NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

DRAFT ACCREDITATION PROCESS

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ACCREDITATION PROCESS

4.0 ACCREDITATION PROCESS

(NB. MANY OF THE STANDARDS AND ELEMENTS LISTED IN THIS CHAPTER ARE REFLECTIVE OF STANDARDS WORKED OUT AND SET FORTH IN OTHER CHAPTERS DEALING WITH DETAILED EXPLANATIONS OF THESE ELEMENTS. THEREFORE, IT IS ANTICIPATED THAT MANY OF THE DETAILS (EG. THE NUMBER OF PERFORMANCE EVALUATION SAMPLES TO BE DONE) WILL CHANGE AS THE DISCUSSIONS AND CONCLUSIONS IN THESE OTHER CHAPTERS CHANGE.)

4.1 COMPONENTS OF ACCREDITATION

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. For the following discussion of standards, in general (laboratories involved in environmental testing or measurement, analysis, monitoring or compliance), governmental, federal, state, municipal, county, local, commercial and private laboratories should all be accredited in a State with which they do business.

4.1.1 Personnel Qualifications

This component ensures that the elements of education, training and experience are addressed. 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.

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

The laboratory shall ensure that the training of its personnel is kept up-to-date.

Training is considered up to date when documentation in the files indicate acceptable performance of a blind sample at least once per year and a signature that technical personnel have read, understood and agreed to perform the most recent version of the method or operating procedures. Evidence must be on file that demonstrates all employees are aware and using the latest edition of the laboratories in house quality documentation.

All personnel 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.

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 specified 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. A state regulatory authority may delegate the responsibility of both Announced and Unannounced Assessments to a third party. However, the responsibility and accountability for meeting the standards of the NELAC are the responsibility of the State regulatory authority. The accrediting authority is the primary state in which the laboratory conducts business; however the ultimate decision as to the proper accrediting authority is determined by the individual state in which the laboratory headquarters management is located. Refer to On-site Assessment Section for additional information regarding frequency, procedures, criteria, scheduling and documentation of On-site Assessments.

Individual sites are generally subject to the same application process, fees, inspections and other requirements as environmental laboratories (NB. A site that only does sample collections is not considered an environmental laboratory and will not be subject to these requirements). In addition to laboratories, any site that reports environmental data to clients and/or regulatory authorities will be subject to some or all of these requirements.

Announced Assessments - A State regulatory authority may delegate the responsibility for Announced Assessments to a third party. However, the responsibility and accountability for meeting the standards of the NELAC are the responsibility of the State regulatory authority. 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 two years and must be conducted on-site; i.e., the site at which the actual analyses take place. A **site** is defined as a structure or group of structures at the same geographical location. In the case of **mobile laboratories** (i.e. On the back of trucks, in vans, on boats or ships etc.), **site** is defined as the mobile unit itself as long as the actual analysis or any portion of that analysis takes place on this unit. Any remote laboratory sites are considered separate

sites and subject to separate Announced and Unannounced Assessments, again provided that the analysis or any portion of the analysis take place at that site;

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

c) The inspector must have access to all information and data in the areas the lab has or is requesting accreditation both for analyses completed and laboratory personnel. This includes information designated as Confidential Business Information (CBI). The inspector must be cleared to have access to and view such CBI. The inspector (whether from the accrediting authority or a third party) cannot remove, copy and remove copies or otherwise communicate CBI (40 CFR Part 2). Under no circumstances are auditors to reveal CBI, for profit or not. Violation will result in the loss of the ability to audit and is libel for criminal prosecution;

d) The results of the assessment and performance will be sent to the National Database on Environmental Laboratories. All information contained in the National Database will be considered to be public information and accessible to any individual;

e) At least two Performance Evaluation (PE) samples of different concentrations, once per quarter in each category for which they have applied for accreditation, 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 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; and

f) The number of individuals conducting the on-site assessments should not be excessive, and the accreditation authority should be sensitive to fee structure, cost, and the number of inspectors.

Unannounced Assessments - A State regulatory authority may delegate the responsibility for Unannounced Assessments to a third party. However, the responsibility and accountability for meeting the standards of the NELAC are the responsibility of the State regulatory authority. The elements and criteria for the unannounced assessments for the purpose of the national accreditation program are:

a) Upon presentation of appropriate credentials, the assessor must be provided access to the laboratory facility or site at reasonable times;

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 assessor. The Performance Evaluation samples and requested analyses must be performed by methods approved by NELAC or the appropriate regulatory authority under which the analyses are being conducted. At the discretion of the inspector, he(she) may leave the PE samples for analysis and not be required to be on-site when the actual analysis (analyses) is (are) performed;

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;

e) The unannounced assessment should not unduly disturb the normal operating routine of the laboratory or site, and should be conducted during normal working hours;

f) The inspector for an unannounced audit should make every effort to ascertain that the laboratory or site is

   i. operational and
   ii. currently performing the appropriate type of analysis before initiating such an inspection.

g) The number of individuals conducting the On-site assessments should not be excessive, and the accreditation authority should be sensitive to fee structure, cost, and the number of inspectors.

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 must be documented as appropriate.

Laboratories will be furnished with an Deficiency 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 and Confidential Business Information will be excepted from all public records as provided by the procedures described in Section 3.4.6.

4.1.3 Performance Evaluation Samples

When appropriate for the evaluation and available, 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) Each laboratory or site seeking 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.

b) Each laboratory seeking accreditation shall also be required to perform analyses on at least two Performance Evaluation samples of different concentrations, once per quarter 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 their score on the Performance Evaluation samples by the state agency or authorized third party contractor within 60 days from the closing date of submission. The results of all of the Performance Evaluation sample tests indicating satisfactory or unsatisfactory compliance will also be public record.

d) The results of the Performance Evaluation sample analysis will be considered by the State or authorized third party accreditor to the State, 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 method within a category, or whether the laboratory should lose accreditation for a category or method within a category.

4.1.4 Corrective Action Reports

For purposes of this document, Deficiency Report refers to the report of items to be corrected/addressed and is issued by the accrediting authority or authorized third party. Corrective Action Report refers to the report issued by the laboratory in response to deficiencies.

a) The accrediting authority or authorized third party must present a Deficiency Report to the laboratory within 60 working days of the inspection.

b) After being notified of deficiencies, the laboratory will have no more than 20 working days from the date of receipt of the report to provide a Corrective Action Report to correct deficiencies noted in the Deficiency Report.

c) The state authority or authorized third party contractor will respond to the action noted in the Corrective Action Report within 30 working days of receiving it.

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

i. Failing to submit/respond with a Corrective Action Report that addresses all deficiencies that are noted in a Deficiency Report;
ii. Failing to implement Corrective Actions in Corrective Action Reports two times within the time limits specified by the accrediting authority;
iii. Providing an unacceptable response in a Corrective Action Report;

e) 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. Categories and/or methods for which the laboratory is currently accredited and date of accreditation; and/or
iii. Categories and/or methods for which the laboratory has lost accreditation during the current accreditation period and the date of loss of accreditation.
iv. State contact(s).

f) If the laboratory fails to implement corrective actions to remedy deficiencies noted within the required time period, accreditation for categories or specific methods within those categories will be immediately revoked or suspended. All such reports are public record and any or all of the information contained therein may be put into the National Database. Proprietary data and Confidential Business Information will be excepted from all public records.

4.1.5 Accountability for Analytical 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 requires that each laboratory seeking national accreditation have a named Quality Assurance Officer or a person designated as accountable for data quality. 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 requires that each laboratory seeking national accreditation have a Quality Assurance Manual on-site that may be reviewed as part of the inspection process.

c) NELAC will consider that the accountability for negligence, the falsification of data, records or instrument parameters will rest upon the analyst, the laboratory management and the company.

4.1.6 Fee Process for National Accreditation

Refer to Policy and Structure, specifically funding of the program (Section 1.10), 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 and if applicable, accreditation fees will be paid in accordance with existing state regulations, levels and practices to the state granting the accreditation or designated authorized third party accreditor.

c) Where required and if applicable, the level and timing of fee payments will be established by the individual State to which the laboratory is applying for accreditation. Additional fees on the laboratory may be levied by other individual States with which the laboratory chooses to do business.

4.1.7 Application

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.

A state participating in NELAC will include in its application form the following:

a) Legal name of laboratory
b) Laboratory mailing address
c) Billing address (if different from b))and contact person
d) Name of owner
e) Address of owner
f) Location (full address) of laboratory
g) Name and phone number of laboratory contact person
h) Name and phone number of Quality Assurance Officer
i) Name and phone number of laboratory management representative
j) Laboratory hours of operation
k) Primary State of Accreditation (if requesting Mutual Recognition)
l) Accrediting State Agency (also list third party accreditor if applicable)
m) Categories for which the laboratory is requesting accreditation
n) Methods employed
o) Equipment in the laboratory specific to environmental methods
p) 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)_____
q) Certification of compliance by laboratory management (*vide infra*: 4.1.9)
r) Laboratory facilities
s) Fees paid to:
t) Description of geographical location
u) FAX number
v) Lab identification number (for renewal)
w) Key Personnel (include duties, educational background, experience)

A laboratory seeking renewal of accreditation will follow the process outlined by the state in which they are currently accredited.

4.1.8 Transfer of Ownership/Change of Ownership, Change of Analytical Personnel, 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 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 state(s) and the National Environmental Laboratory Accreditation Program within 30 calendar 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 an 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 accountable and liable 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 accountable and liable for any analyses, data and reports generated after the legal transfer of ownership occurs.

   iii. All records and analyses performed pertaining to accreditation must be kept for a minimum of 10 years and are subject to inspection by accrediting State authorities (or their third party designee) during this period without prior notification to the laboratory. This stipulation is applicable regardless of change in ownership, accountability or liability.

iv. If ownership is transferred, the transferee will not be responsible for payment of fees to States during the remainder of the yearly period, provided that the previous owner has fully paid the required fees to the said States (or their third party designees). There may be, however, financial liability incurred in terms of Transfer Fees (*vide supra*).

f) For a change in key analytical laboratory personnel for which educational, training or experience requirements exist, the State or accrediting authorities must be notified within 30 calendar days of when such a change 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, 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 National Environmental Laboratory Accreditation Program's standards and requirements 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 NELAC standards. Additionally, the applicant authorizes the officially designated State inspector to; 1) make copies of any analyses or records relevant to the accreditation process, and 2) remove any or all such copies from the facility for purposes of evaluation or regulatory enforcement. Any refusal to allow entry to the state's representatives at reasonable times or during normal business hours or to allow copies of records relevant to laboratory accreditation to be made shall constitute a violation of a condition of accreditation and grounds for refusal of accreditation, revocation of accreditation, or loss of accreditation.

The applicant hereby certifies that all certified environmental analyses performed are done in accordance with applicable 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 or other designated responsible individual	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 12 months and will be considered to be ongoing once a laboratory has been accredited for that category or method within a category. 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 revocation or suspension of accreditation as specified in Section 4.4. Additionally, failure to pay the required fees as determined by the participating states within the stipulated deadlines or by the stipulated dates may result in loss of accreditation. This information may be entered into the National Database in a timely and effective manner. The NELAC recognizes that different states operate the yearly period with different start times. The individual laboratory being accredited is responsible for tracking the individual State's periods of accreditation and is responsible for paying the necessary fees (if applicable) to those states to maintain accreditation. Individual States may elect to extend the period of accreditation to lessen the impacts on individual laboratories with respect to Announced and Unannounced inspections, however in no case should this extension period of time exceed six months. The extension must specifically state what date the extension period expires. This information should be entered in 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 in a timely and effective manner. All such updates are public record and any or all of the information contained therein shall be put into the National Database. Proprietary data and Confidential Business Information will be excepted from all public records.

4.3 MAINTAINING ACCREDITATION

Accreditation remains in effect 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 4.3.6. Failure to complete or comply with these elements may be cause for downgrading or revoking accreditation. In this element, downgrading refers to the removal and elimination of a portion of methods or categories for which the laboratory was previously certified.

4.3.1 Performance Evaluation Samples

Performance Evaluation samples appropriate for the accredited methodology shall be required to be performed on at least two Performance Evaluation samples of different concentrations, once per quarter in each category for which they have applied for accreditation. These samples must be procured from an acceptable source. It must be 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. In this element, downgrading refers to the removal and elimination of a portion of methods or categories for which the laboratory was previously certified.

4.3.2 On-Site Assessments

On-site assessments shall be performed by the accrediting agency at a minimum frequency of once every two years. Unannounced On-site assessments or follow-up On-site assessments may be conducted more frequently, for cause, at the option of the accrediting authority. 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 acceptable Corrective

Action Report. Failure to pass an On-site assessment or to correct deficiencies according to the provisions of an acceptable 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 served as the basis for initial accreditation including the facility, organization and management, qualifications of key personnel, sample handling procedures, calibration standards, analytical methods, data reduction procedures, Standard Operating Procedures (SOP's) and laboratory quality assurance plan. Failure to maintain, revise, or replace any of these key components may be cause for downgrading accreditation status. In this element, downgrading refers to the removal and elimination of a portion of methods or categories for which the laboratory was previously certified.

4.3.4 Notification and Reporting Requirements

The accredited laboratory shall notify the accrediting body of any changes in key accreditation criteria within 30 calendar days 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. All such updates are public record and any or all of the information contained therein may be put into the National Database.

4.3.5 Record Keeping and Retention

All lab records associated with accreditation parameters must be easily accessible, including raw and processed data associated with each analysis, changes in method standard operating procedures, or the laboratory quality assurance plan, shall be maintained for a minimum of ten years unless otherwise designated for a longer period in another regulation or authority. (NB. This is the floor requirement for records retention. It is the responsibility of the laboratory and/or client to determine and comply with the specific record retention times in order to comply with a particular statute or 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/authority or other regulatory 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. The individual laboratory being accredited is responsible for tracking the individual State's periods of accreditation and is

responsible for paying the necessary fees (if applicable) to those states to maintain accreditation.

4.4 DENIAL, SUSPENSION, AND REVOCATION OF ACCREDITATION

Denial, Suspension or Revocation of accreditation in the primary state will automatically cause the same action within all other states in which the laboratory is accredited. This information, as well as voluntary withdrawals, appeal processes and procedures will be entered into the National Database.

4.4.1 Denial

Denial - shall mean to refuse to accredit a laboratory applying for initial accreditation or renewal of accreditation.

Reasons to deny an initial application or reapplication may include:

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

b) Failure to successfully perform Performance Evaluation tests as required by the accrediting authority.

c) Failure to attest that analysis are performed by approved or documented methodologies and/or in accordance with the requirements of the accrediting authority.

d) Failure to respond to a Deficiency Report from the On-Site Inspection with a Corrective Action Report within the specified amount of time.

e) Failure to implement the Corrective Actions detailed in the Corrective Action Report within the specified time frame.

f) Failure to pay required fees.

g) Failure to pass required On-site Inspection(s)

A laboratory shall have two opportunities to correct the areas of deficiencies which results in a denial of accreditation. If the laboratory is not successful in remedying said deficiencies, it must wait six months before again applying for accreditation. Upon reapplication, the laboratory may again be responsible for all or part of the fees incurred as part of the initial application for accreditation.

4.4.2 Revocation

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 may 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 as your own.

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

d) Denial of entry at reasonable times or during normal business hours for laboratory inspection.

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

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

No laboratory's accreditation will be revoked or denied without the right to due process.

4.4.3 Suspension

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 may 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 within the required time period;

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

d) Failure to pay accreditation application fees.

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

i. Failing to submit/respond with a Corrective Action Report;
ii. Failing to implement corrective actions in Corrective Action Reports two times;
iii. Providing an unacceptable response in a Corrective Action Report;
iv. Failing to address each item noted as a deficiency in the Deficiency Report;
v. Failing the same Performance Evaluation sample analysis two consecutive times for the same analyte; or
vi. Failing to achieve an overall testing event (PE Sample) passing score for two consecutive testing events or two out of three consecutive testing events.

4.4.4 Voluntary Withdrawal

If an environmental laboratory wishes to withdrawal from NELAC, it must notify the accrediting authority no later than 30 days before the end of the accreditation year.

Denial, revocation, and suspension in one state will be applicable for all states participating in NELAC. The status of each laboratory's accreditation (active, denied, revoked, or suspended) will be entered in the National Database.

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 in a timely manner, an interim accreditation may be issued and will be in effect until the assessment requirements have been completed. A state may provide for the use of an authorized third party to accredit laboratories when the state will be unable to perform an On-site Assessment in a timely manner. 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 only in the state where the interim accreditation was granted. Interim accreditation may still be granted when Performance Evaluation samples are not available from a source acceptable to the National Environmental Laboratory Accreditation Program. The period for granting Interim Accreditation may not exceed one year. This period may be extended for an additional period of one year or until NELAC is fully operational. The Interim Accreditation status is considered to be a matter of public record and will be entered into the National Database in a timely manner, along with the reasons for granting an Interim Accreditation.

If a laboratory or site has a valid accreditation based on current standards in a state or by an accrediting authority that do not meet minimum NELAC standards outlined in section 4.1.1 and 4.1.7, the laboratory or site may be granted an Interim Accreditation. This Interim Accreditation will be reviewed on a yearly basis by the state or accrediting authority and either granted or revoked at that time. If the primary state of accreditation is unable to process the Interim Accreditation, another State participating in NELAC may grant an Interim Accreditation on a year-by-year basis. This must be noted in the National Database.

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 authority.

4.5.3 Exception Process

NELAC will develop an Exception Process to allow states to submit detailed plans for step-by-step implementation for two years while coming into NELAC compliance. The NELAC board may then assist the state in formulating an exception process if that state is having difficulties implementing NELAC. Interim Accreditation may be extended an additional year in states while in the process of coming into compliance with NELAC.

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.). Addenda or attachments to the certificate are allowed and will be considered to be official documents. Information on the addenda or attachments may include scope, methods, analytes...etc. The laboratory must have a certificate for each state in which it is accredited. Even though

a parent laboratory is accredited, the subfacilities (laboratories operating under the same parent organization, analytical procedures, and quality assurance system) are also required to become accredited. The subfacilities accredited will be listed on the certificate of the parent laboratory, but each site must be accredited separately and will be issued their own Certificate of Accreditation. A **site** or **subfacility** is defined as a structure or group of structures at the same geographical location. In the case of **mobile laboratories** (i.e. on the back of trucks, in vans, on boats or ships etc.), **site** is defined as the mobile unit itself as long as the actual analysis or any portion of that analysis takes place on this unit. Also, any sub-facilities or remote laboratory sites are considered separate sites and subject to separate Announced and Unannounced Assessments, again provided that the analysis or any portion of the analysis take place at that site.

For awarding of accreditation, NELAC quality of standards will apply to individuals who apply test substances, collect samples, prepare samples, and analyze samples.

4.6.1 The Certificate of Accreditation

The certificate will be signed by a member of the accrediting authority and will be considered an official document. It will be transmitted as a sealed and dated (effective date and expiration date)document containing the NELAC Insignia from the accrediting authority. The certificate will include specific categories, parameters, and methods for which the laboratory or site is accredited.

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 authority upon loss of accreditation. However, this does not require the return of a certificate which has simply expired (reached the expiration date).

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 (NELAC) 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) Since NELAC is a voluntary program, it can not enforce civil or criminal penalties but rather all enforcement actions are taken independently by EPA or state agencies and communicated to all other NELAC participating agencies. Any civil/criminal actions are taken by participating agencies and/or accrediting authorities.

b) NELAC enforcement is limited to suspension (short-to-long-term) of individual accrediting authorities from NELAC only.

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

d) If states have too many enforcement actions against them, a meeting of the executive board will be convened to discuss corrective actions with that state.