NELAP assessment team shall have access to all records of the accrediting authority's environmental laboratory accreditation program to determine compliance with the NELAC standards.

d) The NELAP assessment team shall have the opportunity to interview privately:

1) all management and technical staff of the accrediting authority's environmental laboratory accreditation program; and,

2) any NELAP-accredited laboratory receiving its accreditation from the applicant accrediting authority.

e) The NELAP assessment team must ensure that the assessment is conducted according to the schedule as set forth in subsection 6.4.1 (b)(1) and consists of the following:

1) an opening meeting,

2) the comprehensive on-site assessment of the accrediting authority's environmental laboratory accreditation program, and,

3) an exit interview to discuss all noted deficiencies.

f) The NELAP assessment team shall conduct all assessments in accordance with the NELAP standard operating procedure for conducting on-site assessments of accrediting authorities.

6.4.3 On-Site Assessment Reports

a) The NELAP assessment team will send by certified mail to the accrediting authority an on-site assessment report within 30 calendar days of completion of the on-site assessment. The report shall include, but is not limited to:

1) the date(s) of assessment;

2) the name(s) of the person(s) responsible for the report;

3) the NELAP recognition fields of testing for which initial recognition or renewal is sought; and,

4) the comments of the NELAP assessment team on the accrediting authority's compliance with the requirements of the NELAC standards.

b) If the on-site assessment does not reveal any deficiencies, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.

c) If deficiencies are noted during the on-site assessment, the report will:

1) identify any specific deficiencies noted during the on-site assessment,

2) include references to the specific NELAC standards, and,

3) provide suggested corrective action.

d) If the on-site assessment reveals deficiencies, the accrediting authority shall submit a plan of corrective action to the NELAP assessment team within 30 calendar days of receipt of the on-site assessment report.

1) The plan of corrective action must detail those specific actions taken or that will be taken by the accrediting authority to correct all deficiencies noted by the NELAP assessment team during the on-site assessment.

2) The plan of corrective action must include the accrediting authority's projected time to complete the corrective actions not yet complete at the time of the accrediting authority's response to the on-site assessment report.

3) Except for those deficiencies set forth in Section 6.5, the implementation of corrective actions must take place no more than 65 calendar days from receipt of the on-site assessment report.

e) The NELAP assessment team shall recommend to the NELAP Director revocation or denial of NELAP recognition for on-site assessment deficiencies for any accrediting authority that fails to submit a plan of corrective action within 30 calendar days as set forth in subsection 6.4.3 (d) above.

f) Within 20 calendar days of receipt of the accrediting authority's plan of corrective actions, the NELAP assessment team shall review the plan and respond in writing to the accrediting authority.

1) If the accrediting authority corrects all deficiencies, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.

2) If the accrediting authority's plan of corrective actions does not address all deficiencies, the NELAP assessment team will notify the accrediting authority by certified mail that it must submit another plan of corrective actions for the remaining deficiencies not covered by Section 6.5 within 20 calendar days of the accrediting authority's receipt of this notification.

g) The NELAP assessment team shall review the corrective actions for the remaining deficiencies within 20 calendar days of receipt of a subsection 6.4.3 (f)(2) response from the accrediting authority.

1) If all deficiencies are not corrected and the remaining deficiencies affect only certain fields of testing, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked for those fields of testing for which on-site assessment deficiencies remain.

2) If all deficiencies are not corrected and the remaining deficiencies affect the entire accrediting authority's environmental laboratory accreditation program, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked.

3) If the only remaining deficiencies require legislation or rulemaking as set forth in Section 6.5, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.

4) If remaining deficiencies are corrected, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.

h) If the NELAP assessment team determines that the accrediting authority has falsified information included in its application and supporting documents, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked.

6.5 ACCREDITING AUTHORITY'S REQUEST FOR EXTENSION OF TIME TO COMPLY WITH THE NELAC STANDARDS

a) For all accrediting authorities applying for NELAP recognition prior to July 1, 2000, and upon written request to the NELAP Director, through the NELAP assessment team, an extension of time, not to exceed two years, to correct deficiencies noted in the accrediting authority's application and/or deficiencies noted during the on-site assessment will be granted only:

1) when an applicant accrediting authority has an operating environmental laboratory accreditation program for the fields of testing for which it is seeking or renewing NELAP recognition, and,

2) when implementation of corrective actions to correct application and/or assessment deficiencies requires the accrediting authority to promulgate new or revised regulations, or

3) when implementation of corrective actions to correct application and/or assessment deficiencies requires the accrediting authority to seek new or revised legislation.

b) If the deficiencies continue to exist after two years from the date the extension was granted, the NELAP recognition granted as set forth in subsection 6.4.3 (g)(3) above will not be renewed.

c) The accrediting authority shall include in its request for an extension of time to comply with the NELAC standards a projected time table for correction of the application and/or assessment deficiencies.

d) For an accrediting authority seeking initial NELAP recognition on or after July 1, 2000, all NELAC requirements must be met prior to being granted NELAP recognition.

e) Regardless of the date on which applications for renewal of NELAP recognition of an accrediting authority are submitted, the extension of time provisions to correct deficiencies set forth in Section 6.5 of this Chapter shall remain in effect provided those deficiencies were caused by changes to the NELAC standards.

6.6 NELAP ASSESSMENT TEAM RECOMMENDATIONS TO THE NELAP DIRECTOR

a) All recommendations required by this Chapter from the NELAP assessment team to the NELAP Director must be made in writing.

b) All NELAP assessment team recommendations to the NELAP Director shall include the following documentation when applicable:

1) a recommendation to grant, maintain or revoke NELAP recognition in full or in part;

2) a summary of the reasons supporting the recommendation;

3) a copy of all application review letters sent to the accrediting authority and all corrective action response letters submitted by the accrediting authority to the NELAP assessment team;

4) a copy of all on-site assessment review letters sent to the accrediting authority and all corrective action response letters submitted by the accrediting authority; and,

5) a copy of the accrediting authority's requests for extension of time to implement corrective actions if legislative or additional rulemaking is required pursuant to Section 6.5.

c) A copy of any NELAP assessment team's recommendation with all supporting documentation to the NELAP Director also shall be furnished to the accrediting authority.

d) Within 20 calendar days of receipt of the NELAP assessment team's recommendation, the NELAP Director shall provide written notification to the accrediting authority of acceptance or rejection of the NELAP assessment team's recommendation.

e) The accrediting authority has the option to appeal a revocation or denial decision regarding NELAP recognition by the NELAP Director as set forth in Section 6.10 of this Chapter.

6.7 CERTIFICATE OF RECOGNITION TO THE ACCREDITING AUTHORITY

a) The NELAP Director will issue a certificate of NELAP recognition dated the day on which NELAP recognition is granted.

b) The certificate of NELAP recognition shall include the following items:

1) the name and address of the accrediting authority,

2) the fields of testing for which the accrediting authority is NELAP-recognized,

3) the date of the accrediting authority's most recent on-site assessment,

4) the expiration date of the accrediting authority's NELAP recognition which shall not be more than two years from the date of the most recent date granting NELAP recognition,

5) the signature of the NELAP Director,

6) a statement that the accrediting authority is in compliance with the NELAC standards,

7) a statement that the accrediting authority has been granted the authority to accredit environmental laboratories for the fields of testing for which the accrediting authority is NELAP-recognized,

8) a statement that continued NELAP recognition depends on compliance with the NELAC standards;

9) a seal incorporating the NELAP insignia; and,

10) a unique designator, such as date of issuance and a serial or certificate number.

6.8 USE OF ACCREDITATION BY NELAP ACCREDITED LABORATORIES

a) The accrediting authority shall have requirements for controlling the ownership, use and display of the accrediting authority's NELAP accreditation documents and for controlling the manner in which an accredited laboratory may refer to its NELAP accreditation and/or use of the NELAC/NELAP logo. These arrangements shall include, but are not limited to requirements that:

   1) NELAP accredited laboratories post or display their most recent NELAP accreditation certificate or their NELAP-accredited fields of testing in a prominent place in the laboratory facility;

   2) NELAP accredited laboratories make accurate statements concerning their NELAP accreditation fields of testing and NELAP accreditation status;

   3) NELAP accredited laboratories accompany the accrediting authority's name and/or the NELAC/NELAP logo with at least the phrase "NELAP accredited" and the laboratory's accreditation number or other identifier when the accrediting authority's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials; and,

   4) NELAP accredited laboratories not use their NELAP certificate, NELAP accreditation status and/or NELAC/NELAP logo to imply endorsement by the accrediting authority.

b) The accrediting authority shall have arrangements to ensure that NELAP accredited laboratories choosing to use the accrediting authority's name, making reference to its NELAP accreditation status and/or using the NELAC/NELAP logo in any catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, the NELAP accredited laboratory shall:

   1) distinguish between proposed testing for which the NELAP-accredited laboratory is accredited and the proposed testing for which the NELAP accredited laboratory is not accredited; and,

   2) include the NELAP-accredited laboratory's accreditation number or other identifier.

c) The accrediting authority shall have arrangements to ensure that the NELAP-accredited laboratories upon suspension, revocation or withdrawal of their NELAP accreditation shall:

   1) discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to their past NELAP accreditation status and/or display the NELAC/NELAP logo, and,

   2) return any certificates for NELAP accreditation to the accrediting authority.

d) The accrediting authority shall have arrangements to take suitable actions, including legal action, when incorrect references to the accrediting authority's NELAP accreditation, misleading use of the laboratory's NELAP accreditation status and/or unauthorized use of the NELAC/NELAP logo is found in catalogs, advertisements, business solicitations, proposals, quotations, laboratory analytical reports or other materials.

6.9 REQUIREMENTS OF THE NELAP

a) The NELAP assessment team shall submit all documents, letters, assessment notes, checklists, etc. to the NELAP headquarters office within:

   1) 30 calendar days of the final decision on the application by the NELAP Director, or

   2) 30 calendar days after the final recommendation by the Accrediting Authority Review Board (AARB) as set forth in Section 6.10 of this Chapter.

b) The NELAP Director shall maintain complete and accurate records of all documents relating to the application and on-site assessment processes for each accrediting authority for a minimum of ten years or a longer period of time if required by contractual obligations or pertinent federal laws and regulations.

c) The NELAP Director shall maintain an electronic directory to display the status of all NELAP-recognized accrediting authorities, pending applications for NELAP recognition and currently scheduled announced on-site assessments.

6.9.1 NELAP Assessment Team

a) The NELAP Director shall appoint NELAP assessment team members as set forth in Section 6.3.3 (a)(4) and delegate the responsibilities required by this Chapter to assessment teams.

b) During the time prior to the NELAP issuing the first NELAP recognitions to accrediting authorities, the NELAP assessment team shall consist of at least one member who is an employee of the USEPA and at least one member who is an employee of another operating territorial, State or federal environmental laboratory accreditation program.

c) No later than two years from the date that the first accrediting authority recognitions are announced, the NELAP assessment team shall consist of at least one member who is an employee of the USEPA and at least one member who is an employee of a NELAP-recognized accrediting authority.

d) Prior to conducting the on-site assessment of an accrediting authority's program, at least one member of the NELAP assessment team shall complete the NELAP Accrediting Authority Assessor Training Course.

e) The NELAP assessment team shall:

   1) have at least one member of the NELAP assessment team who meets the education, experience and training requirements for laboratory assessors specified in the NELAC standards, Chapter Three, On-Site Assessment; and,

   2) have at least another member with experience that includes at least one of the following:

      A) certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;

      B) one year of experience implementing federal or State laboratory accreditation rulemaking;

      C) laboratory accreditation management; or,

D) one year experience developing or participating in laboratory accreditation programs.

3) All experience required by this subsection must have been acquired within the five year period immediately preceding appointment as a NELAP assessment team member.

6.10 APPEALING DECISIONS TO DENY OR REVOKE NELAP RECOGNITION

a) Within 20 calendar days of official notification of the NELAP action on an accrediting authority's application for NELAP recognition, the accrediting authority shall notify the NELAP Director if the accrediting authority chooses to appeal the NELAP action. If the accrediting authority does not receive satisfactory resolution, the accrediting authority may request a review by the AARB. This request shall be made within 20 calendar days of the Director's decision.

b) If any AARB member is not free of financial connection to the appealing accrediting authority, or is not free of any other relationship that would bias their review of the case, that AARB member shall be excluded from participating in deliberations on that appeal.

c) The AARB shall carry out an independent review of all relevant parts of the record.

d) The AARB shall conduct interviews with the accrediting authority and the NELAP Director. The AARB also may conduct interviews with the NELAP assessment team member(s) or other individuals deemed appropriate by the AARB.

e) If the accrediting authority so desires, an opportunity for both the NELAP and the accrediting authority to meet jointly with the AARB shall be granted.

f) The AARB shall complete its review and render a final recommendation to the NELAP Director within 90 calendar days following receipt of the notice of appeal. This time frame may be extended by mutual agreement of all parties up to a maximum of 60 additional calendar days.

g) The ultimate decision to grant, maintain, deny or revoke NELAP recognition remains with the NELAP Director. The NELAP Director shall notify the appealing accrediting authority of his/her decision within 20 calendar days of receipt of the recommendation from the AARB.

h) Accrediting authorities shall be limited to one appeal for each application cycle.

i) Upon filing an appeal, the status existing prior to the decision will remain in effect pending resolution of the appeal.

National Environmental Laboratory Accreditation Conference, Accrediting Authority

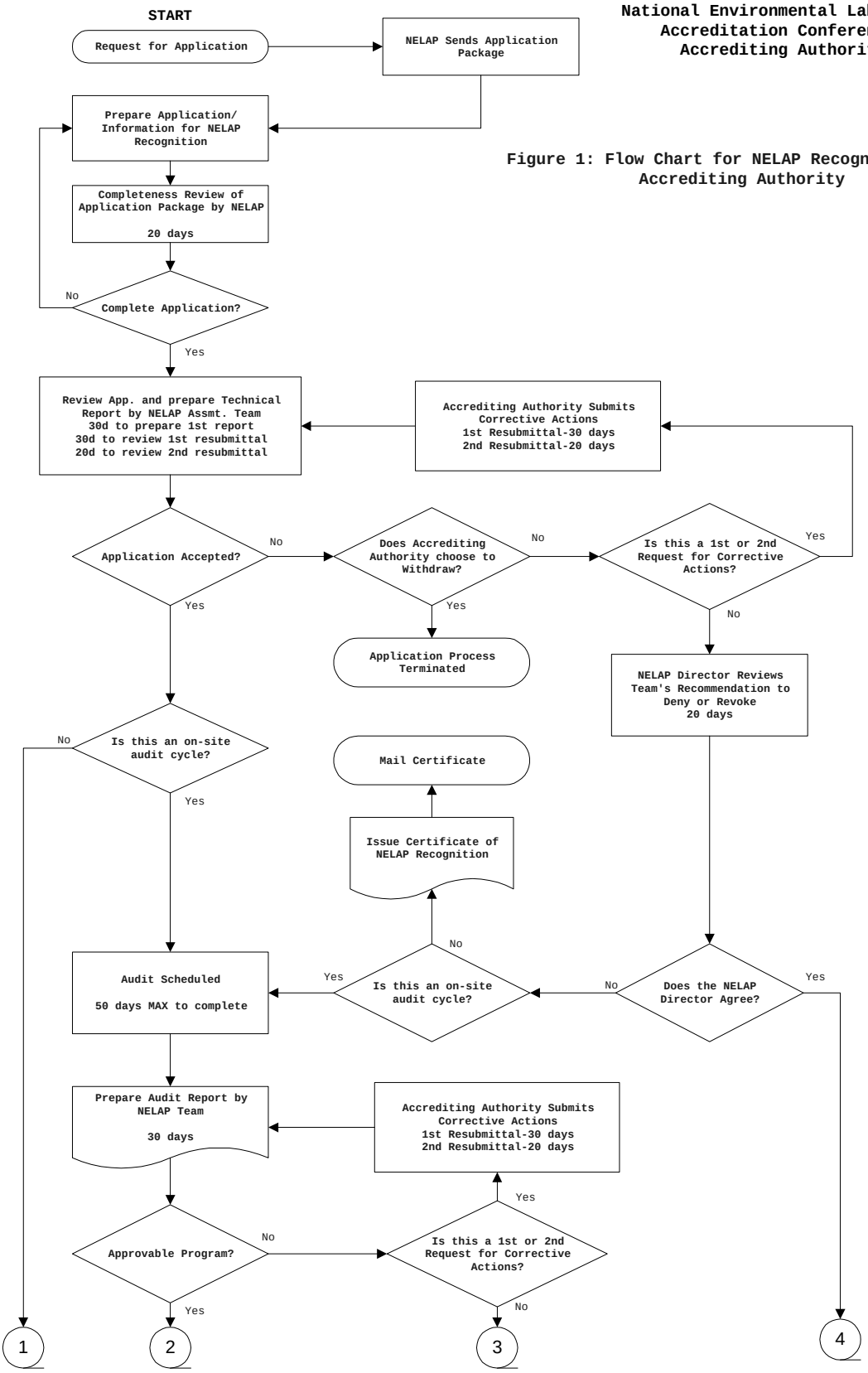

Figure 1: Flow Chart for NELAP Recognition of An Accrediting Authority

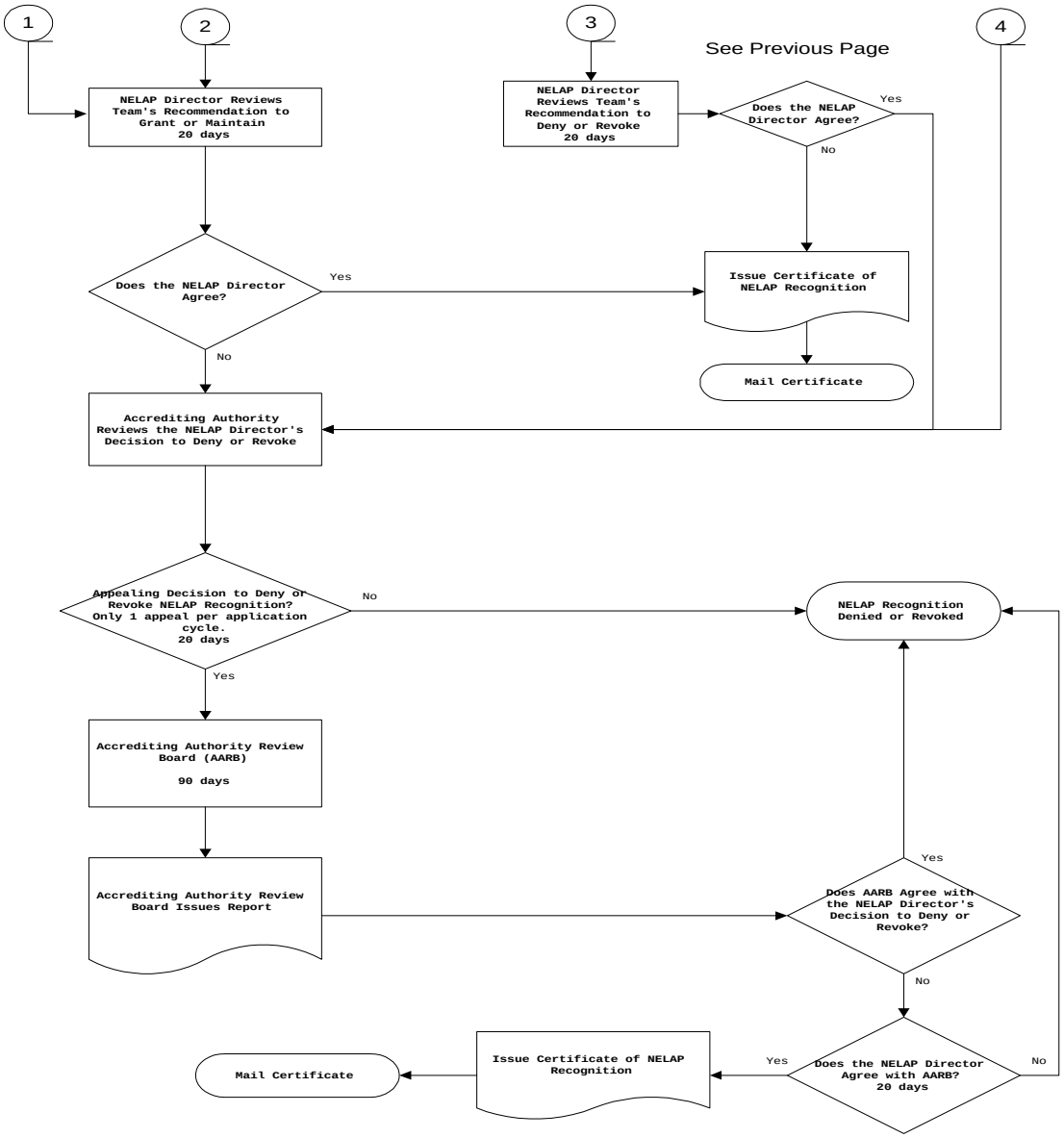

Figure 1: Flow Chart for NELAP Recognition of An Accrediting Authority