National Environmental Laboratory **Accreditation** Conference

nelac

PROGRAM POLICY AND STRUCTURE

PROPOSED CHANGES

May 15, 2002

Note that the NELAC standards now have two significant dates: 1) the date the standards were approved at the annual meeting, and 2) the date the standards are effective and must be implemented. This is especially important as some portions of the standards have different effective dates. The approval date is part of the document control header on each page. The cover of each chapter shows both the approval date and the effective date. Changes approved for implementation at a time other than the effective date (on the chapter cover) are noted in the chapter, showing the approved text and its effective date.

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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

[Effective July 1, 2001]

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 accreditation 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 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.

[Effective July 1, 2001]

c) To provide for recognition 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.

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

[Effective July 1, 2001]

e) To incorporate, to the extent applicable, ISO 17025, 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

[Effective July 1, 2001]

1.4.2.1 Scope of NELAC

The scope of NELAC shall encompass the necessary environmental sampling and 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. Organizations are encouraged to use the NELAC standards for all other environmental sampling and testing.

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 accreditation promulgated by any of the accrediting authorities.

1.4.2.3 Exemptions

The NELAC standards apply to federal and state mandated testing. Exceptions to EPA-mandated testing include those 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.

[Effective July 1, 2001]
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 recognition, accepts 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.

[Effective July 1, 2001]
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 accreditation (see section 1.8), laboratories may obtain primary accreditation for that particular field of accreditation 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.

[Effective July 1, 2001]
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 accept the laboratory accreditations through recognition, 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.

[Effective July 1, 2001]
1.5.3 Recognition

Recognition means that an accrediting authority will accept the accreditation status of a laboratory issued by another NELAP accrediting authority. This principle of recognition is an element of the national accreditation standard to which all accrediting authorities are held. In accepting the accreditation status of a laboratory through recognition, 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.

Recognition among the environmental laboratory accreditation authorities is necessary to the success of a national program. The essential ingredient of recognition 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 recognition is equitable.

Federal accrediting authorities shall serve as the accrediting authority only for governmental laboratories. Non-governmental laboratories shall not claim either primary or secondary accreditation by a federal agency, even if the laboratory is performing analyses under contract to that agency.

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. Such policies shall have effective and expiration dates and/or shall be referred to the appropriate committee for potential incorporation into the standards by a NELAC vote. 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) shall be an independent body composed of five voting members and one non-voting member. Each member shall be appointed for a five-year term.

a) The non-voting member shall be a representative of the USEPA and appointed by the NELAP Director. The appointment should be rotated among the EPA Regions and EPA Headquarters.

b) The five voting members shall consist of one federal accrediting authority official and four state accrediting authority officials, of which at least three must be from NELAP-recognized state accrediting authorities.

    1) The state accrediting authority officials should be from different EPA Regions.

    2) The appointments must be made in such a manner that the correct mix of membership is maintained at all times. Any AARB member appointed prior to July 1, 1999 will remain an AARB member even though the correct mix of membership may not be attained until July 1, 2004.

c) Appointments to the AARB are made by the NELAP Director after consultation with the NELAC Board of Directors. The Director will solicit nominees from the NELAC stakeholders and present them to Board of Directors. Nominations are to be submitted to the NELAP Director at least three months prior to the NELAC annual meeting.

d) Voting members of the AARB shall not be NELAP staff, on the NELAC Board of Directors or a member of a NELAC standing committee. The AARB annually selects one of its members to serve as its chair.

e) The AARB has responsibilities to:

    1) monitor NELAP to assure that EPA is following the NELAC standards for recognizing accrediting authorities;

    2) serve as a review board for accrediting authorities that have been denied NELAP recognition or have had such recognition revoked (see Chapter 6, section 10), and providing advice to the NELAP Director, who will make the final decision;

    3) report on its activities to the NELAC Board of Directors at each annual meeting;

    4) conduct an annual assessment of the NELAP process for recognizing accrediting authorities in accordance with the NELAC standards.

1. The AARB shall report its findings at the general opening session of each NELAC annual meeting; and

2. The report of the annual assessment shall be provided for posting on the NELAC web site; and

5) provide advice on issues referred by the NELAP Director, which may include matters raised by entities other than the accrediting authorities.

1.6.4 The Participants in NELAC

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.

[effective July 1, 2001]
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 accreditation.

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 recognition 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

Prior to NELAP initial accreditation and to maintain continuing accreditation, laboratories must meet all relevant EPA regulatory requirements, including quality assurance/quality control requirements. Laboratories must also 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.

For laboratory testing, accreditation may be granted in conformance with a Field of Accreditation tiered approach as follows:

Matrix — Technology/Method — Analyte/Analyte Group.

When adopted by the Conference, for Field Sampling, accreditation will be granted in conformance with a Field of Accreditation tiered approach as follows:

Matrix — Field Sampling Method — Analyte/Analyte Group.

Technology/method is a specific arrangement of analytical instruments and detection systems, and/or preparation techniques combined with a test method as defined in the glossary. Examples of technologies are GC/ECD, ICP/MS, etc. Technology groupings will be published on the NELAC Website. The tables will be amended from time to time as deemed appropriate by the Program Policy and Structure Committee.

Matrix is a description of sample type. Matrices include 1) Drinking Water, 2) Non-Potable Water (to include all aqueous samples that are not public drinking water, e.g. RCRA water samples, treatment plant additives, etc.), 3) Solid and Chemical Materials (to include soils, sediments, other solids and non-aqueous liquids), 4) Biological Tissues (not as yet defined in the scope of NELAC) and 5) Air and Emissions (to include ambient air and stack emissions). Other more specific matrices are used elsewhere in the standards.

Analyte/Analyte Group indicates that a laboratory may be accredited by individual analyte or for a group of analytes. If accredited by analyte group, the laboratory must perform a Demonstration of Capability (DOC) for each analyte, and the laboratory must perform all required QC and satisfactorily meet the PT requirements as defined in Chapter 2. It is possible that PT samples may not be available for all analytes. Accrediting authorities may grant accreditation by analyte group. All accrediting authorities accrediting by analyte group must use the same analyte groups, which will be determined by the Program Policy and Structure Committee and published on the NELAC web site.

Typical examples of Fields of Accreditation using the tiered approach, including PBMS examples, are:

Drinking Water — HPLC - UV/EPA 555 — Pentachlorophenol

Non-Potable Water — GC - MS/EPA 625 — PAHs

Solid and Chemical Materials — ICPAES/EPA 6010 — Arsenic

Drinking Water — GC - ECD/EPA 505 — Atrazine

Drinking Water — CVAA (with EPA 1631 extraction)/PBMS — Mercury

Non-Potable Water — Headspace GCMS/PBMS — Tetraethyl Lead

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/ 8260). 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.

Additional accrediting authorities may recognize a laboratory's primary accreditation for certain tiers without additional review and on-site assessment.

For example, under a tiered approach:

1. A laboratory's home state (State A) only provides accreditation for Drinking Water. As primary accrediting authority, State A accredits the laboratory for the Field of Accreditation

   Drinking Water — GC-ECD/EPA 505 — Atrazine.

2. The laboratory then applies to a second state (State B) to be its primary accrediting authority for the Field of Accreditation

   Non-Potable Water — GC-ECD/EPA 612 — 1,2-dichlorobenzene.

3. State B recognizes the technology GC-ECD, since that technology was accredited by State A: i.e., State A has examined the instrumentation, checked run logs, interviewed the analyst(s) operating that instrument, etc.

4. To accredit the laboratory for the requested Field of Accreditation, State B may only require the SOP (for Method 612), the DOC, other QC data and satisfactory PT results (where PT's are available, see Chapter 2) for the analyte 1,2-dichlorobenzene. State B may obtain these documents from the laboratory and PT providers as appropriate, review them and approve them without the need for an on-site assessment. If there is any concern about the laboratory performance, the NELAC standards allow any accrediting authority to conduct announced or unannounced on-site assessments at any time.

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

[Effective July 1, 2001]
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 NELAP Director.

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 accreditation. 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)

[Effective July 1, 2001]
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); Detection Limits (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).

[Effective July 1, 2001]
1.8.8 Radiochemistry Requirements

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

1.8.9 Microscopy Requirements

(To be developed)

[Effective July 1, 2001]
1.8.10 Field Measurement Requirements

(To be developed)

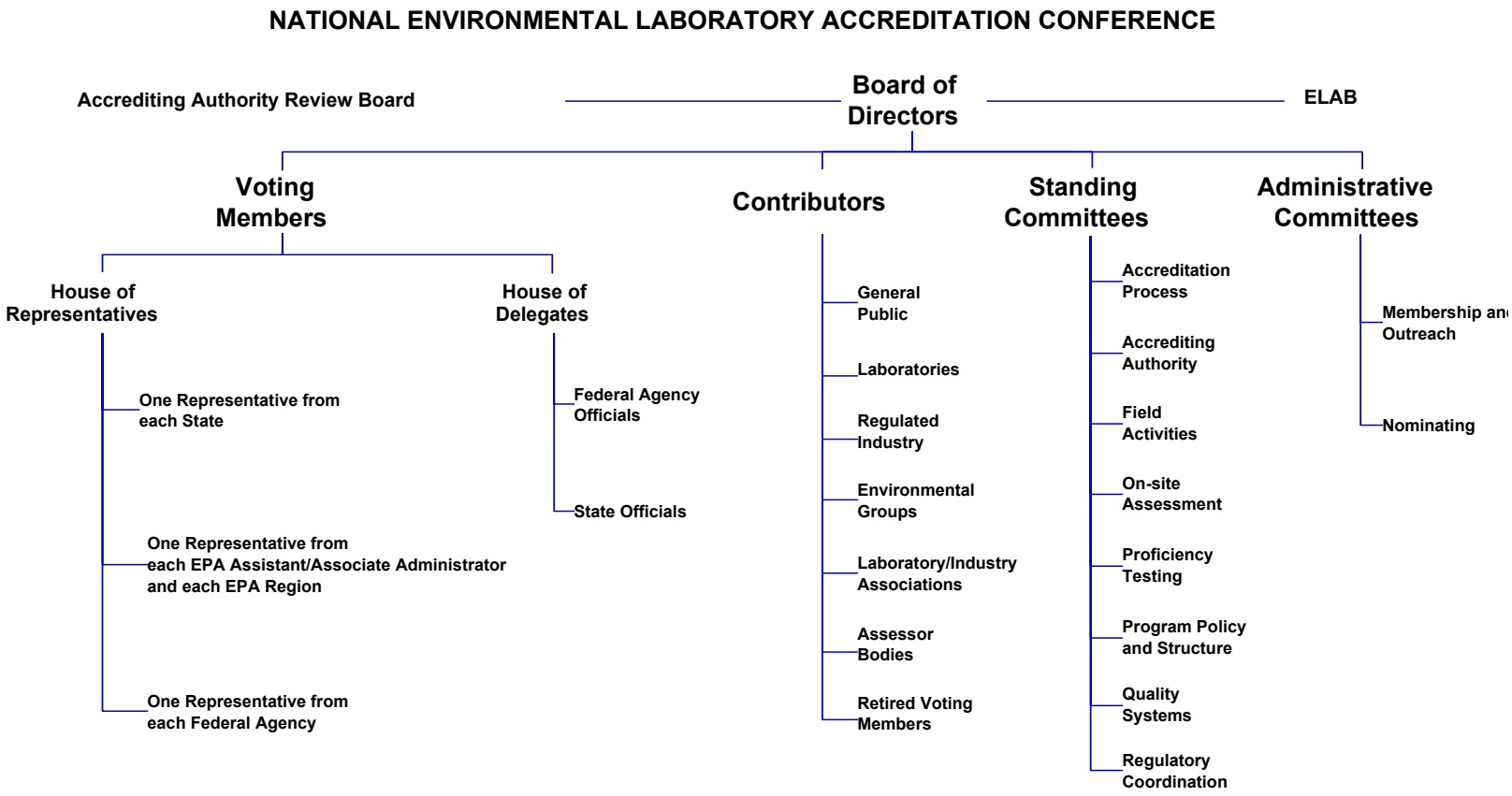

Figure 1-1. NELAC Structure

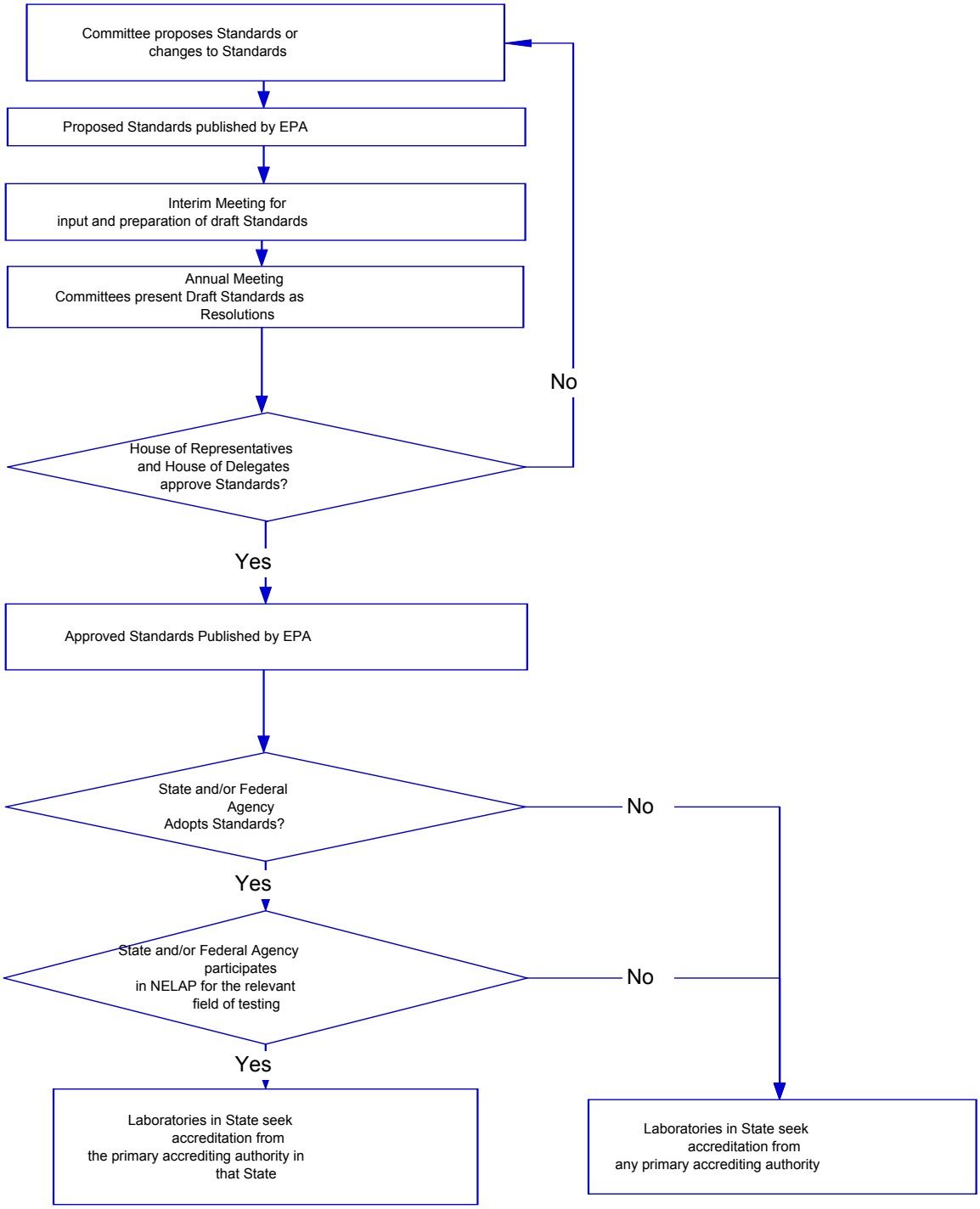

Figure 1-2. Flowchart for Standards Development and Implementation

PROGRAM POLICY AND STRUCTURE
APPENDIX A

GLOSSARY

APPENDIX A - 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]

Accrediting Authority Review Board (AARB): five voting members from Federal and State Accrediting Authorities and one non-voting member from USEPA, appointed by the NELAP Director, in consultation with the NELAC Board of Directors, for the purposes stated in 1.6.3.e. (NELAC) [1.6.3]

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)

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)

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. Blanks include:

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

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)

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

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)

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

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)

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 and state 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 identified, measured, and reported with confidence that the analyte concentration is not a false positive value. 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)

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)

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)

[effective July 1, 2001[
Field of Accreditation: (previously Field of Testing) NELAC's approach to accrediting laboratories by matrix, technology/method and analyte/analyte group. Laboratories requesting accreditation for a matrix-technology/method-analyte/analyte group combination or for an updated/improved method are required to submit only that portion of the accreditation process not previously addressed (see NELAC, section 1.8 ff). (NELAC)

Field of Proficiency Testing: NELAC's approach to offering proficiency testing by matrix, technology, and analyte/analyte group.

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)

Governmental Laboratory: as used in these standards, a laboratory owned by a Federal, state, or tribal government; includes government-owned contractor-operated laboratories. (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)

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)

International System of Units (SI): the coherent system of units adopted and recommended by the General Conference on Weights and Measures. (CCGPM) (VIM 1.12)

Laboratory: a body that calibrates and/or tests. (ISO 25)

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. 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)

Legal Chain of Custody Protocols: procedures employed to record the possession of samples from the time of sampling until analysis and are performed at the special request of the client. These protocols include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. **In addition, these protocols document all handling of the samples within the laboratory**. (NELAC)

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 substrate of a test sample.

Field of Accreditation Matrix: these matrix definitions shall be used when accrediting a laboratory (see Field of Accreditation).

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

Non-Potable Water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

Solid and Chemical Materials: includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.

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

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

Quality System Matrix: These matrix definitions are an expansion of the field of accreditation matrices and shall be used for purposes of batch and quality control requirements (see Appendix D of Chapter 5). These 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 and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent 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: see Test Method

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-governmental Laboratory: any laboratory not meeting the definition of the governmental laboratory. (NELAC)

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 measurement processes which will 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]

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)

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: levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported at a specified degree of confidence . (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)

[effective July 1, 2001[
Recognition: previously known as 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]

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)

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 Tracking: procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples. (NELAC)

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 **Recognition** 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)

Statistical Minimum Significant Difference (SMSD): the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased. (NELAC)

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]

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

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

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 or published by a recognized authority. (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)~~ the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

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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