National Environmental Laboratory **Accreditation** Conference

nelac

ACCREDITATION PROCESS

PROPOSED CHANGES

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4.0 ACCREDITATION PROCESS

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

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

a) An individual fixed-base laboratory requires a separate accreditation. The primary accrediting authority shall determine what constitutes an individual fixed-base laboratory when noncontiguous laboratory facilities operate under the same ownership, technical directorship, and quality system as the parent laboratory.

b) The primary accrediting authority shall determine if a separate accreditation is required for a mobile laboratory that is owned by an accredited fixed-base laboratory, operates under the same quality system as the fixed-based laboratory, performs a subset of the analyses for which the fixed-base laboratory is accredited, and ~~operates~~ analyzes samples exclusively from within the state in which the parent fixed-base laboratory is located.

c) Separate accreditation by the primary accrediting authority is required for a mobile laboratory that is owned by an accredited fixed-base laboratory, operates under the same a quality system as the fixed-based laboratory, performs a subset of the analyses for which the fixed-base laboratory is accredited, and ~~operates~~ analyzes samples from outside of the state in which the parent fixed-base laboratory is located.

d) Separate accreditation by the primary accrediting authority is required for a mobile laboratory that is owned by a fixed-base laboratory but operates under a different quality system or performs analyses for which the parent fixed-base laboratory is not accredited.

e) Separate accreditation by the primary accrediting authority is required for a mobile laboratory that is not owned and operated by a fixed-base laboratory.

4.1 COMPONENTS OF ACCREDITATION

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

4.1.1 Personnel Qualifications

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

4.1.1.1 Definition, Technical Director(s)

The technical director(s) means a full-time member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of testing and reporting of results. The title of such person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager. A laboratory may appoint one or more

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

Qualifications of the technical director(s) .

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

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

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

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

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

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

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

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

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

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

4.1.1.2 Personnel Qualification Clarifications and Exceptions

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

b) A full-time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision in environmental analysis shall be deemed to meet the requirements for serving as the director of an accredited laboratory devoted exclusively to the examination of environmental samples taken within such facility for the scope of that facility's regulatory permit. Such accreditation for a industrial waste treatment facility shall be limited to laboratories analyzing industrial waste treatment samples collected within the state where the laboratory is situated, and the scope of accreditation shall be determined by the state accrediting authority.

4.1.2 On-site Assessments

On-site assessments are a requirement of the Accreditation Process and a summary of the process requirements are described. Refer to On-site Assessment (Chapter 3) for additional information regarding frequency, procedures, criteria, scheduling and documentation of on-site assessments. On-site assessments shall be of two types: announced and unannounced. The on-site assessment of each accredited laboratory must be performed a minimum of one time per two years. On-site assessments may be conducted more frequently for cause or at the option of the primary accrediting authority. Situations which might trigger more frequent on-site assessments include, review of a previously deficient on-site assessment, poor performance on a proficiency testing (PT) sample, change in other accreditation elements, or other information concerning the capabilities or practices of the accredited laboratory. The on-site assessment ensures that the environmental laboratory is in compliance with NELAC standards.

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

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

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

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

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

4.1.3 Corrective Action Reports In Response to On-Site Assessment

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

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

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

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

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

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

f) All information included and documented in an assessment report and the corrective action report are considered to be public information and are to be released pursuant to Chapter 3, Section 3.7.4.

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

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

4.1.4 Proficiency Testing Samples

A critical component of laboratory assessments is the analysis of PT samples. Refer to Proficiency Testing (Chapter 2) for additional information. PT samples are used and evaluated in the accreditation process as follows:

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

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

c) The laboratory shall be informed of its score on the PT samples by the primary accrediting authority or the NELAP approved PT provider within 21 calendar days from the closing date of submission. The results of all of the PT sample tests including acceptable or not acceptable shall be part of the public record. PT sample results shall apply to all accredited methods for an analyte in a particular matrix.

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

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

4.1.5 Accountability for Analytical Standards

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

a) In accordance with Chapter 5, each laboratory seeking or maintaining NELAP accreditation shall have a named quality assurance officer or a person designated as accountable for data quality.

b) NELAC requires that each laboratory seeking or maintaining NELAP accreditation have a developed and maintained Quality Assurance Manual on-site, as required in Chapter 5.

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

4.1.6 Fee Process for National Accreditation

Refer to Policy and Structure, Chapter 1, for specific information on funding of this program (Section 1.5.2.3.3).

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

4.1.7 Application

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

4.1.7.1 Primary Application Package

A laboratory seeking accreditation shall complete and submit an application package to the primary accrediting authority(ies). An accrediting authority participating in NELAP shall include in its application form the following:

a) Legal name of laboratory,
b) Laboratory mailing address,
c) Billing address (if different from b),
d) Name of owner,
e) Address of owner,
f) Location (full address) of laboratory,
g) Name and phone number of technical director(s),however named, and the lead technical director (if applicable),
h) Name and phone number of Quality Assurance Officer,
i) Name and phone number of laboratory contact person,
j) Laboratory hours of operation,
k) Primary Accrediting Authority,
l) Fields of Testing for which the laboratory is requesting accreditation,
m) Methods employed including analytes,
n) Description of laboratory type (for example),
   - Commercial
   - Federal
   - Hospital or health care
   - State
   - Academic Institutes
   - Public water system
   - Public wastewater system
   - Industrial (an industry with discharge permits)
   - Mobile
   - Other (Describe)_____
o) Certification of compliance by laboratory management (*vide infra*: 4.1.9),
p) Fee enclosed (if applicable),
q) Description of geographical location,
r) FAX number,
s) Lab identification number, ~~and,~~
t) Unique vehicle identification number, such as manufacturer's Vehicle Identification Number (VIN#), serial number, or license number (if a mobile laboratory), and,
~~t~~u) Quality Manual enclosed (if required with application)

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

4.1.7.2 Secondary Accreditation Package

A laboratory seeking accreditation from a secondary accrediting authority (ies) shall complete and submit a secondary application package as required by the secondary accrediting authority. Refer to

Section 4.2 for the assessment of fees (if applicable) and Section 4.4.1 (1) and (2) for the reasons to deny a secondary application package.

4.1.8 Change of Ownership and/or Location of Laboratory

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

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

a) Any change in ownership and/or location of an accredited laboratory must be reported in writing to the primary accrediting authority within 30 calendar days and entered into the national database by the primary accrediting authority. Required notification for change in location shall apply only to fixed-based laboratories.

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

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

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

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

4.1.9 "Certification of Compliance" Statement

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

CERTIFICATION BY APPLICANT

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

I hereby certify that I am authorized to sign this application on behalf of the applicant/owner and that there are no misrepresentations in my answer to the questions on this application.

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

4.2 PERIOD OF ACCREDITATION

For a laboratory in good standing, the period for accreditation within fields of testing for methods or analytes shall be 12 months and will be considered to be ongoing once a laboratory has been accredited for that field of testing method or analyte within a field of testing. To maintain accreditation the laboratory shall meet the requirements of Section 4.3, Maintaining Accreditation. Failure to meet the requirements delineated in Section 4.3 shall constitute grounds for suspension or revocation of accreditation as specified in Section 4.4. Additionally, failure to pay the required fees to the primary accrediting authority (ies) within the stipulated deadlines or by the stipulated dates shall result in revocation of accreditation by all the accrediting authorities (primary and secondary) with which the laboratory maintains accreditation. Failure to pay required fees to a secondary accrediting authority shall result in revocation of accreditation by that secondary accrediting authority. This information may be entered into the national database in a timely and effective manner. The NELAP recognizes that different accrediting authorities operate the yearly period with different start times. The individual laboratory being accredited is responsible for tracking an accrediting authority's period of accreditation and is responsible for paying the necessary fees (if applicable) to those accrediting authorities to maintain accreditation.

4.3 MAINTAINING ACCREDITATION

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

4.3.1 Quality Systems

Laboratories seeking accreditation under NELAP must assure consistency and promote the use of quality assurance/quality control procedures. Chapter 5, Quality Systems provides the details concerning quality assurance and quality control requirements for the evaluation of laboratories. The quality assurance policies, which establish essential quality control procedures, are applicable to all environmental laboratories regardless of size, volume of business and fields of testing. Failure to maintain, revise, or replace any of these key components may be cause for suspending or revoking a laboratory's accreditation status, as specified in Section 4.4 of this Chapter.

4.3.2 Notification and Reporting Requirements

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

4.3.3 Record Keeping and Retention

All laboratory records associated with accreditation parameters shall meet the requirements of Chapter 5, Section 5.12 and shall be maintained for a minimum of five years unless otherwise designated for a longer period in another regulation or authority. In the case of data used in litigation, the laboratory is required to store such records for a longer period upon written notification from the accrediting authority.

4.4 DENIAL, SUSPENSION, AND REVOCATION OF ACCREDITATION

4.4.1 Denial

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

a) Reasons to deny an initial application shall include:

   1) Failure to submit a completed application;

   2) Failure to pay required fees;

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

   4) Failure to successfully analyze and report proficiency testing samples as required by the NELAC standards, Chapter 2;

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

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

   7) Failure to implement a quality system as defined in Chapter 5;

   8) Failure to pass required on-site assessment(s) as specified in the NELAC standards, Chapter 3.

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

   10) Denial of entry during normal business hours for an on-site assessment as required by the NELAC standards, Chapter 3.

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

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

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

4.4.2 Suspension

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

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

b) Reasons for suspension shall include:

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

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

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

4) Failure to maintain a Quality System as defined in Chapter 5.

5) Failure of laboratory to employ staff that to meet the personnel qualifications for education, training and experience as required by the NELAC standards.

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

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

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

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

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

4.4.3 Revocation

Revocation - shall mean the in part or total withdrawal of a laboratory's accreditation by the accrediting authority. After correcting the reason/cause for revocation and satisfying any legal remedies, the laboratory may reapply for accreditation.

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

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

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

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

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

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

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

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

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

   5) Denial of entry during normal business hours for an on-site assessment as required by the NELAC standards, Chapter 3;

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

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

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

4.4.4 Voluntary Withdrawal

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

4.5 INTERIM ACCREDITATION

4.5.1 Interim Accreditation

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

4.5.2 Revocation of Interim Accreditation

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

4.6 AWARDING OF ACCREDITATION

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

a) name of laboratory,

b) address of the laboratory,

c) fields of testing (program, method, analyte), and,

d) addenda or attachments (these shall be considered to be official documents).

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

4.6.1 Use of NELAC Accreditation by Accredited Laboratories

An accredited laboratory shall not misrepresent its NELAP accredited fields of testing, methods, analytes, or its NELAP accreditation status on any document. This includes laboratory reports, catalogs, advertising, business solicitations, proposals, quotations or other materials (pursuant to NELAC Chapter 6, Section 8).

4.6.2 Changes in Fields of Testing

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

An addition of a new technology or test method requiring specific equipment may require an on-site assessment.

4.7 DUE PROCESS

Regardless of the language in this chapter concerning actions such as denial, suspension and revocation of accreditation, a laboratory is always entitled to the right of due process. Due process rights are delineated in the appropriate state laws and regulations of the accrediting authorities. Since these laws and regulations may vary from state to state, laboratories seeking accreditation are encouraged to become familiar with the specific laws and regulations governing due process for each of the accrediting authorities of interest.

4.8 ENFORCEMENT

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

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

a) The program should be equitable to all participants.

b) The rules should be well publicized.

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

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