

National Environmental
Laboratory Accreditation
Conference

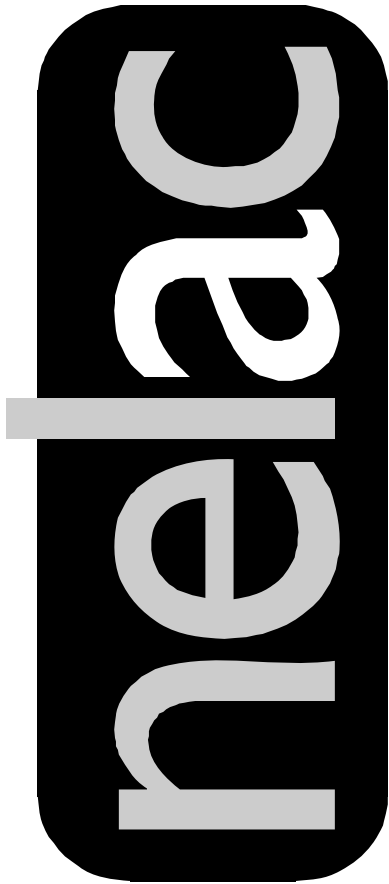
**NELAC
Standard**

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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Page numbering for each chapter appears in the header at the chapter.



**National Environmental
Laboratory Accreditation
Conference**

**PROGRAM POLICY
AND STRUCTURE**

Approved June 5, 2003
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1.0 PROGRAM POLICY AND STRUCTURE

1.1 INTRODUCTION

Chapter One describes the scope of NELAC, the roles and responsibilities of the federal and state government participants, the process for standards review and adoption, and the structure of fields of accreditation. (A portion of this section was removed and placed in the *NELAC 101 Handbook*).

1.2 SCOPE

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.

1.2.1 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.

1.2.2 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.

1.2.3 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.

1.3 APPLICATION OF NELAC STANDARDS TO SMALL LABORATORY OPERATIONS

This language was removed and placed in the *NELAC 101 Handbook*.

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

1.4.1 EPA

EPA provides support to NELAC as stated in the bylaws. EPA assists NELAC by providing an EPA document number for all final standards

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

1.4.1.1 National Environmental Laboratory Accreditation Program

EPA administers the National Environmental Laboratory Accreditation Program (NELAP), which oversees 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) reporting to NELAC on the evaluation of the conformance of State and federal accreditation program activities to NELAC standards;
- d) reporting to NELAC on results of evaluations of proficiency testing sample providers and assessor training programs; and
- e) approving supplemental accreditation requirements proposed by accrediting authorities (see Section 1.6.2).

1.4.2 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.

1.4.2.1 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.

1.4.2.2 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.

1.4.2.3 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 1.2). 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 recognition, accepts the accreditation of a primary accrediting authority.

1.4.2.3.1 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 or its agent 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 accreditation (see Section 1.6), 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.

1.4.2.3.2 Responsibilities of Secondary Accrediting Authorities

A secondary accrediting authority must be a NELAP recognized accrediting authority. A secondary accrediting authority shall require laboratories to submit an application, should 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.

1.4.2.3.3 Accreditation Fees

Accrediting authorities may adopt and impose laboratory accreditation fees.

1.4.3 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 1.4.2.3.2. 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.

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. (A portion of this section was removed and placed in the *NELAC 101 Handbook*).

1.4.4 Joint Federal and State Roles

This language was removed and placed in the *NELAC 101 Handbook*.

1.4.5 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.

1.4.6 Other Parties

This language was removed and placed in the *NELAC 101 Handbook*.

1.4.7 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-d) This language was removed and placed in the *Policy on Formation of the Accrediting Authority Review Board (AARB)*.

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, 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.

1.5 CONDUCT OF CONFERENCE BUSINESS

This section was removed and placed in the *NELAC Standards Review Committee Consolidated Standard Operating Procedures*.

1.6 ORGANIZATION OF THE ACCREDITATION REQUIREMENTS

1.6.1 Fields 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 or Analyte Group, or

Matrix – Technology – Analyte or 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 or Analyte Group.

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

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 or 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. Typical examples of Fields of Accreditation using the two approaches are:

Matrix – Technology/Method – Analyte or Analyte Group

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

Matrix – Technology – Analyte or Analyte Group

Non-Potable Water – CVAA (with EPA 1631 extraction) – Mercury

Non-Potable Water — Headspace GCMS — Tetraethyl Lead

The following example shows the tiered approach applied to a laboratory seeking accreditation for

a specific method. 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 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.

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.

1.6.2 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.

PROGRAM POLICY AND STRUCTURE
APPENDIX A

GLOSSARY

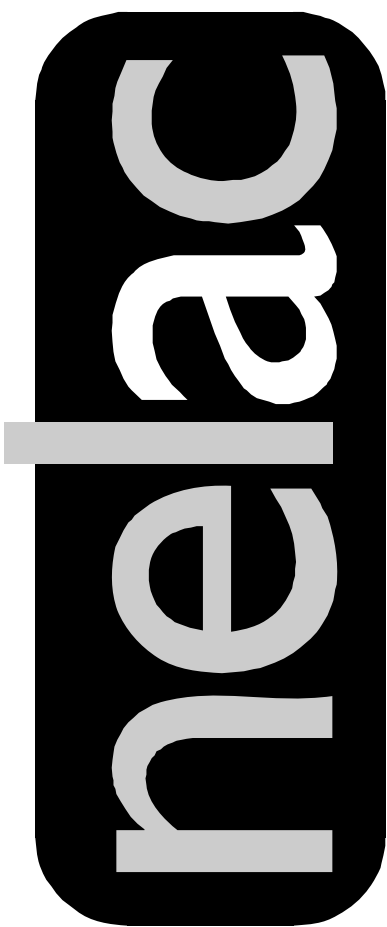
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APPENDIX A - GLOSSARY

Glossary: Administrative definitions

This language was removed and placed in the *NELAC Standards Review Committee Consolidated Standard Operating Procedures*.

Glossary: Technical definitions

This language was removed and placed in the *NELAC 101 Handbook*.



**National Environmental
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PROFICIENCY TESTING

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2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

For fields of accreditation for which proficiency testing (PT) samples are not available from a designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) (e.g., National Institute of Standards and Technology (NIST)) accredited 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 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), F (Environmental Toxicology), and G (Radiochemistry). 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 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) This language was removed and placed in the *NELAC 101 Handbook*.
- 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

This language was removed and placed in the *NELAC 101 Handbook*.

2.1.3 Fields of Proficiency Testing

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

- a) matrix,
- b) technology/method, and
- c) analyte/analyte group

Current NELAC fields of proficiency testing are located on the NELAC Website.

Note: Laboratories are permitted to analyze one PT sample by multiple methods for a given analyte within a technology. If a laboratory reports more than one method per technology per study, an unacceptable result for any method would be considered a failed study for that technology for that 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.

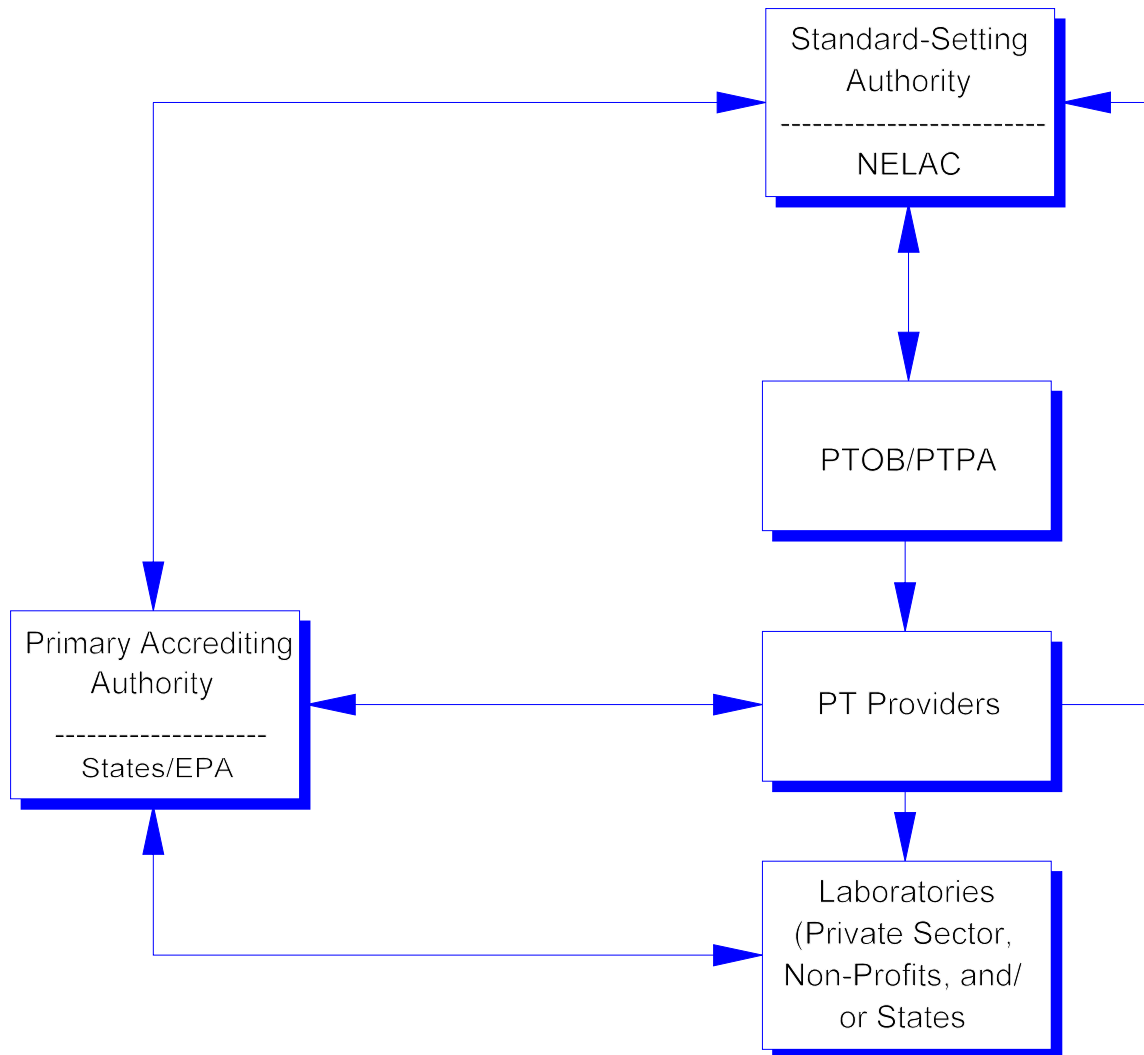


Figure 2-1. NELAP Proficiency Testing

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, and the PTOB/PTPA. 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. PT Providers may not supply PT samples outside their Fields of Accreditations as determined by the PTOB/PTPA.

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. (A portion of this section was removed and placed in the *Standard Operating Procedure for Evaluating Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor*).

2.2.3 Laboratories

Laboratories that seek to obtain or maintain accreditation shall perform analyses of PT samples for each field of proficiency testing as defined in Section 2.1.3. PT samples shall be obtained from 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.

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 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-proficiency testing basis, as described in Section 2.1.3. As NELAC standards, PT acceptance criteria and codes are revised and expanded, PT providers shall modify their operations to conform. PT providers are encouraged to modify their operations as soon as possible. The timeline for implementation shall be no more than six months from the date the revisions and expansions are posted on the NELAC website.

2.3.1 PT Provider Accreditation

A provider of PT samples for NELAC accreditation must be accredited by a Proficiency Testing Oversight Body (PTOB)/PTPA that meets the NELAC PTOB/PTPA requirements contained in this Chapter and associated appendices. The PTOB/PTPA communicates the names of PT Providers that meet the NELAC requirements to the NELAC Board of Directors. A listing of organizations that meet the NELAC PTOB/PTPA requirements is available from the Chair of NELAC.

2.3.2 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.

2.3.3 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 except as described in Section 2.7.3. The PT Providers shall neither provide inappropriate assistance to the laboratories nor encourage the non-routine analysis of the PT samples.

2.3.3.1 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 field of proficiency testing shall be determined by the PT Board and shall be evaluated and updated, as necessary.

2.3.3.2 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 field of proficiency testing.

2.3.4 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.

2.3.4.1 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.

2.3.5 Generation of Study Reports

Each PT Provider shall evaluate the data and issue a report to the laboratories within 21 calendar days of the close of each study. The report shall be issued within the same 24 hour period to the participating laboratory and the Primary Accrediting Authority(s) as designated by the laboratory.

2.3.6 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.

2.3.7 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.

2.3.8 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 field of proficiency 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 field of proficiency 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 proficiency 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, 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 opening of the study (i.e., first day that samples are shipped or available to laboratories). 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.

When analyzing a PT sample, a laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.

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 (*routine or supplemental studies*) 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 PT Board 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:

- a) Provider information:
 - ! Provider name and PTOB/PTPA accreditation number in the header.
- b) Laboratory information:
 - ! Laboratory name and address (location) of the laboratory, in the header. Note: This is not the address of the corporate headquarters but the address of the actual laboratory completing the testing.

- ! Primary Accrediting Authority ID or USEPA ID, if applicable, in the header. Name, title and telephone number of the laboratory point of contact, in the header or cover letter.

c) Study information:

- ! Study number and study type, in the header.
- ! Opening date and closing date of the study, in the header.
- ! Date of amended report, if applicable, in the header.

d) Report information:

- ! Analyte name for each analyte included in the standard.
- ! Method description.
- ! Laboratory value as reported.
- ! Assigned values and acceptance values reported to three significant figures.
- ! The acceptable/not acceptable status.
- ! A "No evaluation" score for reported values containing alpha characters.
- ! An indication of "Not reported" when an analyte within a PT sample is left blank.
- ! An indication of the length of the report, presented by either Page X of Y or the total number of pages with each page consecutively numbered.

This report shall be sent no later than 21 calendar days from the study closing date to the participating laboratories and the appropriate Primary Accrediting Authority(s) as designated by the laboratory. This report (hardcopy and electronic format) shall be sent to the laboratory and its Primary Accrediting Authority within the same 24 hour period. If the report and other PT study information is available in electronic format, it shall be available only to the designated laboratory representatives who participated in the PT study and the Primary Accrediting Authority. 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 field of proficiency 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 or Continuing PT Studies

A laboratory seeking to obtain or maintain accreditation shall successfully complete two initial or continuing PT studies for each requested field of proficiency testing within the most recent three rounds attempted. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date. Successful performance is described in Appendix C. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of proficiency testing and maintain a history of at least two acceptable PT studies for each field of proficiency testing out of the most recent three. For initial accreditation, the laboratory must successfully analyze two sets of PT studies, the analyses

to be performed at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study.

Initial or continuing PT Studies must meet all applicable criteria described in this chapter and associated appendices.

2.7.3 Supplemental PT Studies

A NELAP-accredited laboratory may elect to participate in supplemental PT studies when the laboratory desires to add field(s) of proficiency testing to their scope or when the laboratory fails an initial or continuing PT study and wishes to re-establish its history of successful performance. These additional studies are not distinguished from the initial or continuing PT studies except as described in this section.

Analysis dates of supplemental PT studies must be at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For supplemental studies, laboratories report to their PT Provider results for all analytes for which they are demonstrating corrective action or requesting an expansion of their existing accreditation.

2.7.3.1 Supplemental PT Studies for Demonstrating Corrective Action

A laboratory that has attained NELAP accreditation is required to maintain acceptable performance in PT studies conducted on a semiannual schedule. If an accredited laboratory fails to maintain a record of passing two out of the most recent three PT studies, it may be subject to loss of accreditation for one or more fields of accreditation in its current scope of accreditation. A laboratory that is out of compliance with this PT requirement may choose to participate in a Supplemental PT Study for Demonstrating Corrective Action. Corrective Action PT samples must meet the following criteria.

- a) The standard must be obtained from a PT Provider that meets the accreditation requirements of NELAC.
- b) The standard must be from a lot that has been demonstrated to have met all of the design, testing, and verification requirements of Chapter 2 and associated Appendices. PT samples from previously released NELAC compliant PT studies may be used in Corrective Action PT studies so long as they are within the stability period (e.g., an expiration date) for that sample.
- c) The PT provider cannot supply the laboratory with a sample that has been previously sent to the laboratory. The original sample tracking ID must be masked and the sample tracking ID shall be unique. (See Chapter 2, section A.5.2)
- d) For corrective action supplemental studies, the assigned values for all analytes requested by the laboratory must not be equal to zero with the exception of the qualitative PCB group and qualitative microbiology.

All other aspects of Supplemental PT studies for Demonstrating Corrective Action including scoring and distribution of final reports must meet all other requirements of the NELAC PT program.

2.7.3.2 Supplemental PT Studies for Expanding an Accredited Laboratory's Scope of Accreditation

A laboratory that has attained NELAC accreditation may add fields of accreditation to its current scope of accreditation. As part of the request to expand its scope of accreditation, the laboratory is required to submit to its Primary Accrediting Authority, results of participation in two successful PT studies. The laboratory may use the results of a PT study that meets the requirements of either Section 2.7.2 or 2.7.3.1. After the laboratory is granted accreditation for the requested fields of testing (FOT), the laboratory is required to participate in regular semiannual PT studies.

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 field of proficiency 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 or Continuing PT Studies.

2.7.5 Second Failed Study

The PT Provider shall report laboratory PT performance results to the Primary Accrediting Authority(s) as designated by the laboratory within the same 24 hour period that it reports the results to the laboratory. If a laboratory fails a second study out of the most recent three for a given analyte, as described in Section 2.7.4, the Primary Accrediting Authority shall take action, pursuant to Chapter Four, within 60 calendar days. The Primary AA shall also determine the accreditation status for all technologies/methods for which unacceptable results were reported for the analyte(s) in each 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 NELAC 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

PTOB/PTPA which currently accredits the PT Provider for the particular analyte(s) and matrices. The AA shall follow all procedures for filing complaints as specified by the PTOB/PTPA. If the AA is not satisfied by the response of the PTOB/PTPA which granted the accreditation, the AA shall submit a written complaint to the PT Board. The PT Board shall evaluate the complaint. If the complaint is determined to be valid, then the PT Board shall notify the PTOB/PTPA of any steps that may result in the revocation of the PTOB/PTPA being recognized by NELAP as a 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 that field of accreditation, or may require the laboratories 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 17025, (General Requirements for the Competency of Testing and Calibration Laboratories) and the relevant sections 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 PT Board 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, 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 the PT Provider's 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. (A portion of this section was removed and placed in the *Standard Operating Procedure for Evaluating Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor*).

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. For Supplemental PT studies for Demonstrating Corrective Action, the requirements in section 2.7.3.1 of the standard shall apply.

A.5.2 Procedures for Tracking Studies

PT Providers must have procedures in place to track which laboratories have received which studies if the PT Providers are following section 2.7.3.1. These procedures shall include a written SOP and specific, auditable tracking methods.

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 NELAC designated PTOB/PTPA shall review the data from 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 PT Board 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

The PT Provider shall prepare a written summary of all written complaints regarding technical aspects of the studies and the corrective action taken for every complaint. This report shall be available to the PTOB/PTPA on demand. All PT Provider complaints that remain unresolved after 90 days shall be referred to the PTOB/PTPA.

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.

If the provider loses PTOB/PTPA approval it shall lose NELAP approval to supply samples for the NELAC PT program. (A portion of this section was removed and placed in the *Standard Operating Procedure for Evaluating Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor*).

A.10 NOTIFICATION OF SAMPLE INTEGRITY

The PT Pprovider is responsible for notifying all laboratories, PTOB/PTPA and Primary Accrediting Authorities designated by the laboratory when a particular analyte was determined not to meet the requirements of Appendix B within 21 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

One or more specific analyte(s) may not be included in a sample, yet those analyte(s) shall be counted and scored with the analytes that are present in the PT study. The value assigned to these unspiked analytes would be zero. The PT Provider shall prepare samples including a minimum number of analytes 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 \times 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.1.3 PT Sample Matrix

Refer to the NELAC Glossary for definition of matrices. Note: PT samples are not currently available for all matrices. Refer to the NELAC field of proficiency testing lists for sample availability.

B.1.4 PT Sample Composition for Solid Matrices

Soil PT samples shall be well-characterized natural soil and cannot contain 100% sand.

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 for each PT study shall be available ONLY to the designated laboratory representatives participating in that study. 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 field of proficiency testing basis.

C.1 ANALYTE ACCEPTANCE LIMITS

Acceptance limits are established for each analyte as described in this appendix. The tables containing all analyte acceptance limits established by the PT Board and from the USEPA Criteria Document shall be posted on the NELAC Website and reviewed annually by the PT Board.

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 field of proficiency testing 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 field of proficiency testing 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 PT Board

For analytes not included in the "National Standards for Water Proficiency Testing, Criteria Document," Proficiency Test providers shall use acceptance limits established by the PT Board and shall be made available to PTOB/PTPA-approved PT Providers by 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 PT Board 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 PT Board 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 PT Board 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 \pm two standard deviations for potable water analytes and the mean \pm 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 disproportionately large failure rates or reporting anomalies to the Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor. If bimodal or multimodal distribution is found and acceptance criteria are calculated using robust statistical analysis, data should be scored by method specific robust statistical analysis. 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 PT Board 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 PT Board 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 Board on any new matrix/analyte combinations shall be reviewed annually by the PT Board. The purpose of this annual review is to ensure that the limits represent the actual capabilities of the laboratories. For any additional matrix or analyte groups added to the NELAC field of proficiency testing by the PT Board, laboratories shall complete two successful PT studies within 12 months of the date the additional groups were added.

C.5 NELAC PT STUDY PASS/FAIL CRITERIA

NELAC PT studies are designed to meet the requirements of Chapter 2 and associated appendices. Once data acceptability has been determined as described in Sections C.1 through C.3 of this appendix, the laboratory's PT "Pass" or "Fail" evaluation is determined as described in this section. Pass/Fail criteria are used when groups of analytes are evaluated as a unit for the laboratory's initial demonstration of proficiency.

C.5.1 Analyte Group PT Studies

Analyte Group PT Studies are those that are 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. Analyte groups shall be as defined in the Accrediting Authority quality systems manual and published on the NELAC website.

C.5.2 Promulgated USEPA Pass/Fail Criteria

In all cases, promulgated EPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), will be used as NELAC PT pass/fail criteria as applicable. The criteria described in Section C.5.3 shall be used in the absence of promulgated USEPA pass/fail guidelines.

C.5.3 Pass/Fail Criteria For Analyte Group PT Samples

Proficiency testing pass/fail evaluations for Analyte Group PT studies shall be determined as follows. To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for 80% of the analytes in an Analyte Group PT study. Greater than 20% "Not Acceptable" results shall result in the laboratory receiving a score of "Fail" for that group of analytes. For example, a laboratory must report all "Acceptable" results for an Analyte Group PT Study containing 1-4 analytes, and may report no more than one "Not Acceptable" result for a study containing 5-9 analytes or two "Not Acceptable" results for a study containing 10-14 analytes. A "Not Acceptable" result for the same analyte in two out of three consecutive PT studies shall also result in the laboratory receiving a score of "Fail" for that analyte. The PCB analyte group is exempt from the 80% pass/fail criteria.

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 NELAC 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 its associated Appendices. (A portion of this section was removed and placed in the *Standard Operating Procedure for Evaluating Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor*).

D.1 TECHNICAL AND ADMINISTRATIVE QUALIFICATIONS

An organization shall demonstrate to the PT Board 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 PT Board 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 PT Board 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 PT Board 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 PT Board 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 and their Fields of Accreditation. 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

This language was removed and placed in the *NELAC 101 Handbook*.

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:

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

Furthermore, each set shall contain the following samples:

- C One to four samples containing an aerogenic strain of *Escherichia coli* for total and fecal coliform positive results using all USEPA approved methods.
- C 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.
- C One to four samples containing *Pseudomonas sp.* or other microorganisms ensuring a total and fecal coliform negative result using all USEPA approved methods.
- C One to four blank samples.
- C 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 interval defined by the mean plus or minus two standard deviations for SDWA analytes or within the 99% confidence limits as set by the mean, standard deviation and set size (n) for their respective data set for all other analytes.

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 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.1 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 reference 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 will not carry the same weight as PT samples for chemical analytes for an interim period of duration yet to be determined. 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 language of various protocols.

F.2 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAMS

F.2.1 Required Level of Participation

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

F.2.2 Requirements for Laboratory Testing of PT Study Samples

- a) Analyze within 45 calendar days of sample receipt; report results within 45 calendar days of completion.
- b) Samples shall be analyzed in the same manner as routine samples within the limits of the method code.

F.3 PT CRITERIA FOR LABORATORY ACCREDITATION

F.3.1 Initial and Continuing Accreditation

Laboratories which seek to obtain or maintain accreditation for environmental toxicology shall complete at least one PT sample per year for a given field of accreditation (i.e., not more than 12 months apart) and at least 15 calendar days apart (i.e., participation in a second round or remedial study may not occur within 15 calendar days of the first or failed study). Failure to meet the annual schedule shall be regarded as a failed study.

F.4 FIELDS OF PROFICIENCY TESTING

The environmental toxicology PT program shall be organized by fields of proficiency 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 accreditation, or portions thereof.

F.4.1 Whole Effluent Toxicity (WET)

Laboratories seeking WET accreditation shall be assessed through on-site assessment and evaluation of EPA Discharge Monitoring Report - Quality Assurance (DMR-QA) test results when available. 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 actions on the part of the laboratory and/or the AA. There shall be no loss of accreditation based solely on PT results during this interim period.

If a laboratory's response is unacceptable and the AA does not require additional on-site assessments the laboratory is required to complete another study. Such additional studies must be conducted, at least 15 calendar days from the previous PT study, until the results are acceptable to the AA. The AA may conduct additional on-site assessments as necessary based on the results of any additional studies. The default for the WET PT program is accreditation without PT samples.

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

PROFICIENCY TESTING
APPENDIX G

RADIOCHEMISTRY

Appendix G - RADIOCHEMISTRY

G.0 PURPOSE

This appendix contains the NELAC requirements for radiochemical proficiency testing under the Safe Drinking Water Act (SDWA). The appendix supplements the requirements of Chapter 2 and Appendices A, B, and C with requirements specific for NELAC radiochemical proficiency testing studies.

Radiochemical proficiency testing for other USEPA Programs shall be added as the necessary resources, proficiency testing objectives and supporting data are available.

Other pertinent information concerning the SDWA radiochemical proficiency testing samples are available from the Executive Director of NELAP.

G.1 PROFICIENCY TESTING PROVIDER LICENSING

Possession, transfer and use of many radioactive materials is regulated by the Nuclear Regulatory Commission (NRC) or State radiological departments. The PT Provider shall ensure that they are licensed not only for the possession and use of radioactive materials in their facility but also for the explicit distribution of these materials in commerce.

G.2 SDWA SAMPLE DESIGN

The PT Provider must ensure that the sample design used for the SDWA radiochemical PT samples meets the applicable criteria contained in the USEPA's "National Standards for Water Proficiency Testing Studies, Criteria Document".

G.2.1 ASSIGNED VALUES

Assigned values must be within the ranges established by the USEPA in the "National Standards for Water Proficiency Testing Studies, Criteria Document", where they apply. Assigned values are selected such that the concentration of each analyte will vary over time throughout the concentration range. The PT Provider must also ensure that the method for selecting an assigned value meets the applicable criteria contained in the EPA's "National Standards for Water Proficiency Testing Studies, Criteria Document". The assigned value is determined based on the mass of standard added to the volume of water as follows:

Assigned value (pCi/L) = pCi activity added ÷ volume preserved water ÷ dilution factor.

G.3 SCORING

The results from a participating laboratory testing under the SDWA are classified as "Acceptable" or "Not Acceptable" based on the criteria in US EPA's "National Standards for Water Proficiency Testing Studies, Criteria Document". The tests in the document include an evaluation of the average of the required three independent determinations for each radionuclide in the study and an evaluation of the range of the three results for each radionuclide. Acceptance limits are provided in the "NELAC PT Acceptance Limits for Radionuclides" table which is located on the NELAC website.

G.4 STUDY TIMETABLES

Semi-annual proficiency testing is required per the schedule contained in Section 2.4. The samples shall be analyzed and the results returned to the PT Provider within the applicable time frames specified in the USEPA's "National Standards for Water Proficiency Testing Studies, Criteria Document."

PROFICIENCY TESTING
APPENDIX H

PERFORMANCE TESTING
REQUIREMENTS FOR FIELD AIR
MEASUREMENT

Appendix H - PERFORMANCE TESTING REQUIREMENTS FOR FIELD AIR MEASUREMENT

H.0 INTRODUCTION: PURPOSE, SCOPE, AND APPLICABILITY

This Appendix defines the criteria to be used by any entity which seeks to participate as a Proficiency Test Provider and score the results obtained from the analyses of samples in an air measurement NELAC PT Study. This appendix specifically covers performance testing (PT) requirements for Source and Ambient air field measurement conducted for regulatory compliance.

There are two categories of performance testing performed for compliance related air sample field measurement: 1) calibration-based performance testing conducted for field instruments for which delivery of a representative, quality controlled PT sample is not practical, and 2) performance testing for field instruments for which delivery of a representative, quality controlled PT sample is possible. For example, EPA Method 5 is used to collect (on a batch, time-integrated basis) particulate matter from stationary emission sources. The equipment metering box and probe are calibrated per the method prior to and then upon its return from the field after sampling is completed. During its use in the field there is no practical means of introducing a controlled PT sample (category 1 example). In contrast, continuous emission monitors (CEMs) for both ambient air and source emission monitoring can be challenged with a PT gas in a cylinder to determine performance of that instrument during its operation in the field (category 2 example).

In category 1 for field measurements in which the delivery of acceptable and appropriate PT samples is not possible, calibration and maintenance requirements outlined in Chapter 5 Quality Systems or Chapter 7 Field Activities will be used to assure the quality and representativeness for field measurement data.

This standard is being developed only for the category 2 performance testing of field measurements where delivery of a standard PT sample is possible. Calibration-based performance testing will be a subset of either the NELAC Quality Systems or Field Activities Chapters, as appropriate.

For field measurements that fall under this standard, two distinct sets of scoring criteria are defined: 1) whether or not an individual analyte result is either "Acceptable" or "Not Acceptable" and 2) whether or not a laboratory's initial PT performance for a group of interdependent analytes can be evaluated as "Pass" or "Fail." The PT Providers will submit all field measurement performance rating(s) to the Primary Accrediting Authority, as described in Chapter 2 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 field of proficiency testing basis.

H.1 PROFICIENCY TESTING FOR FIELD AIR MEASUREMENT

Field air measurements refer to measurements taken in the field for regulatory compliance. Examples include continuous emission monitors (CEM) used to obtain real-time measurements of emissions from industrial point source discharges or from ambient air monitoring. Also included are gaseous organic emissions by gas chromatography (GC) and Fourier transform infrared (FTIR) spectroscopy real-time monitors used to monitor criteria pollutants at a Superfund site fence line.

NELAC intends to develop PT criteria for relevant field measurements. The criteria will be developed to mirror PT criteria for laboratory sample analysis; however, for many field measurements, delivery of representative, quality controlled PT samples will be problematic. The standard will be developed to address those field measurements for which PT sample delivery is possible. For field measurements in which delivery of acceptable PT samples is not possible, calibration and

maintenance requirements outlined in Ch. 5 Quality Systems will be used to assure the quality and representativeness of field measurement data.

H.2 ACCEPTANCE LIMITS

Acceptance limits are established for each analyte. Whether or not a laboratory has passed or failed a group of interdependent analytes is based on the number of results that are determined to be acceptable.

H.2.1 Analyte Acceptance Limit Categories

Acceptance limits are separated into two categories. Results for analytes with acceptance limits determined as described in Sections H.2.1.1 and H.2.1.2 shall be used in the determination of a laboratory's field of proficiency testing pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section H.2.1.3 shall not be used as part of the field of proficiency testing pass/fail evaluation.

H.2.1.1 Analytes with USEPA Established Acceptance Limits (Prepared \pm fixed percentage or Mean \pm 2 standard deviations)

PT Providers shall utilize the proficiency test acceptance limits that have been established by USEPA in the National Standards for air proficiency testing studies where they apply. The National Standards are incorporated into this Appendix by reference. EPA's established proficiency test acceptance limits for chemical analytes are typically expressed in the following manner:

Prepared \pm fixed percentage. Acceptance limits shall be set at plus and minus the published fixed percentage of the analyte's verified prepared value.

Mean \pm 2 standard deviations. The PT Board has a process for establishing linear regression equations relating a PT samples prepared value to mean and prepared value to standard deviation; acceptance limits shall be set using said equations and the sample's verified prepared value. Linear regression equations may only be used for prepared values that fall within the range of prepared values used to establish said equations. In the event that there are no linear regression equations available for a given analyte, that analyte shall be treated as described in Section H.2.1.3.

H.2.1.2 Analytes with acceptance limits derived from regression equations established by the PT Board

When USEPA Program regulations for establishing acceptance criteria are not available, Proficiency Test providers shall set acceptance limits using regression equations that predict the mean and standard deviation for an analyte in a given range of concentrations. Regression equations shall be derived by the PT Board and shall be made available to PTPA-approved PT Providers by the Executive Director of NELAP. Data from sources such as the USEPA PE studies, interlaboratory results from professional organizations such as ASTM, other proficiency testing providers, commercial and non-profit organizations, shall be used to establish the equations. All regression equations shall be approved by the PT Board prior to use by a PTPA-approved PT Provider. For these analytes, the PT Provider shall use the sample's verified prepared value and said equations to determine the mean and standard deviation.

H.2.1.3 Experimental Data: Analytes without promulgated acceptance limits or established regression equations

For those analytes not included in categories H.2.1.1 or H.2.1.2 (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 PT Board 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 PT Board 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.

H.3 ACCEPTABLE PT RESULTS FOR CHEMICAL ANALYTES IN FIELD AIR PT MEASUREMENTS

Criteria for acceptable results will be dependent on the precision and accuracy of the accepted field measurement method. A laboratory's PT analyte result is acceptable when it falls within the regulatory promulgated acceptance limits (Section H.2.1.1). For Section H.2.1.2 analytes, PT Providers shall use the PT sample's verified prepared value and said regression equations to determine the mean and standard deviation. Acceptance limits shall be set at the mean \pm two standard deviations for ambient air or source sample analytes. A result is acceptable when it falls within these derived acceptance limits.

H.4 NOT ACCEPTABLE PT RESULTS FOR SOURCE AND AMBIENT PT SAMPLES

Criteria for acceptable results will be dependent on the precision and accuracy of the accepted field measurement method. A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

- a) The result falls outside the USEPA's promulgated acceptance limits (Section H.2.1.1) or outside prediction interval derived from established regression equations;
- b) The lab reports a result for an analyte not present in the PT sample (i.e., a false positive);
- c) The lab reports a result of "Not Detected", (or similar indication of no detection), for an analyte present in the PT sample (i.e., a false negative);

NOTE: If a laboratory reports a result less than the lowest concentration contained in the NELAC-approved PT concentration range for an analyte present in the PT sample at a concentration within the NELAC-approved PT concentration range, the result shall be classified as a false negative and scored as "not acceptable".

- d) The lab fails to submit its results to the PT Provider on or before the deadline for the PT study.

H.5 NELAC PT STUDY PASS/FAIL CRITERIA

NELAC PT samples are designed to meet the requirements of Chapter 2 and associated appendices. Once data acceptability has been determined as described in Sections H.1 through H.3 of this appendix, the laboratory's PT "Pass" or "Fail" evaluation is determined as described in this Section. Pass/Fail criteria are used when groups of interdependent analytes are evaluated as a unit for the laboratory's initial demonstration of proficiency.

H.5.1 Interdependent Analyte PT Samples

Interdependent analyte PT Samples are those that are 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.

An example of interdependent PT analytes includes GC monitoring of a suite of VOC analytes using EPA Method 18.

H.5.2 Non-interdependent Analyte PT Samples

Non-interdependent PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate an analyte or a series of analytes in a sample is not indicative of the laboratory's ability to correctly identify and quantitate similar analytes. Non-interdependent analyte PT samples may contain a single analyte, or may contain multiple analytes. Currently, non-interdependent analytes are not expected to apply to the air matrix.

H.5.3 Promulgated USEPA Pass/fail Criteria

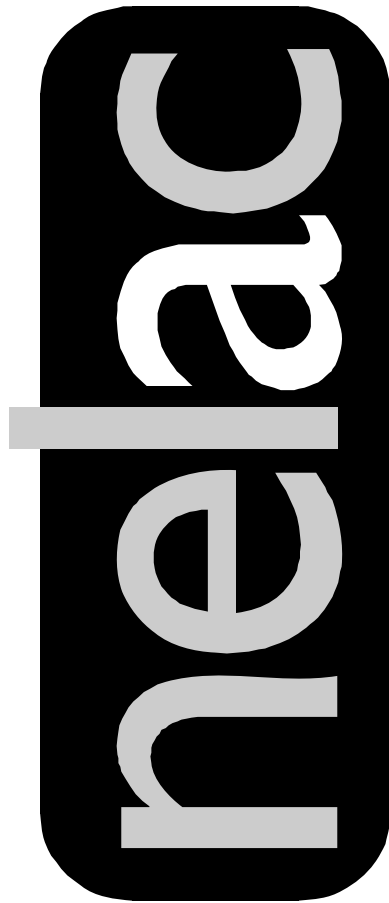
In all cases, promulgated USEPA pass/fail criteria (e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1)), shall be used as NELAC PT pass/fail criteria as applicable. The criteria described in Section 5.4 shall be used in the absence of promulgated USEPA pass/fail guidelines.

H.5.4 Pass/fail Criteria For Interdependent Analyte PT Samples

Proficiency Testing pass/fail evaluations for Interdependent Analyte PT samples shall be determined as follows. To receive a score of "Pass", a laboratory must produce "Acceptable" results for XX% of the analytes in an Interdependent Analyte PT Sample. Greater than 100-XX% "Not Acceptable" results shall result in the laboratory receiving a score of "Fail" for that series of analytes. For example, a laboratory must report all "Acceptable" results for an Interdependent Analyte PT Sample containing 1-4 analytes and may report no more than one "Not Acceptable" result for a sample containing 5-9 analytes or two "Not Acceptable" results for a Sample containing 10-14 analytes. A "Not Acceptable" result for the same analyte in two consecutive PT studies shall also result in the laboratory receiving a score of "Fail" for that analyte.

H.5.5 Pass/fail Criteria For Non-Interdependent Analyte PT Samples

For non-interdependent analytes one unacceptable result would be failing for laboratory analysis. Currently, non-interdependent analytes are not expected to apply to the air matrix.



National Environmental
Laboratory Accreditation
Conference

ON-SITE ASSESSMENT

Approved June 5, 2003
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3.0 ON-SITE ASSESSMENT

3.1 INTRODUCTION

The on-site assessment is an integral and requisite part of the NELAC laboratory accreditation program and is one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team¹ collects and evaluates information and makes observations which are used to judge the laboratory's conformance with established accreditation standards.

It is essential that the on-site assessments conducted by all accrediting authorities recognized by the National Environmental Laboratory Accreditation Program be conducted in a uniform, consistent manner.

This section describes the essential elements that must 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

An assessor must be an experienced professional and hold at least a Bachelor's degree in a scientific discipline or have equivalent experience in environmental laboratory assessment.

Each assessor must satisfactorily complete a training program approved by the accrediting authority responsible for on-site assessments. Each accrediting authority shall be responsible for ensuring that the training course used to train its assessors meets the NELAC standards. This program shall include:

- a) Participation in the NELAC Basic Training Course (Section 3.2.3.1 and Appendix A), including attainment of a passing score on the written examination for the course;
- b) Participation in at least four actual NELAC on-site assessments under the supervision of a qualified assessor (Assessors employed by an accrediting authority [either directly or as a third party] when the accrediting authority is granted NELAP recognition [See Section 6.7] are exempt from the requirement to undergo training with a qualified assessor, provided they have previously conducted four assessments and been judged proficient by the accrediting authority.) and,

¹An assessment team is comprised of a lead assessor, and one or more assessors or technical specialists. In some cases a single lead assessor may conduct an On-site assessment. In those instances the single assessor is considered the "team."

- c) Completion of the applicable technical training requirements for at least one field of accreditation (Section 3.2.3.2 and Appendix B).

Assessors must take annual refresher/update training as defined in Section 3.2.3.3. 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) Have a working knowledge and be conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling and preservation procedures; 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, an accrediting authority must qualify the individual. 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 makes 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 assessor training program is implemented by either accrediting authorities, assessor bodies, or other entities. All assessor training programs, must meet the standards defined in this Chapter. (A portion of this section was removed and placed in the *NELAC 101 Handbook*).

3.2.3.1 Basic Training

The purpose of the basic assessor training is to familiarize the assessor with the NELAC standards and the skills and techniques associated with the laboratory assessment. The basic assessor training course shall encompass all the material described in Appendix A.

The specific training associated with the NELAC standards is required and must be successfully completed. All assessor candidates must pass the written examination.

3.2.3.2 Technical Training

In addition to the basic NELAC assessor training, each assessor must successfully complete training in at least one technical discipline.

The technical training program is defined in Appendix B. The purpose of the technical training is to ensure consistency of knowledge and techniques among the NELAC assessors. The technical training assumes a level of basic knowledge of the subject and concentrates on the elements of the technology or methods that are key to properly assure laboratory competency to deliver data of known and documented quality. The technical training program consists of the following :

NELAC Technical Training for Assessors	
TECHNICAL DISCIPLINES	
1.	<u>Microbiology</u> -- Bacteriology -- Viruses/Parasites -- Microscopic Particulate Analysis (MPA)
2.	<u>Biological</u> -- Whole Effluent Toxicity (WET) Testing -- Sediment Toxicity Testing and Variants -- Soils Toxicity Testing -- Specialized Toxicity Testing -- Taxonomy and Community Structure
3.	<u>Inorganic - Nonmetals/Misc.</u> -- Spectrophotometric -- Titrimetric -- Potentiometric -- Colorimetric -- TOC/TOX -- Residue/Solids -- COD/BOD -- IR -- IC

4. Inorganic - Metals
 - FAA
 - GFAA
 - ICP
 - ICP/MS
 - Sample Preparation (Digestion/TCLP/etc.)
5. Organics
 - Sample Preparation
 - HPLC
 - GC
 - GC/MS
 - Instrument Software
6. Asbestos
 - Bulk
 - Air
 - Water/TEM
7. Radiochemistry
8. Field Activities
 - Source/Ambient Testing (CAA, RCRA, TSCA)
 - e.g. Air Source Testing
 - Basic Principles of Manual Methods
 - Basic Principles of Instrumental Methods
 - Soil/Groundwater (SARA, RCRA, TSCA, FIFRA)
 - Surface Water (CWA, RCRA, TSCA, FIFRA)
 - Drinking Water (SDWA)
 - Multi-media (mix of above)
 - Biological

3.2.3.3 Refresher Training

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 assessment. Assessors are expected to maintain proficiency on an on-going basis. Assessors must complete refresher/update training annually. Initially, the refresher/update training is conceptualized as follows:

NELAC Refresher/Update Training for Assessors

- Changes to the NELAC Standards and the Resulting Checklist Changes
- New Interpretations of the NELAC Standards
- Technical Changes Associated with Approved Methodology and the Resulting Checklist Changes
- Assessment Skills and Techniques
- Current Developments

3.3 FREQUENCY AND TYPES OF ON-SITE ASSESSMENTS

3.3.1 Frequency

The accrediting authority must conduct a comprehensive on-site assessment of each laboratory prior to granting accreditation, except as allowed by interim accreditation (see Section 4.5.1). In addition, an on-site assessment of each accredited laboratory must be completed at least every two years. Assessments for cause are conducted more frequently, at the option of the accrediting authority.

3.3.2 Follow-up On-site Assessments

If directed by an accrediting authority, an assessment team must 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 must be completed and reported within thirty (30) calendar days after the receipt of the laboratory's plan of corrective action. (A portion of this section was removed and placed in the *Policy on Accrediting Authority Responsibilities for Conducting On-Site Assessments*).

3.3.3 Changes in Laboratory Capabilities

When a change occurs in a laboratory's ownership, location, key personnel, or major instrumentation, notification of the accrediting authority is required within 30 days (see Section 4.3.2). The accrediting authority must evaluate the significance of a change that might alter or impair the laboratory's capability and quality, and indicate to the laboratory the results of their evaluation in writing. The accrediting authority must retain records to indicate that such an evaluation was conducted.

3.3.4 Announced and Unannounced Visits

The accrediting authority, at its discretion, conducts either unannounced or announced on-site assessments. The accrediting authority is not required to provide advance notice of an assessment. (A portion of this section was removed and placed in the *Policy on Accrediting Authority Responsibilities for Conducting On-Site Assessments*).

3.4 PRE-ASSESSMENT PROCEDURES

3.4.1 Assessment Planning

Pre-assessment activities include: determining the scope of the assessment; reviewing NELAP/State information; providing advance notification of the assessment to the laboratory, when appropriate; obtaining any security clearances and determining any special safety procedures which may be necessary; coordinating the assessment team; and gathering assessment documents. Section 3.4.5 discusses Confidential Business Information (CBI) issues. (A portion of this section was removed and placed in the *NELAC 101 Handbook*).

3.4.1.1 Assessment Team

The accrediting authority determines the number and expertise of the assessment team and support personnel that are required to conduct the on-site assessment based on the type of assessment and the scope of accreditation of the accredited or applicant laboratory. (A portion of this section was removed and placed in the *NELAC 101 Handbook*).

3.4.1.2 Technical Support Personnel

An assessment team may include technical support personnel approved by the primary accrediting authority as capable of providing assistance to the assessors. These individuals need not be formally qualified by the accrediting authority as assessors (see Section 3.2.2). If not so qualified, these individuals must still meet the requirements of the standards concerning conflicts of interest and professional conduct. Members of the assessment team who provide technical assistance but are not qualified as assessors are not eligible to conduct interviews in the absence of the assessor nor to cite deficiencies.

3.4.2 Scope of the Assessment

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 accreditation must cover the complete scope of accreditation for which the laboratory seeks or maintains accreditation within the specific field of accreditation as authorized by the accrediting authority. (A portion of this section was removed and placed in the *NELAC 101 Handbook*).

3.4.2.1 Laboratory Assessments

A laboratory assessment must review the ability of the laboratory 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 must 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 the 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, the quality system, and other information to technically substantiate reports previously issued. During a records review, the assessment team conducts an overall assessment of data and compares the data with submitted reports to determine whether the data collected, generated, and reported follow 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 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 Manual(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 (federal and state); and
- g) The most recently approved or in use laboratory methods for which the laboratory has requested or maintains accreditation.

3.4.4 Assessment Documents

Documents necessary for the assessment must be provided to the laboratory management or staff and assembled before the assessment, whenever possible. The lead assessor must obtain copies of all forms required for the assessment, including the appropriate checklist(s). Other types of documents 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 must provide information to the laboratory on how to obtain assessment information from the accrediting authority.

3.4.5 Confidential Business Information (CBI) Considerations

During assessments, if the assessment team comes into possession of information claimed as business confidential, the laws and regulations of the primary accrediting authority will govern the procedures for handling and disclosure of this information. If the primary accrediting authority is not subject to laws or regulations pertaining to confidential business information, the EPA regulations for handling confidential business information, detailed in Title 40, Code of Federal Regulations, Part 2, Subpart B, will apply. 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." The assessment team must inform the responsible laboratory official at the beginning of the assessment of their right to claim any portion of the information requested during the assessment as CBI. The assessment team must describe any procedures that the laboratory must follow to claim information as CBI. Assessors must have training on handling claims of CBI. The assessors must be familiar with the procedures for asserting a CBI claim and handling information that contain the information claimed as CBI. The assessment team must take custody of all CBI information before leaving the laboratory, and must maintain it in custody, using all proper procedures and safeguards, until it can be received by an authorized official of the accrediting authority, who must also treat such information as CBI, until an official determination has been made in accordance with federal or State laws and regulations.

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 that 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 applicable state or federal laws and regulations.

If a business confidentiality claim is received after the on-site assessment by the accrediting authority, the accrediting 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 members of the on-site assessment team 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

If the accrediting authority questions the claim that certain information is CBI, 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 in accordance with the NELAC standards, or
- 6) withdraw their NELAC accreditation application for the field of accreditation associated with the CBI information.

The accrediting authority shall notify the laboratory technical director of all decisions regarding the acceptance or denial of a claim of CBI within the time frames established by applicable state or federal laws and regulations. If no time frames are specified, the accrediting authority shall notify the laboratory technical director of a decision regarding the acceptance or denial of a claim of CBI within 30 calendar days of receiving the claim. In no instance shall the accrediting authority declassify CBI-claimed information without notification of the laboratory.

3.4.6 National Security Considerations

Assessment teams performing assessments at laboratories owned and/or operated by Federal departments/agencies/contractors must review the need for security clearances, appropriate badging, and/or a security briefing before proceeding with the on-site assessment. The laboratory must inform the assessors in writing of any information, including data, that is controlled for national security reasons and cannot be released to the public.

NELAP assessment teams performing an on-site assessment of a Federal agency 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 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 depends upon a number of factors such as the scope of 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 accrediting authority must 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 extent the laboratories' operations meet NELAC standards.

3.5.2 Opening Conference

Arrival at the facility for routine NELAC assessments occurs during established working hours unless special arrangements are made with the laboratory.

A laboratory's refusal to admit the assessment team for assessment results 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 accrediting authority. The assessment 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 primary areas 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 member of the assessment team during an inspection to gain access to the facility);
- h) the standards that will be used by the assessment team in judging the adequacy of the laboratory operation;
- i) the confirmation of the tentative time for the exit conference;

- j) the presentation of the assessment appraisal form to the responsible laboratory official for submittal to the accrediting authority; and
- k) the discussion of any questions the laboratory may have about the assessment process.

3.5.3 On-site Laboratory Records Review and Collection

Assessment team members must review laboratory records for accuracy, completeness and the use of proper methodology. NELAC Chapter 5, Section 4.12 lists the records required for review during the assessment. The assessors must document the required elements of the records review on the NELAC assessment checklists.

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 is confidential, the information must 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 evaluates the analysis process by requesting that the analyst(s) normally conducting the test(s) give a step-by-step description of exactly what is done and what equipment and supplies are needed to complete the analysis. Any deficiencies shall be noted and discussed with the analyst and must be discussed again in the closing conference unless otherwise provided in Section 3.5.5.

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 the complete scope of accreditation 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. The assessment team shall in no way be limited in its ability to identify additional problem areas in the final assessment report should it become necessary. The assessment team shall provide only preliminary determinations of potential findings, their severity, and whether they are critical in nature, and must inform the laboratory that final determinations concerning the number, nature, and extent of assessment findings shall be made by the accrediting authority, after reviewing reported findings. The assessment team must describe all deficiencies identified-to-date during the closing conference with the possible exception of any issues of improper and/or potentially illegal activity, which may be the subject of further action.

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 accrediting authority for consideration. The accrediting authority shall make a determination as to the validity of the contested elements.

The assessment team must 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 Reporting Procedures

The assessment team shall summarize potential assessment findings for the accrediting authority to consider. The accrediting authority shall make final determinations of the validity and severity of the potential findings identified by the assessment team. The accrediting authority or its authorized third party must present an assessment report identifying all confirmed findings to the laboratory within thirty (30) calendar days of the assessment.

The laboratory has thirty (30) calendar days from the date of receipt of the report to provide a plan of corrective action to the accrediting authority (see Section 4.1.3). In those circumstances where a possible enforcement investigation or other action has been initiated, an exception to these deadlines is allowed. The laboratory shall give priority to correcting critical findings identified or confirmed by the accrediting authority.

3.5.7 Assessment Closure

After reviewing the assessment report and any corrective action(s) reported by the laboratory, the accrediting authority shall make a determination of the accreditation status for a laboratory. Additional on-site assessments may be conducted before a final decision for accreditation is made following the procedures of the accrediting authority.

3.6 STANDARDS FOR ASSESSMENT

3.6.1 Areas of Assessment

The areas to be evaluated during an on-site assessment to determine the competence of an environmental laboratory shall include:

- a) Organization and Management
- b) Quality System - Establishment, Assessments, Essential Quality Controls and Data Verification
- c) Personnel
- d) Physical Facilities - Accommodation and Environment
- e) Equipment and Reference Materials
- f) Measurement Traceability and Calibration
- g) Test Methods and Standard Operating Procedures
- h) Sample Handling, Sample Acceptance Policy and Sample Receipt
- i) Records
- j) Laboratory Report Format and Contents
- k) Subcontracting of Analytical Samples
- l) Outside Support Services and Supplies
- m) Complaints

These areas must be evaluated against the standards detailed in Chapter 5, Quality Systems, Chapter 2, Proficiency Testing and Chapter 4, Accreditation Process of the NELAC Standards and the appropriate method references. Sufficient detail is provided in Chapter Five (5) and/or the method reference(s) cited to enable accrediting authorities to evaluate laboratories consistently and uniformly.

3.6.2 Assessor's Role

The on-site assessor uses 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 depends primarily upon the assessment team's findings. Much of the on-site assessment depends upon the assessor's observations of existing conditions (i.e. observing operations and processes). 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 assessment report of the On-site assessment. The assessment team must use specific documentation in its reporting of deficiencies.

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 must 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 must 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 must continue to gather the information necessary to complete the accreditation assessment.

3.6.3 Use of Checklists

Standardized checklists 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 that assists in conducting a thorough and efficient assessment. A checklist is not a substitute for assessor training and experience.

3.6.4 Standards of Professional Conduct for Assessors

Professional standards apply to every NELAC assessor, whether a government employee or an employee of a third party organization conducting assessments under an agreement with a NELAP accrediting authority. Assessors that knowingly engage in unprofessional activity may be liable for punitive actions as initiated by the affected accrediting authority.

The Standards for Professional Conduct, as outlined in this section, are based upon 5 CFR 2635, "Standards of Ethical Conduct for Employees of the Executive Branch" and will be followed in NELAP related matters. NELAC assessors shall:

- a) have no interest at play other than that of the accrediting authority and NELAC during the entire accreditation process;
- b) act impartially and not give preferential treatment to any organization or individual;

- c) provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and/or disability;
- d) not use their position for private gain;
- e) not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative, or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accrediting authority;
- f) not hold financial interests that conflict with the conscientious performance of their duties;
- g) not engage in financial transactions using information gained through their positions as assessors to further any private interest;
- h) not engage in employment activities (seeking or negotiating for employment) or attempt to arrange contractual agreements with a laboratory that would conflict with their duties and responsibilities as an assessor;
- i) not knowingly make unauthorized commitments or promises of any kind purporting to bind the affected accrediting authority; and,
- j) attempt to avoid any actions that could create even the appearance that they are violating any of the standards of professional conduct outlined in this section.

Assessors are reminded that it is their responsibility to report to the affected accrediting authority any personal issues or activities that constitute a conflict of interest before an assessment occurs. It is up to the affected accrediting authority to determine if the reported issues and activities regarding a specific assessor constitute, or be construed as, a conflict of interest. (A portion of this section was removed and placed in the *Policy on Accrediting Authority Responsibilities for Conducting On-Site Assessments*).

3.7 DOCUMENTATION OF ON-SITE ASSESSMENT

3.7.1 Checklists/Records

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. The assessor shall specify the laboratory records, documents, equipment, procedures, or staff evaluated and the observations that contributed to the evaluation of "No" for each assessment checklist item. This information must be documented in the comments section or referenced on the checklist. The assessment report must contain sufficient evidence to support all assessment findings and the overall evaluation of the laboratory.

3.7.2 Report Format

The final assessment report shall be written to contain a description of the adequacy of the laboratory as it relates to the assessment standards in Section 3.6.1. Assessment reports must be generated in a narrative format. Documentation of existing conditions at the laboratory must be included in each report to serve as a baseline for future contacts with the facility.

Assessment reports must 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.

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 assessment report conform to established standards for the evaluated parameters.

Accrediting authorities may devote a section to comments and recommendations in assessment reports to convey suggestions aimed at helping laboratories improve operations.

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 On-site Assessment Report

On-site assessment reports must 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 (see 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, must 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 accrediting authority for a period of at least five (5) years, or longer if required by specific State or Federal regulations (see Sections 4.3.3 & 5.4.12.2.4(b)).

ON-SITE ASSESSMENT
APPENDIX A

NELAC BASIC ASSESSOR TRAINING

Appendix A - NELAC BASIC ASSESSOR TRAINING

A.1 INTRODUCTION

Appendix A specifies the minimum standards for NELAC Basic Assessor Training Courses. This appendix must be used to design basic training courses for laboratory assessors. Appendix A and its technical counterpart, Appendix B, specify the principal elements of NELAC laboratory assessor training courses.

A.2 COURSE PURPOSE

The purpose of the NELAC Basic Assessor Training Course is to fulfill the Basic Training requirement for assessors specified in Section 3.2.3.1 of the NELAC Standards.

The Basic Assessor Training Course:

- Instructs assessors on the basic elements of performing NELAC assessments by focusing on evaluating laboratory quality systems and the competency of the laboratory to perform the test methods on the scope of accreditation.
- Provides an overview of the NELAC Standards and the NELAP laboratory accreditation process.
- Promotes uniformity of laboratory assessments performed to obtain NELAP accreditation.
- Facilitates information exchange among assessors.

A.3 COURSE LOGISTICS

The course subject matter and content must be organized in modules or discrete units. Although the order of instructional modules or units is not strictly prescribed, courses must be organized systematically and logically to allow the best assimilation and comprehension of their subject matter.

The course contents can be delivered in a traditional classroom, by teleconferencing, in computer on-line sessions, or by a combination of any of these media. The format for instruction modules or units must be appropriate to the subject matter and can include, but is not limited to, lectures, discussions, demonstrations, critiques, group exercises, written assignments, simulations, fictitious reenactments, or a combination of any of these. Regardless of the medium or format used for content delivery, all courses must provide opportunity for ample interaction between instructors and participants and, must include exercises designed to be completed by teams of participants.

A.3.1 Duration

The duration of the course will depend upon the participants' experience and the course's mode of delivery, but must be sufficient to allow fulfilling all the objectives contained in section A.2 and to cover the content specified in section A.4.

A.3.2 Providers, Instructors, and Participants

Providers of NELAC Basic Assessor Training Courses shall ensure that the number of instructors assigned to a course is commensurate with the number of participants attending and the delivery mode of the course. Although other ratios of instructor to students may be acceptable, a typical Basic Assessor Training Course delivered in a traditional classroom setting assigns one instructor per every 15 participants.

Instructors must maintain credentials and qualification statements and must make them available to course participants or other interested parties.

Accrediting authorities shall approve training for their assessors. Providers of NELAC Basic Training Courses shall not claim NELAP approval of them and are restricted from using the NELAC and NELAP logos in any course or promotional materials.

This Appendix does not limit course participants to those employed by accrediting authorities. All participants, regardless of the course delivery mode, must register prior to taking a course. Providers must maintain records that identify participating students and their status (i.e. whether they have attended the course or completed one by passing an examination); however, it is the responsibility of accrediting authorities to qualify and approve their assessors.

Providers must update established courses and existing training materials to reflect any changes in effect made to the NELAC standards.

A.3.3 Course Documentation Supplied to Participants, Final Examination, and Certificates

After receiving completed registration forms including fees (where charged), providers shall send participants a course agenda. The course agenda should contain titles of the instructional modules and units with a timetable, and should be sent to candidates in sufficient time to be read before the course. Providers must also provide with the agenda a copy of the NELAC Standards and the Quality System Checklist in effect at the time of the course.

A.3.4 Final Examination

Participants must be offered an opportunity to take a written examination that quantitatively measures their knowledge of the NELAC standards and the course contents. Until such time as NELAP or a designated body can maintain a controlled set of questions to be used in written examinations, providers shall design their own questions and grading criteria. Participants that obtain 70% or more correct answers in the final examination are classified as successfully completing the course.

A.3.5 Attendance or Completion Certificate

Course providers shall issue certificates to those participants who attend all the offered modules or instructional units and to those that successfully complete the course. A "Certificate of Attendance" containing a brief description of the course shall be issued to participants who choose not to take the final examination or who do not successfully complete the course, but who have attended all the modules or instructional units.

Participants that attend all the instruction modules and who successfully complete the course shall be issued a "Certificate of Completion".

A.3.6 Appraisal of Course by Participants

Participants shall be offered an evaluation form at the end of the course to invite feedback to providers about the course's quality and content. Such forms shall be available to accrediting authorities and to NELAP upon request.

Providers are also encouraged to include in their courses an open session where participants evaluate a course and offer direct feedback to instructors.

A.4 COURSE CONTENTS

The contents of the Basic Assessor Training Course must address the following items.

A.4.1 Introduction

The purpose of this module is to establish the intent and tone of the course. It should create an atmosphere that will encourage participation, feedback, and questions, and should clarify participant expectations about the intent and content of the course.

This module should provide an opportunity to:

1. Welcome participants
2. Introduce course content
3. Describe method of assessment of participants
4. Describe administrative and physical arrangements (e.g. lunches, telephone, timing)
5. Have participants introduce themselves

A.4.2 Historical Perspective on National Accreditation

This course module will provide a background on laboratory accreditation and the history included Chapter 1 of the NELAC standard. The historical perspective and overview of the requirements of assessors should enable participants to understand the benefits of national accreditation and how a uniform national accreditation process will improve the quality of environmental data.

1. The Need for National Accreditation
2. Past Efforts toward National Consistency
3. Genesis of the National Environmental Laboratory Accreditation Program (NELAP)

A.4.3 Fundamentals of NELAC and NELAP

The purpose of this module is to familiarize the course participants with the function and structure of NELAC, NELAP, and the essential role that the accrediting authorities have in the laboratory accreditation process. The module should establish for each participant a working knowledge of NELAC and the mechanics of the program.

What is NELAC?

1. Objectives of NELAC
2. Structure and Operation of NELAC
 - a. NELAC Standards
3. What is NELAP?
 - a. Current Status of NELAP
4. Structure and Operation of NELAP
5. Primary Accrediting Authorities
 - a. Requirements and Functions of Primary Accrediting Authorities
 - b. Process for Recognition of Accrediting Authorities
6. Secondary Accrediting Authorities
 - a. Requirements and Functions of Secondary Accrediting Authorities
 - b. Reciprocal Accreditation
7. National Accreditation Database
8. Scope of Accreditation

A.4.4 Qualifications and Training Requirements for Assessors

The purpose of this module is to examine the requirements for becoming a qualified NELAC Assessor as defined in Chapter 3. At the end of the session each participant should understand the process and timing involved for becoming a NELAC assessor.

1. Basic Qualifications
 - a. Qualification by an Accrediting Authority
 - b. Absence of Conflict of Interest Certification
2. Purpose of Training Assessors
3. Basic Assessor Training
4. Technical Training
5. Refresher Training

A.4.5 Accreditation of Laboratories

The purpose of this module is to define the NELAC laboratory accreditation process. Participants should understand the requirements of laboratories seeking accreditation and the process through which accreditation is granted.

1. Accreditation Requirements
2. Order of the Accreditation Process
3. Role of the Laboratory Assessor in Accreditation of Laboratories
4. Personnel Qualifications

A.4.6 Proficiency Testing

The purpose of this module is to provide a comprehensive view of the role that the proficiency testing (PT) plays in the accreditation process. Participants should understand the importance of proficiency testing, the requirements for PT providers and laboratories, and the elements of the PT process that should be assessed during the on-site assessment.

1. Purpose of Proficiency Testing
2. Definitions
3. Mechanisms, Criteria, Current Programs, Follow-Up Actions
4. Oversight and Delivery of Proficiency Testing Program
 - a. Proficiency Testing Providers
 - b. Proficiency Testing Oversight Body
 - c. Primary Accrediting Authorities
5. Laboratory Requirements
 - a. Types of PT Samples Required to be Analyzed
 - i. PT Fields of Testing
 - b. Frequency of PT Sample Analysis
 - c. Requirements for Handling and Analyzing PT Samples
6. Role of the Laboratory Assessor in Reviewing PT Sample Data

A.4.7 Ethical Conduct Standards for Assessors

This module will review the elements of ethical conduct of assessors, establishing an expectation that assessor conduct be “above reproach,” and the consequences of unethical conduct. In addition, the module will examine circumstances when an assessor activity might constitute a potential conflict of

interest, and the need for disclosure. At the end of this session, participants should know the NELAC expectations and requirements for assessor conduct.

1. Professional Conduct of Assessors
2. Defining, Determining, and Avoiding Conflicts of Interest for Assessors

A.4.8 Quality Systems

This module establishes the fundamental components of a quality system and trains assessors on how to evaluate them. It requires a group exercise in which a laboratory's quality manual is evaluated for conformance with the NELAC Standards. This case study can be used to emphasize the importance of key quality system elements.

1. Definition of a Quality System
 - a. Quality Assurance
 - b. Quality Control
 - c. Elements of a Quality System
2. Quality System Requirements for Laboratories
 - a. Quality Manual
 - b. Quality Assurance Policies and Procedures
 - c. Standard Operating procedures
 - d. Corrective Actions
 - e. Document and Records Control
 - f. Data Review and Evaluation
3. Monitoring and Effectiveness of the Quality System
 - a. Internal Audits
 - b. Management review

A.4.9 NELAC Quality System Checklist

This module will explore the proper use of the Quality Systems Checklist, including how and when the checklist should be completed, and the techniques that a good assessor follows when using any checklist. At the end of this module, participants should be familiar with the Quality Systems Checklist and how it relates to NELAC Chapter 5. Participants will learn how to use the Quality Systems Checklist as an assessment tool, rather than as the primary vehicle of the assessment.

1. Purpose
2. Mandatory Use
3. Use of the Quality Systems Checklist Before, During, and After Laboratory Assessments
4. Procedure for Documentation of Findings

A.4.10 Interviewing Techniques for Assessors

The purpose of this module is to instruct participants on good interviewing techniques and the personal dynamics of an on-site assessment. Participants will learn communication skills, including effective questioning techniques; methods for gathering information in an objective and professional manner; and potential ethical concerns. Group exercises and simulations are particularly effective in this sub-unit.

1. Utility of Interviews During Laboratory Assessments
2. Interview Structure
3. Verbal and Non-Verbal Communication
4. Modes of Gathering Information

5. Ways of Asking Questions
6. Dealing with Difficult Interviewees

A.4.11 NELAC Laboratory Assessments

This module of the course presents all phases of the assessment process: pre-assessment, on-site assessment, and post-assessment activities. The session should instruct participants in the use of assessment tools (e.g., observation, interviewing, documentation review, and tracking) to review the quality system, documented test procedures, test method validation, and the technical competence of a laboratory.

1. Purpose of Assessments
2. Frequency and Types of Assessments
3. Phases of an Assessment

A.4.11.1 Pre-Assessment Activities

1. Planning an Assessment
 - a. Scope of an Assessment
 - b. Appointment of Lead Assessor and other Team Members
 - c. Roles of Assessment Team Members
2. Document Review
 - a. PT Sample Results
 - b. Quality Manual
 - c. Corrective Action Reports and Plans
3. Previous Assessment Reports
4. Preparation of Agenda and Schedule
5. Notifications

A.4.11.2 On-site Assessment Components

A “mock” assessment exercise can be used during this sub-unit to instruct participants on the components of on-site assessments.

A.4.11.2.1 Opening Conference

1. Schedule and Agenda
2. Assessment Appraisal Form
3. Confidential Business Information (CBI)

A.4.11.2.2 Facility Walk-Through

A.4.11.2.3 On-site Assessment Proper

1. Use of the Quality Systems Checklist
2. Detailed Tour and Observation of Operations
3. Staff Interviews
4. Calibration and Traceability of Measurements
5. Data and Document Review
6. Records Retention and Reporting

A.4.11.2.4 Assessment Team Meetings

A.4.11.2.5 Closing Conference

1. Reporting Non-Conformances

A.4.11.3 Post On-site Assessment Activities

During this sub-unit participants should be instructed on how to correctly cite instances of non-conformance in assessment reports as well as effective ways of formatting them. Critiques of fictitious reports, or a writing assignment in which participants write a report of a “mock” assessment are particularly effective in this sub-unit.

1. On-site Assessment Report
2. Report Format
3. Report Release
4. Corrective Action Reports in Response to On-site Assessment
5. Surveillance and Re-Assessment
6. Retention of Assessment Documents

A.4.12 Handling Assessment Challenges

The purpose of this sub-unit is to identify effective methods of handling potential problems during an assessment. Participants should gain useful conflict resolution tools during this session. Group exercises and simulations can be used effectively in this sub-unit.

1. Dealing with Improper Practices and Potentially Illegal Activities
2. Dealing with Unexpected Circumstances
3. Technical Disagreements
4. Absence of Key Laboratory Personnel
5. Hostile Reception
6. Conduct of Assessors During On-site Assessments

A.5 COURSE SUMMARY AND CONCLUSIONS

This module should conclude the instructional components of the course. It should present a course review that gives a global perspective of the purpose of NELAC and the laboratory assessment process. Participants should be given an opportunity to ask final questions about specific aspects of the assessment and accreditation process at this time.

A.6 FINAL EXAMINATION

The last module of the course is the final examination. The examination determines whether a participant has sufficient knowledge of the NELAC Standards and effective assessment procedures to be a NELAC assessor.

A.7 REFERENCES

1. ILAC-G3; 1994, “Guidelines for training Courses for Assessors Used by Laboratory Accreditation Schemes”

ON-SITE ASSESSMENT
APPENDIX B

TECHNICAL TRAINING COURSES FOR
ASSESSORS

Appendix B - TECHNICAL TRAINING COURSES FOR ASSESSORS

B.1 INTRODUCTION

The purpose of the technical training courses is to ensure consistency of technical knowledge among the NELAC assessors. Prerequisites for the training course for the assessor are:

1. Basic knowledge of the technology, i.e. familiarity with the principles and application of the technology used by the laboratory.
2. An understanding of Quality Systems.

The technical courses must concentrate on the elements and details of the technology and/or methods that are critical to assuring that the laboratory is implementing it or them properly.

Technical training courses provided to meet the requirements defined in Section 3.2.3 of the NELAC Standard must address the elements listed below. Assessor technical training courses must also focus on how to review these elements during the on-site assessment. The skills obtained during these training courses must also enable assessors to evaluate quality systems components present in the laboratory, as they relate to technical disciplines, to ensure compliance with the NELAC Standard.

B.2 COURSE CONTENT

Technical training courses must provide, identify, or review:

- C Basic theoretical and operating principles of the analytical technology and associated instrumentation and software.
- C Critical steps and processes of the analytical technology or technique that must be executed to ensure quality data, including critical quality control (QC) measures and QC criteria based on the technology.
- C Major sources of error, and how to control them, for the analytical technology or technique.
- C Inappropriate procedures or practices for the analytical technology or technique.
- C Key information required to document completely the reported results.
- C Essential elements for assessing data generated.
- C Ways to detect improper practices.
- C Exercises in the evaluation of raw data to reported results.

The training course must also include an examination covering the material presented to ensure an understanding of the above elements. Results of the examination will be submitted to the accrediting authority for action. All attendees will receive a course certificate.

B.3 COURSE OBJECTIVES

The assessors successfully completing the course shall have acquired the following:

1. Knowledge sufficient to assess the implementation of the technology by the laboratory.
2. An understanding as to how the technology is used in the various methods.

3. An understanding of the key elements of data packages, and raw data to review and check effectively.

ON-SITE ASSESSMENT
APPENDIX C

**MINIMUM ELEMENTS FOR
ACCREDITING AUTHORITY
STANDARD OPERATING PROCEDURES
FOR ON-SITE ASSESSMENTS**

Appendix C - MINIMUM ELEMENTS FOR ACCREDITING AUTHORITY STANDARD OPERATING PROCEDURES FOR ON-SITE ASSESSMENTS

C.1 INTRODUCTION

Chapter 6 of the NELAC standard defines the process and criteria used by NELAP to determine whether an accrediting authority meets the standard required for recognition. Under this standard (Section 6.2.3.a.1), accrediting authorities are required to maintain documentation about the laboratory accreditation process. Section 6.3.2.1.3.b.8 also states that the accrediting authority's Quality Manual shall include the policies and procedures to implement the accreditation process. This appendix summarizes the elements to be included by accrediting authorities in SOPs describing on-site assessments of laboratories seeking NELAP accreditation.

At a minimum, the following elements shall be included in the SOPs to ensure consistency of laboratory assessments performed by accrediting authorities.

C.2 PRE-ASSESSMENT

C.2.1 Assessment Planning

C.2.1.1 Description of how the type of assessment is determined, e.g., initial, renewal, follow-up, etc.

C.2.1.2 Procedures for determining whether the assessment is announced or unannounced, the scope of accreditation (technology, matrix, method, analyte or analyte groups), the estimated time spent on-site, and the assessment team resources needed.

C.2.2 Assessment Team

C.2.2.1 Qualifications, roles, and responsibilities of the assessment team members, e.g., lead assessor, assessors, and technical support personnel.

C.2.2.2 Assessment team procedures to be followed if improper or potentially illegal activities are encountered.

C.2.2.3 Circumstances under which the assessment may be terminated including how the assessment team communicates this to the accrediting authority.

C.2.3 Laboratory Documents Review

C.2.3.1 Description of how the assessment team will identify and select specific laboratory documents and records for review before and during an on-site assessment as required in NELAC Sections 3.4.3, 3.5.3, and 5.4.12.

C.2.3.1.1 The assessment team may present preliminary findings before the on-site assessment so the laboratory has time to correct them before the assessment team arrival.

C.2.3.1.2 If the assessment team determines that the laboratory is not ready for an on-site assessment, the SOP shall describe the procedures for laboratory notification.

C.2.3.2 The laboratory documents review process, to be performed before and/or during the on-site phase of each assessment, shall include the following records:

- C.2.3.2.1 The laboratory's accreditation application,
- C.2.3.2.2 Previous assessment reports,
- C.2.3.2.3 Proficiency Test sample results,
- C.2.3.2.4 Official laboratory communications with the accrediting authority and associated records,
- C.2.3.2.5 Laboratory organization charts,
- C.2.3.2.6 Signature Log,
- C.2.3.2.7 Personnel qualifications, experience and training,
- C.2.3.2.8 Laboratory Quality Manual,
- C.2.3.2.9 SOPs, including those for the test methods for which accreditation is sought,
- C.2.3.2.10 Instrumentation and equipment,
- C.2.3.2.11 Standard and reagent origin, receipt, preparation, and use,
- C.2.3.2.12 Initial method validation studies,
- C.2.3.2.13 Demonstrations of capability for each analyst,
- C.2.3.2.14 Test method precision and accuracy,
- C.2.3.2.15 Sample receipt and handling,
- C.2.3.2.16 Internal audits,
- C.2.3.2.17 Software documentation and verification, software and hardware audits, records of changes to automated data entries,
- C.2.3.2.18 Annual management review,
- C.2.3.2.19 Document control records,
- C.2.3.2.20 Corrective action reports,
- C.2.3.2.21 Complaints,
- C.2.3.2.22 Subcontractor registry,
- C.2.3.2.23 Measurement uncertainty calculations (currently needed for Radiochemical testing), and
- C.2.3.2.24 An example client report.

C.2.4 Accrediting Authority On-site Assessment Documents

Procedures used by the assessment team to assemble the following accrediting authority standardized documents and forms before an assessment:

- C.2.4.1.1 Confidentiality Notice,
- C.2.4.1.2 Conflict of Interest Form,
- C.2.4.1.3 Assessor Credentials,
- C.2.4.1.4 Assessment Notification Letter,
- C.2.4.1.5 Attendance Sheets for opening and closing conferences,
- C.2.4.1.6 Standardized checklists, and
- C.2.4.1.7 Assessment Appraisal Form.

C.2.5 Confidential Business Information

Procedures for handling Confidential Business Information (CBI) in compliance with federal or state laws and regulations.

C.2.6 National Security Considerations

Procedures for handling security requirements at laboratories owned or operated by Federal departments, agencies, or their contractors.

C.3 ASSESSMENT

C.3.1 Opening Conference

Procedures for conducting the opening conference of an on-site assessment, addressing:

- C.3.1.1 The scope and purpose of the assessment,
- C.3.1.2 The schedule with a tentative time for the exit conference,
- C.3.1.3 The NELAC Standard used for the assessment,
- C.3.1.4 Identification of the assessment team,
- C.3.1.5 Test methods to be examined,
- C.3.1.6 Records and SOPs required,
- C.3.1.7 Confidential Business Information,
- C.3.1.8 National Security Considerations, if applicable,
- C.3.1.9 Roles and responsibilities of the laboratory staff,
- C.3.1.10 The assessment appraisal form,
- C.3.1.12 Laboratory safety procedures to be followed by the assessment team (lab coats, safety glasses, etc.)

C.3.2 On-site Records Review and Collection

Procedures and criteria used by the assessment team to determine the accuracy and completeness of the records reviewed or collected on-site, including:

- C.3.2.1 Number or scope of records selected for each type specified in NELAC Chapter 5, Section 5.4.12.

C.3.3 Assessment Areas

C.3.3.1 Procedures for evaluating the following assessment areas against the NELAC Chapter 5 standard, including the types of objective evidence needed to demonstrate conformance with the standard (e.g. records, assessors observation, or interviews):

- C.3.3.1.1 Organization and Management,
- C.3.3.1.2 Quality System,
- C.3.3.1.3 Personnel,
- C.3.3.1.4 Physical facility,
- C.3.3.1.5 Equipment and reference materials,
- C.3.3.1.6 Measurement traceability and Calibration,
- C.3.3.1.7 Test methods and SOPs,
- C.3.3.1.8 Sample handling, sample acceptance policy, and sample receipt,
- C.3.3.1.9 Records,
- C.3.3.1.10 Laboratory report format and contents,
- C.3.3.1.11 Subcontracting of analytical samples,
- C.3.3.1.12 Outside Support Services and supplies, and
- C.3.3.1.13 Complaints.

C.3.4 Staff Interviews

Procedures for conducting and documenting staff interviews.

C.3.5 Closing Conference

Procedures to be followed for the closing conference, including:

- C.3.5.1 The process used for presentation of findings (deficiencies) at the closing conference (e.g., written, checklist, verbal),
- C.3.5.2 Discussion of deficiencies,

- C.3.5.3 Notification that the assessment team may identify additional deficiencies in the final report and potential for a follow-up assessment,
- C.3.5.4 Handling disputed findings,
- C.3.5.4 When to expect the assessment report,
- C.3.5.6 Time frame for submission of the response, and
- C.3.5.7 Schedule for renewal and reassessment.

C.4 ASSESSMENT PROCEDURES FOR TEST METHODS

This section specifies the minimum performance elements of test methods and procedures for their evaluation during on-site assessments that must be included in the accrediting authority's SOPs.

C.4.1 Performance Elements of Test Methods

Performance elements of test methods are those that directly affect data quality and data defensibility.

Although these elements apply to a broad range of test methods and analytical disciplines, assessors may at times encounter test methods for which some of these elements are not applicable. This possibility does not constitute an allowance for assuming the inapplicability of a performance element without an informed determination of this claim by a trained assessor.

In all cases, assessors must ensure that the specifications and criteria of performance elements of test methods are in conformance with the NELAC Standard.

C.4.1.1 Test Method Documentation

- C.4.1.1.1 Written procedure conforming to Section 5.5.10 of the NELAC Standard.
- C.4.1.1.2 Description of all steps necessary to determine the presence, identity, or concentration of an analyte in a sample.
- C.4.1.1.3 Demonstrations of capability of all analytes or work cells performing the test method conforming to Section 5.5.10.2 of the Standard.

C.4.1.2 Laboratory Support Equipment

- C.4.1.2.1 Availability and use of support equipment (e.g. thermometers, balances, volumetric devices).
- C.4.1.2.2 Calibration of standardization procedures.
- C.4.1.2.3 Maintenance procedures.
- C.4.1.2.4 Corrective actions and contingency procedures undertaken in the event of equipment failure.

C.4.1.3 Reagents and Standards

- C.4.1.3.1 Availability and use of reagents, standards, and biological media.

- C.4.1.3.2 Purity of standards, reagents, and biological media.
- C.4.1.3.3 Verification of identity and concentration of prepared standards.
- C.4.1.4 Laboratory Instruments
 - C.4.1.4.1 Availability and use of analytical instruments.
 - C.4.1.4.2 Standardization, tuning, or instrument setup.
 - C.4.1.4.3 Calibration procedures including:
 - C.4.1.4.3.1 Calibration range.
 - C.4.1.4.3.2 Number and concentration of calibration standards.
 - C.4.1.4.3.3 Calibration algorithm.
 - C.4.1.4.3.4 Reduction of calibration data.
 - C.4.1.4.3.5 Frequency of calibration checks or of recalibration.
 - C.4.1.4.4 Maintenance procedures.
 - C.4.1.4.5 Corrective actions and contingency procedures undertaken in the event of instrument failure.
- C.4.1.5 Sample Preparation and Analysis
 - C.4.1.5.1 Use of sample preparation techniques (e.g. filtration, aliquot selection, digestion, distillation, extraction).
 - C.4.1.5.2 Use of clean-up procedures.
 - C.4.1.5.3 Treatment of interferences before or during analysis.
 - C.4.1.5.4 Arrangement of analysis sequence or run.
- C.4.1.6 Quality Control Indicators
 - C.4.1.6.1 Type and frequency of positive (Laboratory Control Samples), negative (Method blanks), and sample specific (Matrix Spikes, Matrix Spike Duplicates, Matrix Duplicates, and Surrogates) controls.
 - C.4.1.6.2 Sensitivity and selectivity of analyses.
 - C.4.1.6.3 Acceptance criteria.
 - C.4.1.6.4 Corrective actions and contingency procedures undertaken when quality control indicators do not meet acceptance criteria.
- C.4.1.7 Data Reporting and Documentation

- C.4.1.7.1 Collection, documentation, and retrieval of raw data.
- C.4.1.7.2 Raw data media (e.g. hard copy, electronic), storage, and security.
- C.4.1.7.3 Capacity for reconstructing final results.
- C.4.1.7.4 Chronology of data reduction operations.
- C.4.1.7.5 Formulas used to derive quantitative results.
- C.4.1.7.6 Procedures for confirming or verifying qualitative assessments of reported analytes.
- C.4.1.7.7 Traceability of data to test methods, analysts, and instruments used to derive them.
- C.4.1.7.8 Procedures for allowing manual correction of raw data (e.g. manual integration) and for overriding instrument qualitative results.
- C.4.1.7.9 Procedures for data review.

C.4.2 Evaluation Phases for Test Methods

Assessors shall evaluate performance elements of test methods by completing the three phases specified below for a representative set of test methods from each analytical technology and at least Phase I (one) for all test methods used by a laboratory. This does not preclude an accrediting authority, when specified by a regulatory program, from requiring that assessors evaluate all test methods for all three phases.

C.4.2.1 Phase I – Laboratory SOPs or Methods Manuals

Assessors must confirm that SOPs or Methods Manuals:

- C.4.2.1.1 Document all tests for which the laboratory requests or maintains accreditation,
- C.4.2.1.2 Include or reference performance elements of test methods,
- C.4.2.1.3 Are controlled in conformance to the laboratory's quality system and the latest revisions are in use.

C.4.2.2 Phase II - Verification of Proper Execution of Test Methods

Assessors must verify that analysts complete performance elements of test methods and determine whether analysts adhere to laboratory SOPs or Methods Manuals by:

- C.4.2.2.1 Inspecting areas where test methods are performed, and
- C.4.2.2.2 Direct observation of analysts performing test methods, and/or
- C.4.2.2.3 Interviewing analysts that perform test methods or authorized laboratory representatives when analysts are unavailable.

C.4.2.3 Phase III - Audit of Data Generated Using Test Methods:

Assessors must ascertain that:

C.4.2.3.1 Results reported are traceable to their raw data.

C.4.2.3.2 Results reported can be traced back to calibration data and quality control indicators.

C.4.2.3.3 Documents associated with reported results validate or verify the correct execution of a test method.

C.5 ASSESSMENT REPORTING

C.5.1 Assessment Report

The SOP shall specify the content and format of assessment reports. The assessment reports shall include, at a minimum:

C.5.1.1 Identification of organization assessed (name and address)

C.5.1.2 Date of the assessment,

C.5.1.3 Identification and affiliation of the each assessment team member,

C.5.1.4 Identification of participants in the assessment,

C.5.1.5 Statement of the objective or goal of the assessment,

C.5.1.6 Summary,

C.5.1.7 Identification of assessment findings (deficiencies) and requirements with reference to the specific NELAC Standard(s).

C.5.2 Roles and Responsibilities

The SOP shall specify the roles and responsibilities of the assessment team and the accrediting authority in:

C.5.2.1 Report generation,

C.5.2.2 Report distribution,

C.5.2.3 Report release.

C.5.3 Report Release

The SOP shall specify the procedures for:

C.5.3.1 Assessment report release to the laboratory and to the public.

C.5.3.2 Handling of proprietary or confidential information.

C.6 ASSESSMENT CLOSURE

The SOP shall specify procedures, and the roles and responsibilities of the assessment team and the accrediting authority for:

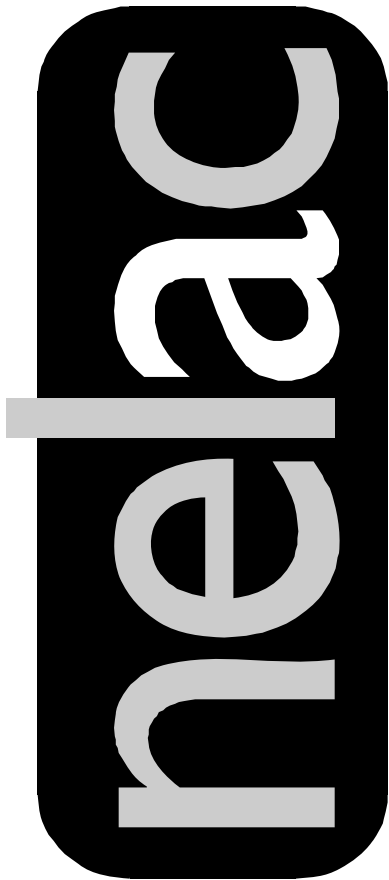
C.6.1 Evaluating the laboratory's corrective action plan.

C.6.2 Ensuring that all required time frames are met.

C.6.3 Determining a laboratory's accreditation status.

C.6.4 Performing a follow-up assessment and the minimum documentation required for such an assessment.

C.6.5 Retaining records used in or obtained during an assessment, including reports, checklists, and laboratory responses.



**National Environmental
Laboratory Accreditation
Conference**

ACCREDITATION PROCESS

Approved June 5, 2003
Effective July 1, 2005

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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.)

Laboratories applying for accreditation may be fixed-base or mobile.

- a) An individual fixed-base laboratory requires a separate accreditation. The primary accrediting authority shall determine what constitutes an individual fixed-base laboratory when noncontiguous laboratory facilities operate under the same ownership, technical directorship, and quality system as the parent laboratory.
- b) The primary accrediting authority shall determine if a separate accreditation is required for mobile laboratories that are located within and analyze samples exclusively from within their jurisdiction.
- c) The primary accrediting authority shall determine if mobile laboratories that are not individually accredited by a primary accrediting authority will need separate accreditation to operate within their jurisdiction.

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 shall qualify as technical director(s) subject to the following conditions.

- a) The person must be a technical director of the laboratory on the date the laboratory applies for NELAP accreditation and/or becomes subject to NELAP accreditation, and must have been a technical director in that laboratory continuously for the previous 12 months or more.
- b) The person will be approved as a technical director for only those fields of accreditation for which he/she has been technical director in that laboratory for the previous 12 months or more.
- c) A person who is admitted as a technical director under these conditions, and leaves the laboratory, will be admitted as technical director for the same fields of accreditation in another NELAP laboratory.
- d) A person may initially be admitted as a technical director under the provisions of this section during the first twelve months that the primary accrediting authority offers the NELAP fields of accreditation for which the person seeks to be technical director or during the first twelve months that the program is required by the state in which the laboratory is located.

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 operations for the appropriate fields of accreditation 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 accreditation 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. An individual shall not be the technical director 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 system. 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, and when the facility's laboratory is analyzing water treatment/sewage treatment samples collected within the state where the laboratory is situated, the scope of accreditation shall be determined by the accrediting authority.
- 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. Such accreditation for a industrial waste treatment facility shall be limited to laboratories analyzing industrial waste treatment samples collected within the state where the laboratory is situated, and the scope of accreditation shall be determined by the state accrediting authority.

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 3) 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 primary accrediting authority has the responsibility for conducting on-site assessments for national accreditation based on the following factors:

- a) The assessment may consist of all of the fields of accreditation and/or methods for which the laboratory wants to obtain accreditation.
- b) This language was removed and placed in the *NELAC 101 Handbook*.
- c) 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. Upon the request of the primary accrediting authority, documentation showing the implementation of corrective action(s) must be forwarded to the primary accrediting authority within the timeframe specified in the corrective action report.

- 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 accreditation, a method, or analyte within a field of accreditation.
- 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 3, Section 3.7.4.
 - g) If the laboratory fails to implement and maintain the corrective action(s) as stated in their corrective action report(s), accreditation for fields of accreditation, specific methods, or analytes within those fields of accreditation 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 2) 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 accreditation (matrix-technology/method-analyte/analyte group) 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 accreditation (matrix-technology/method-analyte/analyte group) 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 acceptable or not acceptable shall be part of the public record. PT sample results shall apply to all accredited methods for an analyte in a particular matrix.

(Effective July 1, 2003)

- d) When a laboratory initially requests accreditation, it must successfully analyze two sets of PT samples, the analyses to be performed in accordance with the timeframes specified in Chapter 2. Each set shall contain one sample for each requested field of accreditation (matrix-technology/method-analyte/analyte group). 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 accreditation (matrix-technology/method-analyte/analyte group).
-
- 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 accreditation (matrix-technology/method-analyte/analyte group) or an analyte within a field of accreditation (matrix-technology/method-analyte/analyte group).

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 5, 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 5.
- 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

This language was removed and placed in the *NELAC 101 Handbook*.

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.

4.1.7.1 Primary Application Package

A laboratory seeking accreditation shall complete and submit an application package to the primary accrediting authority(ies). An accrediting authority participating in NELAP 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 accreditation 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,
 - t) Unique vehicle identification number, such as manufacturer's Vehicle Identification Number (VIN#), serial number, or license number (if a mobile laboratory), and
 - u) Quality Manual enclosed (if required with application)

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

4.1.7.2 Secondary Accreditation Package

A laboratory seeking accreditation from a secondary accrediting authority(ies) shall complete and submit a secondary application package as required by the secondary accrediting authority. Refer to Section 4.2 for the assessment of fees (if applicable) and Section 4.4.1 for the reasons to deny a secondary application package.

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 conduct an on-site assessment to verify affects of such changes on laboratory performance. (A portion of this section was removed and placed in the *NELAC 101 Handbook*).

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 within 30 calendar days and entered into the national database by the primary accrediting authority. Required notification for change in location shall apply only to fixed-based laboratories.
- 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 primary accrediting authority.
- d) Any change in ownership must assure historical traceability of the laboratory accreditation number(s).
- e) When there is a change in ownership 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

Authorized Agent (Title)

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 accreditation 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 accreditation method or analyte within a field of accreditation. 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 Sections 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 5, 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 accreditation. 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 5, Section 5.4.12 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 to pay required fees;
- 3) Failure of laboratory staff to meet the personnel qualifications of education, training, and experience as required by the NELAC standards;
- 4) Failure to successfully analyze and report proficiency testing samples as required by the NELAC standards, Chapter 2;

- 5) 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;
 - 6) Failure to implement the corrective actions detailed in the corrective action report within the time frame as approved by the primary accrediting authority;
 - 7) Failure to implement a quality system as defined in Chapter 5;
 - 8) Failure to pass required on-site assessment(s) as specified in the NELAC standards, Chapter 3;
 - 9) Misrepresentation of any fact pertinent to receiving or maintaining accreditation;
 - 10) Denial of entry during normal business hours for an on-site assessment as required by the NELAC standards, Chapter 3.
- 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 accreditations, 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 accreditation out of the three most recent proficiency testing studies as defined in NELAC, Chapter 2; 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.
 - 4) Failure to maintain a Quality System as defined in Chapter 5.
 - 5) Failure of laboratory to employ staff that meet the personnel qualifications for education, training and experience as required by the NELAC standards.

- c) A suspended laboratory cannot continue to analyze samples for the affected fields of accreditation 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. After correcting the reason/cause for revocation and satisfying any legal remedies, the laboratory may reapply for accreditation.

- 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 accreditation, 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 accreditation as defined in NELAC Chapter 2.
- 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 2;
 - 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 3;
 - 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) No laboratory's accreditation shall be revoked without the right to due process.

4.4.4 Voluntary Withdrawal

This language was removed and placed in the *Policy on a Laboratory's Voluntary Withdrawal of Accreditation(s) Issued By NELAP Accrediting Authorities (AAs)*.

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 NELAP insignia. The certificate shall include:

- a) name of laboratory,
- b) address of the laboratory,
- c) fields of accreditation (matrix-technology/method-analyte/analyte group), 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 for which it is accredited. 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 accreditation, 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 6, Section 8).

4.6.2 Changes in Fields of Accreditation

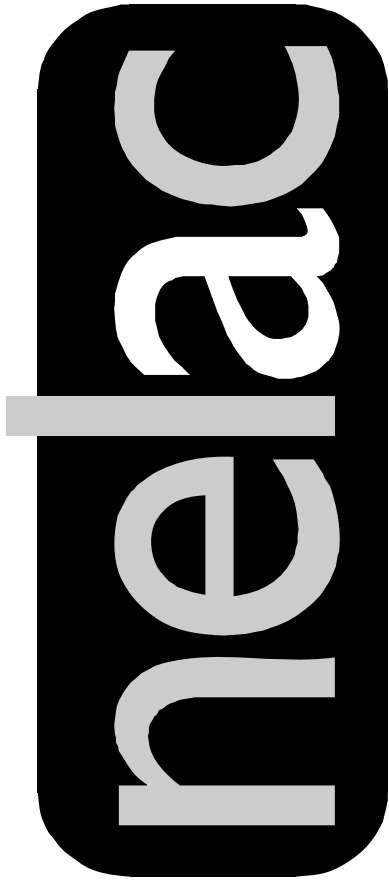
An accrediting authority may approve a laboratory's application to add an analyte or method to its scope of accreditation by performing a data review, without an on-site assessment. An addition to the scope of accreditation via a data review of proficiency testing performance (if available), quality 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 DUE PROCESS

This language was removed and placed in the *NELAC 101 Handbook*.

4.8 ENFORCEMENT

This language was removed and placed in the *NELAC 101 Handbook*.



**National Environmental
Laboratory Accreditation
Conference**

**QUALITY
SYSTEMS**

Approved July 12, 2002
Effective July 1, 2004 unless otherwise noted

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5.0 QUALITY SYSTEMS

INTRODUCTION

Each laboratory shall have a quality system. The laboratory's quality system is the process by which the laboratory conducts its activities so as to provide the client with data of known and documented quality with which to demonstrate regulatory compliance and for other decision-making purposes. This system includes a process by which appropriate analytical methods are selected, their capability is evaluated and their performance is documented. The quality system shall be documented in the laboratory's quality manual.

This chapter contains detailed quality system requirements for consistent and uniform implementation by both the laboratories conducting testing under these standards and the evaluation of those laboratories by accrediting authorities. Each laboratory seeking accreditation under NELAP must assure that they are implementing their quality system and that all quality control (QC) procedures specified in this chapter are being followed. The quality assurance (QA) policies, which establish QC procedure, are applicable to environmental laboratories regardless of size and complexity.

The growth in use of quality systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality system that is seen as compliant with ISO 9001 or ISO 9002 as well as with this Standard. Care has been taken, therefore, to incorporate all the requirements of ISO 9001 and ISO 9002 that are relevant to the scope of environmental testing services that are covered by the laboratory's quality system.

Environmental testing laboratories that comply with this Standard will therefore also operate in accordance with ISO 9001 or ISO 9002.

Certification against ISO 9001 and ISO 9002 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results.

Chapter 5 is organized according to the structure of ISO/IEC 17025, 1999. Where deemed necessary, specific areas within this Chapter may contain more information than specified by ISO/IEC 17025.

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

5.1 SCOPE

5.1.1 This Standard specifies the general requirements for the competence to carry out environmental tests, including sampling. It covers testing performed using standard methods, non-standard methods, and laboratory-developed methods.

It contains all of the requirements that environmental testing laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

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 1.6.2.)

5.1.2 This Standard is applicable to all organizations performing environmental tests. These include, for example, first-, second- and third-party laboratories, and laboratories where environmental testing forms part of inspection and product certification.

This Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of environmental testing activities. When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

5.1.3 The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this Standard.

5.1.4 This Standard is for use by laboratories in developing their quality, administrative and technical systems that govern their operations. Laboratory clients, regulatory authorities and accreditation authorities may also use it in confirming or recognizing the competence of laboratories.

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).

5.1.5 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this Standard. It is the laboratory's responsibility to comply with the relevant health and safety requirements.

5.1.6 If environmental testing laboratories comply with the requirements of this Standard, they will operate a quality system for their environmental testing activities that also meets the requirements of ISO 9001 when they engage in the design/development of new methods, and/or develop test programs combining standard and non-standard test and calibration methods, and ISO 9002 when they only use standard methods. ISO/IEC 17025 covers several technical competence requirements that are not covered by ISO 9001 and ISO 9002.

5.1.7 An integral part of a quality system is the data integrity procedures. The data integrity procedures provide assurance that a highly ethical approach to testing is a key component of all laboratory planning, training and implementation of methods. The following sections in this standard address data integrity procedures:

Management Responsibilities	5.4.2.6, 5.4.2.6.1, and 5.4.2.6.2
Training	5.5.2.7
Control and Documentation	5.4.15

5.2 REFERENCES

See Appendix A.

5.3 TERMS AND DEFINITIONS

The relevant definitions from ISO/IEC Guide 2, ANSI/ASQC E-4 (1994), 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 1 together with further definitions applicable for the purposes of this Standard. General definitions related to quality are given in ISO 8402, whereas ISO/IEC Guide 2 gives definitions specifically related to standardization, certification, and laboratory accreditation. Where different definitions are given in ISO 8402, the definitions in ISO/IEC Guide 2 and VIM are preferred.

See Appendix A, Glossary, of Chapter 1.

5.4 MANAGEMENT REQUIREMENTS

5.4.1 Organization

5.4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

5.4.1.2 It is the responsibility of the laboratory to carry out its environmental testing activities in such a way as to meet the requirements of this Standard and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.

5.4.1.3 The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

5.4.1.4 If the laboratory is part of an organization performing activities other than environmental testing, the responsibilities of key personnel in the organization that have an involvement or influence on the environmental testing activities of the laboratory shall be defined in order to identify potential conflicts of interest.

a) Where a laboratory is part of a larger organization, the organizational arrangements shall be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this Standard.

b) The laboratory must be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment. Environmental testing laboratories shall not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its environmental testing activities.

5.4.1.5 The laboratory shall:

a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing environmental tests, and to initiate actions to prevent or minimize such departures (see also 5.5.2);

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

c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.

The policy and procedures to ensure the protection of clients' confidential information and proprietary rights may not apply to in-house laboratories.

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;

e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

- f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the environmental tests.

Documentation shall include a clear description of the lines of responsibility in the laboratory and shall be proportioned such that adequate supervision is ensured;

- g) provide adequate supervision of environmental testing staff, including trainees, by persons familiar with methods and procedures, purpose of each environmental test, and with the assessment of the environmental test results;
- h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

The technical director(s) (however named) 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)

- i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times. The quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

Where staffing is limited, the quality manager may also be the technical director or deputy technical director;

The quality manager (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 as per 5.4.13 annually; and,
 - 7) notify laboratory management of deficiencies in the quality system and monitor corrective action.
- j) appoint deputies for key managerial personnel. Including the technical director(s) and/or quality-manager; and,

- k) for purposes of qualifying for and maintaining accreditation, each laboratory shall participate in a proficiency test program as outlined in Chapter 2.

5.4.2 Quality System

5.4.2.1 The laboratory shall establish implement 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. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the environmental test results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

5.4.2.2 The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

- a) the laboratory management's commitment to good professional practice and to the quality of its environmental testing in servicing its clients. The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.
- b) the management's statement of the laboratory's standard of service;
- c) the objectives of the quality system;

The laboratory management shall ensure that these policies and objectives are documented in a quality manual.

- b) a requirement that all personnel concerned with environmental testing activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and,
- e) the laboratory management's commitment to compliance with this Standard.

5.4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.

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.

Where a laboratory's quality manual contains the necessary requirements, a separate SOP or policy is not required.

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 manager (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 (see 5.4.2.2);

- 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 (SOPs), 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 quality manager(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 which may include 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) reference to procedures for reporting analytical results; and,

v) a table of contents, and applicable lists of references and glossaries, and appendices.

5.4.2.4 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this Standard, shall be defined in the quality manual.

4.3.1.5 The quality manual shall be maintained current under the responsibility of the quality manager.

5.4.2.6 The laboratory shall establish and maintain data integrity procedures. These procedures shall be defined in detail within the quality manual. There are four required elements within a data integrity system. These are 1) data Integrity training, 2) signed data integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation. The data integrity procedures shall be signed and dated by senior management. These procedures and the associated implementation records shall be properly maintained and made available for assessor review. The data integrity procedures shall be annually reviewed and updated by management.

5.4.2.6.1 Laboratory management shall provide a mechanism for confidential reporting of data integrity issues in their laboratory. A primary element of the mechanism is to assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern.

5.4.2.6.2 In instances of ethical concern, the mechanism shall include a process whereby laboratory management are to be informed of the need for any further detailed investigation.

5.4.3 Document Control

5.4.3.1 General

The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources). Documents include policy statements, procedures, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

The control of data related to environmental testing is covered in 5.5.4.7. The control of records is covered in 5.4.12.

5.4.3.2 Document Approval and Issue

5.4.3.2.1 All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

5.4.3.2.2 The procedure(s) adopted shall ensure that:

- a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;
- b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

- c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

5.4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

5.4.3.3 Document Changes

5.4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

5.4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

5.4.3.3.3 If the laboratory's documentation control system allows for the amendment of documents by hand, pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.

5.4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

5.4.4 Review of Requests, Tenders and Contracts

5.4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for environmental testing shall ensure that:

- a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5.4.2);
- b) the laboratory has the capability and resources to meet the requirements;

The purpose of this review of capability is to establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the environmental tests in question. The review may encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial environmental test programs using samples or items of known value in order to determine uncertainties of measurement, detection limits, confidence limits, or other essential quality control requirements. The current accreditation status of the laboratory must also be reviewed. The laboratory must inform the client of the results of this review if it indicates any potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the client's work.

- c) the appropriate environmental test method is selected and capable of meeting the clients' requirements (see 5.5.4.2).

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client.

A contract may be any written or oral agreement to provide a client with environmental testing services.

5.4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

For review of routine and other simple tasks, the date and the identification (e. g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial inquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced environmental testing tasks, a more comprehensive record should be maintained.

5.4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

5.4.4.4 The client shall be informed of any deviation from the contract.

5.4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel. Suspension of accreditation, revocation of accreditation, or voluntary withdrawal of accreditation must be reported to the client.

5.4.5 Subcontracting of Environmental Tests

5.4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e. g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e. g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a laboratory accredited under NELAP for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed. The laboratory performing the subcontracted work shall be indicated in the final report and non-NELAP accredited work shall be clearly identified.

5.4.5.2 The laboratory shall advise the client of the arrangement in writing and, when possible, gain the approval of the client, preferably in writing.

5.4.5.3 The laboratory is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.

5.4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for environmental tests and a record of the evidence of compliance with 5.4.5.1.

5.4.6 Purchasing Services and Supplies

5.4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the environmental tests. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the environmental tests.

5.4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of environmental tests are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the environmental tests concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

5.4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

5.4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of environmental testing, and shall maintain records of these evaluations and list those approved.

5.4.7 Service to the Client

The laboratory shall afford clients or their representatives' cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.

5.4.8 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 5.4.10).

5.4.9 Control of Nonconforming Environmental Testing Work

5.4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its environmental testing work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that:

- a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports, as necessary) are defined and taken when nonconforming work is identified;
- b) an evaluation of the significance of the nonconforming work is made;
- c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work;
- d) where the data quality is or may be impacted, the client is notified;
- e) the responsibility for authorizing the resumption of work is defined.

5.4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 5.4.10 shall be promptly followed.

5.4.10 Corrective Action

5.4.10.1 General

The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

5.4.10.2 Cause Analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

5.4.10.3 Selection and Implementation of Corrective Actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

5.4.10.4 Monitoring of Corrective Actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

5.4.10.5 Additional Audits

Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 5.4.13 as soon as possible.

5.4.10.6 Technical Corrective Action

- a) In addition to providing acceptance criteria and specific protocols for corrective actions in the Method SOPs (see 5.5.4.1.1), 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 shall 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 quality manager) 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 laboratory defined data qualifier(s).

5.4.11 Preventive Action

Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

5.4.11.1 Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.

5.4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

5.4.12 Control of 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 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 sample handling: 1) sample tracking and 2) legal chain of custody protocols, which are used for evidentiary or legal purposes. All essential requirements for sample tracking (e. g., chain of custody form) are outlined in Sections 5.4.12.1.5, 5.4.12.2.4 and 5.4.12.2.5. If a client specifies that a sample will be used for evidentiary purposes, then a laboratory shall have a written SOP for how that laboratory will carry out legal chain of custody for example, ASTM D 4840- 95 and Manual for the Certification of Laboratories Analyzing Drinking Water, March 1997, Appendix A.

5.4.12.1 General

5.4.12.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions. Records may be in any media, such as hard copy or electronic media.

5.4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

5.4.12.1.3 All records shall be held secure and in confidence.

5.4.12.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

5.4.12.1.5 The record keeping system must allow historical reconstruction of all laboratory activities that produced the 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, sample receipt, preparation 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, e.g., set format for naming electronic files.

- d) All changes to records 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 5.5.4.7.2 for computer and electronic data.

5.4.12.2 Technical Records

5.4.12.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report issued, for a defined period. The records for each environmental test shall contain sufficient information to facilitate identification of factors affecting the uncertainty and to enable the environmental test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each environmental test and checking of results.

5.4.12.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

5.4.12.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

When corrections are due to reasons other than transcription errors, the reason for the correction shall be documented.

5.4.12.2.4 Records Management and Storage

- a) All records (including those pertaining to 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 5.4.12.2.5 shall be retained for a minimum of five years from generation of the last entry in the records. 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. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed.

5.4.12.2.5 Laboratory Sample Tracking

5.4.12.2.5.1 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, sample transmittal forms, (chain of custody form); and,
- d) documented procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.

5.4.12.2.5.2 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 SOPs;
- 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) results of data review, verification, and cross-checking procedures.

5.4.12.2.5.3 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 of analysis and time of analysis is required if the holding time is 72 hours or less or when time critical steps are included in the analysis, e.g., extractions, and incubations;
- c) instrumentation identification and instrument operating conditions/parameters (or reference to such data);
- d) analysis type;
- e) all manual calculations, e.g., manual integrations; and,
- f) analyst's or operator's initials/signature;
- g) sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;
- h) sample analysis;
- i) standard and reagent origin, receipt, preparation, and use;
- j) calibration criteria, frequency and acceptance criteria;
- k) data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- l) quality control protocols and assessment;
- m) electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; and,
- n) method performance criteria including expected quality control requirements.

5.4.12.2.5.4 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.

5.4.13 Internal Audits

5.4.13.1The laboratory shall periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard. The internal audit program shall address all elements of the quality system, including the environmental testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the 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.

5.4.13.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's environmental test results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results may have been affected.

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 test report or test certificate or amendment to a report or certificate.

The laboratory must specify, in the laboratory's quality manual, the time frame for notifying a client of events that cast doubt on the validity results.

5.4.13.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. The laboratory management shall ensure that these actions are discharged within the agreed time frame as indicated in the quality manual and/or SOPs.

5.4.13.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

5.4.14 Management Reviews

5.4.14.1 In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically and at least annually conduct a review of the laboratory's quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- a) the suitability of policies and procedures;
- b) reports from managerial and supervisory personnel;
- c) the outcome of recent internal audits;
- d) corrective and preventive actions;
- e) assessments by external bodies;
- f) the results of interlaboratory comparisons or proficiency tests;
- g) changes in the volume and type of the work;
- h) client feedback;
- i) complaints; and,
- j) other relevant factors, such as quality control activities, resources and staff training.

5.4.14.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

The laboratory shall have a procedure for review by management and maintain records of review findings and actions.

5.4.15 The laboratory, as part of their overall internal auditing program, shall insure that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity. Discovery of potential issues shall be handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified. All investigations that result in finding of inappropriate activity shall be documented and shall include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. All documentation of these investigation and actions taken shall be maintained for at least five years.

5.5 TECHNICAL REQUIREMENTS

5.5.1 General

5.5.1.1 Many factors determine the correctness and reliability of the environmental tests performed by a laboratory. These factors include contributions from:

- a) human factors (5.5.2);
- b) accommodation and environmental conditions (5.5.3);
- c) environmental test methods and method validation (5.5.4);
- d) equipment (5.5.5);
- e) measurement traceability (5.5.6);
- f) sampling (5.5.7);
- g) the handling of samples (5.5.8).

5.5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) environmental tests. The laboratory shall take account of these factors in developing environmental test methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

5.5.2 Personnel

5.5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform environmental tests, evaluate results, and sign test reports. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

The laboratory shall have sufficient personnel with the necessary education, training, technical knowledge and experience for his/her 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.

5.5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for

identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.

5.5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.

5.5.2.4 The laboratory shall maintain current job descriptions for all personnel who manage, perform, or verify work affecting the quality of the environmental tests.

5.5.2.5 The management shall authorize specific personnel to perform particular types of sampling, environmental testing, to issue test reports, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory [see 5.5.2.6.c], including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.5.4.2.2 for chemical testing.

5.5.2.6 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) 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 as defined by the laboratory document control system, 5.4.2.3.d) 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). Note: 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 5030/8260) would only require documentation for one of the test

- methods. The laboratory must determine the acceptable limits of the blind performance sample prior to analysis;
- ii. an initial measurement system evaluation or another demonstration of capability;
 - iii. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory must determine the acceptable limits for precision and accuracy prior to analysis; or
 - iv. if i-iii cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.
- 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 5.5.8) are verified and that samples are logged into the sample tracking system and properly labeled and stored; and,
 - g) documenting the quality of all data reported by the laboratory.

5.5.2.7 Data integrity training shall be provided as a formal part of new employee orientation and must also be provided on an annual basis for all current employees. Topics covered shall be documented in writing and provided to all trainees. Key topics covered during training must include organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping. Training shall include discussion regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring and data integrity procedure documentation. Employees are required to understand that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution. The initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity. Senior managers acknowledge their support of these procedures by 1) upholding the spirit and intent of the organization's data integrity procedures and 2) effectively implementing the specific requirements of the procedures.

Specific examples of breaches of ethical behavior should be discussed including improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards. Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. The data integrity procedures may also include written ethics agreements, examples of improper practices, examples of improper chromatographic manipulations, requirements for external ethics program training, and any external resources available to employees.

5.5.3 Accommodation and Environmental Conditions

5.5.3.1 Laboratory facilities for environmental testing, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the environmental tests.

The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and environmental tests are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of environmental tests shall be documented.

5.5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Environmental tests shall be stopped when the environmental conditions jeopardize the results of the environmental tests.

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.

5.5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities including culture handling or incubation areas and volatile organic chemicals handling areas. Measures shall be taken to prevent cross-contamination.

5.5.3.4 Access to and use of areas affecting the quality of the environmental tests shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

5.5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.5.3.6 Work spaces must be available to ensure an unencumbered work area. Work areas include:

- a) access and entryways to the laboratory;
- b) sample receipt area(s);
- c) sample storage area(s);
- d) chemical and waste storage area(s); and,
- e) data handling and storage area(s).

5.5.4 Environmental Test Methods and Method Validation

5.5.4.1 General

The laboratory shall use appropriate methods and procedures for all environmental tests within its scope. These include sampling, handling, transport, storage and preparation of samples, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of environmental test data.

The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples where the absence of such instructions could jeopardize the results of environmental tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 5.4.3). Deviation from environmental test methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

5.5.4.1.1 Standard Operating Procedures (SOPs)

Laboratories shall maintain SOPs 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 with adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result.
- b) The test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the methods manual (see 5.5.4.1.2).
- 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.
- f) The documents specified in 5.5.4.1.1 a) and 5.5.4.1.1 b) that contain sufficient information to perform the tests do not need to be supplemented or rewritten as internal procedures, if the documents are written in a way that they can be used as written. Any changes, including the use of a selected option must be documented and included in the laboratory's methods manual.

5.5.4.1.2 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 SOPs 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) data analysis and 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.

5.5.4.2 Selection of Methods

The laboratory shall use methods for environmental testing, including methods for sampling, which meet the needs of the client and which are appropriate for the environmental tests it undertakes.

5.5.4.2.1 Sources of Methods

- a) Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.
- b) When the use of specific methods for a sample analysis are mandated or requested, only those methods shall be used.
- c) When the client does not specify the method to be used or where methods are employed that are not required, the methods shall be fully documented and validated (see 5.5.4.2.2, 5.5.4.5, and Appendix C), and be available to the client and other recipients of the relevant reports. The laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client shall be informed as to the method chosen.
- d) The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

5.5.4.2.2 Demonstration of Capability

The laboratory shall confirm that it can properly operate all methods before introducing the environmental tests. If the method changes, the confirmation shall be repeated.

- a) Prior to acceptance and institution of any method, satisfactory demonstration of method capability is required. (See Appendix C and 5.5.2.6.b) In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean quality system matrix sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., drinking 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 cases where a laboratory analyzes samples using a method that has been in use by the laboratory before July 1999, and there have been no significant changes in instrument type, personnel or method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency shall be acceptable. The laboratory shall have records on file to demonstrate that a demonstration of capability is not required.

- d) 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.)
- e) A demonstration of capability must be completed each time there is a change in instrument type, personnel, or method.
- f) 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.
- g) 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 that area of the work cell where they are employed. 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 perform the demonstration of capability (Appendix C).
- h) 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 5.5.2.6).

5.5.4.3 Laboratory-Developed Methods

The introduction of environmental test methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

5.5.4.4 Non-Standard Methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test. The method developed shall have been validated appropriately before use.

5.5.4.5 Validation of Methods

5.5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their published scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. The minimum requirements shall be the initial test method evaluation requirements given in Appendix C.3 of this chapter.

5.5.4.5.3 The range and accuracy of the values obtainable from validated methods (e. g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or

reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the clients' needs.

5.5.4.6 Estimation of Uncertainty of Measurement

5.5.4.6.1 Environmental testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.5.10).

5.5.4.6.2 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

5.5.4.7 Control of Data

5.5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

- a) The laboratory shall establish SOPs to ensure that the reported data are free from transcription and calculation errors.
- b) The laboratory shall establish SOPs to ensure that all quality control measures are reviewed, and evaluated before data are reported.
- c) The laboratory shall establish SOPs addressing manual calculations including manual integrations.

5.5.4.7.2 When computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, reporting, storage or retrieval of environmental test data, the laboratory shall ensure that:

- a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data; and,
- d) 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.

Commercial off-the-shelf software (e. g. word processing, database and statistical programs) in general use within their designed application range is considered to be sufficiently validated. However, laboratory software configuration or modifications must be validated as in 5.5.4.7.2.a.

5.5.5 Equipment

5.5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the environmental tests (including sampling, preparation of samples, processing and analysis of environmental data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this Standard are met.

5.5.5.2 Equipment and its software used for testing and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the environmental tests concerned. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications.

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.

5.5.5.2.1 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.

- a) All support equipment shall be maintained in proper working order. The records of all repair and maintenance activities including service calls shall be kept.
- b) All support equipment shall be calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration or verification 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, and water baths shall be checked in the expected use range, with NIST traceable references where commercially available. 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 including burettes (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 that employ autoclave sterilization see section D.3.8.

5.5.5.2.2 Instrument Calibration

This standard specifies the essential elements that shall define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data must 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.

5.5.5.2.1 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, acceptance criteria and associated statistics must be included or referenced in the test method SOP. When initial instrument calibration procedures are referenced in the test method, then the referenced material must be retained by the laboratory and be available for review.
- 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, analyst's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration.
- c) Sample results must be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program.
- d) All initial instrument calibrations must be verified with a standard obtained from a second manufacturer or lot if the lot can be demonstrated from the manufacturer as prepared independently from other lots. Traceability shall be to a national standard, when commercially available.
- e) Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient or relative percent difference. The criteria used must be appropriate to the calibration technique employed.
- f) The lowest calibration standard shall be the lowest concentration for which quantitative data are to be reported (see Appendix C). Any data reported below the lower limit of quantitation should be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or flags or explained in the case narrative.

- g) The highest calibration standard shall be the highest concentration for which quantitative data are to be reported (see Appendix C). Any data reported above this highest standard should be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or flags or explained in the case narrative.
- h) Measured concentrations outside the working range shall be reported as having less certainty and shall be reported using defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the limit of detection. Noted exception: the following shall occur for instrument technology (such as ICP or ICP/MS) with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard:
 - 1) Prior to the analysis of samples the zero point and single point calibration must be analyzed and the linear range of the instrument must be established by analyzing a series of standards, one of which must be at the lowest quantitation level. Sample results within the established linear range will not require data qualifier flags.
 - 2) Zero point and single point calibration standard must be analyzed with each analytical batch.
 - 3) A standard corresponding to the limit of quantitation must be analyzed with each analytical batch and must meet established acceptance criteria.
 - 4) The linearity is verified at a frequency established by the method and/or the manufacturer.
- i) If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed and all associated samples reanalyzed. If reanalysis of the samples is not possible, data associated with an unacceptable initial instrument calibration shall be reported with appropriate data qualifiers.
- j) If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, (one of which must be at the limit of quantitation) not including blanks or a zero standard with the noted exception of instrument technology for which it has been established by methodologies and procedures that a zero and a single point standard are appropriate for calibrations (see 5.5.5.2.2.1 h). The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.

5.5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented.

5.5.5.4 Each item of equipment and its software used for environmental testing and significant to the result shall, when practicable, be uniquely identified.

5.5.5.5 The laboratory shall maintain records of each major item of equipment and its software significant to the environmental tests performed. The records shall include at least the following:

- a) the identity of the item of equipment and its software;

- b) the manufacturer's name, type identification, and serial number or other unique identification;
- c) checks that equipment complies with the specification (see 5.5.5.2);
- d) the current location;
- e) the manufacturer's instructions, if available, or reference to their location;
- f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
- g) the maintenance plan, where appropriate, and maintenance carried out to date; documentation on all routine and non-routine maintenance activities and reference material verifications.
- h) any damage, malfunction, modification or repair to the equipment.
- i) date received and date placed in service (if available);
- j) if available, condition when received (e.g. new, used, reconditioned);

5.5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

5.5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service, until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous environmental tests and shall institute the "Control of nonconforming work" procedure (see 5.4.9).

5.5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.5.10 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 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) Calibration shall be verified for each compound, element, or other discrete chemical species, except for multi-component analytes such as Aroclors, Total Petroleum Hydrocarbons, or Toxaphene where a representative chemical related substance or mixture can be used.
- c) Instrument calibration verification must be performed:

- 1) at the beginning and end of each analytical batch (except, if an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch);
 - 2) whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria;
 - 3) if the time period for calibration or the most previous calibration verification has expired; or
 - 4) for analytical systems that contain a calibration verification requirement.
- d) 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, or unique equations or coefficients used to convert instrument responses into concentrations. Continuing calibration verification records must explicitly connect the continuing verification data to the initial instrument calibration.
- e) Criteria for the acceptance of a continuing instrument calibration verification must be established, e.g., relative percent difference.

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 acceptable performance after corrective action with two consecutive calibration verifications, or a new initial instrument calibration must be performed. If the laboratory has not verified calibration, sample analyses may not occur until the analytical system is calibrated or calibration verified. If samples are analyzed using a system on which the calibration has not yet been verified the results shall be flagged. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions:

- 1) 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.
- 2) 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.

5.5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e. g. in computer software) are correctly updated.

5.5.5.12 Test equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test results.

5.5.6 Measurement Traceability

5.5.6.1 General

All equipment used for environmental tests, including equipment for subsidiary measurements (e. g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the environmental test or sampling shall be calibrated before being put into service and on a continuing basis. The laboratory shall have an established program and procedure for the calibration of its equipment. This includes balances, thermometers, and control standards. Such a program shall include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform environmental tests.

5.5.6.2 Testing Laboratories

5.5.6.2.1 For testing laboratories, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

- a) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.

5.5.6.2.2 Where traceability of measurements to SI units is not possible or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required. 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.

5.5.6.3 Reference Standards and Reference Materials

5.5.6.3.1 Reference Standards

The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.5.6.2.1. Such 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 shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment. Where commercially available, this traceability shall be to a national standard of measurement.

5.5.6.3.2 Reference Materials

Reference materials shall, where commercially available, be traceable to SI units of measurement, or to certified reference materials. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.5.6.3.3 Intermediate Checks

Checks needed to maintain confidence in the status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

5.5.6.3.4 Transport and Storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

5.5.6.4 Documentation and Labeling of Standards, Reagents, and Reference Materials

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, reagents, reference materials and media 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 its reliability 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 standard and reference material 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, standards and reference materials must bear a unique identifier and expiration date and be linked to the documentation requirements in 5.5.6.4.c above.
- e) Procedures shall be in place to ensure prepared reagents meet the requirements of the test method. The source of reagents shall comply with 5.5.9.2 a) 6) and D.1.4 b).
- f) All containers of prepared reagents must bear a preparation date. An expiration date shall be defined on the container or documented elsewhere as indicated in the laboratory's quality manual or SOP.

5.5.7 Sampling

5.5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent environmental testing. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the environmental test results.

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.

5.5.7.2 Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing environmental test and/or calibration results, and shall be communicated to the appropriate personnel.

5.5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the environmental testing that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant)

and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

5.5.8 Handling of Samples

While the laboratory may not have control of field sampling activities, the following are essential to ensure the validity of the laboratory's data.

5.5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of samples, including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the client.

5.5.8.2 The laboratory shall have a system for identifying samples. The identification shall be retained throughout the life of the sample in the laboratory. The system shall be designed and operated so as to ensure that samples cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of samples and the transfer of samples within and from the laboratory.

- a) The laboratory shall have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples 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 5.5.8.3.1.d) and shall be the link that associates the sample with related laboratory activities such as sample preparation.
- 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.

5.5.8.3 Upon receipt of the samples, the condition, including any abnormalities or departures from normal or specified conditions as described in the environmental test method, shall be recorded. When there is doubt as to the suitability of a sample for environmental test, or when a sample does not conform to the description provided, or the environmental test required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion.

5.5.8.3.1 Sample Receipt Protocols

- a) All items specified in 5.5.8.3.2 below 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 on the same day

that they are collected may not meet these 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 chlorine, prior to or during sample preparation or analysis.
 - 3) Microbiological samples from chlorinated water systems do not require an additional chlorine residual check in the laboratory if the following conditions are met:
 - i. sufficient sodium thiosulfate is added to each container to neutralize at minimum 5 mg/l of chlorine for drinking water and 15mg/l of chlorine for wastewater samples;
 - ii. one container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15mg/l chlorine as appropriate and the check is documented;
 - iii. chlorine residual is checked in the field and actual concentration is documented with sample submission.
- b) The results of all checks shall be recorded.
- c) If the sample does not meet the sample receipt acceptance criteria listed in this standard, the laboratory shall either:
- 1) 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 5.5.8.2), 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 form (Sections 5.4.12.2.5 and Appendix E), if utilized, shall be maintained.

5.5.8.3.2 Sample Acceptance Policy

The laboratory must have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected. 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 show signs of damage, contamination or inadequate preservation.

5.5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, contamination, loss or damage to the sample during storage, handling, preparation and testing. Handling instructions provided with the sample shall be followed. When samples have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a sample or a portion of a sample is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured samples or portions concerned.

- a) Samples shall be stored according to the conditions specified by preservation protocols:
 - 1) Samples that 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 5.5.8.4.a above or according to specifications in the test method.
 - 1) The laboratory shall have SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products.

5.5.9 Assuring the Quality of Environmental Test and Calibration Results

5.5.9.1 General

The laboratory shall have quality control procedures for monitoring the validity of environmental tests undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

- a) regular use of certified reference materials and/or internal quality control using secondary reference materials;
- b) participation in interlaboratory comparison or proficiency-testing program (see Chapter 2);
- c) replicate tests using the same or different methods;
- d) retesting of retained samples; and,
- e) correlation of results for different characteristics of a sample (for example, total phosphate should be greater than or equal to orthophosphate).

5.5.9.2 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 detailed written protocols in place to monitor the following quality controls:
 - 1) positive and negative controls to monitor tests such as blanks, spikes, reference toxicants;
 - 2) 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 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 limit of detection and limit of quantitation 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 5.5.8.3.2, Sample Acceptance Policy)
- d) The quality control protocols specified by the laboratory's method manual (5.5.4.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent the QC in the mandated method or regulations is to be followed.

The essential quality control measures for testing are found in Appendix D of this Chapter.

5.5.10 Reporting the Results

5.5.10.1 General

The results of each test, or series of environmental tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the environmental test.

The results shall be reported, in a test report, and shall include all the information requested by the client and necessary for the interpretation of the environmental test or calibration results and all information required by the method used. This information is normally required by 5.5.10.2, and 5.5.10.3

In the case of environmental tests performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way. Any information listed in 5.5.10.2 to 5.5.10.4 which is not reported to the client shall be readily available in the laboratory which carried out the environmental tests.

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.

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 a) through m) below readily available for review by the accrediting authority. However, formal reports detailing the information are not required if:

- a) the in-house laboratory is itself responsible for preparing the regulatory reports; or
- b) 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.

5.5.10.2 Test Reports

Each test report shall include at least the following information, unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b:

- a) a title (e.g. "Test Report," "Certificate of Results," or "Laboratory Results");
- b) the name and address of the laboratory, the location where the environmental tests were carried out, if different from the address of the laboratory, and phone number with name of contact person for questions;
- c) unique identification of the test report (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report and a clear identification of the end of the test report;
 - 1) 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 (e.g. 3 of 10, or 1 of 20).
 - 2) 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.
- d) the name and address of the client and project name if applicable;
- e) identification of the method used;
- f) a description of, the condition of, and unambiguous identification of the sample(s), including the client identification code;
- g) the date of receipt of the sample(s) where this is critical to the validity and application of the results, date and time of sample collection, the date(s) of performance of the environmental test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours;

- h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- i) the environmental test results with, where appropriate, the units of measurement, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as : g/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;
- j) the name(s), function(s) and signature(s) or equivalent electronic identification of person(s) authorizing the test report, and date of issue;
- k) a statement to the effect that the results relate only to the samples;
- l) 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;
- m) 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.

5.5.10.3 Supplemental Information for Test Reports

5.5.10.3.1 In addition to the requirements listed in 5.5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

- a) deviations from (such as failed quality control), additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions and any non-standard conditions that may have affected the quality of results, including the use and definitions of data qualifiers;
- b) where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications, including identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature;
- c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed when a client's instruction so requires;
- d) where appropriate and needed, opinions and interpretations (see 5.5.10.4);
- e) additional information which may be required by specific methods, clients or groups of clients;
- f) qualification of numerical results with values outside the working range.

5.5.10.3.2 In addition to the requirements listed in 5.5.10.2 and 5.5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

- a) the date of sampling;
- b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);
- c) the location of sampling, including any diagrams, sketches or photographs;
- d) a reference to the sampling plan and procedures used;

- e) details of any environmental conditions during sampling that may affect the interpretation of the test results;
- f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.5.10.4 Opinions and Interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

5.5.10.5 Environmental Testing Obtained from Subcontractors

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable accreditation number. The subcontractor shall report the results in writing or electronically. The laboratory shall make a copy of the subcontractor's report available to the client when requested by the client.

5.5.10.6 Electronic Transmission of Results

In the case of transmission of environmental test results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this Standard shall be met and ensure that all reasonable steps are taken to preserve confidentiality (see also 5.5.4.7).

5.5.10.7 Format of Reports

The format shall be designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse.

5.5.10.8 Amendments to Test Reports

Material amendments to a test report after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

"Supplement to Test Report, serial number ...[or as otherwise identified]", or an equivalent form of wording.

Such amendments shall meet all the requirements of this Standard.

When it is necessary to issue a complete new test report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

QUALITY SYSTEMS
APPENDIX A

REFERENCES

Appendix A - REFERENCES

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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 change in instrument type, personnel or test method (see 5.5.4.2.2).

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 quality system matrix (a sample in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., drinking 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, *Demonstration of Capability Certification Statement*, in this appendix. All data applicable to the demonstration need not be attached to the form, but must be retained and available.

When an analyte not currently found on the laboratory’s list of accredited analytes is added to an existing accredited test method, an initial evaluation must be performed for that analyte.

The following steps shall be performed if required by mandatory test method or regulation. 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, e.g., for Whole Effluent Toxicity Testing see section D.2.1.a.1.

- 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 quality system matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration of 1-4 times the limit of quantitation.
- 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 in the appropriate reporting units 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 must 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, confirms 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.1. 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 5.5.2.5 and 5.4.12.2.5.4.b).

**Demonstration of Capability
Certification Statement**

Date:
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Page ___ of ___

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.

C.3 INITIAL TEST METHOD EVALUATION

For all test methods other than toxicity and microbiology the requirements of C.3.1 and C.3.2 apply. For Toxicity testing, and Microbiology testing, the initial test method evaluation requirements are contained at Appendix D.2. and D.3., respectively. For the evaluation of precision and bias (C.3.3), the requirements of C.3.3.a apply to standard methods. The requirements of C.3.3.b apply to the methods referenced therein.

C.3.1. Limit of Detection (LOD)

- a) The laboratory shall determine the LOD for the method for each target analyte of concern in the quality system matrices. All sample-processing steps of the analytical method shall be included in the determination of the LOD.
- b) The validity of the LOD shall be confirmed by qualitative identification of the analyte(s) in a QC sample in each quality system matrix containing the analyte at no more than 2-3X the LOD for single analyte tests and 1-4X the LOD for multiple analyte tests. This verification must be performed on every instrument that is to be used for analysis of samples and reporting of data.
- c) An LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature, or, when test results are not to be reported to the LOD (versus the limit of quantitation or working range of instrument calibration), according to Appendices D.1.2, D.4.5, D.5.4, and D.6.6. Where an LOD study is not performed, the laboratory may not report a value below the limit of quantitation.

C.3.2. Limit of Quantitation (LOQ)

- a) The laboratory shall determine the LOQ for each analyte of concern according to a defined, documented procedure.
- b) The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate (e.g., pH).
- c) The validity of the LOQ shall be confirmed by successful analysis of a QC sample containing the analytes of concern in each quality system matrix 1-2 times the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy. This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ.

C.3.3. Evaluation of Precision and Bias

- a) Standard methods -- The laboratory shall evaluate the Precision and Bias of a Standard Method for each analyte of concern for each quality system matrix according to the single-concentration four-replicate recovery study procedures in Appendix C.1 above (or alternate procedure documented in the quality manual when the analyte cannot be spiked into the sample matrix and QC samples are not commercially available).
- b) Non-standard methods -- For laboratory-developed test methods or non-standard test methods as defined at 5.5.4.3 and 5.5.4.4. that were not in use by the laboratory before July 2003, the laboratory must have a documented procedure to evaluate precision and bias. The laboratory must also compare results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory.

Precision and bias measurements must evaluate the method across the analytical calibration range of the method. The laboratory must also evaluate precision and bias in the relevant quality system matrices and must process the samples through the entire measurement system for each analyte of interest.

Examples of a systematic approach to evaluate precision and bias could be the following:

Analyze QC samples in triplicate containing the analytes of concern at or near the limit of quantitation, at the upper-range of the calibration (upper 20%) and at a mid-range concentration. Process these samples on different days as three sets of samples through the entire measurement system for each analyte of interest. Each day one QC sample at each concentration is analyzed. A separate method blank shall be subjected to the analytical method along with the QC samples on each of the three days. (Note that the three samples at the LOQ concentration can demonstrate sensitivity as well.) For each analyte, calculate the mean recovery for each day, for each level over days, and for all nine samples. Calculate the relative standard deviation for each of the separate means obtained. Compare the standard deviations for the different days and the standard deviations for the different concentrations. If the different standard deviations are all statistically insignificant (e.g., F-test), then compare the overall mean and standard deviation with the established criteria from above.

A validation protocol such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process.

C.3.4. Evaluation of Selectivity

The laboratory shall evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

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 (5.5.4.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D are incorporated into their method manuals and/or the Laboratory Quality Manual.

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 5, e.g., 5.5.9.2, 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

D.1.1.1 Negative Control - Method Performance

- a) Purpose: The method blank is used to assess the preparation batch for possible contamination during the preparation and processing steps. The method blank shall be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure. Procedures shall be in place to determine if a method blank is contaminated. Any affected samples associated with a contaminated method blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.
- b) Frequency: The method blank shall be analyzed at a minimum of 1 per preparation batch. In those instances for which no separate preparation method is used (example: volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.
- c) Composition: The method blank shall consist of a quality system matrix that is similar to the associated samples and is known to be free of the analytes of interest.
- d) Evaluation Criteria and Corrective Action: While the goal is to have no detectable contaminants, each method blank must be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch. The source of contamination shall be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data shall be appropriately qualified if:
 - 1) The concentration of a targeted analyte in the blank is at or above the reporting limit as established by the test method or by regulation, AND is greater than 1/10 of the amount measured in any sample.
 - 2) The blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives.
 - 3) When a blank is determined to be contaminated, the cause must be investigated and measures taken to minimize or eliminate the problem. Samples associated

with a contaminated blank shall be evaluated as to the best corrective action for the samples (e.g. reprocessing or data qualifying codes). In all cases the corrective action must be documented.

D.1.1.2 Positive Control - Method Performance

D.1.1.2.1 Laboratory Control Sample (LCS)

- a) Purpose: The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Results of the LCS are compared to established criteria and, if found to be outside of these criteria, indicates that the analytical system is "out of control". Any affected samples associated with an out of control LCS shall be reprocessed for re-analysis or the results reported with appropriate data qualifying codes.
- b) Frequency: The LCS shall be analyzed at a minimum of 1 per preparation batch. Exceptions would be for those analytes for which no spiking solutions are available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. In those instances for which no separate preparation method is used (example: volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.
- c) Composition: The LCS is a quality system matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes. NOTE: the matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM). All analyte concentrations shall be within the calibration range of the methods. The following shall be used in choosing components for the spike mixtures:

The components to be spiked shall be as specified by the mandated test method or other regulatory requirement or as requested by the client. In the absence of specified spiking components the laboratory shall spike per the following:

For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.

For those test methods that have extremely long lists of analytes, a representative number may be chosen. The analytes selected should be representative of all analytes reported. The following criteria shall be used for determining the minimum number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a 2-year period.

- 1) For methods that include 1-10 targets, spike all components;
 - 2) For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater; and,
 - 3) For methods with more than 20 targets, spike at least 16 components.
- d) Evaluation Criteria and Corrective Action: The results of the individual batch LCS are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory shall document the calculation.

The individual LCS is compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria.

A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with a LCS determined to be "out of control" shall be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.

- e) If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary. A ME is defined as being beyond the LCS control limit (3 standard deviations), but within the ME limits. ME limits are between 3 and 4 standard deviations around the mean.

The number of allowable marginal exceedances is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails and corrective action is necessary. This marginal exceedance approach is relevant for methods with long lists of analytes. It will not apply to target analyte lists with fewer than 11 analytes.

The number of allowable marginal exceedances is as follows:

- 1) >90 analytes in LCS, 5 analytes allowed in ME of the LCS control limit;
- 2) 71-90 analytes in LCS, 4 analytes allowed in ME of the LCS control limit;
- 3) 51-70 analytes in LCS, 3 analytes allowed in ME of the LCS control limit;
- 4) 31-50 analytes in LCS, 2 analytes allowed in ME of the LCS control limit;
- 5) 11-30 analytes in LCS, 1 analytes allowed in ME of the LCS control limit;
- 6) <11 analytes in LCS, no analytes allowed in ME of the LCS control limit;

Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systemic problem. The source of the error must be located and corrective action taken. Laboratories must have a written procedure to monitor the application of marginal exceedance allowance to the LCS to ensure random behavior.

D.1.1.3 Sample Specific Controls

The laboratory must document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of quality system matrix specific Quality Control (QC) samples and are designed as data quality indicators for a specific sample using the designated test method. These controls alone are not used to judge laboratory performance.

Examples of matrix specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD); sample duplicates; and surrogate spikes. The laboratory shall have procedures in place for tracking, managing, and handling matrix specific QC criteria including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, evaluating and reporting results based on performance of the QC samples.

D.1.1.3.1 Matrix Spike; Matrix Spike Duplicates

- a) Purpose: Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.
- b) Frequency: The frequency of the analysis of matrix specific samples shall be determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the test method.
- c) Composition: The components to be spiked shall be as specified by the mandated test method. Any permit specified analytes, as specified by regulation or client requested analytes shall also be included. If there are no specified components, the laboratory shall spike per the following:

For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.

For those test methods that have extremely long lists of analytes, a representative number may be chosen using the following criteria for choosing the number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a 2 year period.

- 1) For methods that include 1-10 targets, spike all components;
 - 2) For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater;
 - 3) For methods with more than 20 targets, spike at least 16 components.
- d) Evaluation Criteria and Corrective Action: The results from matrix spike/matrix spike duplicate are primarily designed to assess the precision and accuracy of analytical results in a given matrix and are expressed as percent recovery (%R), relative percent difference (RPD), or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory shall document the calculation for %R, RPD or other statistical treatment used.

The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix spike results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

D.1.1.3.2 Matrix Duplicates

- a) Purpose: Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample chosen for duplication.

- b) Frequency: The frequency of the analysis of matrix duplicates may be determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the mandated test method.
- c) Composition: Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known.
- d) Evaluation Criteria and Corrective Action: The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD) or another statistical treatment (e.g., absolute differences). The laboratory shall document the calculation for relative percent difference or other statistical treatments.

Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix duplicates results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

D.1.1.3.3 Surrogate Spikes

- a) Purpose: Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistries of the targeted components of the method. Added prior to sample preparation/extraction, they provide a measure of recovery for every sample matrix.
- b) Frequency: Except where the matrix precludes its use or when not commercially available, surrogate compounds must be added to all samples, standards, and blanks for all appropriate test methods.
- c) Composition: Surrogate compounds are chosen to represent the various chemistries of the target analytes in the method or measurement quality objective (MQO). They are often specified by the mandated method and are deliberately chosen for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds.
- d) Evaluation Criteria and Corrective Action: The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory should determine internal criteria and document the method used to establish the limits. Surrogates outside the acceptance criteria must be evaluated for the effect indicated for the individual sample results. The appropriate corrective action may be guided by the data quality objectives or other site specific requirements. Results reported from analyses with surrogate recoveries outside the acceptance criteria should include appropriate data qualifiers.

D.1.2 Limit of Detection and Limit of Quantitation

All procedures used must be documented. Documentation must include the quality system matrix type. All supporting data must be retained.

D.1.2.1 Limit of Detection (LOD)

The laboratory shall utilize a test method that provides an LOD that is appropriate and relevant for the intended use of the data. An LOD is not required for a test method when test results are not reported outside of the calibration range. LODs shall be determined by the protocol in the mandated test method or applicable regulation. If the protocol for determining LODs is not specified, the selection of the procedure must reflect instrument limitations and the intended application of the test method.

- a) The LOD shall be initially determined for the compounds of interest in each test method in a quality system matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the LOD must be determined in the quality system matrix of interest (see definition of matrix).
- b) LODs must be determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.
- c) The laboratory must have established procedures to relate LOD with LOQ.
- d) The LOD must be verified annually for each quality system matrix, method and analyte according to the procedure specified in C.3.

D.1.2.2 Limit of Quantitation (LOQ)

- a) Any established LOQ must be above the LOD
- b) The LOQ must be verified annually for each quality system matrix, method and analyte according to the procedure specified in C.3. Alternatively, the annual LOQ verification is not required if the LOD is reevaluated or verified according to D.1.2.1.d above.

D.1.3 Data Reduction

The procedures for data reduction, such as use of linear regression, shall be documented.

D.1.4 Quality of Standards and Reagents

- a) The source of standards shall comply with 5.5.6.2.2.2.
- 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.
 - 3) The laboratory will verify the concentration of titrants in accordance with written laboratory procedures.

D.1.5 Selectivity

- a) The laboratory shall evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.
- 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.1.6 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 TOXICITY TESTING

These standards apply to laboratories measuring the toxicity and/or bioaccumulation of contaminants in effluents (whole effluent toxicity or WET), receiving waters, sediments, elutriates, leachates and soils. In addition to the essential quality control standards described below, some methods may have additional or other requirements based on factors such as the type of quality system matrix evaluated.

D.2.1 Positive and Negative Controls

- a) Positive Control - Reference toxicant tests demonstrate a laboratory's ability to obtain consistent results with the test method and evaluate the overall health and sensitivity of test organisms over time.
 - 1) The laboratory must demonstrate its ability to obtain consistent results with standard reference toxicants (SRT) and complete an initial demonstration of capability (DOC) in order to attain accreditation in toxicity testing methods.
 - i) An initial DOC shall consist of five or more acceptable SRT tests for each test method, species and endpoint with different batches of organisms. Appropriate negative controls (water, sediment, or soil) shall be tested at the frequency and duration specified in the test method. Initial DOCs shall be prepared in accordance with the requirements of Appendix C.
 - ii) Initial DOC is established by maintenance of SRT test results on control charts. A laboratory shall record the control performance and statistical endpoints (such as NOEC or ECp) for each method species and endpoint on control charts. Initial DOC is established where 95% of the test results required in D.2.1 a) 1) i) fall within the control limits established in accordance with D.2.1 a) 1) iii) and meet test acceptability criteria (TAC). The laboratory shall evaluate precision (i.e. coefficient of variation, [CV]) or sensitivity (i.e. statistical minimum significant difference, [SMSD] measures [see D.2.1 a) 1) iv]) for these tests against method specific or (lacking the former) laboratory-derived criteria to determine validity of the initial DOC.
 - iii) For endpoints that are point estimates (ICp, ECp) control charts are constructed by plotting the cumulative mean and the control limits which consist of the upper and lower 95% confidence limits (+/- 2 standard deviations). In case of highly

variable point estimates which exceed method-specific criteria the control chart limits are adjusted accordingly. For endpoints from hypothesis tests (NOEC, NOAEC) the values are plotted directly and the control limits consist of one concentration interval above and below the concentration representing the central tendency (i.e. the mode).

- iv) For endpoints that are point estimates the cumulative mean CV is calculated and for endpoints from hypothesis tests, the SMSD is calculated. These values are maintained on a control chart.
- 2) Ongoing laboratory performance shall be demonstrated by routine SRT testing for each test method and species and endpoint in accordance with the minimum frequency requirements specified in D.2.1.a.3.
- i) Intralaboratory precision is determined on an ongoing basis through the use of control charts as established in D.2.1.a.1.ii. The control charts shall be plotted as point estimate values, such as EC25 for chronic tests and LC50 for acute tests, or as appropriate hypothesis test values, such as the NOEC or NOAEC, over time within a laboratory.
 - ii) After initial laboratory DOC is determined, the control limits and CV for an individual test method, endpoints and species shall be adjusted as additional test results are obtained. After 20 data points are collected for a test method and species, the control chart is maintained using only the last 20 data points, i.e. each successive mean value and control limit is calculated using only the last 20 values.
 - iii) Control chart limits are expected to be exceeded occasionally regardless of how well a laboratory performs. Acceptance limits for point estimates (IC_p, EC_p) which are based on 95% confidence limits should theoretically be exceeded for one in twenty tests. Depending on the dilution factor and test sensitivity, control charts based on hypothesis test values (NOEC, NOAEC) may be expected to be exceeded on a similar frequency. Test results which fall outside of control chart limits at a frequency of 5% or less, or which fall just outside control chart limits (especially in the case of highly proficient laboratories which may develop relatively narrow acceptance limits over time), are not rejected *de facto*. Such data are evaluated in comparison with control chart characteristics including the width of the acceptance limits and the degree of departure of the value from acceptance limits.
 - iv) Laboratories shall develop acceptance/rejection policies, consistent with the test methods, for SRT data which considers source of test organisms, the direction of the deviation, test dilution factor, test sensitivity (for hypothesis test values), testing frequency, out-of-control test frequency, relative width of acceptance limits, inter-test CV, and degree of difference between test results and acceptance limits.
 - v) In the case of reference toxicant data which fails to meet control chart acceptance criteria, the test data are examined for defects, corrective action taken, and the test repeated if necessary, using a different batch of organisms or the data is qualified.
- 3) The frequency of ongoing laboratory reference toxicant testing shall be as follows unless the method specifically requires less frequent SRT tests (e.g. sediment tests):

- i) For test methods conducted at a frequency of monthly or greater, SRT tests shall be conducted at an ongoing frequency of monthly.
 - ii) For test methods and species commonly used in the laboratory, but which are tested at a frequency of less than monthly, SRT tests shall be conducted concurrently with the environmental test.
 - iii) If the test organisms are obtained from an outside source the sensitivity of each batch of organisms received from a supplier shall be determined via a concurrent SRT test unless the supplier can provide control chart data for the last five SRT tests using the same SRT and test conditions. Supplied SRT data may not be older than six months.
 - iv) The DOC for an analyst shall be consistent with 5.5.2.6.c.3 but the frequency need not exceed the method specified requirements and D.2.1.a.3.
- 4) These standards 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. All reference toxicant tests conducted for a given test method and species must use the same reference toxicant, test concentrations, dilution water and data analysis methods. A dilution factor of 0.5x or greater shall be used for both acute and chronic tests.
- 5) The reference toxicant tests shall be conducted following the same procedures as the environmental toxicity tests for which the precision is being evaluated, unless otherwise specified in the test method (for example, 10-day sediment tests employ 96-h water-only reference toxicant tests). The test duration, laboratory dilution water, feeding, organism age, range and density, test volumes, renewal frequency, water quality measurements, and the number of test concentrations, replicates and organisms per replicate shall be the same as specified for the environmental toxicity test.
- b) Negative Control - Control, brine control, control sediment, control soil or dilution water -
- 1) The standards for the use, type and frequency of testing of negative controls are specified by the test methods and by permit or regulation and shall be followed. A negative control is included with each test to evaluate test performance and the health and sensitivity of the specific batch of organisms.
 - 2) Appropriate additional negative controls shall be included when sample adjustments (for example, addition of thiosulfate for dechlorination) or solvent carriers are used in the test.
 - 3) Test Acceptability Criteria (TAC) - The test acceptability criteria specified in the test method must be achieved for both the reference toxicant and the effluent or environmental sample toxicity test. The criteria shall be calculated and shall meet the method specified requirements for performing toxicity tests.

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 Toxicity Testing.

D.2.4 Test Sensitivity

- a) The SMSD shall be calculated according to the formula specified by the test method and reported with the test results.
- b) Point estimates: (LCp, ICp, or ECp) - Confidence intervals shall be reported as a measure of the precision around the point estimate value, when the calculation is possible.
- c) The SMSD shall be calculated and reported for only hypothesis test values, such as the NOEC or NOAEC.

D.2.5 Selection of Appropriate Statistical Analysis Methods

- a) If required, methods of data analysis and endpoints are specified by language in the regulation, permit or the test method.
- b) Dose Response Curves – The data shall be plotted in the form of a curve relating the dose of the chemical or concentration of sample to cumulative percentage of test organisms demonstrating a response such as death. Evaluation criteria shall be established for interpretation of concentration or dose response curves.

D.2.6 Selection and Use of Reagents and Standards

- a) The grade of all reagents used in 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 5.5.5.2.1.d.
- c) Only reagent-grade water collected from distillation or deionization units is used to prepare reagents.

D.2.7 Selectivity

This principle is not applicable. The selectivity of the test is specified by permit or regulation.

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 cross-contamination.
- b) Laboratory space must be adequate for the types and numbers of tests performed. The building must provide adequate cooling, heating and illumination for conducting testing and culturing; hot and cold running water must be available for cleaning equipment.
- c) Air used for aeration of test solutions, dilution waters and cultures must be free of oil and fumes.
- d) 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. When organisms are obtained from an outside source the supplier must provide this same information.

- e) Instruments used for routine support measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, ammonia, and weight shall be calibrated, and/or standardized per manufacturer's instructions. As these are support measurements, only the calibration and verification requirements specified at 5.5.5.2.1 apply. All measurements and calibrations shall be documented.
- f) Test temperature shall be maintained as specified for the test method. Temperature control equipment must be adequate to maintain the required test temperature(s). The average daily temperature of the test solutions must be maintained within the method specified range. 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. Where electronic data loggers are used, temperature shall be monitored at a frequency sufficient to capture temporal variations of the environmental control system.
- g) Reagent grade water, prepared by any combination of distillation, reverse osmosis, ion exchange, activated carbon and particle filtration, shall meet the method specified requirements.
- h) The quality of the standard dilution water used for testing or culturing must be sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance. Water used for culturing and testing shall be analyzed for toxic metals and organics 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. It is recognized that the analyte lists of some methods manuals may not include all potential toxicants, are based on estimates of chemical toxicity available at the time of publication and may specify detection limits which are not achievable in all matrices. However, for those analytes not listed, or for which the measured concentration or limit of detection is greater than the method-specified limit, the laboratory must demonstrate that the analyte at the measured concentration or reported limit of detection does not exceed one tenth the expected chronic value for the most sensitive species tested and/or cultured. The expected chronic value is based on professional judgment and the best available scientific data. The "USEPA Ambient Water Quality Criteria Documents" and the EPA AQUIRE database provide guidance and data on acceptability and toxicity of individual metals and organic compounds.
- i) The quality of the food used for testing or culturing must be sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance. The laboratory shall have written procedures for the evaluation of food acceptance.
- j) A subset of organisms used in bioaccumulation tests must be analyzed at the start of the test (baseline) for the target compounds to be measured in the bioaccumulation tests.
- k) Test chamber size and test solution volume shall be as specified in the test method. All test chambers used in a test must be identical.
- l) Test organisms shall be fed the quantity and type food or nutrients specified in the test method. They shall also be fed at the intervals specified in the test methods.
- m) All organisms in a test must be from the same source. Where available certified seeds are used for soil tests.

- n) All organisms used in tests, or used as broodstock to produce neonate test organisms (for example cladocerans and larval fish), must appear healthy, show no signs of stress or disease and exhibit acceptable survival (90% or greater) during the 24 hour period immediately preceding use in tests.
- o) All materials used for test chambers, culture tanks, tubing, etc. and coming in contact with test samples, solutions, control water, sediment or soil or food must be non-toxic and cleaned as described in the test methods. Materials must not reduce or add to sample toxicity. Appropriate materials for use in toxicity testing and culturing are described in the referenced manuals.
- p) 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 and plant tests, the light intensity shall be measured and recorded at the start of each test.
- q) The health and culturing conditions of all organisms used for testing shall be documented by the testing laboratory. Such documentation shall include culture conditions (e.g. salinity, hardness, temperature, pH) and observations of any stress, disease or mortality. When organisms are obtained from an outside source, the laboratory shall obtain written documentation of these water quality parameters and biological observations for each lot of organism received. These observations shall adequately address the 24-hour time period referenced in item D.2.8.n above. The laboratory shall also record each of these observations and water quality parameters upon the arrival of the organisms at the testing laboratory.
- r) Age and the age range of the test organisms must be as specified in the test method. Supporting information, such as hatch dates and times, times of brood releases and metrics (for example, chironomid head capsule width) shall be documented.
- s) The maximum holding time of effluents (elapsed time from sample collection to first use in a test) shall not exceed 36 hours; samples may be used for renewal up to 72 hours after first use except as prescribed by the method and approved by the regulatory agency having authority for program oversight.
- t) All samples shall be chilled to 0 to 6°C during or immediately after collection (see requirements in section 5.5.8.3.1) except as prescribed by the method and approved by the regulatory agency having authority for program oversight.
- u) Organisms used in a given test must be from the same batch.
- v) All tests shall have the minimum number of replicates per treatment as prescribed by the method.
- w) The control population of *Ceriodaphnia* in chronic effluent or receiving water tests shall contain no more than 20% males.
- x) The culturing of *C. dubia* shall be adequate such that blocking by parentage can be established.
- y) Dissolved oxygen and pH in aquatic tests shall be within acceptable range at test initiation and aeration (minimal) is provided to tests if, and only if, acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the test method.
- z) Test soils or sediments must be within the geochemical tolerance range of the test organism.
- a) 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 director and the permitting authority.

D.3 MICROBIOLOGY TESTING

These standards apply to laboratories undertaking microbiological analysis of environmental samples. Microbiological testing refers to and includes the detection, isolation, enumeration, or identification of microorganisms and/or their metabolites, or determination of the presence or absence of growth in materials and media.

D.3.1 Sterility Checks and Blanks, Positive and Negative Controls

a) Sterility Checks and Blanks

The laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure.

- 1) A sterility blank shall be analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory. This shall be done prior to first use of the medium.
- 2) For filtration technique, the laboratory shall conduct one beginning and one ending sterility check for each laboratory sterilized filtration unit used in a filtration series. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series. For pre-sterilized single use funnels a sterility check shall be performed on one funnel per lot. The filtration series is considered ended when more than 30 minutes elapses between successive filtrations. During a filtration series, filter funnels must be rinsed with three 20-30 ml portions of sterile rinse water after each sample filtration. In addition, laboratories must insert a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration.
- 3) For pour plate technique, sterility blanks of the medium shall be made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory.
- 4) Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, pre-sterilized containers. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with non-selective growth media.
- 5) A sterility blank shall be performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with non-selective growth media.
- 6) At least one filter from each new lot of membrane filters shall be checked for sterility with non-selective growth media.

b) Positive Controls

Positive culture controls demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism(s).

- 1) Each pre-prepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested with at least one pure culture of a known positive reaction. This shall be done prior to first use of the medium.

c) Negative Controls

Negative culture controls demonstrate that the medium does not support the growth of non-target organisms or does not demonstrate the typical positive reaction of the target organism(s).

Each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory shall be analyzed with one or more known negative culture controls, i.e. non-target organisms, as appropriate to the method. This shall be done prior to first use of the medium.

D.3.2 Test Variability/Reproducibility

For test methods that specify colony counts such as membrane filter or plated media, duplicate counts shall be performed monthly on one positive sample, for each month that the test is performed. If the lab has two or more analysts, each analyst shall count typical colonies on the same plate. Counts must be within 10% difference to be acceptable. In a laboratory with only one microbiology analyst, the same plate shall be counted twice by the analyst, with no more than 5% difference between the counts.

D.3.3 Method Evaluation

- a) Laboratories are required to demonstrate proficiency with the test method prior to first use. This shall be achieved by comparison to a method already approved for use in the laboratory, or by analyzing a minimum of ten spiked samples whose quality system matrix is representative of those normally submitted to the laboratory, or by analyzing and passing one proficiency test series provided by an approved proficiency sample provider. The laboratory shall maintain this documentation as long as the method is in use and for at least 5 years past the date of last use.
- b) Laboratories shall participate in the Proficiency Test programs identified by NELAP (5.4.1.5.k or 5.5.9.1). The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.

D.3.4 Test Performance

- a) All growth and recovery media must be checked to assure that the target organism(s) respond in an acceptable and predictable manner (see D.3.1.b).
- b) To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method, e.g. by use of the completed test, or by use of secondary verification tests such as a catalase test.

D.3.5 Data Reduction

The calculations, data reduction and statistical interpretations specified by each test method shall be followed.

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 from commercial dehydrated powders or may be purchased ready to use. Media may be prepared by the laboratory from basic ingredients when commercial media are not available or when it can be demonstrated that commercial media do not provide adequate results. Media prepared by the laboratory from basic ingredients must be tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, growth inhibition) prior to first use. Detailed testing criteria information must be defined in either the laboratory's test methods, SOPs, Quality Manual, or similar documentation.
- b) Reagents, commercial dehydrated powders and media shall be used within the shelf-life of the product and shall be documented according to 5.5.6.4.
- 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 chlorine residual, specific conductance, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month.

Analysis for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) shall be performed annually. Results of these analyses shall meet the specifications of the required method and records of analyses shall be maintained for five years. (An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.)

- 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. Documentation for media prepared in the laboratory shall include date of preparation, preparer's initials, type and amount of media prepared, manufacturer and lot number, final pH of the media, and expiration date. Documentation for media purchased pre-prepared, ready-to-use shall include manufacturer, lot number, type and amount of media received, date of receipt, expiration date of the media, and pH of the media.

D.3.7 Selectivity

- a) In order to ensure identity and traceability, reference cultures used for positive and negative controls shall be obtained from a recognized national collection, organization, or manufacturer recognized by the NELAP Accrediting Authority. Microorganisms may be single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.
 - 1) Reference cultures may be revived (if freeze-dried) or transferred from slants and subcultured once to provide reference stocks. The reference stocks shall be preserved by a technique which maintains the characteristics of the strains. 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 and shall not be subcultured to replace reference stocks.

D.3.8 Constant and Consistent Test Conditions

a) Laboratory Facilities

Floors and work surfaces shall be non-absorbent and easy to clean and disinfect. Work surfaces shall be adequately sealed. Laboratories shall provide sufficient storage space, and shall be clean and free from dust accumulation. Plants, food, and drink shall be prohibited from the laboratory work area.

b) Laboratory Equipment

1) Temperature Measuring Devices

Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves and other equipment shall be the appropriate quality to meet specification(s) 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 5.5.6.2.1). Calibration shall be done at least annually.

2) Autoclaves

- i) The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers shall not be used for sterilization of growth media.
- ii) Demonstration of sterilization temperature shall be provided by use of continuous temperature recording device or by use of a maximum registering thermometer with every cycle. Appropriate biological indicators shall be used once per month to determine effective sterilization. Temperature sensitive tape shall be used with the contents of each autoclave run to indicate that the autoclave contents have been processed.
- iii) Records of autoclave operations shall be maintained for every cycle. Records shall include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials.
- iv) Autoclave maintenance, either internally or by service contract, shall be performed annually and shall include a pressure check and calibration of temperature device. Records of the maintenance shall be maintained in equipment logs.
- v) The autoclave mechanical timing device shall be checked quarterly against a stopwatch and the actual time elapsed documented.

3) Volumetric Equipment

Volumetric equipment shall be calibrated as follows:

- i) equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes shall be verified for accuracy quarterly.

- ii) equipment such as filter funnels, bottles, non-class A glassware, and other marked containers shall be calibrated once per lot prior to first use.
 - iii) the volume of the disposable volumetric equipment such as sample bottles, disposable pipettes, and micropipette tips shall be checked once per lot.
- 4) UV Instruments
- UV instruments, used for sanitization, shall be tested quarterly for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Replace bulbs if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.
- 5) Conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments shall be calibrated according to the method specified requirements (see Section 5.5.5.2.1.d).
- 6) Incubators, Water Baths, Ovens
- i) The stability and uniformity of temperature distribution and time required after test sample addition to re-establish equilibrium conditions in incubators and water baths shall be established. Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use.
 - ii) Ovens used for sterilization shall be checked for sterilization effectiveness monthly with appropriate biological indicators. Records shall be maintained for each cycle that include date, cycle time, temperature, contents and analyst's initials.
- 7) Labware (Glassware and Plasticware)
- i) The laboratory shall have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use must be used.
 - ii) Glassware shall be made of borosilicate or other non-corrosive material, free of chips and cracks, and shall have readable measurement marks.
 - iii) Labware that is washed and reused shall be tested for possible presence of residues which may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually, and each time the lab changes the lot of detergent or washing procedures.
 - iv) Washed labware shall be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with a suitable pH indicator such as bromothymol blue. Records of tests shall be maintained.

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 and Positive Controls

a) Negative Controls

- 1) 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 the batch. The method blank result shall be assessed against the specific acceptance criteria [see 5.5.4.1.2.b.18] specified in the laboratory method manual [see 5.5.4.1.2]. When the specified method blank acceptance criteria is not met the specified corrective action and contingencies [see 5.5.4.1.2.b.19 and 20] shall be followed and results reported with appropriate data qualifying codes. The occurrence of a failed method blank acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.5.10.3.1.a].
- 2) In the case of gamma spectrometry, generally a non-destructive analysis, a method blank shall be prepared using a calibrated counting geometry similar to that used for the samples. The container of the appropriate geometry can be empty or filled to similar volume to partially simulate gamma attenuation due to a sample matrix.
- 3) There shall be no subtraction of the required method blank [see D.4.1.a.1] result from the sample results in the associated preparation or analytical batch unless permitted by method or program. This does not preclude the application of any correction factor (e.g. instrument background, analyte presence in tracer, reagent impurities, peak overlap, 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.
- 4) The method blank sample shall be prepared with similar aliquot size to that of the routine samples for analysis and the method blank result and acceptance criteria [5.5.4.1.2.b.18] shall be calculated in a manner that compensates for sample results based upon differing aliquot size.

b) Positive Controls

- 1) 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 the batch. The laboratory control sample result shall be assessed against the specific acceptance criteria [see 5.5.4.1.2.b.18] specified in the laboratory method manual [see 5.5.4.1.2]. When the specified laboratory control sample acceptance criteria is not met the specified corrective action and contingencies [see 5.5.4.1.2.b.19 and 20] shall be followed. The occurrence of a failed laboratory control sample acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.5.10.3.1.a].
- 2) Matrix Spike - Shall be performed at a frequency of one per preparation batch for those methods which include a chemical separation process without the use of an internal standard or carrier, and where there is sufficient sample to do so. Although gross alpha, gross beta and tritium measurements do not involve a chemical separation process, matrix spikes shall be performed for these analyses on aqueous samples. The results of this analysis shall be one of the quality control measures to be used to assess the batch. The matrix spike result shall be assessed

against the specific acceptance criteria [see 5.5.4.1.2.b.18] specified in the laboratory method manual [see 5.5.4.1.2]. When the specified matrix spike acceptance criteria is not met, the specified corrective action and contingencies [see 5.5.4.1.2.b.19 and 20] shall be followed. The occurrence of a failed matrix spike acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.5.10.3.1.a]. The lack of sufficient sample aliquot size to perform a matrix spike shall be noted in the laboratory report.

- 3) The activity of the laboratory control sample shall: (1) be at least 5 times the limit of detection and (2) at a level comparable to that of routine samples when such information is available if the sample activities are expected to exceed 5 times the limit of detection.
 - 4) The activity of the matrix spike analytes(s) shall be greater than five times the limit of detection.
 - 5) 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 and must meet the requirements for reference standards provided in D.4.7 a).
 - 6) The matrix spike shall be prepared by adding a known activity of target analyte after subsampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.). Where a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g. plutonium, Pu 238 and Pu 239, using alpha spectrometry), 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 limit of detection each shall be assessed against the specified acceptance criteria.
 - 7) Where gamma spectrometry is used to identify and quantitate more than one analyte isotope the laboratory control sample 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.
 - 8) The laboratory control sample shall be prepared with similar aliquot size to that of the routine samples for analyses.
- c) Other Controls
- 1) Tracer - For those methods that utilize a tracer (i.e. internal standard) each sample result shall have an associated tracer recovery calculated and reported. The tracer shall be added to the sample after subsampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.) unless otherwise specified by the method. The tracer recovery for each sample result 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 5.5.4.1.2.b.18] specified in the laboratory method manual [see 5.5.4.1.2]. When the specified tracer recovery acceptance criteria is not met the specified corrective action and contingencies [see 5.5.4.1.2.b.19 and 20] shall be followed. The occurrence of a failed tracer recovery acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.5.10.3.1.a].

- 2) Carrier - For those methods that utilize a carrier for recovery determination, each sample shall have an associated carrier recovery calculated and reported. The carrier shall be added to the sample after subsampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.) unless otherwise specified by the method. 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 5.5.4.1.2.b.18] specified in the laboratory method manual [see 5.5.4.1.2]. When the specified carrier recovery acceptance criteria is not met the specified corrective action and contingencies [see 5.5.4.1.2.b.19 and 20] shall be followed. The occurrence of a failed carrier recovery acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.5.10.3.1.a].

D.4.2 Analytical 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 5.5.4.1.2.b.18] specified in the laboratory method manual [see 5.5.4.1.2]. When the specified replicate acceptance criteria is not met the specified corrective action and contingencies [see 5.5.4.1.2.b.19 and 20] shall be followed. The occurrence of a failed replicate acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.5.10.3.1.a].
- b) For low level samples (less than approximately three times the limit of detection) the laboratory may analyze duplicate laboratory control samples or a replicate matrix spike (matrix spike and a matrix spike duplicate) to determine reproducibility within a preparation batch.

D.4.3 Method Evaluation

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

- a) Initial Demonstration of Capability - (section 5.5.4.2.2 and Appendix C) Shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type (e.g., different detection technique), personnel or method.
- b) Proficiency Test Samples - The results of such analysis (5.4.1.5.k and 5.5.9.1) shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

D.4.4 Radiation Measurement Instrumentation-

Because of the stability and response nature of modern radiation measurement instrumentation, it is not typically necessary to verify calibrate of these systems each day of use. However, verification of calibration is required as outlined in D.4.4.b) below. This section addresses those practices that are necessary for proper calibration and those requirements of section 5.5.5.2.2 (Instrument Calibrations) that are not applicable to some types of radiation measurement instrumentation.

- a) Instrument Calibration

- 2) Given that activity detection efficiency is independent of sample activity at all but extreme activity levels, the requirements of subsections f, h and i of 5.5.5.2.2.1 are not applicable to radiochemical method calibrations except mass attenuation in gas-proportional counting and sample quench in liquid scintillation counting. Radiation measurement instruments are subject to calibration prior to initial use, when the instrument is placed back in service after malfunctioning and the instrument's response has changed as determined by a performance check or when the instrument's response exceeds predetermined acceptance criteria for the instrument quality control.
- 3) Instrument calibration shall be performed with reference standards as defined in section D.4.7.a. The standards shall have the same general characteristics (i.e., geometry, homogeneity, density, etc.) as the associated samples.
- 4) The frequency of calibration shall be addressed in the laboratory method manual [see 5.5.4.1.2.b.13] if not specified 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.

b) Continuing Instrument Calibration Verification (Performance Checks)

Performance checks shall be performed using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the detector response has not significantly changed and therefore the instrument 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 calibration verification 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.

- 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 weekly basis and the performance check for counting efficiency shall be performed on at least a monthly basis.
- 3) For gas-proportional and liquid scintillation counters, the performance check for counting efficiency shall be performed on a day of use basis. For batches of samples that uninterruptedly count for more than a day a performance check can be performed at the beginning and end of the batch as long as this time interval is no greater than one week. Verification of instrument calibration does not directly verify secondary calibrations, e.g., the mass efficiency curve or the quench curve.
- 4) For scintillation counters the calibration verification for counting efficiency shall be performed on a day of use basis.

c) Background Measurement

Background 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 may be subtracted from the total measured activity in the determination of the sample activity.

- 1) For gamma spectroscopy systems, background measurements shall be performed on at least a monthly basis.
 - 2) For alpha spectroscopy systems, background measurements shall be performed on at least a monthly basis.
 - 3) For gas-proportional counters, background measurements shall be performed on at least on a weekly basis.
 - 4) For scintillation counters, background measurements shall be performed each day of use.
- d) Instrument Contamination Monitoring

The laboratory shall have a written procedure for monitoring radiation measurement instrumentation for radioactive contamination. The procedure shall indicate the frequency of the monitoring and shall indicate criteria, which initiates corrective action.

D.4.5 Minimum Detectable Activity (MDA)/Minimum Detectable Concentration (MDC)/Lower Level of Detection (LLD)

- a) Must be determined prior to sample analysis and must be redetermined each time there is a significant change in the test method or instrument type.
- b) The procedures employed must be documented and consistent with mandated method or regulation.

D.4.6 Data Reduction

- a) Refer to Section 5.5.4.7.2, computers and electronic data related requirements of this document.
- b) Measurement Uncertainties - each result shall be reported with the associated measurement uncertainty. The procedures for determining the measurement uncertainty must be documented and be consistent with mandated method and regulation.

D.4.7 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), 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 shall 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. The laboratory shall have a written procedure for handling, storing and establishment of expiration dates for reference standards.

- b) All reagents used shall be analytical reagent grade or better.

D.4.8 Constant and Consistent Test Conditions

The laboratory shall maintain a radiological control program that addresses analytical radiological control. The program shall address the procedures for segregating samples with potentially widely varying levels of radioactivity. The radiological control program shall explicitly define how low level and high level samples will be identified, segregated and processed in order to prevent sample cross-contamination. The radiological control program shall include the measures taken to monitor and evaluate background activity or contamination on an ongoing basis.

D.5 AIR TESTING

These standards shall apply to samples that are submitted to a laboratory for the purpose of analysis. They do not apply to field activities such as source air emission measurements or the use of continuous analysis devices.

D.5.1 Negative and Positive Controls

- a) Negative Controls
 - 1) Method Blanks – Shall be performed at a frequency of at least one (1) per batch of twenty (20) environmental samples or less per sample preparation method. The results of the method blank analysis shall be used to evaluate the contribution of the laboratory provided sampling media and analytical sample preparation procedures to the amount of analyte found in each sample. If the method blank result is greater than the limit of quantitation and contributes greater than 10% of the total amount of analyte found in the sample, the source of the contamination must be investigated and measures taken to eliminate the source of contamination. If contamination is found, the data shall be qualified in the report.
 - 2) Collection Efficiency- Sampling trains consisting of multiple sections (e.g. filters, sorbent tubes, impingers) that are received intact by the laboratory, shall be separated into “front” and “back” sections if required by the client. Each section shall be processed and analyzed separately and the analytical results reported separately.
- b) Positive Controls
 - 1) Laboratory Control Sample (LCS) – Shall be analyzed at a rate of at least one (1) per batch of twenty (20) or fewer samples per sample preparation method for each analyte. If a spiking solution is not available, a calibration solution, whose concentration approximates that of the samples, shall be included in each batch and with each lot of media. If a calibration solution must be used for the LCS, the client will be notified prior to the start of analysis. The concentration of the LCS shall be relevant to the intended use of the data and either at a regulatory limit or below it.
- c) Surrogates - Shall be used as required by the test method or if requested by the client.
- d) Matrix spike – Shall be used as required by the test method, or if requested by the client.

D.5.2 Analytical Variability/Reproducibility

Matrix Spike Duplicates (MSDs) or Laboratory Duplicates – Shall be analyzed at a minimum of 1 in 20 samples per sample batch. The laboratory shall document their procedure to select the use of appropriate types of spikes and duplicates. The selected samples(s) shall be rotated among client samples so that various sample matrix problems may be noted and/or addressed. Poor performance in the spikes and duplicates may indicate a problem with the sample composition and shall be reported to the client.

D.5.3 Method Evaluation

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

- a) Demonstration of Capability – (Sections 5.5.2.6 and 5.5.4.2.2) shall be performed prior to the analysis of any samples and with a significant change in instrument type, personnel, quality system matrix, or test method.
- b) Calibration – Calibration protocols specified in Section 5.5.5.2 shall be followed.
- c) Proficiency Test Samples – The results of such analyses (5.4.1.5.k or 5.5.9.1) shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

D.5.4 Limit of Detection

The requirements of D.1.2.1 shall apply.

D.5.5 Data Reduction

The procedures for data reduction, such as use of linear regression, shall be documented.

D.5.6 Quality of Standards and Reagents

- a) The source of standards shall comply with 5.5.6.2.2.2.
- b) The purity of each analyte standard and each reagent shall be documented by the laboratory through certificates of analyses from the manufacturer/vendor, manufacturer/vendor specifications, and/or independent analysis.
- c) In methods where the purity of reagents is not specified, analytical reagent grade or higher quality, if available, shall be used.

D.5.7 Selectivity

The laboratory shall develop and document acceptance criteria for test method selectivity such as absolute and relative retention times, wavelength assignments, mass spectral library quality of match, and mass spectral tuning.

D.5.8 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) The laboratory shall document that all sampling equipment, containers and media used or supplied by the laboratory meet required test method criteria.

- c) If supplied or used by the laboratory, procedures for field equipment decontamination shall be developed and their use documented.
- d) The laboratory shall have a documented program for the calibration and verification of sampling equipment such as pumps, meter boxes, critical orifices, flow measurement devices and continuous analyzers, if these equipment are used or supplied by the laboratory.

D.6 ASBESTOS TESTING

These standards apply to laboratories undertaking the examination of asbestos samples. These standards are organized by analytical technique including transmission electron microscopy (TEM) for the analysis of water, wastewater, air, and bulk samples; phase contrast microscopy (PCM) for analysis of workplace air; and polarized light microscopy (PLM) for analysis of bulk samples. These procedures for asbestos analysis involve sample preparation followed by detection of asbestos. If NIST SRMs specified below are unavailable, the laboratory may substitute an equivalent reference material with a certificate of analysis.

D.6.1 Negative Controls

D.6.1.1 Transmission Electron Microscopy

D.6.1.1.1 Water and Wastewater

- a) Blank determinations shall be made prior to sample collection. When using polyethylene bottles, one bottle from each batch, or a minimum of one from each 24 shall be tested for background level. When using glass bottles, four bottles from each 24 shall be tested. An acceptable bottle blank level is defined as ≤ 0.01 million fibers per liter (MFL) $> 10 \mu\text{m}$. (EPA /600/R-94/134, Method 100.2, Section 8.2)
- b) A process blank sample consisting of fiber-free water shall be run before the first field sample. The quantity of water shall be ≥ 10 mL for a 25-mm diameter filter and ≥ 50 mL for a 47-mm diameter filter. (EPA /600/R-94/134, Method 100.2, Section 11.8)

D.6.1.1.2 Air

- a) A blank filter shall be prepared with each set of samples. A blank filter shall be left uncovered during preparation of the sample set and a wedge from that blank filter shall be prepared alongside wedges from the sample filters. At minimum, the blank filter shall be analyzed for each 20 samples analyzed. (40 CFR Part 763, Appendix A to Subpart E (AHERA), Table 1)
- b) Maximum contamination on a single blank filter shall be no more than 53 structures/mm². Maximum average contamination for all blank filters shall be no more than 18 structures/mm². (AHERA, III.F.2)

D.6.1.1.3 Bulk Samples

- a) Contamination checks using asbestos-free material, such as the glass fiber blank in SRM 1866 (Page C-3, NIST Handbook 150-3, August 1994) shall be performed at a frequency of 1 for every 20 samples analyzed. The detection of asbestos at a concentration exceeding 0.1% will require an investigation to detect and remove the source of the asbestos contamination.
- b) The laboratory must maintain a list of non-asbestos fibers that can be confused with asbestos (Section 7.5, Page C-8, NIST Handbook 150-3, August 1994). The list must include crystallographic and/or chemical properties that disqualify each fiber being identified as asbestos (Section 2.5.5.2.1 Identification, Page 54, EPA/600/R-93/116).
- c) The laboratory should have a set of reference asbestos materials from which a set of reference diffraction and X-ray spectra have been developed.

D.6.1.2 Phase Contrast Microscopy

At least two (2) field blanks (or 10% of the total samples, whichever is greater) shall be submitted for analysis with each set of samples. Field blanks shall be handled in a manner representative of actual handling of associated samples in the set with a single exception that air shall not be drawn through the blank sample. A blank cassette shall be opened for approximately thirty (30) seconds at the same time other cassettes are opened just prior to analysis. Results from field blank samples shall be used in the calculation to determine final airborne fiber concentration. The identity of blank filters should be unknown to the counter until all counts have been completed. If a field blank yields greater than 7 fibers per 100 graticule fields, report possible contamination of the samples.

D.6.1.3 Polarized Light Microscopy

- a) Friable Materials - At least one blank slide must be prepared daily or with every 50 samples analyzed, whichever is less. This is prepared by mounting a subsample of an isotropic verified non-ACM (e.g., fiberglass in SRM 1866) in a drop of immersion oil (n_D should reflect usage of various n_D 's) on a clean slide, rubbing preparation tools (forceps, dissecting needles, etc.) in the mount and placing a clean coverslip on the drop. The entire area under the coverslip must be scanned to detect any asbestos contamination. A similar check must be made after every 20 uses of each piece of homogenization equipment. An isotropic verified non-ACM must be homogenized in the clean equipment, a slide prepared with the material and the slide scanned for asbestos contamination. (This can be substituted for the blank slide mentioned in this section.)
- b) Non-Friable Materials - At least one non-ACM non-friable material must be prepared and analyzed with every 20 samples analyzed. This non-ACM must go through the full preparation and analysis regimen for the type of analysis being performed.

D.6.2 Test Variability/Reproducibility

D.6.2.1 Transmission Electron Microscopy

Quality assurance analyses shall be performed regularly covering all time periods, instruments, tasks, and personnel. The selection of samples shall be random and samples of special interest may be included in the selection of samples for quality assurance analyses. When possible, the checks on personnel performance shall be executed without their prior knowledge. A disproportionate number of analyses shall not be performed prior to internal or external audits. It is recommended that a laboratory initially be at 100% quality control (all samples reanalyzed). The proportion of quality control samples can later be lowered gradually, as control indicates, to a minimum of 10%.

D.6.2.1.1 Water and Wastewater

All analyses must be performed on relocater grids so that other laboratories can easily repeat analyses on the same grid openings. Quality assurance analyses shall not be postponed during periods of heavy workloads. The total number of QA samples and blanks must be greater than or equal to 10% of the total sample workload. Precision of analyses is related to concentration, as gleaned from interlaboratory proficiency testing. Relative standard deviations (RSD) for amphibole asbestos decreased from 50% at 0.8 MFL to 25% at 7 MFL in interlaboratory proficiency testing, while RSD for chrysotile was higher, 50% at 6 MFL.

- a) Replicate – A second, independent analysis shall be performed on the same grids but on different grid openings than used in the original analysis of a sample. Results shall be within 1.5X of Poisson standard deviation. This shall be performed at a frequency of 1 per 100 samples. (EPA /600/R-94/134, Method 100.2, Table 2)
- b) Duplicate – A second aliquot of sample shall be filtered through a second filter, prepared and analyzed in the same manner as the original preparation of that sample. Results shall be within 2.0X of Poisson standard deviation. This shall be performed at a frequency of 1 per 100 samples. (EPA /600/R-94/134, Method 100.2, Table 2)
- c) Verified Analyses – A second, independent analysis shall be performed on the same grids and grid openings used in the original analysis of a sample. The two sets of results shall be compared according to Turner and Steel (NISTIR 5351). This shall be performed at a frequency of 1 per 20 samples. Qualified analysts must maintain an average of $\geq 80\%$ true positives, $\leq 20\%$ false negatives, and $\leq 10\%$ false positives.

D.6.2.1.2 Air

All analyses must be performed on relocater grids so that other laboratories can easily repeat analyses on the same grid openings.

The laboratory and TEM analysts must obtain mean analytical results on NIST SRM 1876b so that trimmed mean values fall within 80% of the lower limit and 110% of the upper limit of the 95% confidence limits as published on the certificate. These limits are derived from the allowable false positives and false negatives given in Section D.6.2.1.2.c, Verified Analysis, below. SRM 1876b shall be analyzed a minimum of once per year by each TEM analyst.

The laboratory must have documentation demonstrating that TEM analysts correctly classify at least 90% of both bundles and single fibrils of asbestos structures greater than or equal to 1 μm in length in known standard materials traceable to NIST, such as NIST bulk asbestos SRM 1866.

Interlaboratory analyses shall be performed to detect laboratory bias. The frequency of interlaboratory verified analysis must correspond to a minimum of 1 per 200 grid square analyses for clients.

If more than 1 TEM is used for asbestos analysis, intermicroscope analyses must be performed to detect instrument bias.

- a) Replicate – A second, independent analysis shall be performed in accordance with Section D.6.2.1.1.a. (AHERA, Table III)
- b) Duplicate – A second wedge from a sample filter shall be prepared and analyzed in the same manner as the original preparation of that sample. Results shall be within 2.0X of Poisson standard deviation. This shall be performed at a frequency of 1 per 100 samples. (AHERA, Table III)c) Verified Analyses – A second, independent analysis shall be performed on the same grids and grid openings in accordance with Section D.6.2.1.1.c. (AHERA, Table III)

D.6.2.1.3 Bulk Samples

Determination of precision and accuracy should follow guidelines in NISTIR 5951, Guide for Quality Control on the Qualitative and Quantitative Analysis of Bulk Asbestos Samples: Version 1. Because bulk samples with low (< 10%) asbestos content are the most problematic, a laboratory's quality control program should focus on such samples. At least 30% of a laboratory's QC analyses shall be performed on samples containing from 1% to 10% asbestos.

- a) Intra-Analyst Precision - At least 1 out of 50 samples must be reanalyzed by the same analyst. For single analyst laboratories, at least 1 out of every 10 samples must be reanalyzed by the same analyst.
- b) Inter-Analyst Precision - At least 1 out of 15 samples must be reanalyzed by another analyst. Inter-analyst results will require additional reanalysis, possibly including another analyst, to resolve discrepancies when classification (ACM vs. non-ACM) errors occur, when asbestos identification errors occur, or when inter-analyst precision is found to be unacceptable.
- c) Inter-Laboratory Precision - The laboratory must participate in round robin testing with at least one other laboratory. Samples must be sent to this other lab at least four times per year. These samples must be samples previously analyzed as QC samples. Results of these analyses must be assessed in accordance with QC requirements. As a minimum, the QC requirements must address misclassifications (false positives, false negatives) and misidentification of asbestos types.

D.6.2.2 Phase Contrast Microscopy

- a) Inter-Laboratory Precision – Each laboratory analyzing air samples for compliance determination shall implement an inter-laboratory quality assurance program that as a minimum includes participation of at least two (2) other independent laboratories. Each laboratory shall participate in round robin testing at least once every six (6) months with at least all the other laboratories in its inter-laboratory quality assurance group. Each laboratory shall submit slides typical of its own workload for use in this program. The round robin shall be designed and results analyzed using appropriate statistical methodology. Results of this QA program shall be posted in each laboratory to keep the microscopists informed.
- b) Intra- and Inter-Analyst Precision – Each analyst shall select and count a prepared slide from a “reference slide library” on each day on which air counts are performed. Reference slides shall be prepared using well-behaved samples taken from the laboratory workload. Fiber densities shall cover the entire range routinely analyzed by the laboratory. These slides shall be counted by all analysts to establish an original standard deviation and corresponding limits of acceptability. Results from the daily reference sample analysis shall be compared to the statistically derived acceptance limits using a control chart or a database. It is recommended that the labels on the reference slides be periodically changed so that the analysts do not become familiar with the samples. Intra- and inter-analyst precision may be estimated from blind recounts on reference samples. Inter-analyst precision shall be posted in each laboratory to keep the microscopists informed.

D.6.2.3 Polarized Light Microscopy

Refer to Section D.6.2.1.3.

D.6.3 Other Quality Control Measures

D.6.3.1 Transmission Electron Microscopy

D.6.3.1.1 Water and Wastewater

- a) Filter preparations shall be made from all six asbestos types from NIST SRMs 1866 and 1867. These preparations shall have concentrations between 1 and 20 structures ($> 10\mu\text{m}$) per 0.01 mm^2 . One of these preparations shall be analyzed independently at a frequency of 1 per 100 samples analyzed. Results shall be evaluated as verified asbestos analysis in accordance with Turner and Steel (NISTIR 5351).
- b) NIST SRM 1876b must be analyzed annually by each analyst. Results shall be evaluated in accordance with limits published for that SRM. Comment: This SRM is not strictly appropriate for waterborne asbestos but analysts can demonstrate general TEM asbestos competence by producing results within the published limits of this (the only recognized TEM counting standard) SRM.

D.6.3.1.2 Air

- a) Filter preparations shall be made from all six asbestos types in accordance with Section D.6.3.1.1.a.
- b) NIST SRM 1876b must be analyzed annually in accordance with Section D.6.3.1.1.b.

D.6.3.1.3 Bulk Samples

All analysts must be able to correctly identify the six regulated asbestos types (chrysotile, amosite, crocidolite, anthophyllite, actinolite, and tremolite). Standards for the six asbestos types listed are available from NIST (SRMs 1866 and 1867). These materials can also be used as identification standards for AEM (Section 3.2.1 Qualitative Analysis, Page 57, EPA/600/R-93/116).

D.6.3.2 Phase Contrast Microscopy

- a) Test for Non-Random Fiber Distribution - Blind recounts by the same analyst shall be performed on 10% of the filters counted. A person other than the counter should re-label slides before the second count. A test for type II error (NIOSH 7400, Issue 2, 15 August 1994, Section 13) shall be performed to determine whether a pair of counts by the same analyst on the same slide should be rejected due to non-random fiber distribution. If a pair of counts is rejected by this test, the remaining samples in the set shall be recounted and the new counts shall be tested against first counts. All rejected paired counts shall be discarded. It shall not be necessary to use this statistic on blank recounts.
- b) All individuals performing airborne fiber analysis must have taken the NIOSH Fiber Counting Course for sampling and evaluating airborne asbestos dust or an equivalent course.
- c) All laboratories shall participate in a national sample testing scheme such as the Proficiency Analytical Testing (PAT) program or the Asbestos Analysts Registry (AAR) program, both sponsored by the American Industrial Hygiene Association (AIHA), or equivalent.

D.6.3.3 Polarized Light Microscopy

- a) Friable Materials - Because accuracy cannot be determined by reanalysis of routine field samples, at least 1 out of 100 samples must be a standard or reference sample that has been routinely resubmitted to determine analyst's precision and accuracy. A set of these samples should be accumulated from proficiency testing samples with predetermined weight compositions or from standards generated with weighed quantities of asbestos and other bulk materials (Perkins and Harvey, 1993; Parekh et al., 1992; Webber et al., 1982). At least half of the reference samples submitted for this QC must contain between 1 and 10% asbestos.

- b) Non-Friable Materials - At least 1 out of 100 samples must be a verified quantitative standard that has routinely been resubmitted to determine analyst precision and accuracy.

D.6.4 Method Evaluation

In order to ensure the accuracy of reported results, the following procedures shall be in place:

- a) Demonstration of Capability – (Refer to Section 5.5.4.2.2) Shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel, or method.
- b) Performance Audits – (Refer to Section 5.4.2 or 5.5.3.4) The results of such analyses shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

D.6.5 Asbestos Calibration

Refer to methods referenced in the following sections for specific equipment requirements.

D.6.5.1 Transmission Electron Microscopy

AEM (Analytical Electron Microscopy) equipment requirements will not be discussed in this document.

D.6.5.1.1 Water and Wastewater

All calibrations listed below (unless otherwise noted) must be performed under the same analytical conditions used for routine asbestos analysis and must be recorded in a notebook and include date and analyst's signature. Frequencies stated below may be reduced to "before next use" if no samples are analyzed after the last calibration period has expired. Likewise, frequencies may have to be increased following non-routine maintenance or unacceptable calibration performance.

- a) Magnification Calibration – Magnification calibration must be done at the fluorescent screen, with the calibration specimen at the eucentric position, at the magnification used for fiber counting, generally 10,000 and 20,000x. A logbook must be maintained with the dates of the calibration recorded. Calibrations shall be performed monthly to establish the stability of magnification. Calibration data must be displayed on control charts that show trends over time. (EPA /600/R-94/134, Method 100.2, Section 10.1)
- b) Camera Constant – The camera length of the TEM in the Selected Area Electron Diffraction (SAED) mode must be calibrated before SAED patterns of unknown samples are observed. The diffraction specimen must be at the eucentric position for this calibration. This calibration shall allow accurate (< 10% variation) measurement of layer-line spacings on the medium used for routine measurement, i.e., the phosphor screen or camera film. This must also allow accurate (< 5% variation) measurement of zone axis SAED patterns on permanent media, e.g., film. Calibrations shall be performed monthly to establish the stability of the camera constant (EPA /600/R-94/134, Method 100.2, Section 10.2). Where non-asbestiform minerals may be expected (e.g., winchite, richterite, industrial talc, vermiculite, etc.), an internal camera constant standard such as gold, shall be deposited and measured on each sample to facilitate accurate indexing of zone axis SAED patterns. In such cases, layer line analysis alone shall not be used. Calibration data must be displayed on control charts that show trends over time.
- c) Spot Size – The diameter of the smallest beam spot at crossover must be less than 250 nm as calibrated quarterly. Calibration data must be displayed on control charts that show trends over time. (EPA /600/R-94/134, Method 100.2, Section 10.3)

- d) Beam Dose - The beam dose shall be calibrated so that beam damage to chrysotile is minimized, specifically so that an electron diffraction pattern from a single fibril $\geq 1 \mu\text{m}$ in length from a NIST SRM chrysotile sample is stable in the electron beam dose for at least 15 seconds.
- e) EDXA System
- 1) The x-ray energy vs. channel number for the EDXA system shall be calibrated to within 20 eV for at least two peaks between 0.7 keV and 10 keV. One peak shall be from the low end (0.7 keV to 2 keV) and the other peak from the high end (7 keV to 10 keV) of this range. The calibration of the x-ray energy shall be checked prior to each analysis of samples and recalibrated if out of the specified range.
 - 2) The ability of the system to resolve the Na $K\alpha$ line from the Cu L line shall be confirmed quarterly by obtaining a spectrum from the NIST SRM 1866 crocidolite sample on a copper grid.
 - 3) The k-factors for elements found in asbestos (Na, Mg, Al, Si, Ca, and Fe) relative to Si shall be calibrated semiannually, or anytime the detector geometry may be altered. NIST SRM 2063a shall be used for Mg, Si, Ca, Fe, while k-factors for Na and Al may be obtained from suitable materials such as albite, kaersutite, or NIST SRM 99a. The k-factors shall be determined to a precision (2s) within 10% relative to the mean value obtained for Mg, Al, Si, Ca, and Fe, and within 20% relative to the mean value obtained for Na. The k-factor relative to Si for Na shall be between 1.0 and 4.0, for Mg and Fe shall be between 1.0 and 2.0, and for Al and Ca shall be between 1.0 and 1.75. The k-factor for Mg relative to Fe shall be 1.5 or less. Calibration data must be displayed on control charts that show trends over time.
 - 4) The detector resolution shall be checked quarterly to ensure a full-width half-maximum resolution of $< 175 \text{ eV}$ at Mn $K\alpha$ (5.90 keV). Calibration data must be displayed on control charts that show trends over time.
 - 5) The portions of a grid in a specimen holder for which abnormal x-ray spectra are generated under routine asbestos analysis conditions shall be determined and these areas shall be avoided in asbestos analysis.
 - 6) The sensitivity of the detector for collecting x-rays from small volumes shall be documented quarterly by collecting resolvable Mg and Si peaks from a unit fibril of NIST SRM 1866 chrysotile.
- f) Low Temperature Asher - The low temperature asher shall be calibrated quarterly by determining a calibration curve for the weight vs. ashing time of collapsed mixed-cellulose-ester (MCE) filters. Calibration data must be displayed on control charts that show trends over time.
- g) Grid Openings - The magnification of the grid opening measurement system shall be calibrated using an appropriate standard at a frequency of 20 openings/20 grids/lot of 1000 or 1 opening/sample. The variation in the calibration measurements (2s) is $< 5\%$ of the mean calibration value.

D.6.5.1.2Air

All calibrations must be performed in accordance with Section D.6.5.1.1, with the exception of magnification. Magnification calibration must be done at the fluorescent screen, with the calibration specimen at the eucentric position, at the magnification used for fiber counting, generally 15,000 to

20,000x (AHERA, III.G.1.c). A logbook must be maintained with the dates of the calibration recorded. Calibrations shall be performed monthly to establish the stability of magnification.

D.6.5.1.3 Bulk Samples

All calibrations must be performed in accordance with Section D.6.5.1.2.

D.6.5.2 Phase Contrast Microscopy

- a) At least once daily, the analyst shall use the telescope ocular (or Bertrand lens, for some microscopes) supplied by the manufacturer to ensure that the phase rings (annular diaphragm and phase-shifting elements) are concentric.
- b) The phase-shift limit of detection of the microscope shall be checked monthly or after modification or relocation using an HSE/NPL phase-contrast test slide for each analyst/microscope combination (refer to NIOSH 7400, Issue 2, 15 August 1994, Section 10b). This procedure assures that the minimum detectable fiber diameter ($< \text{ca. } 0.25\mu\text{m}$) for this microscope is achieved.
- c) Prior to ordering the Walton-Beckett graticule, calibration, in accordance with NIOSH 7400, Issue 2, 15 August 1994, Appendix A, shall be performed to obtain a counting area $100\mu\text{m}$ in diameter at the image plane. The diameter, d_c (mm), of the circular counting area and the disc diameter must be specified when ordering the graticule. The field diameter (D) shall be verified (or checked), to a tolerance of $100\mu\text{m} \pm 2\mu\text{m}$, with a stage micrometer upon receipt of the graticule from the manufacturer. When changes (zoom adjustment, disassembly, replacement, etc.) occur in the eyepiece-objective-reticle combination, field diameter must be re-measured (or re-calibrated) to determine field area (mm^2). Re-calibration of field diameter shall also be required when there is a change in interpupillary distance (i.e., change in analyst). Acceptable range for field area shall be 0.00754 mm^2 to 0.00817 mm^2 . The actual field area shall be documented and used.

D.6.5.3 Polarized Light Microscopy

- a) Microscope Alignment - To accurately measure the required optical properties, a properly aligned polarized light microscope (PLM) shall be utilized. The PLM shall be aligned before each use. (Section 2.2.5.2.3, EPA/600/R-93/116, July 1993)
- b) Refractive Index Liquids - Series of $n_D = 1.49$ through 1.72 in intervals less than or equal to 0.005 . Refractive index liquids for dispersion staining, high- dispersion series 1.550 , 1.605 , 1.680 . The accurate measurement of the refractive index (RI) of a substance requires the use of calibrated refractive index liquids. These liquids shall be calibrated at first use and semiannually, or next use, whichever is less frequent, to an accuracy of 0.004 , with a temperature accuracy of 2°C using a refractometer or RI glass beads.

D.6.6 Analytical Sensitivity

D.6.6.1 Transmission Electron Microscopy

D.6.6.1.1 Water and Wastewater

An analytical sensitivity of 200,000 fibers per liter (0.2 MFL) is required for each sample analyzed (EPA /600/R-94/134, Method 100.2, Section 1.6). Analytical sensitivity is defined as the waterborne concentration represented by the finding of one asbestos structure in the total area of filter examined. This value will depend on the fraction of the filter sampled and the dilution factor (if applicable).

D.6.6.1.2 Air

An analytical sensitivity of 0.005 structures/cm² is required for each sample analyzed. Analytical sensitivity is defined as the airborne concentration represented by the finding of one asbestos structure in the total area of filter examined. This value will depend on the effective surface area of the filter, the filter area analyzed, and the volume of air sampled (AHERA, Table I).

D.6.6.1.3 Bulk Samples

- a) The range is dependent on the type of bulk material being analyzed. The sensitivity may be as low as 0.0001% depending on the extent to which interfering materials can be removed during the preparation of AEM specimens. (Section 2.5.2 Range, Page 51, EPA/600/R-93/116)
- b) There should be an error rate of less than 1% on the qualitative analysis for samples that contain chrysotile, amosite, and crocidolite. A slightly higher error rate may occur for samples that contain anthophyllite, actinolite, and tremolite, as it can be difficult to distinguish among the three types. (Section 3, Page 10, NIST Handbook 150-3, August 1994)

D.6.6.2 Phase Contrast Microscopy

The normal quantitative working range of the test method is 0.04 to 0.5 fiber/ cm² for a 1000 L air sample. An ideal counting range on the filter shall be 100 to 1300 fibers/mm². The limit of detection (LOD) is estimated to be 5.5 fibers per 100 fields or 7 fibers/mm². The LOD in fiber/cc will depend on sample volume and quantity of interfering dust but shall be <0.01 fiber/ cm² for atmospheres free of interferences. (NIOSH 7400, Issue 2, 15 August 1994)

D.6.6.3 Polarized Light Microscopy

The laboratory shall utilize a test method that provides a limit of detection that is appropriate and relevant for the intended use of the data. Limit of detection shall be determined by the protocol in the test method or applicable regulation.

D.6.7 Data Reduction

D.6.7.1 Transmission Electron Microscopy

D.6.7.1.1 Water and Wastewater

- a) The concentration of asbestos in a given sample must be calculated in accordance with EPA /600/R-94/134, Method 100.2, Section 12.1. Refer to Section 5.10.6 of this document for additional data reduction requirements.
- b) Measurement Uncertainties – The laboratory must calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample (EPA /600/R-94/134, Method 100.2, Section 12.2.2).

D.6.7.1.2 Air

- a) The concentration of asbestos in a given sample must be calculated in accordance with the method utilized, e.g., AHERA. Refer to Section 5.10.6 of this document for additional data reduction requirements.
- b) Measurement Uncertainties – The laboratory must calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample.

D.6.7.1.3 Bulk Samples

- a) The concentration of asbestos in a given sample must be calculated in accordance with the method utilized (e.g., EPA/600/R-93/116, July 1993). Refer to Section 5.10.6 of this document for additional data reduction requirements.
- b) Measurement Uncertainties - Proficiency testing for floor tiles analyzed by TEM following careful gravimetric reduction (New York ELAP Certification Manual Item 198.4) has revealed an interlaboratory standard deviation of approximately 20% for residues containing 70% or more asbestos. Standard deviations range from 20% to 60% for residues with lower asbestos content.

D.6.7.2 Phase Contrast Microscopy

- a) Airborne fiber concentration in a given sample must be calculated in accordance with NIOSH 7400, Issue 2, 15 August 1994, Sections 20 and 21. Refer to Section 5.10.6 of this document for additional data reduction requirements.
- b) Measurement Uncertainties – The laboratory must calculate and report the intra-laboratory and inter-laboratory relative standard deviation with each set of results. (NIOSH 7400, Issue 2, 15 August 1994)
- c) Fiber counts above 1300 fibers/mm² and fiber counts from samples with >50% of the filter area covered with particulate should be reported as “uncountable” or “probably biased”. Other fiber counts outside the 100-1300 fibers/mm² range should be reported as having “greater than optimal variability” and as being “probably biased”.

D.6.7.3 Polarized Light Microscopy

- a) The concentration of asbestos in a given sample must be calculated in accordance with the method utilized (e.g., EPA/600/R-93/116, July 1993). Refer to Section 5.10.6 of this document for additional data reduction requirements.
- b) Method Uncertainties - Precision and accuracy must be determined by the individual laboratory for the percent range involved. If point counting and/or visual estimates are used, a table of reasonable expanded errors (refer to EPA/600/R-93/116, July 1993, Table 2-1) should be generated for different concentrations of asbestos.

D.6.8 Quality of Standards and Reagents

D.6.8.1 Transmission Electron Microscopy

- a) The quality control program shall establish and maintain provisions for asbestos standards.
 - 1) Reference standards that are used in an asbestos 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 asbestos. Any reference standards purchased outside the United States shall be traceable back to each country's national standards laboratory. Commercial suppliers of reference standards shall 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.
- b) All reagents used shall be analytical reagent grade or better.

- c) The laboratory shall have mineral fibers or data from mineral fibers that will allow differentiating asbestos from at least the following “look-alikes”: fibrous talc, sepiolite, wollastonite, attapulgite (palygorskite), halloysite, vermiculite scrolls, antigorite, lizardite, pyroxenes, hornblende, richterite, winchite, or any other asbestiform minerals that are suspected as being present in the sample.

D.6.8.2 Phase Contrast Microscopy

Standards of known concentration have not been developed for this testing method. Routine workload samples that have been statistically validated and national proficiency testing samples such as PAT and AAR samples available from the AIHA may be utilized as reference samples (refer to Section D.6.2.2.b) to standardize the optical system and analyst. All other testing reagents and devices (HSE/NPL test slide and Walton-Beckett Graticule) shall conform to the specifications of the method (refer to NIOSH 7400, Issue 2, 15 August 1994).

D.6.8.3 Polarized Light Microscopy

Refer to Section D.6.8.1.

D.6.9 Constant and Consistent Test Conditions

The laboratory shall establish and adhere to written procedures to minimize the possibility of cross-contamination between samples.

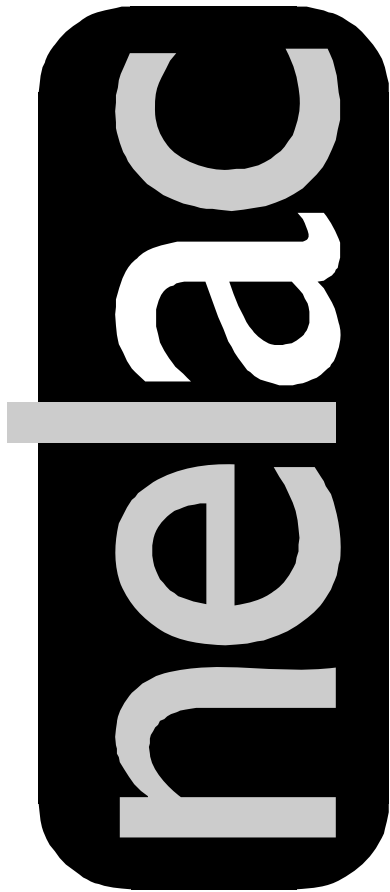
QUALITY SYSTEMS
APPENDIX E

**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**

**ACCREDITING
AUTHORITY**

Approved June 5, 2003
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6.0 ACCREDITING AUTHORITY

6.1 INTRODUCTION

The standards in this chapter define the process and criteria that shall 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 6 is structured so that the requirements of the International Organization for Standardization/the 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 6 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 6. Those ISO/IEC Guide 58 requirements not addressed in Chapter 6 are addressed in the NELAC standards, Chapters 2 through 5. Since Chapter 6 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 2 through 6, 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 6 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 accreditation 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 accreditation of the NELAP accreditation being sought by a laboratory.
- f) This language was removed and placed in the *Policy on Use of the National Environmental Laboratory Accreditation Program (NELAP) Insignia by an Accrediting Authority (AA)*.
- 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."
- i) Time lines stated in Chapter 6 can only be extended by official permission from the NELAP Director upon receipt of written justification. The record of any such extension shall detail the rationale for the extension and is to be maintained as part of the NELAP official record.
- j) Extension of NELAP Recognition of a NELAP Accrediting Authority can be granted by the NELAP Director with written justification. The record of any such extension is to detail the rationale for the extension and is to be maintained as part of the NELAP official record.

6.2.1 Recognition

- a) Except for NELAP-recognized federal accrediting authorities (see 6.2.1 h) and i) below), 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 accreditation, 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 4, to an applicant laboratory within 30 calendar days of receipt of the laboratory's application.

- c) This language was removed and placed in the *NELAC 101 Handbook*.
- 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 accreditation 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 4, 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:
 - i) an initial report of the findings;
 - ii) a description of the actions to be taken; and,
 - iii) 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.

- h) Federal accrediting authorities shall serve as the accrediting authority only for governmental laboratories.
- i) County, municipal, and 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.

6.2.2 Where to Apply for NELAP Accreditation

- a) All county, municipal and non-governmental 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.
- b) Laboratories located in a territory or state that is not NELAP-recognized may seek NELAP accreditation through any NELAP-recognized state or territorial accrediting authority.
- c) Except as noted in subsection 6.2.2 g) below, state governmental laboratories seeking NELAP accreditation or renewal of NELAP accreditation may apply for such accreditation through their home state, home territory or through a NELAP-recognized federal accrediting authority.
- d) Except as noted in subsection 6.2.2 g) below, federal governmental laboratories located in a department or agency that is a NELAP-recognized federal accrediting authority shall follow that department or agency's policy regarding NELAP accreditation or renewal of NELAP accreditation.
- e) This language was removed and placed in the *Policy on Where Federal Laboratories Can Apply For NELAP Accreditation*.
- f) Laboratories that are NELAP accredited by a state accrediting authority that has lost NELAP recognition may seek renewal of NELAP accreditation through any NELAP-recognized state accrediting authority. The laboratory's NELAP accreditation from an accrediting authority that has lost NELAP recognition shall remain valid throughout its current certificate of accreditation.
- g) NELAP accredited laboratories whose home state becomes a recognized NELAP accrediting authority may retain their primary accreditation through the state that holds their current accreditation. The laboratory may retain their existing certificate of accreditation through to the date on the certificate, or until such time that they choose to renew. Depending on the regulations of their home state, the laboratory may still be required to apply for secondary accreditation from their home state until time for renewal for their primary accreditation. At the time of renewal, they must apply for their primary accreditation through their home state accrediting authority as applicable based on requested fields of testing (FOTs).
- h) 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 do not exist; or

- 3) apply for NELAP accreditation through any other NELAP-recognized accrediting authority.
- i) 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 maintain in hard copy, electronic media or by other means; a document or documents describing its environmental laboratory accreditation program.
 - 1) The document or documents shall include the following:
 - i) information setting forth the authority of the accrediting authority to grant laboratory accreditations and whether such laboratory accreditation is mandatory or voluntary;
 - ii) information setting forth the accrediting authority's requirements for an environmental laboratory to become accredited;
 - iii) information setting forth the accrediting authority's assessor training and ongoing internal audit program
 - iv) a list of names of the qualified assessors and a list of technical support personnel (as defined in 3.4.1.2) with areas of responsibility, education and experience.
 - v) information stating the requirements for granting, maintaining, withdrawing, suspending or revoking laboratory accreditation;
 - vi) information about the laboratory accreditation process;
 - vii) information on fees charged to applicants and accredited laboratories;
 - viii) information regarding the rights and duties of accredited laboratories; and
 - ix) 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 evaluation 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 3, 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 shall 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. (A portion of this section was removed and placed in the *Standard Operating Procedure 001: Evaluation of Accrediting Authorities*).
- c) This section was removed and placed in the *Standard Operating Procedure 001: Evaluation of Accrediting Authorities*.
- d) The accrediting authority shall submit a renewal application to the NELAP every three 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 270 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 evaluation 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 and Technical 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 shall 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.
 - i) 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.
 - ii) The NELAP shall notify the accrediting authority in writing when an extension is granted.
 - 4) Within seven (7) calendar days after the application package has been accepted as complete and the technical review has been performed, NELAP shall furnish written notification to the Accrediting Authority.
- d) Within 30 calendar days of the determination that the application is complete, the NELAP evaluation team as established in subsection 6.9.1 shall 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 evaluation team assigned to conduct the on-site evaluation.
- e) The NELAP evaluation team shall 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 2, Proficiency Testing, Chapter 3, On-site Assessment, Chapter 4, Accreditation Process and Chapter 5, Quality Systems.
- f) Should the NELAP evaluation team have questions or need additional application information to determine the accrediting authority's compliance with this chapter, the NELAP evaluation team must seek additional application information and documentation from the accrediting authority.

6.3.2.1 Required Technical Elements of a NELAP-Recognized Accrediting Authority's Program

- a) The NELAP evaluation team shall review the application and supporting documentation to ensure that the accrediting authority's environmental laboratory accreditation program meets the requirements of subsection b) through m) within this section.
- 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) This language was removed and placed in the *NELAC 101 Handbook*.

- 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 evaluators, who meet the education, experience and training requirements set forth in the NELAC standards, Chapter 3, 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 3, 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:
 - i) plan and manage the laboratory accreditation program,
 - ii) coordinate various facets of the laboratory accreditation program with other territory, state and federal accrediting authorities,
 - iii) coordinate development of environmental laboratory accreditation regulations, and
 - iv) 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 6.3.2.1 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 6.3.2.1.3;
- 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 2, Proficiency Testing, Appendix A; and,
- 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.
- o) The accrediting authority shall have a documented procedure to address 6.2.2 g).

6.3.2.1.1 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.

6.3.2.1.2 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:
 - i) the laboratory seeking NELAP accreditation from the accrediting authority employing the contractor; or
 - ii) any other affiliation which would compromise impartiality in the NELAP laboratory accreditation process.

6.3.2.1.3 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 accrediting authority employees or 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 e) and h) and for the accrediting authority's management and technical staff as set forth in subsection 6.3.2.1 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;
 - 9) the policies and procedures for dealing with appeals, complaints and disputes by laboratories; and
 - 10) the policies and procedures for dealing with reports of questionable laboratory practices.

6.3.2.1.4 Mutual Assistance Agreements

Upon mutual agreement, another NELAP-recognized accrediting authority may perform laboratory accreditation functions on behalf of a NELAP-recognized primary accrediting authority. Such an arrangement does not require approval by the NELAP Director.

6.3.2.2 Application Technical Review Report

- a) The NELAP evaluation team shall 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 evaluation team completes its review of an initial application and notes no deficiencies, the NELAP evaluation team shall schedule the on-site evaluation as set forth in subsection 6.4.1.
- b) The NELAP evaluation team shall 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 evaluation team completes its review of a renewal application and denotes no deficiencies, the NELAP evaluation team shall recommend to the NELAP Director that NELAP recognition be maintained.
- c) Except as noted in Section 6.5, the NELAP evaluation team shall not accept the application for continued processing if it notes deficiencies. The NELAP evaluation team will send by certified mail an application technical review report to the accrediting authority. The report:
 - 1) shall identify any specific deficiencies noted during the application technical review,
 - 2) shall include references to the specific NELAC standards, and
 - 3) may 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 evaluation team's subsection 6.3.2.2 c) notification. The NELAP evaluation team shall 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 evaluation team shall notify the accrediting authority that it must submit additional corrective actions within 20 calendar days of receipt of the NELAP evaluation team's response. The NELAP evaluation team shall 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 evaluation team shall make no further suggestions to the accrediting authority for correction of application deficiencies.
 - 3) If application deficiencies still remain after the evaluation team's second attempt to resolve those deficiencies, the NELAP evaluation team shall document those deficiencies which are not resolved and recommend to the NELAP Director that:

- i) the accrediting authority's application for initial NELAP recognition be denied; or
 - ii) 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 6.3.2.2 d), except those deficiencies requiring legislative or rulemaking action as set forth in Section 6.5, the NELAP evaluation team shall schedule the on-site evaluation 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 6.3.2 application technical review process, an accrediting authority must follow the procedure set forth in Section 6.10 (removed and now located in the Policy on Questions of Uniformity Procedure) of this chapter.
- g) After review of the renewal NELAP-recognition application and supporting documents, the NELAP evaluation team shall schedule, when required, an on-site evaluation of the accrediting authority's environmental laboratory accreditation program as set forth in Section 6.4 a) and subsection 6.4.1 a) below.

6.3.3 Reserved

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 facsimile 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 evaluations 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 EVALUATION OF THE ACCREDITING AUTHORITY

- a) An initial on-site evaluation shall be conducted in conjunction with an accrediting authority's initial application process and every three (3) years thereafter; and
- b) The NELAP evaluation team shall arrange on-site evaluations except as stated in subsection 6.4 c) below at the mutual convenience of the parties.

- c) The NELAP evaluation team may make subsequent announced or unannounced on-site evaluations of an accrediting authority's environmental laboratory accreditation program whenever such an evaluation is necessary to determine the accrediting authority's compliance with the requirements of the NELAC standards.
- d) As part of the initial and three (3) year AA renewal process, at least one of the NELAP evaluator(s) shall observe an accrediting authority's laboratory assessor conducting an on-site assessment of a laboratory seeking initial or renewal NELAP accreditation. The NELAP evaluator(s) shall not participate in the laboratory's assessment.

6.4.1 Scheduling the On-site Evaluations

- a) The NELAP evaluation team shall contact the accrediting authority to schedule on-site evaluations as set forth in Section 6.4 a) above within 30 calendar days of the date the NELAP evaluation team accepts an initial or renewal application.
- b) This language was removed and placed in the *Standard Operating Procedure 001: Evaluation of Accrediting Authorities*.
- c) All on-site evaluations shall be conducted no later than 60 calendar days following approval of the application.

6.4.2 Conducting the On-site Evaluation

- a) The purpose of the on-site evaluation 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.
- b) When conducting an on-site evaluation, the NELAP evaluation 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 the training records and conduct interviews of staff designated as qualified assessors to evaluate their training, knowledge of assessment techniques and the NELAC standard;
 - 5) review records of laboratory complaints, disputes and appeals; and,
 - 6) review quality assurance and internal audit procedures employed by the accrediting authority.
- c) The NELAP evaluation team shall only have access to records of the accrediting authority's environmental laboratory accreditation program that are necessary to determine compliance with the NELAC standards. An accrediting authority shall not be required to give the NELAP

- evaluation team access to sensitive or confidential documents, or documents that are part of the record of an ongoing legal proceeding.
- d) NELAP evaluation teams performing an on-site evaluation of a Federal agency may need security clearances, appropriate badge, and/or a security briefing before proceeding with the on-site evaluation. Evaluators shall be informed in writing of any information that is controlled for national security reasons and cannot be released to the public.
 - e) The NELAP evaluation team shall have the opportunity to interview privately:
 - 1) all management, technical staff and assessors of the accrediting authority's environmental laboratory accreditation program; and,
 - 2) any NELAP-accredited laboratory receiving its accreditation from the applicant accrediting authority.
 - f) The NELAP evaluation team must ensure that the evaluation 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 evaluation of the accrediting authority's environmental laboratory accreditation program, and
 - 3) an exit interview to discuss all noted deficiencies.
 - g) The NELAP evaluation team shall conduct all evaluations in accordance with the NELAP standard operating procedure for conducting on-site evaluations of accrediting authorities.

6.4.3 On-site Evaluation Reports

- a) The NELAP evaluation team shall send by certified mail to the accrediting authority an on-site evaluation report within 30 calendar days of completion of the on-site evaluation. The report shall include, but is not limited to:
 - 1) the date(s) of evaluation;
 - 2) the name(s) of the person(s) responsible for the report;
 - 3) the NELAP recognition fields of accreditation for which initial recognition or renewal is sought; and
 - 4) the comments of the NELAP evaluation team on the accrediting authority's compliance with the requirements of the NELAC standards.
- b) If the on-site evaluation does not reveal any deficiencies, the NELAP evaluation 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 evaluation, the report shall:
 - 1) identify any specific deficiencies noted during the on-site evaluation,
 - 2) include references to the specific NELAC standards, and

- 3) provide suggested corrective action.
- d) If the on-site evaluation reveals deficiencies, the accrediting authority shall submit a plan of corrective action to the NELAP evaluation team within 30 calendar days of receipt of the on-site evaluation report.
- 1) The plan of corrective action must detail those specific actions taken or that shall be taken by the accrediting authority to correct all deficiencies noted by the NELAP evaluation team during the on-site evaluation.
 - 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 evaluation 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 evaluation report.
- e) The NELAP evaluation team shall recommend to the NELAP Director revocation or denial of NELAP recognition for on-site evaluation 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 evaluation team shall review the plan and respond in writing to the accrediting authority.
- 1) If the accrediting authority corrects all deficiencies, the NELAP evaluation 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 evaluation team shall 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 evaluation 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 accreditation, the NELAP evaluation team shall recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked for those fields of accreditation for which on-site evaluation 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 evaluation 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 evaluation 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 evaluation team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.
- h) If the NELAP evaluation team determines that the accrediting authority has falsified information included in its application and supporting documents, the NELAP evaluation 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) Upon written request to the NELAP Director, through the NELAP evaluation 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 evaluation shall be granted only:
 - 1) when an applicant accrediting authority has an operating environmental laboratory accreditation program for the fields of accreditation for which it is seeking or renewing NELAP recognition, and
 - 2) when, as set forth in Section 6.4.3 g) 3), implementation of corrective actions to correct application and/or evaluation deficiencies requires the accrediting authority to promulgate new or revised regulations, or
 - 3) when, as set forth in Section 6.4.3 g) 3) implementation of corrective actions to correct application and/or evaluation 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 original extension was granted, the accrediting authority shall reapply to the NELAP Director, through the NELAP evaluation team, for an additional extension time. The additional extension time shall be subject to the following conditions:
 - 1) it shall not exceed two years, unless the Accrediting Authority Review Board recommends to the NELAP Director an additional length of time;
 - 2) the accrediting authority shall meet the conditions given in Section 6.5 a); and,
 - 3) the accrediting authority shall provide documentation to demonstrate that it has made significant progress towards completing its regulatory or legislative process.
- 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 evaluation deficiencies.

6.6 NELAP EVALUATION TEAM RECOMMENDATIONS TO THE NELAP DIRECTOR

- a) All recommendations required by this chapter from the NELAP evaluation team to the NELAP Director must be made in writing.
- b) All NELAP evaluation 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 evaluation team;
 - 4) a copy of all on-site evaluation 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 evaluation team's recommendation with all supporting documentation to the NELAP Director also shall be furnished to the accrediting authority.
 - d) Within 30 calendar days of receipt of the NELAP evaluation team's recommendation, the NELAP Director shall provide written notification to the accrediting authority of acceptance or rejection of the NELAP evaluation 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 shall issue a certificate of NELAP recognition dated the day on which NELAP recognition is granted.
- b) This language was removed and placed in the *Standard Operating Procedure 001: Evaluation of Accrediting Authorities*.

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 accreditation in a prominent place in the laboratory facility;
 - 2) NELAP accredited laboratories make accurate statements concerning their NELAP accreditation fields of accreditation 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;
 - 2) include the NELAP-accredited laboratory's accreditation number or other identifier; and
- 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 evaluation team shall submit all documents, letters, evaluation 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 evaluation 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 evaluations.

6.9.1 NELAP Evaluation Team

- a) The NELAP Director shall appoint NELAP evaluation team members as set forth in Section 6.3.3 a) 4) and delegate the responsibilities required by this chapter to evaluation teams.
- b) The NELAP evaluation 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.

- c) Prior to conducting the on-site evaluation of an accrediting authority's program, at least one member of the NELAP evaluation team shall complete the NELAP Accrediting Authority Evaluator-Training Course.
- d) The NELAP evaluation team shall:
 - 1) have at least one member of the NELAP evaluation team who meets the education, experience and training requirements for laboratory assessors specified in the NELAC standards, Chapter 3, On-site Assessment; and
 - 2) have at least another member with experience that includes at least one of the following:
 - i) certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;
 - ii) one year of experience implementing federal or state laboratory accreditation rulemaking;
 - iii) laboratory accreditation management; or
 - iv) one year experience developing or participating in laboratory accreditation programs.
 - 3) Have documentation that verifies freedom from any conflict of interest that would compromise acting in impartial nondiscriminatory manners.
 - 4) All experience required by this subsection must have been acquired within the five year period immediately preceding appointment as a NELAP evaluation team member.

6.10 APPEALING FINDINGS BASED UPON DIFFERENCES IN STANDARDS INTERPRETATIONS

- a) Though standards are written as clearly and succinctly as possible, conflicts regarding interpretation of standards may arise between the NELAP evaluation team and an accrediting authority, a laboratory and the accrediting authority or between two or more accrediting authorities. Appendix A of this chapter outlines the procedures that must be followed in these instances.
- b) The outcome of the procedure outlined in Appendix A is a final consensus interpretation of a standard. This interpretation must be communicated to the relevant standing committees. The decision shall be posted on the NELAC Website and be accessible to all accrediting authorities and laboratories within 14 days.
- c) The consensus interpretation must be recognized by the NELAP Director, the NELAP evaluation teams, all accrediting authorities and laboratories until such a time as the standard is changed or another consensus interpretation has been issued.

6.11 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 evaluation 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 decision 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 the final AARB 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 shall remain in effect pending resolution of the appeal.

National Environmental Laboratory
 Accreditation Conference,
 Accrediting Authority

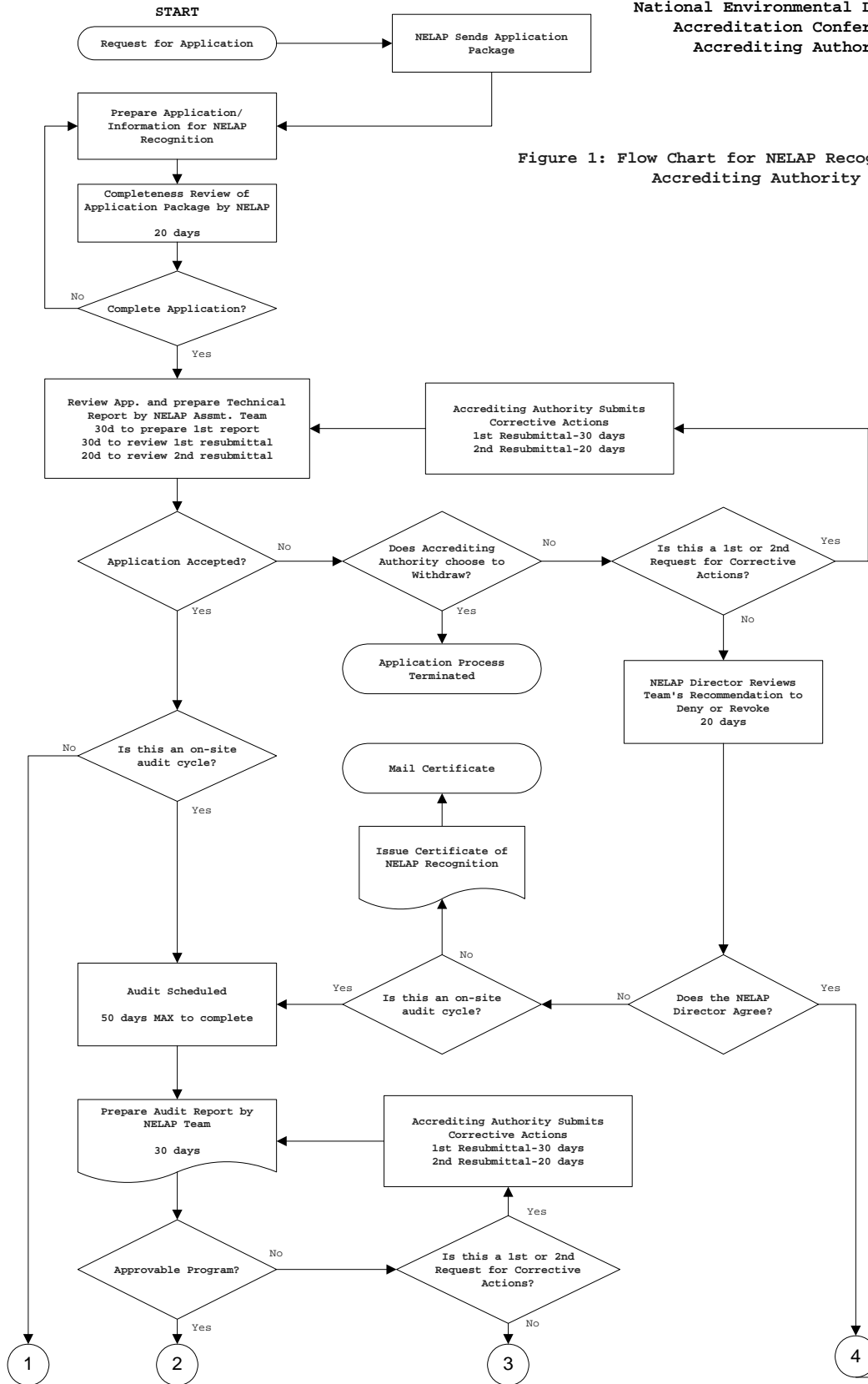


Figure 1: Flow Chart for NELAP Recognition of An Accrediting Authority

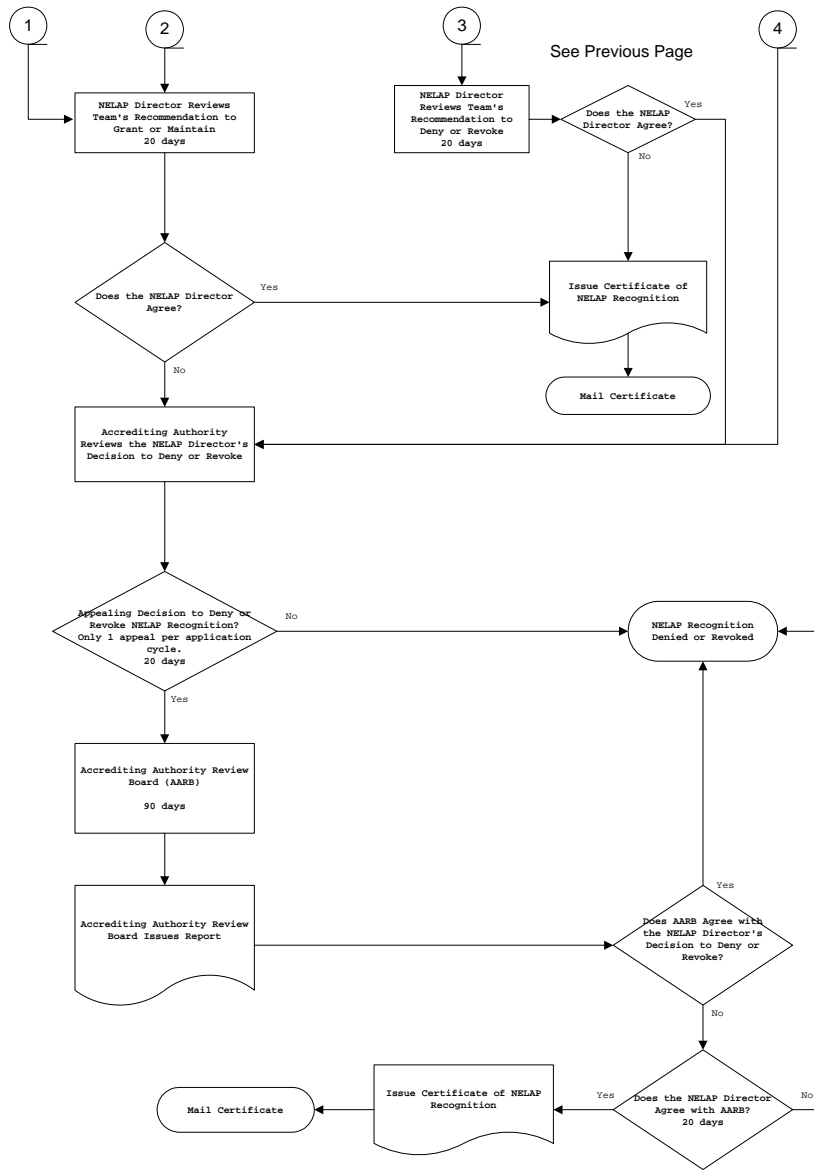


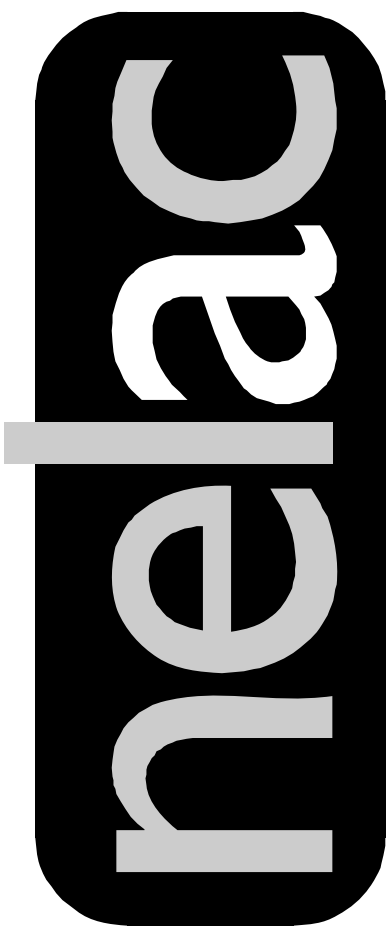
Figure 1: Flow Chart for NELAP Recognition of An Accrediting Authority

ACCREDITING AUTHORITY
APPENDIX A

QUESTIONS OF UNIFORMITY
PROCEDURE

Appendix A – QUESTIONS OF UNIFORMITY PROCEDURE

The appendix on **QUESTIONS OF UNIFORMITY PROCEDURE** was removed and placed in the *Policy on Questions of Uniformity Procedure*.



**National Environmental
Laboratory Accreditation
Conference**

FIELD ACTIVITIES

Approved July 12, 2002
Effective July 1, 2004 unless otherwise noted

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7.0 FIELD ACTIVITIES

INTRODUCTION

This chapter includes standards for sampling and field measurements which are not explicitly covered in other NELAC standards. Because of the use of temporary facilities, field equipment, and the effect of environmental conditions, field standards are necessary to ensure the adequacy of the resulting data.

7.1 GENERAL SAMPLING AND FIELD MEASUREMENT STANDARD

7.1.1 Scope

- a) This standard specifies the general requirements for the competence to carry out sampling and field measurements. It is applicable to laboratories as well as non-laboratory organizations which directly perform environmental sampling and field measurements.
- b) If more stringent standards or requirements are included in a mandated method or by regulation, the organization 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. If a Quality Assurance Project Plan is written for the project, that plan will be followed.

7.1.2 Technical records

Records shall include the identity of personnel responsible for sampling and field measurement. Observations, data, and calculations shall be recorded at the time they are made and shall be identifiable to the specific task (Reference Chapter 5).

7.1.3 Personnel

7.1.3.1 General Requirements for Field Staff

The organization shall use personnel who are employed by, or under contract to the organization. Where contracted and additional technical and key support personnel are used, the organization shall ensure that such personnel are supervised and competent and that they work in accordance with the organization's quality system.

- a) The organization shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.
- b) All personnel shall be responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function.
- c) 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 field operations, test methods, quality assurance/quality control procedures and records management.

- d) The management of the organization shall formulate the goals with respect to the education, training and skills of the assigned personnel. The organization shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated sampling and field measurement tasks of the organization.
- 1) Defining the minimal level of qualification, experience and skills necessary for all sampling and field measurement positions in the organization.
 - 2) Ensuring that all technical staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented.
 - 3) Ensuring that the training of each member of the technical staff is kept up-to-date (on-going) by the following:
 - i. Evidence must be on file that demonstrates that each employee has read, understood, and is using the latest version of the organization's in-house quality documentation, which relates to his/her job responsibilities.
 - ii Training courses or workshops on specific equipment, techniques or procedures shall all be documented.
 - iii 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 penalties for improper, unethical or illegal actions.
 - iv Personnel 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 sampling and field measurements in accordance with the most recent version of the methods, standard operating procedures, and other supporting documents.
- e) The management shall authorize and ensure the competence of specific personnel to perform particular types of sampling and field measurements. The organization shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

7.1.4 Accommodation and Environmental Conditions

The sampling or field measurement team shall ensure that the field conditions do not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and field conditions that can affect the result of tests shall be documented.

7.1.5 Sampling and Field Measurement Methods

The organization shall use appropriate methods and procedures for all tests within its scope, including sampling, equipment decontamination, handling, transport, chain-of-custody, storage, and preservation of samples to be tested.

- a) The organization shall use methods which meet the regulatory or other needs of the client and which are appropriate for the tests it undertakes. Sampling and field measurement methods published in international, regional, or national standards shall preferably be used.
- b) The organization shall validate non-standard methods, in-house designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use.

7.1.6 Equipment and Supplies

- a) The personnel shall be furnished with all items of equipment required for the correct performance of the sampling and field measurement activity. In those cases where the organization needs to use equipment outside its permanent control, it shall ensure that the requirements of this standard are met.
- b) Equipment and its software used for sampling and field measurement shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests concerned. When received, sampling equipment and supplies shall be checked to establish that it meets the organization's specification requirements, complies with the relevant standard specifications, and shall be checked to ensure proper operation and/or calibrated before use.

7.1.7 Sampling and Field Measurement Procedures

- a) The organization shall have a sampling plan and procedures for sampling and field measurement when it carries out sampling for subsequent testing. The sampling plan shall describe the matrix-specific sampling procedures as well as the selection, withdrawal and preparation of samples. The use of field blanks and other quality control samples shall also be included in the plan. The sampling plan as well as the sampling and field measurement procedure shall be available at the location where sampling or field measurement is undertaken. Sampling plans shall be based on communication with the client and, whenever appropriate for the project objectives, be based on applicable statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the tests.
- b) Where the client requires deviations, additions or exclusions from the documented procedure, these shall follow procedures developed by the organization to document the changes and include them with the resultant data. This documentation shall be communicated to the client.
- c) The organization shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and the diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.
- d) The organization shall have procedures and information on storage and transport of samples, including information on sampling factors affecting the test result. These procedures shall be provided to those accepting and transporting samples.

7.1.8 Documentation

Field events shall be documented and shall include the following items as appropriate for the interpretation of test results. When necessary, this information shall be provided to the data user:

- a) sampling/field measurement organization, including address, phone number, and email address;
- b) printed name and signature of technician, plus names of all members of the sampling team;
- c) sample type (grab, composite, etc.), including an identification of the matrix sampled; (aqueous, solids, etc.)
- d) sample identification number including a unique field identification code for each sample container;
- e) reason for sampling/measurement;
- f) date and time of sampling/measurement;
- g) location of sampling, including any diagrams, sketches, or photographs; name of sampling station, and/or latitude, longitude, and altitude when sample point is not otherwise identified;
- h) for water sampling: the water level measure, sample depth, and water discharge rate measure if appropriate/required;
- i) reference to the sampling plan and procedures used, including field blanks, spikes, duplicates, and if applicable, any confirmation samples; field instrument calibration, span, drift, and calibration standards; sampling system bias and response time; and field test standards and reagents as required by the standard/test method;
- j) sample preservation, transportation, and storage, including a description of sample containers and chain of custody;
- k) details of any conditions during sampling that may affect the interpretation of the test results;
- l) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned; and,
- m) The organization collecting samples shall certify that samples and field measurements were collected in accordance with NELAC standards or provide reasons and/or justification if they were not.

7.2 FIELD MEASUREMENT STANDARD (WATER)

Field measurement is done by an accredited laboratory or other accredited organization, e.g., an engineering consulting firm. Field measurement can be, but is not limited to being:

- a) Testing outside of a mobile laboratory, e.g. testing using self-powered instruments either hand-held or contained in personal backpacks, suitcases or other containers.
- b) On-line monitoring that may include a fully enclosed structure with electrical power and an environmental control system critical to the protection of the instruments/analyzers and computers. Generally these units are configured to operate in the same location for a period of one day to several weeks.

- a) Ambient air or NPDES discharge monitoring/sampling systems that collect and /or record data with electrically- operated instruments, usually contained in an environmental enclosure. These field measurement systems normally have a testing probe continuously exposed to the sampling matrix or medium being tested.

- b) Measurements of:
 - 1) Hydrogen ion (pH)
 - 2) Dissolved Oxygen (DO)
 - 3) Temperature
 - 4) Total Chlorine Residual
 - 5) Sulfite
 - 6) Turbidity
 - 7) Conductivity
 - 8) Gaseous analytes
 - 9) Secchi Transparency

- e) Measurements from instruments/tests that provide nearly instantaneous results:
 - 1) Electrometric tests
 - 2) Colorimetric tests
 - 3) Titrimetric tests
 - 4) Gas Chromatography tests
 - 5) UV, Non-dispersive Infrared, or Fluorescence tests
 - 6) Measurements of any parameter where prescribing directives/methods indicate "immediate analysis" (no holding time) is required.

Appendix A - REFERENCES

ISO/IEC 17025:1999(E), "General Requirements for the Competence of Testing and Calibration Laboratories," 1999.