NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

DRAFT STANDARDS
November 1994

Prepared by the
STATE/EPA FOCUS GROUP

TABLE OF CONTENTS

1.0 POLICY AND STRUCTURE

1.1 INTRODUCTION

The Committee on National Accreditation of Environmental Laboratories (CNAEL) in its final report of September 1992 recommended the establishment of a national environmental laboratory accreditation program (NELAP). The States function as the primary accrediting authorities and may contract with a third party as the accrediting body for purposes of carrying out some parts of the accrediting functions, e.g. on-site inspections. As accrediting authorities, the states would maintain the authority to grant accreditation, enforce compliance, etc. EPA shall oversee and approve the state's compliance with all standards applicable to an accrediting authority. The recommended key elements for NELAP include on-site assessments, performance evaluation testing, and data audits. To achieve the stated goals of the CNAEL report, it is proposed to establish a National Environmental Laboratory Accreditation Conference (NELAC), which is modeled after the National Conference on Weights and Measures. NELAC membership shall be voluntary and shall be open to environmental laboratory accrediting authorities. The NELAC shall serve as

the organization that shall establish and modify the accreditation standards. Broad participation in NELAC shall identify laboratories which are capable of providing reliable, uniform laboratory data which are acceptable to both Federal and State environmental programs. National accreditation standards and procedures shall provide a level playing field where reciprocity among the States in environmental laboratory accreditation shall be practicable. The creation of a National Environmental Laboratory Accreditation Program allows coordination of the current accreditation activities of different States or other governmental agencies, and reduces the number of on-site inspections, performance evaluation tests, and related requirements with which the accredited organizations must comply. It is intended that NELAP function in a manner which minimizes negative effects on the current accreditation operations of the States, requires minimum outlay of State and Federal funds to implement, and that is self supporting.

1.2 PURPOSE OF THE CONFERENCE

The National Environmental Laboratory Accreditation Conference shall be a standards setting body. NELAC shall, through the

process described, establish consensus uniform standards on which the national accreditation program shall be based. These uniform standards shall include, but are not limited to, quality systems, performance evaluation, audit programs, and other key elements as established by the standing committees of NELAC. It is NOT the purpose of NELAC to function as an accrediting body, oversee or approve accrediting bodies, or administer any of the main elements of the accreditation program.

1.3 STRUCTURE OF THE CONFERENCE

The structure of the Conference is shown in Figure 1-1. The Board of Directors shall assume the overall supervisory, administrative, and procedural duties. The Standing Committees and Administrative Committees are overseen by the Board of Directors. The Standing Committees shall receive input regarding standards and test procedures, then process this input into resolutions which shall be put before the Membership at the Annual Conference. These resolutions shall be voted on by Active Members. The non-voting Contributors shall also have the opportunity to make presentations and comments on the resolutions throughout the process and at the

Annual Conference. The NELAC may also take into consideration advise and comment provided to the Environmental Protection Agency through the Environmental Laboratory Advisory Board (ELAB) chartered under the Federal Advisory Committee Act (FACA). The composition and relationships of these bodies is described below.

1.3.1 The Board of Directors

The Board of Directors consists of the Conference Chair, the Chair-Elect, the most recent still active Past Chair, the Treasurer, six members elected at large from the active membership (to serve 3-year staggered terms), an EPA official to be appointed by the EPA Administrator as the NELAP Director (see section 1.4.1), and an Executive Secretary to be named by the Director. The Board of Directors serves as a policy and coordinating body in matters of national and international significance. The Board of Directors also makes interim policy decisions when necessary before the Voting Delegates have an opportunity to vote on the issues in question.

1.3.2 The Environmental Laboratory Advisory Board

The ELAB consists of nine members composed of eight non-governmental representatives and chaired by an EPA representative. The members may be selected from a slate of nominees prepared by the Contributors' Committee. This FACA board advises the EPA on matters affecting the interests of the contributors and other interested parties.

1.3.3 The Committees

The committees are the Standing Committees and the Administrative Committees. Both are overseen by the Board of Directors.

1.3.3.1 The Standing Committees

These committees each consist of five members elected from the Active Membership of the Conference. They serve five years and one new member is elected each year. The committee elects a chair. The committees shall generate standards and policies for which they have responsibility to be presented at the annual Conference for vote. The committees shall receive input via comments and presentations at the interim and annual conferences. The committees shall draft resolutions which

shall be published by EPA in the Federal Register. The committees shall prepare and arrange timely agendas for Interim Meetings and Annual Conferences.

The **Program Structure Committee**. This committee shall develop modifications to the scope, structure, and requirements to the tiers and fields of testing.

The **Accrediting Authority Committee**. This committee provides the standards used by EPA to approve state authorities.

The **Quality System Committee.** This committee shall establish and keep current the key elements of a quality system including record keeping and staffing requirements. The Committee shall also define uniform standard criteria for each of the elements of the quality system.

The **Performance Evaluation Program Committee.** This committee shall determine the requirements for the Performance Evaluation Program. The committee shall generate the standards for the Performance Evaluation Samples, provide criteria for selection of the provider of the Performance Evaluation Samples, and provide and update the protocol for

the use of Performance Evaluation Program in the accreditation of laboratories.

The **On-Site Assessment Committee**. This committee shall establish the training and experience requirements of the assessors; establish the frequency of inspections; and generate the procedures for on-site visits.

The **Accreditation Process Committee**. This committee shall establish and develop modifications for the accreditation process including the requirements for accreditation; procedural requirements for suspension, revocation and denial of accreditation; relative roles and responsibilities of laboratories; and appeal processes. The Committee considers matters concerning reciprocity of accreditation.

The **Regulatory Committee**. This committee provides the Standing Committees with current information on Federal regulations which affect the testing that the laboratories do. The Regulatory Committee annually presents a report for Conference action. Its scope embraces all matters regarding the development and interpretation of uniform laws and regulations; the study and analysis of bills for legislative

enactment; and the establishment and maintenance of published guidelines and other effective means of encouraging uniformity of interpretation and application of laboratory accreditation laws and regulations. This committee shall develop language which shall assist the states in the preparation and adoption of standardized statutes and regulations.

1.3.3.2 The Administrative Committees

The Administrative Committees, with the exception of the Contributors Committee, shall consist of members appointed from the active membership. The functions and the responsibilities of the Administrative Committees are described below.

The **Nominating Committee.** The Nominating Committee annually presents a slate of nominees for all elective offices at the national annual conference.

The **Conference Management and Funding Committee.** This committee sets annual membership fees and conference registration fees, manages the logistical details of the interim meetings and annual conferences, prepares an annual

budget for the Conference to be submitted for approval to the Board of Directors, and publicizes the interim meetings and annual conferences. The Treasurer shall be an ex-officio member of this committee.

The **Membership Committee**. This committee initiates membership invitations and publicizes the Conference to prospective members. The committee also provides coordination and participation of Contributors in all affairs of the Conference.

The **Fiscal Auditing Committee**. This committee is responsible for the conduct and review of the annual audit of the Conference and shall report such findings to the Board of Directors. It also audits the Treasurer's books annually.

The **Liaison Committee**. This committee shall provide liaison with other federal agencies such as the Department of Energy and the Department of Defense. In addition this committee shall provide liaison with other national and international standard setting bodies such as the National Institutes of Standards and Technology (NIST) and the International Organization for Standardization (ISO). The function of this

committee is to provide and solicit information and develop a spirit of cooperation between NELAC and outside organizations.

The **Contributors Committee.** This committee is composed of five Contributors. Its function is to serve as a focal point for the Contributors. The committee shall propose a slate of candidates to the EPA as potential appointees to the ELAB. It solicits information from and provides feedback to the Contributors.

1.3.4 The Membership

The Membership consists of two classes - Active Members and Contributors

Active Membership - Active membership is limited to State and Federal Officials. The Active Members may vote and serve on the Committees. At the annual conference the voting Members are divided into a House of Representatives and a House of Delegates. The House of Representatives is composed of one officially designated State Representative from each State or Territory, two representatives from each of seven EPA

Assistant/Associate Administrators (OSWER, OAR, ORD, OW, OPPTS, OECA, and OROSLR), and one officially designated Federal Representatives from each other participating federal program. The state representative should be the director of the state environmental laboratory accreditation, or a high level technically competent scientist who is knowledgeable about environmental laboratory analysis and accreditation programs, or his or her designee. The Federal Representative is designated by the appropriate person in charge of the federal program. All other State and Federal Officials are grouped as a body known as the House of Delegates.

Contributors - The contributors are all other interested parties and groups. They include, but are not limited to, laboratory personnel, industry representatives, environmental groups, the general public, laboratory associations, industry associations, accreditation associations, and retired active members. The Contributors may not vote, but can make presentations, comments or input at all stages of the standards and procedures making process.

1.3.5 The Generation of Standards

The standards for the accreditation of laboratories begin in the various committees (see Figure 1-2). Draft standards proposed by the committees are published in the Federal Register by EPA. After providing an appropriate time for review, an Interim Meeting is held and presentations, comments and other input are received. The draft proposals are processed and either presented at the Annual Conference or returned to committee for further work. These resolutions presented at the Annual Conference are voted upon by the Active Membership. (See Constitution and Bylaws for voting procedures.) If rejected, they go back to committee for reassessment or shelving. If approved, they are presented in the Federal Register in final form by EPA.

1.3.6 Adoption of Standards

Participating States must adopt the standards to maintain status as a NELAP accreditor. If a State chooses not to participate in all or part of the accreditation program, laboratories in that State may obtain certification from a participating State that is approved under NELAP.

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

1.4.1 Federal Government (USEPA)

The role of the federal government, as represented by the USEPA (the Agency), shall be that of oversight and evaluation of the accrediting authorities and that of administration of NELAP program elements which require a high degree of standardization between different accrediting authorities. In addition, the USEPA shall provide staff support to the Conference as provided for in the Bylaws and agreed to by the Agency. The EPA shall assist the Conference by publishing in the Federal Register all proposed and final standards. The EPA will also evaluate state and federal laboratories to assure compliance with NELAC standards. The EPA Administrator will appoint a Director of the National Environmental Laboratory Program. The Director shall serve as an ex officio member of the Board of Directors. He or she shall select a senior member of EPA with laboratory accreditation experience as the Executive Secretary of the Conference (a full time position). The Director's Office shall establish a program which evaluates, approves, and reports on the accreditation

programs implemented by the state accrediting authorities. In these reports, state accreditation programs shall be evaluated against the national standard as established by the Conference. The EPA shall evaluate, inspect, and approve state and federal laboratories as complying with NELAC standards. In addition, the Agency shall establish a five member board, the Accrediting Authority Review Board, composed of representatives from the states, EPA, and other federal agencies, to review the process and procedures used by EPA to approve State and Federal laboratories and accrediting authorities. It is recommended that the Agency provide administrative support to a performance evaluation sample program so as to ensure uniformity of sample composition and performance evaluation standards.

1.4.2 State Governments

State governments shall be the primary accrediting authority. The state's Laboratory Accreditation Program will be audited and approved by the Director's Office. As the accrediting

authority, states will have full responsibility for ensuring conformance with the national standard established by NELAC. States will be responsible for accrediting applicant organizations through approving applications, performing on-site assessments and maintaining performance evaluation sample programs. States are responsible for ensuring that on-site inspectors are trained in accordance with NELAP requirements. States shall submit the names, and appropriate accreditation material, to the EPA for inclusion in the National Laboratory Database. States may choose to contract accreditation activities to a third party (non-government) agency. If contracted to a third party, states remain the accrediting authority and retain responsibility for ensuring compliance with the standards established by NELAC.

1.4.3 Joint Federal and State Roles

The NELAC (Conference) shall be the joint responsibility of the Federal Government (Agency) and the state accrediting authorities. As provided in the following section on structure of the Conference and the Conference Bylaws, state accrediting authorities and the Agency share responsibilities of governance, analysis and establishment of policy, and

analysis and establishment of technical standards as they apply to the NELAP.

1.4.4 Other Parties

All other interested parties including, but not limited to, the laboratory industry, clients of the laboratory industry, environmental or other public interest groups, and the general public, shall function as contributors to the Conference. In this role, these other parties shall bring technical and policy issues to the attention of the Conference, its managing Board, or its subcommittees. It is anticipated that these issues shall be brought to the Conference in the form of reports, presentations, discussion material, or other forms of documentation for presentation at the annual Conference, committee, or subcommittee meetings.

1.5 SCOPE OF THE PROGRAM

The scope of the National Environmental Laboratory Accreditation Program shall encompass the necessary scientific testing to serve all U.S. Environmental Protection Agency (EPA) monitoring, compliance or other functions mandated by

statutes and pursuant regulations. Some of the statutes are the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Safe Drinking Water Act (SDWA); the Resource Conservation and Recovery Act (RCRA); the Comprehensive Environmental Response Compensation and Liability Act (CERCLA): the Federal Water Pollution Control Act (Clean Water Act); the Clean Air Act (CAA); and the Toxic Substances Control Act (TSCA). In addition, the program shall also include provisions to permit special requirements or fields of testing promulgated by any of the States and/or Territories.

However, the program 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. This program shall not apply to those government laboratories engaged solely in the analysis of forensic evidence.

1.6 STRUCTURE OF THE ACCREDITATION REQUIREMENTS

The structure of the NELAP shall be based on the field of testing (see Figure 1-3). It shall consist of a set of general requirements that all applicants must satisfy. Applicants for a particular field of testing must also meet the necessary number of additional levels of specific requirements or functions that are linked to the general requirements. The number and the degree of difficulty of the required additional levels shall depend on the complexity of the test procedures in question.

It is proposed that the different fields of laboratory testing be structured into groupings based on parameter, group of parameters, or method. In addition, a category of supplemental accreditation will be designated. A "supplemental" accreditation means accreditation of a laboratory which has met additional methods or parameters required by a state accrediting authority.
"Supplemental" accreditation shall be needed only for those few methods and/or parameters which are unique to a particular state. These supplemental requirements shall be limited in number and scope.

1.6.1 General Requirements

The general requirements are applicable to all applicants regardless of their size, volume of business, or field of testing. The organizational structure, or procedures used by applicant organizations to meet these general requirements may differ as a function of size or scope of testing of an organization. The general requirements shall include all the elements outlined in General Requirements for the Competence of Calibration and Testing Laboratories, ISO/IEC Guide 25: 1990 (E).

General requirements shall include Health and Safety, and Waste Management Programs. Applicant organizations shall be required to be in compliance with all applicable federal, state, and local rules and regulations covering environmental, and occupational health and safety. Responsibility for the evaluation of compliance with these rules and regulations shall remain with the appropriate regulatory body.

The relevant elements listed in the document are as follows:

1.6.1.1 Organization and management

The organization shall be legally identifiable; the organization shall have managerial staff with the authority and resources needed to discharge their duties; this includes technical management with overall responsibility for the technical operations, and quality management with responsibility for the quality system and its implementation.

1.6.1.2 Quality system, audit and review

The organization shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes; the quality manual, and related quality documentation, shall state the organization's policies and operational procedures; the organization shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system.

1.6.1.3 Personnel

The organization shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

1.6.1.4 Accommodation and environment

Organization facilities shall have suitable space, energy sources, lighting, heating and ventilation for proper performance of calibrations or tests.

1.6.1.5 Equipment and reference materials

The organization shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests.

1.6.1.6 Measurement traceability and calibration

Standards used for calibration must be traceable;.

1.6.1.7 Calibration and test methods

The organization must document instructions on the use and operation of all relevant equipment.

1.6.1.8 Handling of calibration and test items

The organization must document a system used to identify the items to be calibrated or tested.

1.6.1.9 Records

The organization shall maintain a record system to suit its particular circumstances and comply with any applicable regulations.

1.6.1.10 Certificates and reports

The organization certifies and reports the calibration and/or test results.

1.6.1.11 Sub-contracting of calibration or testing

The organization shall sub-contract work only to organizations that are accredited by a NELAC accrediting authority. Subcontractors must be clearly identified.

1.6.1.12 Outside support services and supplies

The organization must use only those outside support services and supplies that are of adequate quality.

1.6.1.13 Complaints

The organization shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the organization's activities with records maintained of all complaints and of the actions taken by the organization; where a complaint, or any other circumstance, raised doubt concerning the procedures, or other requirements or otherwise concerning the quality of the organization's calibrations or tests, the organization involved is promptly audited in accordance with pre-established procedures.

1.6.2 Specific Requirements Linkage

Additional tiers of requirements can be linked to the general requirements. To illustrate the tiered approach, a schematic representing the accreditation scope and structure by field of testing is given in Figure 1-3. It indicates that all NELAP applicants must meet the basic requirements. Additional specific tiers of requirements are linked to the basic requirements for a particular test or activity. An organization seeking accreditation in hazardous waste organic testing must meet all the requirements listed in basic requirements, general laboratory, organic, and hazardous waste. The specific and detailed requirements under this scheme have not been developed at this time. The appropriate and necessary requirements of the various tiers and fields of testing will be developed by the Program Structure Committee.

1.6.3 Discussion

The field of testing structure proposed for the national environmental laboratory accreditation program provides flexibility. This allows for the incorporation of new methods or new instrumentation without the applicants repeatedly demonstrating the basic requirements that the accreditation applicants have previously satisfied. Redundancy of

qualification assessment is avoided. Avoidance of redundant reviews and assessments shall significantly expedite the processing of applications which cover different fields of testing. Such a scheme provides a structure whereby appropriate and specific accreditation requirements can be established to meet the prevailing needs of environmental laws and regulations. Regulators are thus provided with environmental sample testing results generated by laboratories according to specified or equivalent methods and quality assurance protocols.

Additionally, the adoption of parameter, method specific and supplemental classifications allows for the design of accreditation to suit needs of individual laboratories and states. This flexibility shall promote reciprocity among all the participating States. The field of testing approach proposed shall also allow for the future incorporation of performance based methods (PBM) by substituting an approved PBM for the specified analytical methods. Any supplemental requirements essential to meet state needs would be added at the parameter or method specific level.

1.7 FUNDING OF THE PROGRAM

Funding shall be needed to cover the costs arising from at least three areas: the administration and functions of NELAC; expenses incurred by EPA through its oversight and related administrative duties; and expenses incurred by the States because of accreditation functions including on-site visits, performance evaluation samples, processing applications, and other duties. Funding mechanisms for each of these cost areas is proposed below:

1.7.1 Self supported NELAC

The NELAC should be self-sustaining financially insofar as possible. The Interim meetings and Annual Conferences expenses should be financed by registration fees and annual dues for Members and Contributors. These dues and registration fees should be set by the Conference Management and Funding Committee. Other expenses of committee members shall be paid by their organizations.

1.7.2 EPA Program Support

The EPA should provide support for the National Environmental Laboratory Accreditation Program. This program includes oversight and evaluation of accreditation authorities, evaluation and approval of state and federal laboratories, administrative support for the Conference, and publications in the Federal Register.

1.7.3 Fee Supported State Programs

All costs of state accreditation programs may be covered through the collection of application fees from the applicant organizations. Such fees would cover the cost of application and processing, performance evaluation, site assessments, staff training, Conference membership and participation, and other appropriate activities, whether such activities were carried out directly by the state accrediting authority or by contract to a third party. It is recommended that a dual fee structure be implemented by the state authorities. A full fee should be charged applicants for which the state is the primary accreditor. A reduced fee should be charged applicants for which the state is the secondary accreditor. This fee structure is based on the principle that fees shall cover the actual cost of an accreditation. The primary

accrediting authority shall incur the full cost of accreditation. The secondary accrediting authority, having accepted the accreditation of another authority through reciprocity, shall only incur the cost of registration of the accredited organization. Costs incurred by a secondary accrediting authority related to supplemental requirements, as described in section 1.8.2, should be reflected in supplemental fees.

1.8 RECIPROCITY

All member accrediting authorities shall grant reciprocity to all other member accrediting authorities which have met the national standard. This principle of reciprocity is an element of the national accreditation standard, to which all member accrediting authorities are held.

Reciprocity among the environmental laboratory accrediting authorities is essential to the success of a national program. The principal accrediting authorities shall be the states. The states or federal agencies which act as accrediting authorities, must accept accreditation from other accrediting authorities in order for a national uniform program to

succeed. Three policy issues are presented which are key to acceptance of the reciprocity principle by accrediting authorities.

1.8.1 Fair Representation of Accrediting Authorities

The accrediting authorities must have a fair and representative voice in the National Environmental Laboratory Accreditation Conference. NELAC shall establish the basic scope, structure, and standards of the national program. Acceptance of the national program, in lieu of state programs, shall be significantly enhanced by fair and meaningful participation of state accrediting authorities in the establishment of the national program.

1.8.2 Scope and Essential Quality Standards

The national program (the national consensus standard) adopted by NELAC shall have a scope and essential quality standards which meet or exceed the requirements of the existing state accrediting authorities. NELAC must consider the range of scope and quality systems requirements of the state accrediting authorities in the adoption of a national program.

A national program which falls significantly short of the existing state program requirements, shall either not be accepted by state authorities, or shall require such extensive state supplementary requirements as to make the national program irrelevant. It is recognized that certain state authorities shall have special requirements which arise from a unique statutory, economic, or ecological situation. Reciprocity shall be possible if state mandated supplementary requirements are limited in number and complementary to the national program.

1.8.3 Fee Structures

NELAC shall adopt a policy which recommends that all accrediting authorities institute a fee structure which reflects the cost of operation of the accreditation program. NELAC requires that laboratories apply for accreditation in the state of their primary operation.

NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

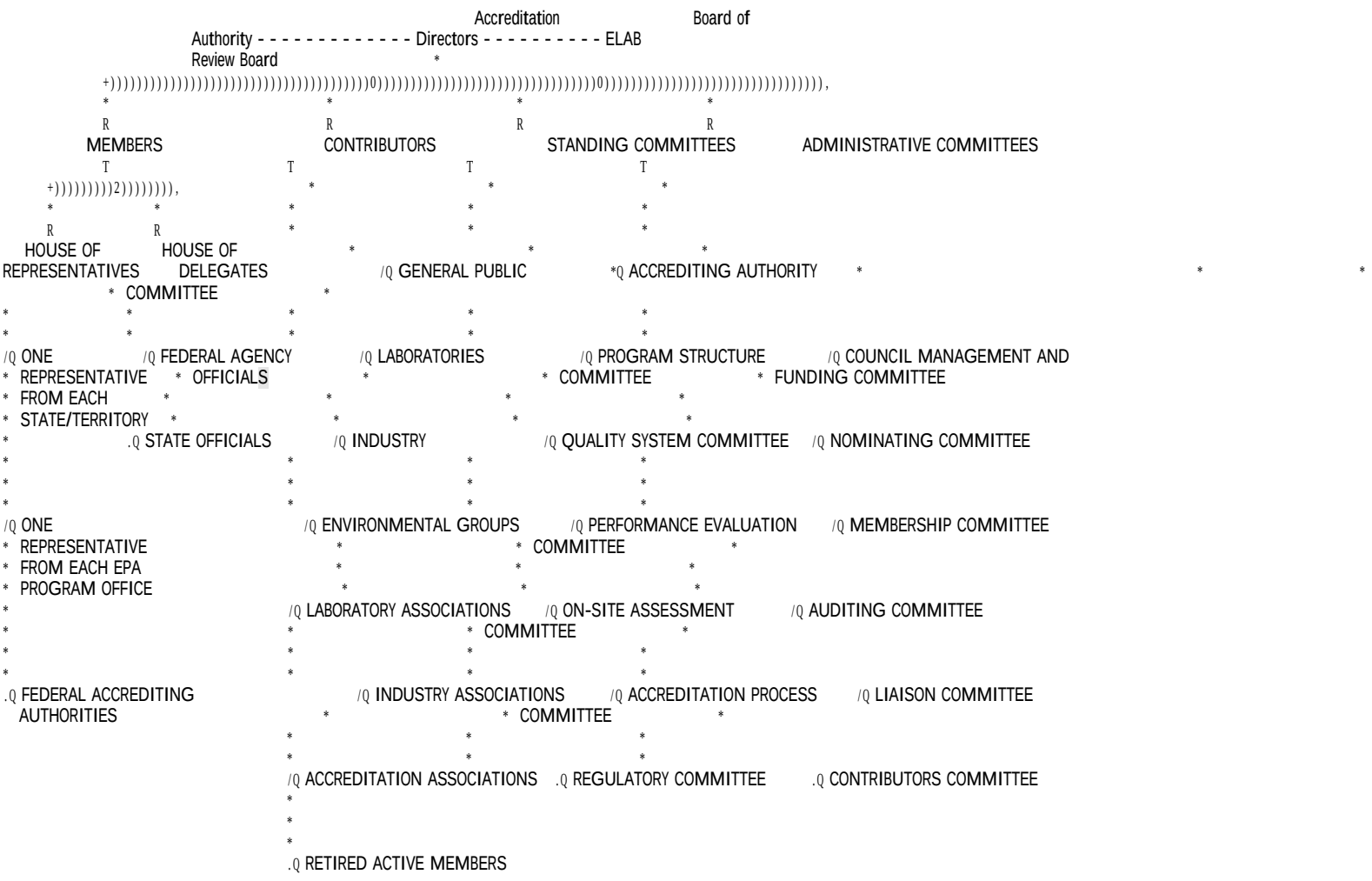
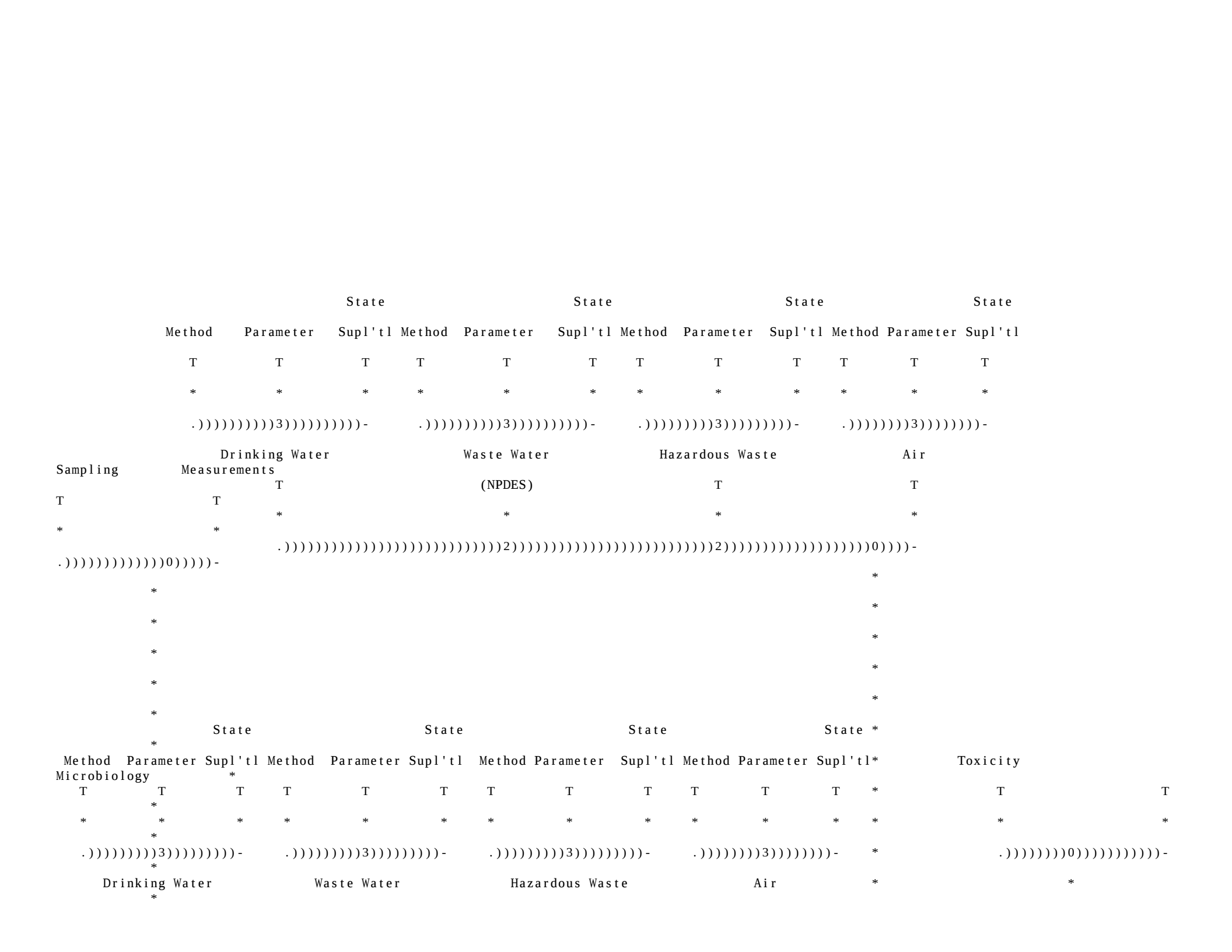


FIGURE 1-1 NELAC STRUCTURE


State
State
State
State
Method
Parameter
Supl'tl
Method
Parameter
Supl'tl
Method
Parameter
Supl'tl
Method
Parameter
Supl'tl
Drinking Water
Waste Water
Hazardous Waste
Air
Sampling
Measurements
(NPDES)
State
State
State
State
Method
Parameter
Supl'tl
Method
Parameter
Supl'tl
Method
Parameter
Supl'tl
Method
Parameter
Supl'tl
Toxicity
Microbiology
Drinking Water
Waste Water
Hazardous Waste
Air

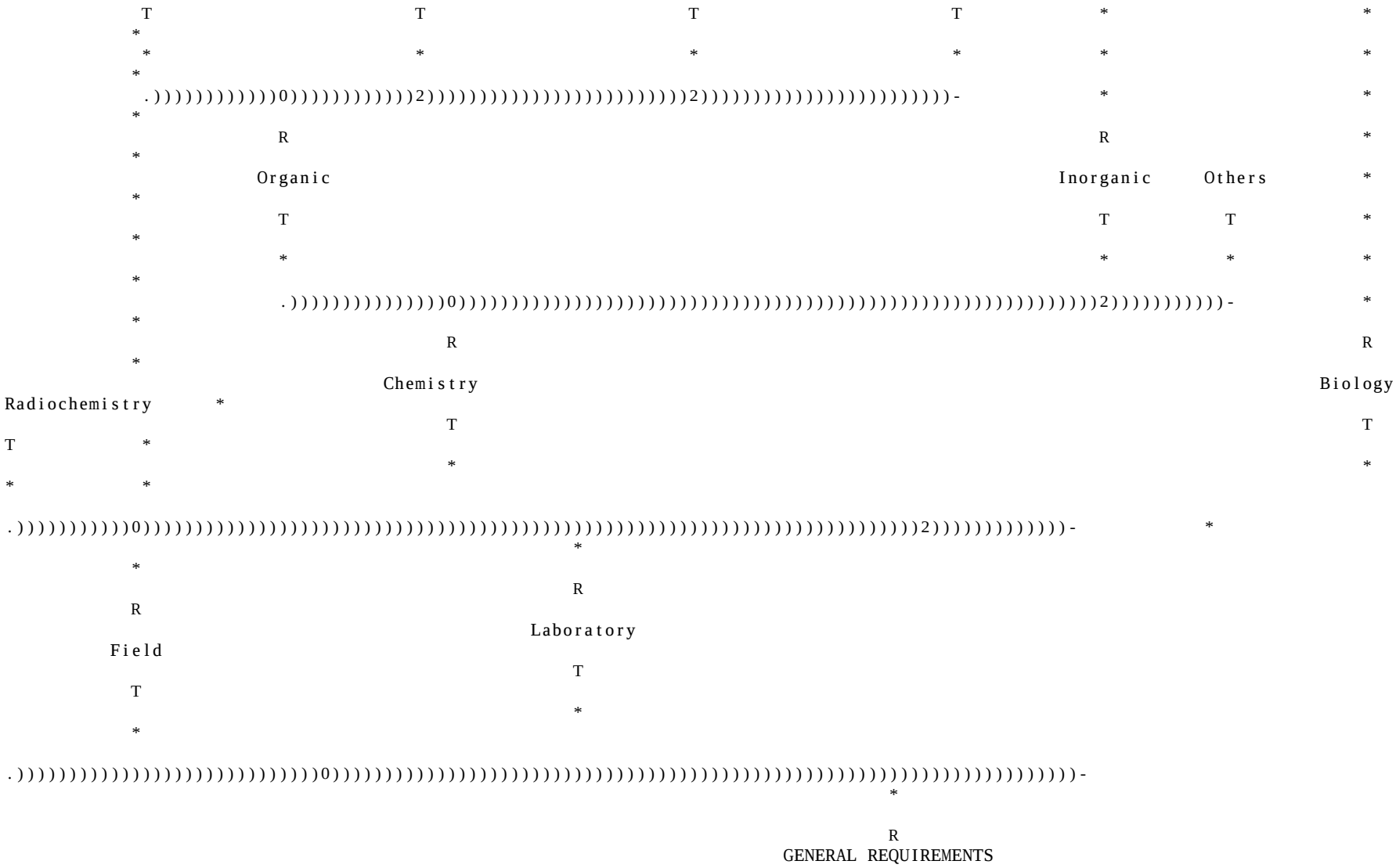


FIGURE 1-3: ILLUSTRATION OF SCOPE AND STRUCTURE BY FIELD OF TESTING

2.0PERFORMANCE EVALUATION TESTING PROGRAM

2.1 ENROLLMENT IN PE TESTING PROGRAM

Each laboratory must enroll in a performance evaluation (PE) testing program that meets the criteria detailed by the National Environmental Laboratory Accreditation Program (NELAP). The laboratory must participate in an approved program or programs for each field of testing for which it seeks accreditation. Participation shall mean the analysis and reporting of all test samples. Laboratories shall participate in PE testing for all fields of testing at a frequency determined by the NELAC standards.

The laboratory must notify the accreditation agency of the NELAP-approved program or programs in which it chooses to participate to meet PE testing requirements. For those tests performed by the laboratory for which PE testing is not currently available, the laboratory must establish and maintain the accuracy and reliability of its testing procedures by a system of internal quality management.

For each field of testing for which the laboratory seeks accreditation, it must participate in the designated, NELAP-approved PE testing program for at least twelve months before designating a different program. The laboratory must notify the primary accreditor before any change in designation.

Laboratories shall bear the cost of any subscription to a PE testing program required by NELAP.

Each participant must authorize the PE testing program to release to the primary accreditor all data required to determine the laboratory's compliance with the criteria. The primary accreditor shall make individual performance results available to all requesters.

2.2 APPROVAL OF PE TESTING PROGRAMS

In order for a PE testing program to receive approval, the program must be offered by a Federal or State agency, or entity acting as a designated agent for the Federal or State agency. A Federal or State program seeking approval or renewal for its PE program for the next calendar year must submit an application to the NELAP director providing the required information by July 1 of the current year. The program must provide technical assistance to

resolve problems that the participants experience such as anomalies during analysis of the samples, lost samples, or receipt of broken sample containers, etc. In addition, the PE testing program must,

a) assure the quality of test samples, appropriately evaluate and score the PE test results, and identify performance problems in a timely manner;

b) demonstrate to the primary accreditor (or NELAP) that it has:
   1) The technical ability required to:
      i. either prepare samples or evaluate samples purchased from manufacturers, who prepare the samples in conformance with the appropriate good manufacturing practices; and
      ii. distribute samples with at least two levels of analytes. Rigorous quality control must assure that samples mimic actual environmental samples when possible and that samples are homogeneous and remain stable over the period of testing. Stability shall be verified by routine testing on stored samples, within the time frame for analysis by PE test participants. Samples shall be maintained by the PE testing program to retest laboratories with unsatisfactory performance, or which have significant changes in accreditation status;

   2) a scientifically defensible process for determining the correct result for each challenge offered by the program;

   3) a program of sufficient challenge, with a frequency of no less than two times per year, to establish that a laboratory has met performance requirements;

   4) the resources needed to distribute, analyze and interpret individual laboratory performance. The PE program will provide
      i. individual results to the laboratories,
      ii. statewide and nationwide reports to regulatory agencies on individual laboratory performance on PE test events,
      iii. cumulative reports and scores for each laboratory, and
      iv. reports of specific laboratory failures using grading criteria acceptable to NELAP.

   These reports must be provided on a timely basis.

(5) provisions on each PE report form used by the laboratory to record PE results, an attestation statement that PE test samples were tested in the same manner as routine samples, with a signature block to be completed by the individual performing the test as well as by the laboratory management;

6) a mechanism for notifying participants of the PE shipping schedule and for participants to notify the PE testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and

7) a process to resolve technical, administrative, and scientific problems about program operations;

c) provide and maintain the following documentation as described:

1) reports of PE test results and all scores for each laboratory's performance (an electronic or a hard copy, or both) must be provided to the primary accreditor, NELAP, and the participating laboratory in the format required by NELAP within 60 days after the date by which the laboratory must report PE test results to the PE testing program;

2) records of each laboratory's performance must be maintained for a period of five years or such time as may be necessary for any legal proceedings; and

3) an annual report must be provided to the primary accreditor and NELAP with, if needed, an interim report, which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PE samples, which may adversely affect the ability of the primary accreditor or NELAP to evaluate laboratory performance.

If a PE testing program is determined by NELAP to fail to meet any criteria for acceptance as an approved performance evaluation testing program, NELAP will notify the PE testing program and the primary accreditor. The PE program must notify all laboratories enrolled in their PE program of the nonapproval and the reasons for nonapproval, within 30 days of the notification.

2.3 TESTING OF SAMPLES

The laboratory must examine or test, as applicable, the PE samples it receives from the PE testing program in the same manner as it tests environmental samples, and return the results by the deadline stated in the sample package. The analyst testing or examining the samples and the laboratory management must attest to the routine integration of the samples into the workload using the laboratory's routine methods. The laboratory must test samples the same number of times that it routinely tests environmental samples.

Laboratories that perform tests on PE samples must comply with the following restrictions and limitations on communications and sample transfer:

a) laboratories must not engage in any interlaboratory communications pertaining to the results of PE sample(s) until after the date by which the laboratory must report the results to the PE program for the PE test event in which the samples were sent;

b) laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning PE sample results until after the date by which the laboratory must report the PE test results to the program; and

c) the laboratory must not send PE samples or portions of samples to another laboratory for any analysis for which they seek accreditation.

Any laboratory that the primary accreditor or NELAP determines intentionally referred its PE samples to another laboratory for analysis and submits the other laboratory's results as their own, will have its certification revoked for a minimum period of one year. Any laboratory that receives PE samples from another laboratory for testing must notify the accreditation program of the receipt of those samples. Laboratories not doing so may have their accreditation suspended for a period not to exceed one year. This policy is not intended to prevent interlaboratory testing designed as part of a methods development or evaluation study, and applies only to PE samples.

The laboratory shall initiate chain of custody procedures upon receipt of all PE samples. The laboratory must maintain a copy of

all records, including analytical worksheets, for a minimum of five years. This record must include a copy of the PE program report forms used by the laboratory to record PE results, and an attestation statement signed by the analyst and the laboratory management stating that PE samples were tested in the same manner as routine samples.

2.4 SCORING

OPTION I: PRE-ESTABLISHED PASS/FAIL RANGE SET BY CALCULATING 95% CONFIDENCE INTERVAL DETERMINED BY PREVIOUS STUDIES.

OPTION II: STATISTICAL EVALUATION OF DATA FROM ALL PARTICIPANTS IN THE CURRENT STUDY. CALCULATION OF 95% AND 99% CONFIDENCE INTERVALS TO SET MARGINAL AND UNSATISFACTORY PERFORMANCE.

OPTION III: PRE-ESTABLISHED PASS/FAIL INTERVALS AS ESTABLISHED IN 40 CFR 136, APPENDIX B.

OPTION IV: THE FOLLOWING SCORING PROTOCOL APPLIES TO: ALL CHEMICAL ANALYTES; BACTERIOLOGY SAMPLES THAT REQUIRE QUANTITATION (TOTAL AND FECAL COLIFORM IN NON-POTABLE WATER); FIBERS IN AIR DETERMINED BY PHASE CONTRAST MICROSCOPY; ASBESTOS IN FRIABLE SOLID MATERIAL BY POLARIZED LIGHT MICROSCOPY; AND ASBESTOS IN AIR AND POTABLE WATER BY TRANSMISSION ELECTRON MICROSCOPY.

THE TRUE VALES MAY BE ESTABLISHED THROUGH ROBUST STATISTICAL ANALYSIS OF THE RESULTS REPORTED BY ALL LABORATORIES, IN ORDER TO REJECT GROSS OUTLIERS AND ESTABLISH A MEAN RESULT AND STANDARD DEVIATION, OR THROUGH RESULTS OBTAINED BY A PANEL OF 12 REFERENCE LABORATORIES (THIS IS DONE FOR ASBESTOS IN FRIABLE MATERIAL). A LABORATORY'S RESULT ON A GIVEN SAMPLE IS THEN ASSESSED AS:

> *<u>GOOD</u> IF IT IS WITHIN THE 95% CONFIDENCE INTERVAL ABOUT THE MEAN, OR REPORTED AS "LESS THAN" THE METHOD DETECTION LIMIT IF THE SAMPLE IS A BLANK;*
>
> *<u>MARGINAL</u> IF IT IS OUTSIDE THE 95% CONFIDENCE INTERVAL, BUT WITHIN THE 99% CONFIDENCE INTERVAL ABOUT THE MEAN, OR REPORTED AS "LESS THAN" TWICE THE METHOD DETECTION LIMIT; OR*
>
> *<u>UNSATISFACTORY</u> IF IT IS ANY OTHER RESULT.*

FOR EACH TEST, A LABORATORY RECEIVES 2 PE SAMPLES FOR EACH CERTIFIED ANALYTE. ON TWO CONSECUTIVE TESTS, A LABORATORY MUST OBTAIN A PASSING SCORE OF AT LEAST 75% ON THE 4 SAMPLES ANALYZED, CALCULATED BY APPLYING THE FOLLOWING FORMULA.

$$SCORE = \frac{(GOOD\ RESULTS\ X\ 4) + (MARGINAL\ RESULTS\ X\ 2)\ X\ 100}{(TOTAL\ RESULTS\ X\ 4)}$$

HENCE, THE LABORATORY MUST OBTAIN AT LEAST TWO GOOD RESULTS PLUS TWO MARGINAL RESULTS, OR THREE GOOD RESULTS PLUS ONE UNSATISFACTORY RESULT, OVER TWO CONSECUTIVE TESTS.

IN RESPONSE TO THE ACCREDITATION PROGRAM GUIDELINES, CERTAIN CHEMISTRY ANALYTES ARE SCORED BY TAKING FIXED INTERVALS ABOUT THE KNOWN TARGET VALUE, WHERE GOOD PERFORMANCE IS DEFINED AS A RESULT WITHIN THOSE FIXED TARGET INTERVALS, AND UNSATISFACTORY PERFORMANCE IS ANY OTHER RESULT.

FOR THE POTABLE WATER TOTAL COLIFORMS, WHERE QUALITATIVE ANALYSIS IS REQUIRED (I.E., PRESENCE/ABSENCE), A LABORATORY IS REQUIRED TO MAINTAIN AN AVERAGE PASSING SCORE OF 90% ON TWO CONSECUTIVE TESTS.

LABORATORIES BEING TESTED FOR THE DETERMINATION OF RADON IN AIR ARE REQUIRED TO SUBMIT 5 SAMPLING DEVICES TO THE PE TESTING PROGRAM. FOUR OF THESE ARE EXPOSED TO A KNOWN CONCENTRATION IN A STANDARD ATMOSPHERE EXPOSURE CHAMBER, AND THE REMAINING DEVICE IS LEFT UNEXPOSED AS A "BLANK". THE DEVICES ARE THEN RETURNED TO THE LABORATORIES FOR ANALYSIS, AND THEY ARE REQUIRED TO REPORT RESULTS WITHIN 25% OF THE TARGET VALUE ON AT LEAST 4 OF THE 5 DEVICES.

2.5 SUCCESSFUL PARTICIPATION

Each laboratory must successfully participate in a PE testing program approved by NELAP for each field of testing in which the laboratory is accredited. If a laboratory's accreditation is suspended or revoked because it fails to participate in PE testing for one or more fields of testing, or voluntarily withdraws its accreditation for the failed field of testing, the laboratory must then demonstrate satisfactory performance on two consecutive PE test events, one of which may be on-site, before the primary accreditor will consider it for reinstatement.

Laboratories shall agree to test additional samples at the option of the primary accreditor for the following situations:

a) a major change in ownership or supervision of the laboratory;

b) complaints by users or employees;

c) unsatisfactory performance on most recent PE test event; or

d) request by the laboratory to be reinstated in a field of testing.

Failure to participate in a PE test event shall result in an automatic rating of unsuccessful performance and results in a score of zero for the PE test event. Consideration may be given to those laboratories failing to participate in a PE test event only if:

a) routine testing was suspended during the time frame allotted for testing and reporting PE test results; and

b) the laboratory notifies the primary accreditor and the PE testing program within the time frame for submitting PE test results of the suspension of routine testing and the circumstances associated with failure to perform tests on PE samples.

Failure to return PE test results to the PE program within the time frame specified by the program is unsuccessful performance and results in a score of zero for the PE test event. The PE testing program will specify the conditions and procedures for late submissions, e.g. lost or broken samples. For those late submission categories, the participant will be allowed to test the samples on an alternate schedule.

For any unsatisfactory PE test event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a PE test failure.

Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for five years from the date of participation in the PE test event.

Failure to achieve an overall PE test event passing score for two consecutive PE test events or two out of three consecutive PE test events is unsuccessful performance.

3.0 ON-SITE ASSESSMENT

3.1 INTRODUCTION

The on-site assessment is an integral part of a lab accreditation program and will be one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team will collect information and make observations which will be used to evaluate the laboratory's conformance with established accreditation criteria. It is essential that the on-site assessment be conducted in a uniform, consistent manner throughout the nation to facilitate reciprocity among States, and for the laboratory community to accept the accreditation process. This section contains proposals and recommendations for conducting on-site assessments.

3.2 ON-SITE ASSESSMENT PERSONNEL

3.2.1 Training

The National Environmental Laboratory Accreditation Conference (NELAC) will specify the minimum level of education and training for assessors, including refresher/update training. The NELAC will also develop criteria for training requirements. The assessor training course will be developed and implemented by EPA, NIST, or a non-Federal entity with oversight by EPA. A state may develop and implement it's own assessor training program, subject to EPA oversight, if the state program can meet the NELAC standards.

3.2.2 Qualifications

A laboratory assessor may work for a Federal, State, or a third party accrediting body. An assessor, including each member of an inspection team, must be an experienced professional and hold at least a B.S. degree, or equivalent education and experience, in the specific discipline being evaluated. Each assessor must also have satisfactorily completed a laboratory accreditation training course and a health and safety training course, and take periodic update/refresher training, as specified by NELAC. Each new candidate assessor must undergo on-the-job training during one or more inspections until judged proficient.

3.2.3 Additional qualifications

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 technically conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling procedures;

d) Be able to communicate effectively, both orally and in writing; and

e) Be free of any commercial interest that might cause the assessor to act in other than an impartial or non-discriminatory manner.

3.2.4 Assessor Certification

Before an assessor can conduct on-site inspections, the individual must be certified to do so, in writing, by either the NELAP or State in which the individual will assess laboratories. For each laboratory inspection performed by a state-designated third party assessor (i.e. non-EPA, non-State), the assessor must sign a statement before the inspection, certifying that no conflict of interest exists.

3.3 FREQUENCY OF ON-SITE ASSESSMENTS

3.3.1 Frequency

Accreditors should perform a routine on-site assessment at least annually. Assessments may be more frequent at laboratories where a problem exists, including complaints about laboratory quality, questions of fraud, or recurring failure on performance evaluation samples.

3.3.2 Follow-up evaluations

In addition to routine evaluations, assessors may need to conduct one-time follow-up evaluations at laboratories where a significant deficiency was identified by the previous evaluation. These evaluations may be limited to determining whether a laboratory has corrected its deficiency(ies), or determining the merit of a formal appeal from the laboratory. When deficiencies may result in

downgrading of accreditation status, follow-up evaluations should occur as soon as possible but no later than 60 days after the original evaluation.

3.3.3 Changes in laboratory capabilities

The accrediting authority may also deem necessary a limited one-time evaluation when a major change occurs at a laboratory in personnel, equipment, or a laboratory location that might impair analytical/biological capability and quality. A major change in personnel is defined as the loss or replacement of the laboratory management staff, or loss of a trained and experienced individual who performs a particular test for which accreditation has been granted.

3.3.4 Announced and unannounced visits

The accrediting authority is not required to provide advance notice of an assessment. However, the policy is to provide such notification, based on the circumstances of the particular assessment and laboratory. Since these highly technical assessments may involve sensitive information and because there is a need to ensure that appropriate personnel and records are available for assessment, the testing laboratory usually is notified in advance of a planned assessment. The accrediting authority, at its discretion, may conduct unannounced evaluations for cause (e.g., questions of fraud, tips, complaints, or problems with performance evaluation samples) or as part of a routine practice.

3.4 PRE-ASSESSMENT PROCEDURES

3.4.1 Introduction

A good assessment begins with planning, which should commence well before the assessment team visits the laboratory. Planning is the means by which the lead assessor identifies all the required activities to be completed during the assessment process. These activities include obtaining records before the assessment, conducting the assessment, writing reports and following up.

Pre-assessment activities include: deciding the scope of the assessment (Section 3.4.2); assessment planning (Section 3.4.3); reviewing NELAP/State information (Section 3.4.4); providing advance notification of the assessment to the laboratory (Section 3.4.5); coordinating the assessment team (Section 3.4.6); and gathering assessment documents and equipment (Section 3.4.7). Section 3.4.8 discusses Confidential Business Information issues.

3.4.2 Scope of the assessment

The first step in the assessment planning process is deciding what type of assessment will be conducted. The assessments usually include a laboratory evaluation and a records review.

3.4.2.1 Laboratory evaluations

A laboratory assessment obtains a "snapshot in time" at a testing laboratory by evaluating what activities are being conducted when the assessment takes place. During a laboratory evaluation, the assessment team may identify a number of samples or a recently completed or on-going project and evaluate to what extent the tests are being conducted according to NELAP or client requirements.

3.4.2.2 Records review

The purpose of a records review is to learn if the testing laboratory has maintained data and other information necessary to support reports previously issued. During a records review, team members will conduct an overall audit of data, and will compare data with submitted reports to determine whether the data were generated or collected following the proper procedures in the NELAP/State, EPA, or client requirements.

3.4.3 Assessment planning

Planning includes conducting a thorough review, prior to the assessment, of NELAP and/or State records pertaining to the laboratory to be inspected. This will save time because familiarity with the operation, history, and compliance status of the laboratory increases the efficiency and focus of an on-site visit. Planning also promotes a better relationship with the

laboratory community because the lead assessor will be better able to answer questions concerning the application of NELAP/ State requirements to a particular laboratory. It also enhances the laboratory's confidence in the lead assessor and aids in establishing good relationships with laboratory representatives.

Another important benefit of planning is to enhance the lead assessor's ability to identify and document potential problems and plan to collect necessary information to assist the accrediting authority in their subsequent decisions concerning the laboratory. Planning an assessment will result in an efficient and productive assessment overall.

3.4.4 Reviewing NELAP/State information

The lead assessor's responsibilities start with receipt of the Assessment Assignment. For a records review, copies of all appropriate documents related to the laboratory will be forwarded by the accrediting authority to the lead assessor or directly to a team member, if appropriate, ideally at least six weeks prior to the start of the assessment. The lead assessor should request any other information that will be useful in preparing for the assessment. Such information may include:

a) Copies of previous assessment reports and PE sample results;

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

c) Correspondence with laboratory personnel;

d) Discussion with appropriate NELAP/State staff;

e) Available documents from recipients of reports from the laboratory; and

f) Relevant program documents such as NELAP/State guidelines or SOPs.

3.4.5 Providing Advance Notification

No fewer than two weeks prior to an announced assessment, the accrediting body will contact the responsible management official at the laboratory to schedule the assessment. The initial telephone notification will be confirmed by a notification letter. A copy of the notification letter also will be given to the lead assessor. An assessment assignment that gives the name and telephone number of the laboratory contact person and of each assessment team member, as well as other available information necessary to the planning and conduct of the assessment will also be provided to the lead assessor.

Once the laboratory has been notified by the accrediting authority that an assessment will be conducted, the primary responsibility for the conduct of the assessment passes to the lead assessor. Any further communications with the laboratory personnel should be made by the lead assessor. The lead assessor should keep his/her supervisory personnel informed of the status of the assessment, and should consult with them on any substantive problems that may arise or changes that may be required.
There are several items to be addressed in the advanced notification. The lead assessor should make note of when and to whom advance notification was provided. Written advance notification should do the following:

a) Introduce the lead assessor and team members to the laboratory;

b) Schedule the assessment, including establishing time of arrival;

c) Obtain verbal agreement for entry;

d) Confirm the appropriate address for the assessment, including identifying the location of necessary records, as specified in the assessment plan;

e) Ensure that laboratory personnel are available to accompany assessors during the assessment;

f) Encourage the laboratory to transfer all records to the assessment site before the assessment;

g) Obtain directions to the laboratory; and

h) Allow discussion of problems, concerns, or questions about the assessment or any other issues.

Especially when the laboratory has not previously been assessed by the accrediting authority, the lead assessor should be certain that laboratory personnel are aware of what an assessment involves, what data and records should be made available and what personnel should be present. If the laboratory representative does not cooperate, the lead assessor's supervisor and the accrediting authority management should be consulted for instructions on how to proceed.

3.4.6 Assessment Team Coordination

When the identity of the assessment team is known, the lead assessor should contact each person and begin planning the conduct of the assessment. As early as possible the lead assessor should:

a) Coordinate travel plans, including the hotel and transportation arrangements;

b) Notify each team member of the dates of the assessment and pre-assessment team meeting;

c) Ensure that each team member has been briefed on specific procedures for the assessment;

d) Define the time allotted for the assessment. The lead assessor should be careful not to underestimate the time needed to conduct the assessment; and

e) Confirm for those individuals who will be conducting the records review, their familiarity with the records to be reviewed. Each member of the assessment team should be aware of their responsibilities during the assessment.

The lead assessor should also arrange to provide copies of applicable NELAP/State standard operating procedures (SOPs) to team members who do not already possess these documents. In addition, the lead assessor may need to assure that the assessment team is aware of proper procedures for receipt and handling of confidential business information (CBI). The lead assessor should determine the level of experience of each team member in conducting laboratory evaluations or records reviews under NELAP/State requirements. The lead assessor may need to guide less experienced team members, both prior to and during the assessment as well as with report preparation. The lead assessor should assemble the team just prior to the assessment to attend to last minute details.

3.4.7 Gathering assessment documents and equipment

Besides preparing the assessment plan and reviewing accrediting body records and laboratory submissions prior to conducting the assessment, the lead assessor should gather and prepare the necessary documents and equipment to be used during the assessment. No single list of documents and equipment can be appropriate for all assessments. The lead assessor's experience in the field and information obtained during pre-assessment planning should assist in preparing lists tailored to specific assessment sites and needs. Specific needs will be determined by the requirements of the assessment, the availability of equipment, conditions at the laboratory, NELAP/State policies, and whether advance notification of an assessment is given.

3.4.7.1 Types of documents

Documents necessary for the assessment should be prepared before the assessment, whenever possible. The lead assessor should obtain copies of the required assessment forms. Several spare copies of each form should always be carried. Assessments may require:

- notice of assessment;
- assessment confidentiality notice;
- conflict of interest form;
- assessor credentials;
- assessment assignment;
- assessment notification letter;
- attendance sheet, opening and closing conference; and
- assessment appraisal form.

In addition, the lead assessor should be certain to take the following documents and materials on an assessment:

a) Copies of NELAP/State requirements. Lead assessors should have copies of the applicable NELAP/State requirements available upon request. Having such data available can help improve the relationship between NELAP/State and the laboratory community, which can foster better laboratory compliance;

b) NELAP/State checklists for evaluations;

c) NELAP/State outreach materials. Lead assessors should provide current, relevant educational, and/or guidance information to

laboratory officials upon request or as deemed appropriate by the lead assessor; and

d) Administrative information. Travel authorizations and telephone numbers of travel and procurement personnel who may need to be contacted should be taken by the lead assessor when on travel.

3.4.7.2 Assessment equipment

The types of equipment that a lead assessor takes to an assessment site will vary from assessment to assessment, depending upon the nature and extent of the assessment and the type of testing laboratory to be inspected. Therefore, prior to each assessment, the lead assessor should check the equipment to make sure that it is in good working condition. Since each assessment is unique, no single list of equipment or forms can be devised that will fit every assessment situation.

3.4.8 Confidential Business Information Considerations

NELAP/State SOPs protect Confidential Business Information (CBI) from disclosure. CBI includes trade secrets (including process, formulation, or production data) and certain financial information, the uncontrolled disclosure of which could cause damage to a laboratory's competitive position. In general, disclosure of CBI is prohibited, except in certain limited situations.

The lead assessor should keep in mind that information obtained from a laboratory during an assessment can, for the most part, be disclosed in response to a request from the public, or other requesting party, under Federal or State Freedom of Information requirements. However, if the data has been properly claimed as CBI, it may not generally be disclosed under these requirements.

A lead assessor must present notice to laboratory representatives of their right to claim data at the laboratory as CBI and such claims are frequently made. Because the lead assessor is very likely to require access to CBI before (i.e., while preparing for an assessment), during, and after an assessment, the lead assessor must be knowledgeable of NELAP/State procedures governing access to, handling of, and disclosure of CBI. The lead assessor and others who may use the information must have CBI access authorization, since only authorized individuals may have access to CBI. A CBI-cleared lead assessor may obtain access to CBI

documents from the accrediting authority by requesting access to the information from the appropriate official.

Whether or not it is anticipated that CBI documents will be collected during an assessment, the lead assessor must provide a NELAP/State assessment confidentiality notice to the responsible laboratory official at the beginning of the assessment. This notice informs laboratory officials of their right to claim part of the assessment data as CBI. The lead assessor should be familiar with the procedures for asserting a CBI claim, and the criteria that the claimed information must meet.

The lead assessor must take custody of all CBI documents before leaving the laboratory, and must maintain them in custody, using all proper procedures and safeguards, until they can be received by the accrediting authority.

3.5. ASSESSMENT SCHEDULE/FORMAT

3.5.1 Length of evaluation

The length of an on-site assessment will depend upon a number of factors, such as the number of tests evaluated, 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 body should assign an adequate number of assessors to complete the evaluation within a reasonable period of time. Assessors must strike a balance between thoroughness and practicality, assuring that the assessment covers all aspects of the laboratory operation.

3.5.2 Opening conference

Arrival at the facility should occur during normal working hours. The facility representative should be located as soon as the assessment team arrives on the premises. A laboratory's refusal to admit the assessment team for an evaluation may result in an automatic failure or loss of accreditation on the part of the laboratory, unless there are extenuating circumstances that are accepted by the accreditation body. The team leader should notify the accrediting body as soon as possible after refusal of entry.

When the appropriate official has been located, the team leader should introduce the team and should present credentials. Many companies require that the assessment team sign a visitor's sheet

that contains the name, time, reason for visit, organization, etc., which should be signed. However, any request for any assessment team member to sign a "visitor's release" or "waiver" that would relieve the company of responsibility for injury or that would limit the rights of the accrediting body to use the data obtained should not be signed. If such a waiver or release is presented, the team leader should politely explain that they cannot sign and request a blank sign-in sheet. The assessment team leader should brief the appropriate responsible official(s) of the facility to introduce team members, explain areas to be evaluated and verify application information.

The assessment team leader should request relevant documents for review that were not part of the application materials, such as standard operating procedures, chain-of-custody forms, report forms, etc.

The assessment appraisal form should be presented to the appropriate laboratory official with a request that the form be completed and returned to the accrediting authority after the assessment. This form will allow feedback from the laboratory on the manner in which the assessment was conducted.

3.5.3 Records review

The records requested during the opening conference will be reviewed by assessment team members for accuracy, completeness and proper methodology for each area to be evaluated.

Trade secrets and confidential business information are protected from public disclosure. The type of information that may be considered confidential business information is defined in Title 40, Code of Federal Regulation, Part 2. All financial and trade information should be kept confidential, if so requested by the laboratory. All other information for all aspects of application, assessment and accreditation of laboratories is considered public information. If the laboratory requests that information other than that noted above is confidential, the information should be treated as confidential until a ruling can be made by the accreditation body.

The team leader must mark all confidential information received and handle it as required by appropriate laws and regulations.

3.5.4 Staff interviews

The assessment team will evaluate a test by having the individual that normally conducts the specific procedure walk through the procedure, including a step-by-step description of exactly what is done and what equipment and supplies are employed. The assessor will note and record the procedure on the standardized checklists for that particular test and application. Any deficiencies shall also be noted and discussed with the individual.

The assessment team members shall have the authority to conduct interviews with any/all staff and, if necessary, conduct private interviews. Calculations, data transfers, calibration procedures, quality control/assurance practices and adherence to SOP's shall be assessed for each test.

During the evaluation, sufficient information may become available to indicate that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information should be carefully documented, since it may be used in a legal action. When the possibility of additional legal investigation exists, the assessor should not discuss the legal implications of the suspected violation with the individual or any laboratory representative. However, the assessor should continue to gather the information necessary to complete the accreditation assessment.

3.5.5 Closing conference

The assessment team should meet with representatives following the evaluation of the laboratory for an informal debriefing and discussion of findings.

In the event the laboratory disagrees with the findings of the assessor(s), and the team leader adheres to the original findings, the area(s) protested shall be documented by the team leader and included in the report to the accreditation body for consideration. The accrediting authority will make the final determination.

The assessment team should provide the accreditation body with an assessment report encompassing all relevant information concerning the ability of the applicant laboratory to comply with the accreditation requirements. If data is available from performance evaluation testing, this should be included in the final report.

3.5.6 Follow-up procedures

The accrediting authority will issue the assessment to the applicant laboratory that outlines any areas of deficiencies. The applicant laboratory should then submit a plan of corrective action, if necessary, and provide any missing documentation required within 45 days from the date of report receipt.

After reviewing documentation and corrective actions, the accrediting authority will make the decision to pass, fail or provide interim accreditation for a laboratory. If the deficiencies listed are substantial or numerous, an additional assessment (possibly unannounced) may be conducted before a final decision for accreditation can be made.

3.6 CRITERIA FOR ASSESSMENT

3.6.1 Assessor's Manual

The NELAC will develop a manual(s) for on-site assessors to assure that on-site assessments are performed in a uniform, consistent manner. The manual(s) will be provided when assessors take the NELAC required training (section 3.2.1) and will serve as guidance for on-site assessment personnel.

The manual(s) provided to on-site assessors should include instructions for evaluating the following items:

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

b) Organization and management of the laboratory;

c) Qualifications and experience of laboratory personnel;

d) Receipt, tracking and handling of samples;

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

f) Preparation and traceability of calibration standards;

g) Analytical and biological methodology (including the laboratory's standard operating procedures as well as confirmation of individuals' adherence to SOPs, and the individual's proficiency with the methodology);

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

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

j) General health and safety procedures as they relate to good scientific practices;

k) Laboratory waste disposal procedures;

l) Environmental and toxicological test methods and SOPs; and

m) Care, use, and maintenance of test organisms.

3.6.2 Assessors role

When performing an on-site laboratory evaluation, the assessor must appraise each of the areas listed in section 3.6.1. The on-site assessor should use a variety of tools in the evaluation process. The experience of the assessor, his/her observations, interviews with laboratory staff, and examination of SOPs, raw data, and the laboratory's documentation will all play an important role in the assessment. The role of the on-site assessor is a critical one in the entire laboratory accreditation process. The accreditation of a particular laboratory will depend to a large extent on the assessor's recommendation. While much of the on-site assessment will depend upon the assessor's judgement, the recommendation not to accredit a laboratory must be based on factual information, not on opinions or suppositions. 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. Also the assessor should discuss any deficiencies with the laboratory's management in order to allow them to provide additional information which might affect the assessor's recommendations.

3.6.3 Checklists

Standardized checklists for the on-site assessment must be used. The use of checklists does not discourage the need for additional observations and staff interviews, but is merely another tool in the assessor's inventory which assists in conducting a thorough and

efficient evaluation. Using a checklist as a substitute for assessor training and experience must not occur.

NOTE: It is anticipated that standardized checklists will be developed or adopted by NELAC's On-Site Assessment Committee for the assessor's review of analytical and biological methodology.

3.6.4 Evaluation criteria

The following considerations should be taken into account by on-site assessors when evaluating the areas listed in section 3.6.1:

3.6.4.1 Facility assessment

The assessor(s) should tour the laboratory facility with the laboratory management representative. Usually the tour will occur during the initial phase of the on-site visit, perhaps after the opening conference. During the tour, the assessor should visually inspect the facility with respect to general housekeeping, cleanliness, lighting, bench space and continuous temperature monitoring (if required). The assessor should note whether the appropriate laboratory services (e.g., vacuum system, compressed air, gases, etc.) are available. It may be necessary to have the laboratory representative demonstrate that certain pieces of equipment are working properly, for example, a fume hood may be turned on to assure that it does indeed exhaust air from the laboratory. This type of demonstration is not intended to certify that the hood meets design specifications or safety requirements, but merely that it is operational. During the tour, the assessor(s) should determine if sample storage areas are sufficient and whether there are problems with laboratory operations which would affect data quality. For example, an extraction operation located in the same room where volatile organic analyses are performed could contribute contamination to the volatile organic analyses.

Any problems or deficiencies with the laboratory facility should be brought to the attention of the laboratory management at the time of the tour and reinforced at the closing conference. If discrepancies are noted between statements made by the laboratory representative and visual observations, it may be necessary to interview other laboratory personnel to obtain an explanation of the situation. As with all areas of the on-site assessment, the experience and training of the on-site assessor are critical to the success of the facilities evaluation.

3.6.4.2 Organization assessment

The assessor should review laboratory QA plans, SOPs, organizational charts and/or other documentation to determine the laboratory's operational structure. If a documented organizational plan exists, the assessor should ascertain during subsequent interviews with laboratory personnel if the laboratory operation follows the documented plan. The assessor should interview laboratory management to determine the roles of management and how laboratory policy is created. The absence of a documented organizational structure, clearly defined functional responsibilities, and lines of communication, should be considered a deficiency.

3.6.4.3 Personnel assessment

The assessor should review the laboratory's written qualification requirements for each position, and the qualifications of those persons currently holding the positions. Key personnel, e.g., laboratory management staff, quality assurance coordinator, section managers, chief analysts, etc., should be interviewed to verify their qualifications for their positions. These interviews may be conducted concurrently with interviews on analytical and biological procedures, quality control requirements, etc., in order to expedite the process. The assessor should be cautious when making judgments on personnel qualifications, and must be aware that experience may be an acceptable substitute for formal education. When in doubt concerning personnel qualifications, the assessor should conduct an in-depth interview with the individual to determine his/her expertise in a given area.

Note: Section 5, Quality Systems, contains details on personnel qualifications.

3.6.4.4 Sample handling assessment

The assessor should review the laboratory's SOP for sample receipt to assure that all appropriate elements (e.g., proper sample containers, preservatives, chain of custody, sample storage, sample rejection policy, etc.) are included. Any omissions should be brought to the attention of the laboratory management and appropriate laboratory staff person. Absence of a written sample receipt SOP should be considered a serious deficiency. The assessor should inspect the sample storage areas to insure that the facilities are adequate and secured. Cold storage facilities

should be checked for maintenance of proper temperatures, proper monitoring devices (thermometers, etc.) and appropriate documentation. Sample receipt personnel should be interviewed to determine their adherence to the SOP. Sample receipt documentation and chain-of-custody records should be reviewed to determine if documentation is adequate. Failure to follow SOPs may be considered a serious deficiency, depending on the degree of deviation. Failure to keep sample receipt and chain-of-custody documentation should be considered a serious deficiency.

3.6.4.5 Equipment assessment

The assessor should determine if the laboratory has all equipment and instrumentation necessary to perform the analyses for which certification is requested. This determination should be performed by visual inspection of the laboratory. The assessor should determine if the equipment is in reasonable working condition. An actual demonstration of equipment performance is not necessary in all circumstances, but should be required if the assessor has doubts about the condition of certain pieces of equipment. The absence of a required piece of equipment or instrument for a particular test should be considered a serious deficiency. The assessor should determine if the laboratory has written records of equipment repairs, maintenance, testing and calibration.

3.6.4.6 Calibration standards assessment

The assessor shall ascertain whether the laboratory has the necessary stock calibration standards and should spot check calibration standards to see if they are within expiration dates. The assessor should determine if stock standards are properly stored, e.g., volatile organic standards are stored in sealed vials in a freezer. The assessor should examine the laboratory's records for stock standards and the preparation of working standards to determine if the records are complete.

3.6.4.7 Methodology assessment

The assessor should determine whether the laboratory has standard operating procedures for all test methods used by the laboratory. The standard operating procedures should be reviewed to determine if they adequately address all aspects of the analytical and biological procedures, e.g., sample preparation, calibration standard preparation, instrument calibration, etc. The analysts

should be interviewed to verify that they have access to and are following the standard operating procedures for all methods. The lack of analytical and biological standard operating procedures or significant deviations from the standard operating procedures should be considered as serious deficiencies.

While the ideal on-site assessment would consist, in part, of observing each individual perform his/her assigned work, time considerations will not permit this approach in a laboratory which conducts a wide variety of analytical or biological procedures. Consequently, the on-site assessor will need to rely more heavily on interviews with laboratory personnel, observations, and review of records to determine proficiency with, and knowledge of, the analytical or biological methodology. The assessor's experience and training will play a key role in this process.

The assessor should be familiar with the performance of a test, so that the appropriate technical questions may be asked of the laboratory's analysts. The assessor should pose questions to the laboratory's staff in such a way as to not lead the individual into the correct response. The individual's responses should be cross-checked with the laboratory's documentation. During interviews with the individuals, it may be unclear as to how the analytical and biological procedures are being performed. If this occurs, then the assessor should ask the individual to demonstrate the procedure.

3.6.4.8 Data audit

The assessor should perform a data audit on an appropriate number of sample sets which contain all the tests for which the laboratory is seeking accreditation. It may be necessary to audit multiple sample sets in order to cover all tests. The assessor should verify that the required sample receipt documentation and chain-of-custody records are on file and that they contain all necessary information. The assessor should obtain final data reports for the sample set being audited. The assessor should verify that the final reports contain the following information:

- Sample receipt date;
- Sample analysis date;
- Sample identification;
- Method used for analysis;
- Quantitation units, e.g., mg/L, mg/Kg, $\mu g/m^3$, etc.;

- If sample is a solid, whether results are calculated on a wet weight or dry weight basis, and if a on dry weight basis, the percent moisture or percent solids;
- The sample result (if the result is none detected, the method detection limit should also be reported); and
- Method of statistical determination of test result, if applicable.

The assessor should assure that all information needed to verify the final result is on file, including reasons for invalidating testing results if this has occurred. The information may include sample preparation data, instrument output (chromatograms, mass spectra, strip charts), instrument calibration records, and records of dilutions. Once the information is located, the assessor should recreate the calculation in order to verify the final reported result. The absence of the required information needed to verify the final result should be considered a serious deficiency. If the assessor is unable to recreate a calculation, the problem should be discussed with laboratory personnel in an attempt to resolve the issue. If any calculations/final results are determined to be incorrect, the assessor should examine approximately ten percent of the data for the test in question over a selected time period to see if a systematic error has occurred.

In addition to auditing results from routine sample analyses, assessors must also audit results of performance evaluation (PE) samples analyzed by the laboratory for the NELAP. Assessors should verify that the sample(s) were analyzed using the criteria set forth by NELAP. The data generated during the analysis of PE samples should be examined and compared with final results reported to the NELAP.

3.6.4.9 QA Plan assessment

The assessor should examine the laboratory's written QA Plan to determine if it conforms to the Quality Systems requirements in Section 5.0. The assessor should examine the laboratory's raw data to ascertain if the required QC checks have been documented. If QC criteria were exceeded, the assessor must determine if corrective action was initiated. Laboratory personnel should be interviewed to determine if they understand and follow the requirements of the QA Plan. Laboratory management should be interviewed to determine their commitment to the QA program. The absence of a QA Plan, or an incomplete QA Plan, should be considered a major deficiency.

The lack of appropriate corrective action or documentation of corrective action should be considered a serious deficiency.

3.6.4.10 General health and safety procedures

The responsibility for promulgating and enforcing occupational safety and health standards rests with the U.S. Department of Labor[1]. While it is not within the scope of the assessment team to evaluate all health and safety regulations, any obviously unsafe condition(s) should be described to the appropriate laboratory official, and reported to the appropriate state or federal agency. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with all applicable health and safety regulations.

3.6.4.11 Laboratory waste disposal assessment

The assessor(s) should ask if adequate facilities are available for the collection, storage and/or treatment (if applicable) of all laboratory wastes. The waste disposal system(s) should be operated in such a manner to protect the air, water, and land by minimizing and controlling all releases from fume hoods and bench operations. Compliance is also required with any wastewater discharge permits and regulations. It is the laboratory's responsibility to comply with all federal, state, and local regulations governing waste management, particularly the hazardous waste regulations. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with all applicable waste disposal regulations.

3.7 DOCUMENTATION OF ON-SITE ASSESSMENT

3.7.1 Checklists

The checklists used by the assessors during the assessment should become a part of the permanent file kept by the NELAP/State on each laboratory.

3.7.2 Report Format

---

[1] Handbook for Analytical Quality Control in Water and Wastewater Laboratories, EPA-600/4-70-019, March 1979.

Evaluation reports should be generated in a narrative format, allowing for differences in style and technique between accrediting authorities. Deficiencies must be addressed at a minimum, however, documentation of positive aspects should be included. Documentation of existing conditions at the laboratory should be included in each report to serve as a baseline for future contacts with the facility.

3.7.3 Distribution

The accrediting authority should be recognized as having the responsibility for the content of the evaluation reports. The team leader should compile, edit and submit the final report to the accrediting authority. The team leader must assure that the results within the final report conform to established criteria for the evaluated parameters.

3.7.4 Report Deadline

No longer than thirty (30) days should elapse from the last day of an on-site evaluation until the report is submitted to the accrediting authority for review and final decision.

3.7.5 Release of Report

On-site evaluation reports should be released by the accrediting authority only. The reports will be released to the management of the affected laboratory and to those persons nominated by the laboratory to receive a copy of the report. The assessment report shall not be released until the assessment and all other appropriate action has been completed. In accordance with the Freedom of Information requirements, any documentation adjudged to be proprietary, financial and/or trade information will be considered exempt from release to the public.

3.7.6 Report Storage Time

At a minimum, copies of all evaluation reports must be retained by the evaluators and the accrediting authority for a period of five years, or longer if required by regulation.

4.0 ACCREDITATION PROCESS

4.1 COMPONENTS OF ACCREDITATION

These criteria must be fulfilled for accreditation. The components and criteria are herein described.

4.1.1 Personnel Qualifications

This component ensures that the managerial and supervisory personnel in the environmental laboratory meet a minimum set of qualifications that address the elements of education, training and experience. It should be recognized that some of these elements are interconnectable, i.e. a greater magnitude of training and/or experience may substitute for lesser degrees of formal education. Refer to Quality Systems for a detailed review of supervisors and managers, and the criteria to be maintained by the supervisors and managers for awarding accreditation.

4.1.2 On-site Assessments

On-site assessments and evaluations may be of two types: announced and unannounced. The assessment ensures that the environmental laboratory is capable of performing analyses to the level, precision and accuracy required by the specific method or performance based method. Announced assessments test these methods and evaluate the results against the criteria under the best circumstances in a controlled environment. The unannounced assessment measures the abilities of the laboratory to meet these standards for methods on an average day under normal working conditions and in a normal working environment. Each type of assessment has limitations and advantages, but the information obtained from both will provide a higher degree of confidence in the ability of the laboratory to attain a required level of competence in the quality of data produced for regulatory and compliance purposes. Refer to on-site assessment for additional information regarding frequency, procedures, criteria, scheduling and documentation of on-site assessments.

Announced Assessments - The elements present in and criteria for announced assessments for national accreditation are:

a) The assessment must be performed a minimum of one time per year and be conducted on-site; i.e., the site at which the actual analyses take place;

b) The assessment may consist of any or all of the categories for which the laboratory wants to obtain accreditation;

c) The inspector must have access to all information and data requested both for analyses completed and laboratory personnel;

d) The results of the assessment and the Performance Evaluation sample analyses indicating satisfactory or unsatisfactory performance will be sent to the National Database on environmental laboratories; and

e) At least two performance evaluation (PE) samples, twice per year, for each method or field of testing, must be successfully analyzed according to the standards established for quality assurance/quality control, precision and accuracy. It may not be required to analyze PE samples during the on-site assessment. Marginal performance on any previous PE samples can be grounds for requiring that a subsequent PE sample analysis be performed under the observation of an inspector.

Unannounced Assessments - The elements and criteria for the unannounced assessments for the purpose of the national accreditation program are:

a) The inspector may not be denied immediate access to the laboratory facility;

b) Elements a) through d) under announced assessments are also applicable to unannounced assessments;

c) Performance evaluation samples may be distributed and analyses run in the categories and for the methods that are determined by and prescribed by the inspector; and

d) All performance evaluation samples and other analyses required by the inspector are to be done as directed by the inspector. These include parameters such as: specified equipment, analysts and times, but are not limited to these factors.

Factors Examined in Announced and Unannounced Laboratory Assessments

Refer to On-site Assessments for assessment criteria required to be satisfied for accreditation. It should be noted, the inspector is

not limited to these factors in reaching an evaluation and conclusion. Other factors may be considered and documented as appropriate.

Laboratories will be furnished with an inspection report documenting any deficiencies found in the factors listed above or any others considered by the inspector. It shall also include whether a specific method passed or failed based on the Performance Evaluation sample. All such reports are public record and any or all of the information contained therein may be put into the National Database. Proprietary data will be excepted from all public records.

The laboratory will have no more than 45 days from the date of receipt of the report to correct deficiencies noted in the inspection report. At that time, if no remedial action has been taken to correct the noted deficiencies, accreditation for categories or specific methods within those categories will be immediately revoked.

4.1.3 Performance Evaluation Samples

A critical component of laboratory assessments is the analysis of the Performance Evaluation Samples. Refer to Performance Evaluation Testing, specifically Testing of Samples, for additional information regarding separate treatment of Performance Evaluation samples, discussion of issues of availability, and purity and distribution. Performance Evaluation samples would be used and evaluated in the accreditation process in the following manner:

a) All laboratories seeking National Accreditation must receive, examine and analyze initial performance evaluation sample(s) for each category (e.g., drinking water, hazardous waste, etc.) in which they are requesting accreditation. The analysis must be completed and the results reported to the performance evaluation testing organization or the Inspector within 45 days of the receipt of the sample.

b) Each laboratory seeking national accreditation shall also be required to perform analyses on at least two performance evaluation samples, two concentrations, two times per year in each category for which they have applied for accreditation or for which the laboratory is currently accredited.

c) The laboratory will be informed of the results of the performance evaluation sample analysis within 60 days of receipt by the state agency or authorized third party contractor. The results of all of the performance evaluation sample tests indicating satisfactory or unsatisfactory compliance will be public record and will be recorded on the national database.

d) The results of the performance evaluation sample analysis will be considered, along with other information obtained from announced and/or unannounced assessments in determining whether accreditation should be granted, denied or modified for a category, or whether the laboratory should lose accreditation for a category or method within a category.

4.1.4 Corrective Action Reports

The purpose of the corrective action report is to have a written record of response to deficiencies that are noted in the laboratory assessment procedure.

a) After being notified of deficiencies from the laboratory inspection, the laboratory has 45 days from the date of receipt of the deficiency report to submit a corrective action report.

b) The state authority or authorized third party contractor will respond to the action noted in the corrective action report within 30 days of receiving it. The report must address each of the deficiencies noted on the deficiency report.

c) A laboratory can lose accreditation in a category or a method within a category by any or all of the following items:

   i. Failing to respond to corrective action two times;
   ii. Failing to submit a corrective action report;
   iii. Failing to address each item noted as a deficiency in the corrective action report;
   iv. Failing the same performance evaluation sample analysis two consecutive times for the same analyte; or
   v. Failing to achieve an overall testing event passing score for two consecutive testing events or two out of three consecutive testing events.

d) All information included and documented in a deficiency report and the corrective action report are considered to be public information. Other states participating in the National Environmental Laboratory Accreditation Program would have access to this information through a national database. At a minimum, the database would include the following information:

i. Name and location of laboratory;
ii. Number and dates of assessments performed and whether they were announced or unannounced;
iii. Performance evaluation samples and analyses done, the date completed and the status (in process; passed, failed);
iv. Categories and methods for which the laboratory is currently accredited and date of accreditation; and/or
v. Categories and method for which the laboratory has lost accreditation and the date of loss of accreditation.

4.1.5 Ethical Standards

Elements in a national program that ensure consistency and promote the use of quality assurance/quality control procedures to generate quality data for regulatory purposes are

a) NELAC strongly recommends requires that each laboratory seeking national accreditation have a named Quality Assurance Officer. NELAC strongly recommends that the Quality Assurance Officer be a person other than any supervisor of laboratory analysts, who reports directly to the laboratory management and not to the laboratory supervisor in matters related to quality assurance and quality control of analyses, methods relating to these analyses, and instrumentation.

b) NELAC will consider that responsibility for falsification of data, records or instrument parameters will rest upon the Quality Assurance Officer (named in 4.1.4a above), the laboratory management and the company.

c) The National Environmental Laboratory Accreditation Program shall establish a "Laboratory Fraud Hotline" telephone number. Alleged cases of data, record or analytical fraud reported via this hotline will be referred to the relevant state authority for investigation. The fact that a federal or state has taken regulatory, legal, or contractual action against a laboratory will be made available on the national database.

4.1.6 Fee Process for National Accreditation

Refer to Policy and Structure, specifically funding of the program 1.7.3, regarding the funding of state accreditation programs, including a fee structure covering the actual cost of an accreditation.

a) The cost incurred in the application process for national environmental laboratory accreditation will be called an accreditation fee.

b) Where required, accreditation fees will be paid to the state(s) which grants accreditation to the laboratory. These fees must be paid in accordance with existing state regulations, levels and practices.

c) Failure to remit the accreditation fee within the time limit as established by the individual state authority will be grounds for immediate loss of accreditation in that state. The loss of accreditation will immediately be entered in the national database.

4.1.7 Application Process

The National Environmental Laboratory Accreditation Program encompasses a standardized set of elements in each application for accreditation that will 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.

The application form for national environmental laboratory accreditation shall include:

a) Legal name of laboratory
b) Laboratory mailing address
c) Name of owner
d) Location (full address) of laboratory
e) Name and phone number laboratory contact person
f) Name and phone number of Quality Assurance Officer
g) Name and phone number of laboratory management representative
h) Laboratory hours of operation
i) States for which the laboratory is requesting accreditation
j) Categories for which the laboratory is requesting accreditation

k) Description of laboratory type
   - Commercial
   - Federal
   - Hospital or health care
   - State
   - University
   - Public water system
   - Public wastewater system
   - Industrial (an industry with discharge permits)
   - Other (Describe)_____
l) Certification of compliance by laboratory management (*vide infra*: 4.1.9)

4.1.8 Transfer of Ownership/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 accrediting agency may charge a transfer fee and shall conduct an on-site assessment to verify affects of such changes on laboratory performance.

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

a) Any change in ownership and/or location of an accredited laboratory must be reported in writing to the primary state(s) and the National Environmental Laboratory Accreditation Program within twenty business days of such a change taking effect.

b) Such a change in ownership and/or location will 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 a mandatory on-site assessment with the elements of the assessment being determined by the inspector.

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

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

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

ii. The buyer (transferee) must agree in writing to be responsible for any analyses, data and reports generated before the legal transfer of ownership occurs.

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 for that laboratory.

CERTIFICATION BY APPLICANT

The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the National Environmental Laboratory Accreditation Program's rules and regulations concerning laboratory accreditation and standards and will be subject to the penalty provisions provided therein.

The applicant understands and acknowledges that accreditation is specifically subject to unannounced assessments.

Authorized representatives of any state in which the laboratory is accredited may make an announced or unannounced inspection, search, or examination of an accredited or interim approved laboratory whenever the state, at its discretion, considers such an inspection, search or examination necessary to determine the extent of the laboratory's compliance with the conditions of its accreditation and these regulations. Any refusal to allow entry to the state's representatives shall constitute a violation of a condition of accreditation and grounds for revocation of accreditation or loss of accreditation.

The applicant hereby certifies that all analyses performed are done in accordance with applicable U.S. Environmental Protection Agency Guidelines.

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	Name of Quality Assurance Officer
Print Name of Applicant Laboratory (Legal Name)	Date
Signature Laboratory Management Representative	Name Laboratory Management Representative

4.2 PERIOD OF ACCREDITATION

For a laboratory in good standing, the period for accreditation within categories for methods or analytes will be reevaluated yearly and will be considered to be ongoing once a laboratory has been accredited for that category, method, or analyte. The loss of accreditation for categories, methods or analytes will occur upon not fulfilling any of the conditions outlined below in the sections on maintaining accreditation and supervision, revocation and loss of accreditation. Additionally, failure to pay the required fees as determined by the participating states within the stipulated deadlines or by the stipulated dates will result in loss of accreditation. This information will be entered into the National Database.

There is a separate process for accreditation for new categories, methods and analytes (*vide supra*: Application Process, 4.1.7).

Each year the National Environmental Laboratory Accreditation Program will provide each laboratory with a current directory with information on what categories, methods, and analytes for which they are accredited. Additionally, new categories, methods, and analytes will appear on the actual certificate that is reissued as these items are added and/or deleted during the year. All new categories will be included in updates to the database.

4.3 MAINTAINING ACCREDITATION

Accreditation remains in affect until revoked by the accrediting authority, until discontinued by the accredited laboratory, or until expiration of accreditation date. To maintain accreditation, the accredited laboratory shall complete or comply with elements 4.3.1 TO 4.3.7. Failure to complete or comply with these elements may be cause for downgrading or revoking accreditation.

4.3.1 Performance Evaluation Samples

Performance evaluation samples appropriate for the accredited methodology shall be acquired twice per year from a source acceptable to the National Environmental Laboratory Accreditation Program, successfully analyzed, and reported to the accrediting body within required deadlines. In the event of unsatisfactory performance and required reanalysis, repeat analysis shall also be completed and reported within established deadlines. Poor performance on a performance evaluation sample or failure to submit results within required deadlines may be cause for downgrading accreditation.

4.3.2 On-Site Assessments

Announced on-site assessments shall be performed by the accrediting agency at a minimum frequency of one assessment every year. Unannounced on-site assessments or follow-up on-site assessments may be conducted more frequently, for cause, at the option of the accrediting agency. Situations which might trigger an unannounced on-site assessment or follow-up on-site assessment include, review of a previously deficient on-site assessment, poor performance on a performance evaluation sample, change in other accreditation elements, or other information concerning the capabilities or practices of the accredited laboratory. On-site assessments, regardless of frequency, shall be successfully completed to maintain accreditation. Deficiencies identified during the on-site assessment shall be corrected within deadlines established in these guidelines or according to deadlines in an approved correction action plan. Failure to pass an on-site assessment or to correct deficiencies according to the provisions of an approved corrective action plan may be cause for downgrading accreditation.

4.3.3 Other Accreditation Elements

The accredited laboratory shall maintain other key accreditation elements which originally served as the basis for accreditation including the facility, organization and management, qualifications

of key personnel, sample handling procedures, calibration standards, analytical methods, data reduction procedures, and laboratory quality assurance plan. Failure to maintain, revise, or replace any of these key components may be cause for downgrading accreditation status.

4.3.4 Notification and Reporting Requirements

The accredited laboratory shall notify the accrediting body of any changes in key accreditation criteria including but not necessarily limited to the laboratory ownership, location, key personnel, and major instrumentation. The accredited lab shall also comply with any other reporting requirements identified in these guidelines.

4.3.5 Record Keeping and Retention

All lab records associated with accreditation parameters, including raw data associated with each analysis, changes in method standard operating procedures, or the laboratory quality assurance plan, shall be maintained for a minimum of five years unless otherwise designated for a longer period in another regulation. 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 agency.

4.3.6 Payment of Fees

The accredited lab shall pay all fees associated with maintaining accreditation to the accrediting body within established deadlines.

4.4 SUSPENSION, REVOCATION AND DENIAL OF ACCREDITATION

Reasons to deny an initial application or reapplication shall include:

a) Failure of laboratory staff to meet the personnel qualifications as required by NELAC. These qualifications include education, training and experience requirements.

b) Failure to successfully perform performance evaluation test as required by NELAC.

c) Failure to attest that analysis are performed by approved methodologies and/or in accordance with NELAC requirements.

A laboratory shall have two opportunities to correct the areas of deficiencies which results in a denial of applications. If the laboratory is not successful in remedying said deficiencies, it must wait six months before again applying for accreditation.

Revocation - shall mean the total withdrawal of a laboratory's accreditation by the accrediting authority. The laboratory cannot reapply for accreditation for 6 months, by which time the reason/cause of the revocation must be corrected.

Reasons for revocation shall include:

a) Failure to participate or unsatisfactory performance in the performance evaluation testing program as required by the program.

b) Submitting performance evaluation sample results generated by another laboratory.

c) Misrepresentation of any material fact pertinent to receiving initial approval.

d) Denial of entry for laboratory inspection.

e) Conviction of charges of the falsification of any report of or relating to a laboratory analysis.

f) Failure to pay accreditation fees.

No laboratory's accreditation will be revoked or a renewal denied without the opportunity to request a hearing.

Suspension shall mean the temporary removal of a laboratory's accreditation for a defined period of time. The purpose of suspension is to allow a laboratory time to correct deficiencies or area of non-compliance with program requirements as defined by regulation. A suspended laboratory would not have to reapply for accreditation if the cause/causes for suspension are corrected within six months. A laboratory's accreditation may be suspended in total or in part. It may retain those areas of accreditation where it continues to meet the standards and requirements of the program.

Reasons for suspension shall include:

a) Failure to successfully perform performance evaluation tests pursuant to the requirements of the program;

b) Failure to submit and implement corrective action related to deficiencies found during laboratory inspections;

c) Loss of personnel with the required educational, training and experience qualifications; or

d) Failure to pay accreditation application fees.

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 an interim accreditation shall be issued and will be in effect until the assessment requirements have been completed. Interim accreditation will allow a laboratory to perform analyses and report results of samples with the same status as a fully accredited laboratory until an on-site assessment has been completed. Accreditation will still be granted when performance evaluation samples are not available.

4.5.2 Revocation of Interim Accreditation

Revocation of interim accreditation may be initiated for due cause as described in 4.4.0 by order of the accrediting agency, without right to a hearing.

4.6 AWARDING OF ACCREDITATION

When a participating laboratory has met the requirements specified for receiving accreditation, the laboratory will receive a single certificate awarded on behalf of the state accrediting authority. The certificate will provide the following information: the name of the laboratory, address of the laboratory, the specifications of the accreditation action (for example, the laboratory may be accredited for analysis of water or for use of a specific analytical methodology, etc.), the states in which the laboratory may operate. Even though a parent laboratory is accredited, the subfacilities (laboratories operating under the same parent organization, analytical procedures, and quality assurance system) are also required to become accredited. The subfacilities

accredited will be listed on the certificate of the parent laboratory.

4.6.1 The Certificate of Accreditation

The certificate of accreditation will briefly define the rules of obtaining and maintaining accreditation. Finally, the certificate will be signed by a member of the accrediting authority.

To address the concern that an individual state may revoke a laboratory's accreditation for work in that state, the certificate will explain that continued accredited status depends on successful ongoing participation in the program. The certificate will urge a customer to verify the laboratory's current accreditation standing within a particular state. The certificate must be returned to the accrediting agency upon loss of accreditation.

4.6.2 Changes in Areas of Accreditation

If an accredited laboratory increases its areas of accreditation, a new certificate will be awarded which details the spectrum of accreditations the laboratory has achieved.

4.7 ENFORCEMENT

The development of an enforcement component of the National Environmental Laboratory Accreditation Program (NELAP) should be based on explicit values, or principles, with which all participants concur. The proposed basic principles are:

a) The program should be fair to all participants;

b) The rules should be well publicized;

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

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

The major components of the program shall include:

a) All enforcement actions are taken independently by EPA or state agencies and communicated to all other NELAP participating agencies.

b) NELAP enforcement is limited to suspension (short-to-long-term) from NELAP only. Any other civil/criminal actions are taken by participating agencies.

c) An effective information-sharing database used by all participating agencies is essential to ensure informed decision-making based on lab performance.

4.7.1 Role of Enforcement vs QA/QC

Most agencies have historically conducted laboratory QA/QC programs designed to help laboratories identify and correct technical problems affecting their performance. This is basically a technical assistance function by government. Enforcement, on the other hand, is an oversight process of taking informative ("warning/information gathering letters") or punitive actions to ensure the public's desired objectives ("reliable data") are achieved. QA/QC and enforcement are different functions and need to be kept separate.

4.7.2 Defining Enforceable Violations

The NELAP will need to specify what actions by laboratories will result in enforcement action. Furthermore, enforcement actions should be developed in increasing severity to allow laboratory correction with minimal enforcement effort. This could be done with tiers of enforcement actions, e.g. warning letter, suspension investigation order, suspension order, and suspension hearing.

Enforceable violations will also need to be established to provide the basis for the enforcement program. Categories of enforceable violations could include:

a) Data falsification - intentional, by lab management, by employees, etc.;

b) False advertising - misinforming clients regarding their accreditation and capabilities; and

c) Continuing technical problems - lack of technical staff, failure to follow required SOP's, lack of equipment, etc.

4.7.3 Recommendation

Given resource constraints, strong interest in encouraging state support, and the greater potential for implementation in the mid-term (2 to 5 years), a variation of the decentralized option is recommended. This approach will still require a federal-state laboratory integrated effort to ensure the objectives, structure, and issues are defined in the necessary detail.

5.0 QUALITY SYSTEMS

5.1 INTRODUCTION

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a QA Plan to help ensure and document the quality of the analytical data. These shall include QA policies, which will establish essential QC procedures applicable to environmental laboratories regardless of size and complexity. The laboratory shall meet any additional or more stringent requirements as specified by the analytical methods, specific programs or Agencies.

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

5.2 QUALITY SYSTEM

5.2.1 Quality Assurance Plan

All laboratories shall prepare and have available for review a written description of the laboratory's quality assurance activities, i.e., a QA plan. The QA plan must be an independent document that may incorporate by reference, already available standard operating procedures (SOPs) or other material, e.g., methods, guidance documents, etc., that are approved by the laboratory management. Analysts in the laboratory should either have copies of the document or easy access to the document. The items listed below constitute essential requirements of a Quality System. All laboratories should be encouraged to add any additional items thought to improve the analytical data. The following items shall be included:

- General QC procedures
- Performance evaluation samples
- Staff
- Equipment
- Test methods & standard operating procedures (SOPs)
- Physical facilities
- Sample acceptance policy & sample receipt
- Sample tracking
- Record keeping, data review and reporting
- Corrective action policy and procedures
- Definition of terms
- Bibliography

5.3 GENERAL QUALITY CONTROL PROCEDURES

The following are the essential requirements and routines to calculate and assess analytical precision, accuracy, and method detection limits. All records and related quality control procedures shall be documented and maintained.

The required essential quality control shall be as specified in the analytical methods or as listed below, whichever is more stringent.

5.3.1 Chemical Testing

a) Method Reagent Blanks - A minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation.

b) Matrix Spikes (MS), Matrix Spike Duplicates (MSDs),and Sample Duplicates (SD)

   i. Matrix spikes: required frequency as per the method reagent blank, except for analytes for which standards are not available (BOD, TSS, O&G, and pH, etc.).

   ii. Matrix spike duplicates or sample duplicates shall be analyzed at the same frequency as the original matrix spike (MS).

c) Laboratory Fortified Blanks - (QC Check Samples)
It is suggested that these be analyzed at the same frequency as the matrix spikes, but are mandatory if the matrix spikes are not within quality control acceptance limits.

d) Surrogates - Surrogate compounds must be added to all samples, standards, and blanks whenever possible for all organic chromatography methods. Limits must be used to determine acceptable surrogate recoveries on a daily basis.

e) Quality Control Validation Studies or Initial Demonstration of Analytical Capability - QC Validation Studies shall be performed on a one-time basis (initially and with a significant change, e.g., new analyst, instrument or technique).

f) Methods Used to Assess Precision and Accuracy - The laboratories shall calculate and track precision and accuracy of test measurements and the associated acceptance ranges using the data from the duplicate, MS, blank and surrogate measurements. The resulting acceptance ranges (and/or quality control charts) shall be used to assess data acceptance and shall be readily accessible in an identifiable file to all personnel involved with the data review/data acceptance process.

g) Method detection Limits - Method detection limits shall be determined by an approved protocol or by a method specified by the accrediting authority. The detection limit is to be determined for the compounds of interest in each method in laboratory pure water and the matrix of interest. The procedure used must be documented.

h) Qualitative Identifications - Qualitative quality control refers to the identification of a specific compound. Identification of all analytes must be accomplished with a verified standard of the analyte.

When analyzing a new matrix, a new analyte or where other reasons for doubt exists, a confirmatory analysis shall be performed. Such analysis shall be a technique with a different scientific principle and may include:
- Second column confirmation
- Alternate wavelengths
- Derivatization
- Mass spectral interpretation
- Alternate detectors
- Additional cleanup procedures

i) Reagent Quality, Water Quality and Checks

i. Reagents - In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than that specified by the method shall not be used. The labels on the container should be checked and the contents examined to verify that the purity of the reagents meets the needs of the particular method.

ii. Water - Where the method does not specify the type of water (e.g., distilled, deionized, etc.), the water quality shall be free from all constituents that may

potentially interfere with the sample preparation or analytical test. The quality of water sources shall be monitored and documented.

j) Glassware Cleaning - In the analysis of samples containing components in the parts per billion range, the preparation of scrupulously clean glassware is mandatory. Particular care must be taken with glassware such as Soxhlet extractors, Kuderna-Danish evaporative concentrators, sampling-train components, or any other glassware coming in contact with an extract that will be evaporated to a lesser volume.

Any cleaning and storage procedures that are not specified by the method shall be documented in laboratory records and SOPs.

k) Internal audits - The laboratory shall have a system in place for conducting internal audits of the methods, data, and staff employed at the lab. The audits shall be conducted at least twice annually and the results shall be documented.

5.3.2 Bioassays

a) Dilution Water Control - Every toxicity test or range-finding test shall include a dilution water control treatment consisting of the same dilution water, conditions, procedures, types and number of organisms as used in the effluent treatments, except that none of the effluent being tested shall be added to the dilution water.

Whenever artificial sea salts are used in the salinity adjustment of either the dilution water sample or effluent sample, an additional control treatment shall be included. This additional control treatment shall consist of replicate chambers containing only artificial saltwater made with the same artificial sea salts used to adjust the samples. The artificial saltwater shall be made to the same standardized salinity and Ph as the other test treatments.

b) Distribution of Test Organisms - Test organisms must be randomly distributed to the test chambers either by:

i. Adding to each chamber no more than 20% of the total number to be assigned to each chamber, then repeating the process until each test chamber contains the total number of test organisms desired; or

ii. Randomly assigning one test organism to each test chamber, then randomly assigning a second test organism to each test chamber, etc., continuing the random assignments until the total number of test organisms desired has been distributed to each test chamber.

c) Dissolved Oxygen Requirement - The DO in the test chambers shall be maintained at greater than 40% of saturation but less than 100% when testing chronic toxicity for all species except Ceriodaphnia which must be adjusted only prior to test initiation or sample renewal. Acute tests shall assure that a minimum level of 4.0 mg/L DO is maintained.

d) Duplicate Requirements - When the purpose of a definitive acute toxicity test is to determine compliance with an LC50, or EC50 permit limitation, the test shall consist of one or more control treatments and a series of at least five effluent concentrations, in duplicate.

i. If the toxicity of the effluent to the test organism is not known, then the concentration of effluent in each treatment, except for the highest concentration and the control(s) shall be at least 50% of the next higher one. The concentrations selected shall be evenly spaced on either a logarithmic or geometric scale.

ii. Definitive test concentration series must, at a minimum, be conducted in duplicate. Additional replicate series may be necessary in order to achieve required test precision. Only true replicates, with no water connections between test chambers shall be used.

iii. A minimum of twenty test organisms shall be exposed to each effluent concentration and each control treatment; this means, when conducting the test in duplicate, at least ten organisms per test chamber. The number of organisms used in each effluent concentration shall be equal to the number used in other effluent concentrations and to the number used in the control. Organism loading limits shall be observed.

e) No Measurable Acute Toxicity - When the purpose of "no measurable acute toxicity (N.M.A.T.) is to determine compliance with a N.M.A.T. permit limitation, the effluent must be known to generally have an LC50 of greater than or

equal to 100%, and the toxicity test design must comply with the following:

i. The test series shall consist of one or more control treatments, a 100% effluent-by-volume concentration and a 50% effluent-by-volume concentration. The test shall be conducted with at least four replicates, and at least ten organisms per chamber. Additional duplicate series may be necessary in order to achieve required test precision. Only true duplicates, with no water connections between test chambers, shall be used.

ii. Forty or more test organisms shall be exposed to each control treatment and each effluent treatment.

f) Range Finding Toxicity Test - If required by the accrediting agency and in the event historical aquatic toxicological data are not available on an effluent, the lab shall conduct a range finding toxicity test to ascertain the range of effluent concentrations for subsequent definitive tests. Range finding toxicity tests shall at a minimum consist of one or more control treatments, and treatments of 100% effluent-by-volume, 50% effluent-by-volume, and 12.5% effluent-by-volume. A single test series is adequate, although duplicates may be used. Five or more test organisms shall be exposed to each control treatment and each effluent treatment.

g) Species Identification

i. For species identification, the laboratory shall maintain or have access to a type specimen collection.

ii. The laboratory must, at a specified frequency, use taxonomic experts to corroborate species identification. In-house or outside experts are acceptable for taxonomic identification of test species.

h) Criteria for Test Types - All definitive acute toxicity tests and N.M.A.T definitive acute toxicity tests must be conducted as either static non-renewal, static-renewal, or flow-through tests. Range-finding toxicity tests (if required) must be conducted as either static or flow-through.

i) Reference Toxicants - Reference toxicants shall be used as specified by method.

5.3.3 Microbiology

a) Blanks (Sterility checks)

i. Membrane Filter (MF) Analysis Blank - A membrane filter sterile control test of rinse water, media and supplies shall be inoculated with at least 10 milliliters of sterile phosphate buffered dilution water (dilution blank control). These shall be performed at the beginning and end of all processed samples and after every tenth sample.

ii. Multiple Tube Fermentation (MTF) Analysis Blank - A MTF blank shall be performed with each MTF sample. A single tube of LTB broth media shall be inoculated with 10 milliliters of sterile phosphate buffered dilution water (dilution blank control).

b) Laboratory Pure (Reagent) Water Requirements

i. Laboratory pure water shall be analyzed annually by the Suitability Test for bactericidal properties for distilled water.

ii. Laboratory pure water shall be analyzed monthly for pH, chlorine residual, standard plate count, and conductivity.

iii. The laboratory pure water must be analyzed annually for trace metals.

c) MPN Analysis - The MPN test for all water samples shall be completed on 10% of positive confirmed samples, except that gram staining need not be performed for drinking water samples. If no positive tubes result from the tested drinking water samples, the complete MPN test, but not gram staining, must be performed on a quarterly basis on at least one positive water source.

d) MF Analysis - 5% of all positive environmental samples analyzed and at least 10 of the sheen colonies for drinking water by membrane filter shall be verified per method requirements.

e) Duplicates - At least 5% of the positive samples shall be duplicated. In laboratories with more than one analyst, have each make parallel analyses on at least one positive sample per month.

f) Positive and Negative Controls - Positive and negative control cultures shall be analyzed for the microorganisms under test for each lot of media used with each analytical procedure.

5.3.4 Radiochemistry

a) Instrument Blanks - Instrument blanks are blanks at the background levels for any of the nuclide emission of interest. Instrument blanks consist of a clean planchet, ampule or sealed canister that is placed in the instrument to duplicate sample counting geometry. The purpose of the instrument blank is to verify instrument operation and ensure that no contamination has occurred in the counting chamber. Instrument blanks are used for calculation of lower limits of detection. The frequency of instrument analysis depends on the type of instrument. Essential frequencies for analysis of instrument blanks on typical instruments are:

Instrument	Frequency
Gamma spectrometers	Monthly
Low background proportional counters	Daily
Low level liquid scintillation counters	Daily
Scintillation counters	Weekly
Alpha spectrometers	Weekly
Radon flask counters	Monthly

b) Method Blanks - The required frequency for method blanks shall be at least once each batch or one out of every 20 samples, whichever is greater. These specifications are applicable to all radiochemistry techniques except for gamma spectroscopy where no chemical separation or other chemical manipulation is performed.

c) Laboratory Control Samples (LCS) - At least one LCS shall be included with each batch or one out of every 20 analytical samples, whichever is greater.

d) Matrix Spikes - Matrix spikes shall be included with each sample batch where chemical manipulations and separations are

performed. The frequency for measurement of matrix spikes shall be at least one per batch or one out of every 20 samples, whichever is greater.

The following criteria is recommended for spiking:

i. Samples should be spiked at random within each batch. There should be adequate samples available for duplicate analysis, if necessary.

ii. Spikes should be prepared in a manner to minimize alteration of the original matrix (i.e., minimize dilution of the sample during the spiking).

iii. Spikes should be prepared at a level that is at least two times the concentration of the analyte of interest.

e) Laboratory Duplicates - Sample analysis shall be duplicated on a randomly selected sample (not field blanks) within every batch or one per 20 samples, whichever is greater.

5.3.5 Air Testing - *To be added as document undergoes review.*

5.4 PERFORMANCE EVALUATION SAMPLES

Each laboratory shall participate in a performance evaluation program as outlined in Chapter 2.0.

5.5 ENVIRONMENTAL LABORATORY STAFFING REQUIREMENTS

5.5.1 General requirements for laboratory staff

The testing laboratory shall have sufficient supervisory and other personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

Job descriptions shall be available for all positions.

The laboratory shall have available a clear description of the lines of responsibility in the laboratory and shall be proportioned such that adequate supervision is ensured. An organizational chart is recommended.

5.5.2 Laboratory Staff Responsibilities and Credentials

Laboratory management shall be responsible for:

a) All analytical and operational activities of the laboratory, including those of any auxiliary or mobile laboratory facilities;

b) Supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary or mobile laboratory facilities, and those persons designated as principle analysts;

c) Assuring that all sample acceptance criteria (Section 5.9) are met and that samples are logged into the sample tracking system and properly labeled and stored; and

d) The production and quality of all data reported by the laboratory, including any auxiliary or mobile laboratory facilities.

Each analyst and other members of the staff shall be responsible for complying with all QA requirements. Each laboratory position 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, analytical methods, quality assurance/quality control procedures and records management.

5.5.3 Quality Assurance Officer

A quality assurance officer shall:

a) serve as the focal point for QA/QC and be responsible for analytical data review (sign off on data is required);
b) have functions independent from laboratory management;
c) be able to objectively evaluate data and perform assessments without outside (e.g., managerial) influence;
d) have formal training and experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAP;
e) have a general knowledge of the analytical methods for which data review is performed; and
f) conduct internal audits on the entire operation twice annually.

5.6 EQUIPMENT

A laboratory must have access to all equipment specified by the analytical procedures for which accreditation is sought. All maintenance activities, both routine and nonroutine, shall be documented. The following records shall be maintained for each piece of equipment:

- Name of item;
- Manufacturer's name, type identification and serial number;
- Date received and placed in service;
- Current physical location;
- Maintenance log; and
- Calibration information, if appropriate.

5.7 TEST METHODS AND STANDARD OPERATING PROCEDURES

When the use of approved methods for a specific sample matrix is required, only those methods shall be used. In addition, where performance-based methods or non-legally mandated methods are permitted, the relevant start-up and ongoing validation procedures, and calibrations as specified in 5.7.2 must be followed and documented.

The criteria listed in 5.7 must be met for all methods and SOPs.

5.7.1 Laboratory Method Manual(s) and Standard Operating Procedures

Each certified laboratory shall have and maintain an in-house methods manual(s) and SOPs. The methods manual(s) and any associated reference works (if required) shall be available to the bench analyst.

For each analyte certified, a method or methods to be used by the laboratory shall be described in the methods manual. The method description shall include:

- analyte name and qualifier (the qualifier is a word, phrase or number that better identifies the method; e.g., "Iron, Total", or "Chloride, Automated Ferricyanide", or "Our Lab. Method SOP No. 101");
- applicable matrix or matrices;
- method detection limit;
- scope and application;
- summary of the method;
- definitions;

- interferences;
- safety;
- equipment and supplies;
- reagents and standards;
- sample collection, preservation, shipment and storage;
- quality control;
- calibration and standardization;
- procedure;
- data analysis and calculations;
- method performance;
- pollution prevention;
- waste management;
- references; and
- any tables, diagrams, flowcharts and validation data

5.7.2 Method Validation/Initial Demonstration of Method Performance (Performance-based methods and non-approved methods)

Prior to acceptance and institution of any method, satisfactory initial demonstration of method performance, in conformance with the relevant EPA guidelines, is required. In the absence of method-specified requirements, this demonstration shall follow the outlined protocols of Paragraph 8.1.1 and Section 8.2 in the methods published in 40 CFR Part 136, Appendix A. Thereafter, continuing demonstration of method performance, in conformance with the relevant EPA guidelines, is required. In both cases, the appropriate standard Performance Based Method System (PBMS) checklist (see Appendix B) must be completed, submitted to the accrediting organization, and a copy must be retained in the laboratory. All associated supporting data necessary to reproduce the analytical results summarized in the checklists must be retained by the laboratory. Initial demonstration of method performance must be completed each time there is a change in equipment, personnel or procedure.

5.7.3 Calibration

5.7.3.1 Documentation and Labeling

The laboratory shall retain records (e.g., manufacturer's statement of purity), of the origin, purity and traceability of all standards and reagents (including balance weights and thermometers). These records shall include the date of receipt, the date of opening and an expiration date.

Detailed records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchase stocks or neat compounds, and must include the date of preparation and preparer's initials.

Where calibrations do not include the generation of a standard curve (e.g., thermometers, balances, titrations, etc.), records shall indicate the calibration date and type (e.g. balance weight, thermometer serial number, primary standard concentration, etc.) of calibration standard that was used.

All prepared reagents and standards shall be clearly identified with preparation date, concentration(s) and preparer's initials.

All standard curves shall be dated and labeled with method, analyte and standard concentrations and instrument responses.

The axes of the calibration curve should be labeled. For electronic data processing systems, that automatically compute the calibration curve, the equation for the curve and the correlation coefficient must be recorded. The equation for the line and the correlation coefficient shall also be recorded when the calibration curve is prepared manually.

A criteria for an acceptable correlation coefficient shall be established.

5.7.3.2 Initial Calibrations

All initial calibrations shall be verified with standards of high quality obtained from a second or different source. These verification standards shall be analyzed with each initial calibration or quarterly, whichever is more frequent.

Standard curves shall be prepared as specified in the method.

The lowest standard should approach the method detection limit.

If a method does not provide guidance in the preparation of a standard curve, the following guidelines shall be followed: For all methods, use a blank and at least three (3) standards that lie within the linear portion of the curve. Additional standards are required for non-linear calibration curves. In all cases, the sample results must be closely bracketed by calibration standards.

A new curve shall be run if two successive runs of one continuing calibration check is outside acceptable limits.

5.7.3.3 Continuing Calibration Verification

When an initial calibration curve is not run on the day of analysis, the integrity of the initial calibration curve shall be verified on each day of use (or 24 hour period) by initially analyzing a blank and a standard at a concentration equal to or near the lowest calibration standard (the lowest calibration standard shall be in the range of 4 to 8 times the calculated method detection limit).

Additional standards shall be analyzed after the initial calibration curve or the integrity of the initial calibration curve (see previous paragraph) has been accepted.

a) These standards shall be analyzed at a frequency of 5% or every 8 hours whichever is more frequent and may be standards used in the original calibration curve or standards from another source.

b) The concentration of these standards shall be determined by the anticipated or known concentration of the samples. To the extent possible, the samples in each interval (i.e. every 20 samples or every 8 hours) should be bracketed with standard concentrations closely representing the lower and upper range of reported sample concentrations. If this is not possible, the standard calibration checks should vary in concentration throughout the range of the data being acquired.

When not specified by the analytical method, these calibration verification standards shall be within 15% of the true value.

5.8 PHYSICAL FACILITIES

5.8.1 Environment

The laboratory facilities shall be maintained to permit the production of analytical data of needed quality. In addition to adequate housekeeping that must be performed to assure that contamination is unlikely, the following elements shall be controlled:

- temperature;
- humidity;
- electrical power;
- vibration;
- electromagnetic fields;
- dust;
- direct sunlight;
- ventilation (exhaust hoods, air exchangers, etc.); and
- lighting.

5.8.2 Work Area

Adequate work spaces to ensure an unencumbered work area must be available. These include:

- controlled access to the laboratory;
- separation of incompatible analyses;
- sample receipt area;
- sample storage area;
- chemical and waste storage area(s); and
- data handling and storage area(s)

5.9 SAMPLE ACCEPTANCE POLICY AND SAMPLE RECEIPT

Regardless of the laboratory's level of control over sampling activities, the following are essential to ensure sample integrity and valid data.

5.9.1 Sample Acceptance Policy

The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted. Data from any samples which do not meet the following criteria must be flagged in an unambiguous manner clearly defining the nature and substance of the variation. This document should be circulated to sample collecting personnel with other sampling instructions and shall include the following areas of concern:

a) Submittal of field quality control samples as required by the accrediting agency. The samples may include trip blanks, field blanks, equipment blanks, duplicates or other field-submitted quality control measures;

b) Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservative added, sample type and any special remarks concerning the sample;

c) 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;

d) Evidence of proper preservation and use of appropriate sample containers. The type of sample containers and preservatives are as specified by the individual programs, a Performance Based Method System or NELAP;

e) Adherence to specified holding times. The maximum allowable holding time prior to analyses are as specified by individual Programs, a Performance Based Method System or NELAP; and

f) Adequate sample volume. Sufficient sample volume must be available to perform the necessary analysis.

5.9.2 Sample Receipt Protocols

Samples shall be checked upon receipt for thermal preservation (if applicable) and all other aforementioned items. Chemical preservation (e.g., appropriate Ph) shall be checked upon receipt or prior to sample preparation/analyses. The results of such checks shall be recorded. Data from any samples which do not meet the criteria must be flagged in an unambiguous manner clearly defining the nature and substance of the variation.

If applicable, a complete chain of custody record (Section 5.11.3) shall be maintained.

5.9.3 Storage Conditions

The samples shall be properly preserved and stored in approved containers specified by the individual EPA or state programs, the Performance Based Method System or NELAP.

Samples shall be stored in a secure area.

5.10 SAMPLE TRACKING

The laboratory shall design a system to unequivocally identify all samples, subsamples and subsequent extracts and/or digestates so that each aliquot is uniquely identified.

The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. Multiple aliquots of a sample that have been received for different analytical tests (e.g., nutrients, metals, VOCs, etc.) must be assigned a different ID code. The use of container shape, size or other physical characteristic (e.g., amber glass, purple top, etc.) is not an acceptable means of identifying the sample.

This laboratory code shall maintain an unequivocal link with the unique field ID assigned each container.

The laboratory ID number shall be placed on the sample container as a durable label.

The laboratory ID number shall be entered into the laboratory records (see 5.11.2) and shall be the link that associates the sample with related laboratory activities (i.e., sample preparation, calibration, etc.).

In cases where the sample collector and analyst are the same individual or the laboratory preassigns numbers to sample containers, the laboratory ID number may be the same as the field ID number.

5.11 RECORD KEEPING, DATA REVIEW AND REPORTING

The laboratory shall implement protocols that will produce unequivocal, accurate records which document all laboratory activities associated with sample receipt, preparation, analysis, review and reporting.

There are two levels of record keeping: 1) sample custody or tracking and 2) legal or evidentiary chain of custody. All essential requirements for sample custody are outlined in Sections 5.11.1.1, and 5.11.1.2. The basic requirements for legal chain of custody (if required or implemented) are specified in Section 5.11.3.

5.11.1 Sample Custody Requirements

5.11.1.1 Essential Documentation

a) Sample Handling - Sample custody shall document all procedures and activities to which a sample is subjected. These activities shall include but are not limited to:

- Sample preservation including appropriate sample container and compliance with holding time;
- Sample identification, receipt, acceptance or rejection and log-in;
- Sample storage and tracking (includes shipping receipts, transmittal forms, and internal routing and assignment records);
- Sample preparation (includes cleanup and separation protocols, ID #s, volumes, weights, instrument printouts, meter readings, calculations, reagents, etc.);
- Sample analysis;
- Standard and reagent origin, receipt, preparation, and use;
- Equipment receipt, use, specification, operating conditions and preventative maintenance;
- Calibration criteria, frequency and acceptance criteria;
- Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- Method performance criteria including expected quality control requirements;
- Quality control protocols and assessment;
- Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;
- All automated sample handling systems;
- Records storage and retention; and
- Sample disposal including the date of sample or subsample disposal and name of the responsible person.

b) Laboratory Support Activities - In addition to documenting all the above-mentioned activities, the following shall be retained:

- 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);
- Copies of final reports;
- Archived standard operating procedures;
- Correspondence relating to laboratory activities for a specific project;
- All corrective action reports, audits and audit responses;
- Performance evaluation results and raw data; and
- Data review and cross checking.

c) Analytical Records - The essential information to be recorded on all raw data associated with analysis (e.g., strip charts, tabular printouts, computer data files, analytical notebooks, run logs, etc.) shall include:

- Laboratory sample ID number;
- Date of analysis;
- Instrumentation identification and instrument operating conditions/parameters (or reference to such data);
- Analysis type;
- All calculations (automated and manual); and
- Analyst's or operator's initials/signature.

5.11.1.2 Record Keeping System and Design

Each organization shall design and maintain a record keeping system that is succinct, self-explanatory and efficient and allows historical reconstruction of all laboratory activities that produced the resultant sample analytical data. The history of the sample must be readily understood through the documentation. This shall include interlaboratory transfers of samples and/or extracts.

All information relating to the laboratory facilities equipment, analytical methods, and related laboratory activities (e.g., sample receipt, sample preparation, data review, etc.) shall be documented. All documentation shall be maintained to reflect current operating protocols.

The organization should establish essential personnel qualifications and shall maintain records on personnel training.

Organizations shall maintain standard operating procedures (SOPs) that accurately reflect all phases of current laboratory activities including assessing data integrity.

a) These documents may be specific sample preparation or analytical references, (e.g. analytical method numbers), equipment manuals (provided by the manufacturer), or internally written documents.

b) The SOPs shall also include a list of analytical methods that are used by the laboratory. This list shall be indexed according to NELAC accreditation categories (e.g., drinking water, solid waste, etc.).

c) In cases where minor modifications to accepted methods have been made (e.g., change in type of column, change in operating conditions, etc.), or where the referenced method is ambiguous or provides insufficient detail (e.g., reagent purity, reagent concentration, etc.), these changes or clarifications shall be documented as an appendix to the referenced method.

Copies of the above-mentioned SOPs shall be accessible to the workplace.

The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes.

All documentation entries shall be signed or initialed by responsible staff. The reason for the signature or initials shall be clearly indicated in the records (e.g., sampled by, prepared by, reviewed by, etc.).

Entries into all records shall be legibly written in indelible ink.

Entries in records shall not be obliterated by erasures 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.

5.11.1.3 Laboratory Report Format and Contents

The laboratory shall report results, accurately, clearly, unambiguously and objectively and in a manner that is understandable to the recipient. The basic information to be included in the report includes the following:

a) Report title (e.g. "Certificate of Results", "Laboratory Results", etc.) with the name, address and phone number of the laboratory (or laboratories, see subcontracted laboratories below);

b) Name and address of client and/or project;

c) Description and identification of sample (including client ID number);

d) Date of sample receipt, sample collection and sample analysis;

e) Time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 48 hours;

f) Test method or unambiguous description of any non-standard method;

g) Test results with any failures or deviations from methods or quality control criteria identified (i.e., data qualifiers);

h) Signature and title of individual(s) accepting responsibility for the content of the report and date of issue; and

i) Clear identification of any results that were performed by a subcontracted laboratory.

If appropriate, the laboratory shall certify that the test results meet all requirements of NELAP or provide reasons and/or justification if they do not.

Once issued, the laboratory report shall remain unchanged. Any corrections, additions and/or deletions from the original reports shall be supported by supplementary documentation, shall clearly identify its purpose, and shall contain all reporting requirements specified above.

5.11.1.4 Records Management and Storage

a) All records of an organization that are pertinent to a specified project shall be retained for a minimum of five years unless otherwise designated for a longer period of time in another regulation. The records specified in 5.11.1.1 and 5.11.1.2 above shall be retained.

b) Records that are stored or generated by computers or personal computers (PCs) shall have hard copy and write-protected backup copies.

c) When a procedure or document (e.g., initial calibration records, SOPs, etc.) becomes obsolete or is replaced, the records shall clearly indicate the time period (or sample sets, if applicable) during which the procedure or document was in force.

d) All access to archived information shall be documented.

e) If an organization goes out of business or changes ownership before the time period for records retention has expired, all documentation shall be transferred in whole to the archives of the sponsor (client) of the work or to the new owner as described in Section 4.1.8.

5.11.2 Sample Custody Tracking and Data Documentation for Laboratory Operations

5.11.2.1 Sample Receipt, Log In and Storage

All records pertinent to sample receipt, log in and storage shall be maintained. In addition, the laboratory shall:

a) Retain all correspondence and/or official conversations concerning the final disposition of rejected samples;

b) Fully document any decision to proceed with the analysis of compromised samples:
- The condition of these samples shall be noted in all documentation associated with the sample.
- The analysis data shall be appropriately "qualified as estimated" on all internal documentation and on the final report.

c) Utilize a permanent, chronological log to document receipt of all sample containers. The following information must be recorded in the laboratory sequential log:
- Date of laboratory receipt of sample;
- Sample collection date;
- Unique laboratory ID code (see 5.10 above);
- Field ID code supplied by sample submitter;

- Requested analyses, including approved method number, if applicable;
- Signature or initials of data logger;
- Comments resulting from inspection for sample acceptance rejection; and
- Sampling kit code (if applicable).

d) All documentation that is transmitted to the laboratory by the sample transmitter shall be retained (e.g., memos, transmittal forms, etc.).

5.11.2.2 Intralaboratory Distribution of Samples for Analysis

a) The laboratory shall utilize a proactive procedure to ensure that all samples and subsamples are analyzed within allowed maximum allowable holding times.

b) All distribution of samples and subsamples for preparation and analysis shall be documented as to task assignment and analysis date deadline.

5.11.3 Legal or Evidentiary Custody Procedures

The use of legal chain of custody (COC) protocols is strongly recommended and may be required by some state or federal programs. In addition to the records listed in 5.11.1.1 and 5.11.1.2, the following protocols shall be incorporated if legal COC is implemented by the organization.

5.11.3.1 Basic Requirements

The chain of custody records shall establish an intact, contiguous record of the physical possession, storage and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates. For ease of discussion, the above-mentioned items shall be referred to as samples:

a) The COC records shall account for all time periods associated with the samples.

b) The COC records shall include signatures of all individuals who were involved with physically handling the samples.

c) In order to simplify record-keeping, the number of people who physically handle the sample should be minimized.

d) The COC records are not limited to a single form or document. However, organizations should attempt to limit the number of documents that would be required to establish COC.

e) Legal chain of custody shall begin at the point established by the federal or state oversight program. This may begin at the point that cleaned sample containers are provided by the laboratory or the time sample collection occurs.

f) The COC forms shall remain with the samples during transport or shipment.

5.11.3.2 Required Information in Custody Records

In addition to the information specified in 5.11.1.1 and 5.11.1.2, tracking records shall include, by direct entry or linkage to other records:

a) Time of day and calendar date of each transfer or handling procedure;
b) Signatures of all personnel who physically handle the sample(s);
c) All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting; and
d) Common carrier documents.

5.11.3.3 Controlled Access to Samples

Access to all legal samples and subsamples shall be controlled and documented.

5.11.3.4 Transfer of Samples to Another Party

Transfer of samples, subsamples, digestates or extracts to another party are subject to all of the requirements for legal chain of custody.

5.11.3.5 Sample Disposal

a) If the sample is part of litigation, disposal of the physical sample shall occur only with the concurrence of the affected

legal authority, sample data user and/or submitter of the sample.

b) All conditions of disposal and all correspondence between all parties concerning the final disposition of the physical sample shall be recorded and retained.

c) Records shall indicate the date of disposal, the nature of disposal (i.e. sample depleted, sample disposed in hazardous waste facility, sample returned to client, etc.), and the name of the individual who performed the task.

5.12 CORRECTIVE ACTION POLICY AND PROCEDURES

The laboratory shall develop contingencies for unacceptable quality control results. These policies shall be specified in written SOPs and shall include the following:

a) Identification of such problems, and the anticipated and/or recommended corrective actions to correct and/or eliminate future occurrences;

b) Requirement for written records that document the problem, the corrective measures, and the final outcome; and

c) An established policy requiring that a laboratory does not accept samples on a routine basis without the capability of meeting the maximum holding times.

APPENDIX A

DEFINITIONS

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

Accreditation Authority Review Board: a five member group appointed by EPA from the states, EPA, and other federal agencies to review the process and procedures used by EPA to approve state and federal laboratories and accreditation authorities.

Accrediting Authority: the agency having responsibility and accountability for environmental laboratory accreditation and who grants accreditation. For the purposes of NELAC, this is EPA, other federal agencies, or the state.

Accrediting Body: the organization that actually executes the accreditation process, i.e., receives and reviews accreditation applications, reviews QA documents, reviews performance evaluation testing results, surveys the site, etc., whether EPA, the state, or contracted private party.

Accuracy: the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Administrative Committee: a committee of the National Environmental Laboratory Accreditation Conference involved with the internal business affairs of the conference. Currently, these are the Conference Management and Funding, Nominating, Membership, Auditing, Liaison, and Contributor Committee.

Applicant: any environmental laboratory seeking accreditation.

Assessment: the physical process of inspecting, testing and documenting results from a laboratory for purposes of accreditation.

Assessment Team: an individual or group of individuals who perform the on-site assessment of a laboratory.

Board of Directors: the guiding body of NELAC composed of the Director, Executive Secretary, Chair, Chair-elect, Past Chair, Treasurer, and six at-large members.

Calibration Standard: a solution prepared from the primary dilution standard solution or stock standard solutions and the internal standards and surrogate analytes. The Calibration solutions are used to calibrate the instrument response with respect to analyte concentration. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

CNAEL: the Committee on National Accreditation of Environmental Laboratories chartered by EPA in 1991 to assess the need, feasibility, and practicability of a national environmental laboratory accreditation program. Dissolved after its report to EPA in September 1992.

Compromised Samples: those samples which were improperly sampled, or with insufficient documentation (chain of custody and other sample records and/or labels), improper preservation and/or containers were used, or the holding time has been exceeded. Under normal conditions compromised samples are not analyzed. If emergency situations require analysis, the results must be appropriately qualified.

Contracted Organization: a private accrediting body meeting the standards for accreditation of environmental laboratories and employed by an accrediting authority to perform certain accrediting functions, e.g. on-site audits.

Contributors: any person or group having an interest in environmental laboratory accreditation other than a state or federal official involved in environmental laboratory affairs, who may participate in the deliberations of the conference by presenting papers, debating issues, etc. but without vote or formal membership on a committee.

Deficiency Report: a report generated by the Inspector who is a state employee or authorized agent of the state in response to deficiencies noted in the course of a laboratory assessment, inspection or performance evaluation sample analysis result.

Denial: the refusal to grant approval to all or part of a laboratory's initial or subsequent application for certification by the National Environmental Laboratory Accreditation Program.

Environmental Laboratory Advisory Board: the name of the Federal Advisory Committee Act body chartered by EPA and composed of special interest groups or persons to interact with the Board of Directors.

Equipment Blank (Sample Equipment Blank): a clean sample (e.g., distilled water) that is collected in a sample container with the sample-collection device and returned to the laboratory as a sample. Sampling equipment blanks are used to check the cleanliness of sampling devices. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Failure: failing one or more of the criteria outlined in factors examined in announced and unannounced laboratory assessments which include: competence of staff, qualifications of staff and supervisors, working conditions, equipment, supplies, supervision, methods used, quality assurance/quality control procedures, recordkeeping, and compliance with good laboratory practices.

Field Blank: a clean sample (e.g., distilled water), carried to the sampling site, exposed to sampling conditions (e.g., bottle caps removed, preservatives added) and returned to the laboratory and treated as an environmental sample. Field blanks are used to check for analytical artifacts and/or background introduces by sampling and analytical procedures. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Holding Times (Maximum Allowable Holding Times): the maximum times that samples may be held prior to analysis and still be considered valid. (40 CFR Part 136).

Initial Demonstration of Analytical Capability: procedure to establish the ability to generate acceptable accuracy and precision which is included in many of the EPA's analytical methods. In general the procedure includes the addition of a specified concentration of each analyte (using a QC check sample) in each of four separate aliquots of laboratory pure water. These are carried through the entire analytical procedure and the percentage recovery and the standard deviation are determined and compared to specified limits. (40 CFR Part 136).

Inspection Report: the written results listing specific deficiencies and levels of performance that result from a laboratory assessment. This is a public record document prepared by the inspector.

Inspector: the authorized representative of the appropriate department within a state who directly conducts the laboratory assessment of inspection. This representative may be a third party contractor to the state who inspects and acts under the authority of the state. All actions and requests made by such a third party are made under the regulatory authority of the state.

Instrument Blank: a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Laboratory: a facility engaged in the collection or analysis and reporting of environmental samples, whether fixed or mobile.

Laboratory Control Sample (quality control sample): an uncontaminated sample matrix spiked with known amounts of analytes from a source independent of the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Legal Chain of Custody (COC): an unbroken trail of accountability that ensures the physical security of samples, data and records. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Local: an individual state.

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

Matrix Spike (spiked sample, fortified sample): prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example,

to determine the effect of the matrix on a method's recovery efficiency. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Matrix Spike Duplicate (spiked sample/fortified sample duplicate): a second replicate matrix spike is prepared and analyzed to obtain a measure of the precision of the recovery for each analyte. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Member (or active member): a state or federal official engaged in setting regulatory standards or accreditation of environmental laboratories, eligible for committee assignment and having voting privileges in the NELAC.

Method Blank: a clean sample processed simultaneously with and under the same conditions as samples containing an analyte of interest through all steps of the analytical procedures. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

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

National Database: a database run by the Federal Government or its authorized agent that has public information readily available to the states participating in the NELAP program. It would include information regarding the current accreditation and accreditation process and status on a laboratory by laboratory basis.

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

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

On-site: the laboratory facility, whether fixed or mobile, in the context of actually visiting the facility for evaluation or review of its program.

Reagent Blank (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced

into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

PBM: Performance Based Methods.

Participating Member: a state or federal agency identified by EPA as having met all the standards for an accrediting authority to accredit environmental laboratories.

Performance Evaluation Program: the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results in comparison to peer laboratories and the collective demographics and results summary of all participating laboratories.

Performance Evaluation Sample (PE): a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified performance limits. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Precision: the degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Preservation: refrigeration and or reagents added at the time of sample collection to maintain the chemical and or biological integrity of the sample.

Pure Reagent Water: water in which an interferant is not observed at the MDL of the parameters of interest. (40 CFR Part 136)

Quality Assurance Plan: a written description of the laboratory's quality assurance activities.

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets

defined standards of quality with a stated level of confidence. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Quality Control Sample: an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Quality Control Validation Studies: the formal study of a sampling and/or analytical method, conducted with replicate, representative matrix samples, following a specific study protocol and utilizing a specific written method, by a minimum of seven laboratories, for the purpose of estimating inter-laboratory precision, bias and analytical interferences. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Sample Container: the specific requirements for sample containers are to assure a representative samples and sample integrity, e.g., septa vials, glass or plastic.

Sample Duplicate: two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Standard Operating Procedures (SOPs): a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Standing Committee: a committee of NELAC involved with establishing the technical standards for accreditation of environmental laboratories. Currently, these are the Quality Systems, Performance Evaluation Testing, On-site Assessment,

Accreditation Process, Regulatory, Accrediting Authority, and Program Structure Committees.

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

Surrogate: a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Technical Employee: the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required Good Laboratory Practice notices and other pertinent Quality Controls to meet the required level of quality.

Trip Blank: a clean sample of matrix that is carried to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

APPENDIX B

BIBLIOGRAPHY

REFERENCES FOR WATER, SEDIMENTS, SOILS, SLUDGES, HAZARDOUS WASTES AND BIOLOGICAL ANALYSES

These methods or methods specified by the accreditation authority shall be used when analyzing samples.

DRINKING WATER

1) 40 CFR Part 141, National Primary Drinking Water Regulations, July 1, 1992, Subpart C and Subpart I.

2) "Methods for the Determination of Organic Compounds in Drinking Water," EPA 600/4-88-039, December 1988.

3) "Methods for Chemical Analysis of Water and Wastes," EPA 600/4-79-020,revised March 1983.

4) "Manual for Certification of Laboratories Analyzing Drinking Water, Criteria and Standards Quality Assurance" EPA 570/9-90-008, April 1990 and the first update (Change I) EPA 570/9-90-008a, October 1991.

5) 40 CFR Part 136, Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act, July 1, 1991, Appendix A.

6) Standard Methods for the Examination of Water and Wastewater, APHA-AWWA-WPCF, 18th Edition, 1992.

7) "Guidance on the Evaluation of Safe Drinking Water Act Compliance Monitoring Results from Performance Based Methods", September 30, 1994, Second draft.

SURFACE WATER, GROUNDWATER, AND WASTEWATER MUNICIPAL/INDUSTRIAL EFFLUENTS

1) 40 CFR Part 136, Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act, Tables IA, IB, IC, ID and IE, as published in the Federal Register, Vol. 65, No. 165, pp. 50758-50770, October 8, 1991.

2) Methods for Chemical Analysis of Water and Wastes, EPA 600/4-79-020, revised March 1983.

3) Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, (SW-846), Third edition, 1986, as amended by Updates 1 and IIA, August 31, 1993.

4) 40 CFR Part 261, Identification and Listing of Hazardous Waste, July, 1991, Appendix III (Chemical Analysis Test Methods)

5) Standard Methods for the Examination of Water and Wastewater, APHA-AWWA-WPCF, 17th Edition, 1989.

Notes:

1) Laboratories analyzing samples in support of NPDES Permits are limited to methods specified in Reference 1 above or those specifically approved for use by EPA.

<u>SOILS AND SEDIMENTS, MUNICIPAL AND INDUSTRIAL SLUDGES (RESIDUALS) AND SOLID AND HAZARDOUS WASTES</u>

1) "Test Methods for Evaluation of Solid Waste, Physical and Chemical Methods", Third Edition (EPA SW-846), 1986 as amended by Final Updates I and II, November, 1990 and 1991.

2) "Procedures for Handling and Chemical Analysis of Sediments and Water Samples" EPA/Corps of Engineers, EPA/CE-81-1, 1981.

3) *USEPA Contract Laboratory Statement of Work for Inorganic Analysis", ILMO 2.1 (September 1991).

4) *USEPA Contract Laboratory Program Statement of Work for Organic Analysis", ILMO 2.0 (July 1990) and ILMO 2.1 (September 1991).

5) "POTW Sludge Sampling and Analysis Guidance Document" USEPA Permits Division, August 1989.

* Methods from these references shall be used by laboratories participating in the EPA Contract Laboratory

Program to perform analyses for Superfund (CERCLA) site investigations.

AIR

To be added as document goes through review.

BIOLOGICAL

Microbiological

1) Drinking Water Analyses - 40 CFR Part 141, Subpart C (Monitoring and Analytical Requirements, section 141.21) July 1, 1991.

2) Water and Wastewater Analyses - 40 CFR Part 136, Table IA as published in the Federal Register, Vol. 65, No. 165, pp. 50758-50770, October 8, 1991.

3) "Microbiological Methods for Monitoring the Environment" EPA-600/8-78-017, 1978.

4) Standard Methods for the Examination of Water and Wastewater, APHP-AWWA-WPCF, 17th Edition, 1989.

Bioassay

1) "Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms (Fourth Edition)" EPA 600/4-90-027, September, 1991.

2) "Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms (Third Edition)" EPA 600/4-91-002, 1991.

3) "Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms (Second Edition)" EPA 600/4-91/003, 1991.

Macrobenthic Identification and Enumeration

1) "Macroinvertebrate Field and Laboratory Methods for Evaluating the Biological Integrity of Surface Waters", ORD, Washington, D.C., November, 1990.

2) Standard Methods for the Examination of Water and Wastewater, Part 10500, 17th Edition, APHA, 1989.

RADIOCHEMISTRY

1) 40 CFR Part 141.25, "Analytical Methods for Radioactivity", July 1, 1992 edition.

2) Analytical Methods for Radiochemistry Analyses, EPA 600/4-80-032 and EPA 600/5-84-006.