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National Environmental Laboratory **Accreditation** Conference

2003 NELAC Standard

Approved at Ninth NELAC Annual Meeting
June 5, 2003

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National Environmental Laboratory **Accreditation** Conference

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ACCREDITATION PROCESS

Approved June 5, 2003
Effective July 1, 2005

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ACCREDITATION PROCESS

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

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

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

b) 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. Upon the request of the primary accrediting authority documentation showing the implementation of corrective action(s) must be forwarded to the primary accrediting authority within the timeframe specified in the corrective action report.

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

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

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

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

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

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

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

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

4.1.4 Proficiency Testing Samples

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

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

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

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

(Effective July 1, 2003)

d) When a laboratory initially requests accreditation, it must successfully analyze two sets of PT samples, the analyses to be performed in accordance with the timeframes specified in Chapter 2. Each set shall contain one sample for each requested field of accreditation (matrix-technology/method-analyte/analyte group). When a laboratory has been granted accreditation status, it must maintain a history of at least two passing results out of the most recent three for each field of accreditation (matrix-technology/method-analyte/analyte group).

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

4.1.5 Accountability for Analytical Standards

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

current accreditation standing within a particular State. The certificate must be returned to the accrediting authority upon loss of accreditation. However, this does not require the return of a certificate which has simply expired (reached the expiration date). If an accredited laboratory changes its scope of accreditation, a new certificate shall be issued which details the laboratory's accreditation(s).

4.6.1 Use of NELAC Accreditation by Accredited Laboratories

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

4.6.2 Changes in Fields of Accreditation

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

4.7 DUE PROCESS

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.

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QUALITY SYSTEMS

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QUALITY SYSTEMS

laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.

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

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

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

5.5.2.6 The laboratory management shall be responsible for:

a) defining the minimal level of qualification, experience and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills such as using a balance, colony counting, aseptic or quantitative techniques shall be considered;

b) ensuring that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented. (See Appendix C);

Note: In laboratories with specialized "work cells" (a well defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.

c) ensuring that the training of each member of the technical staff is kept up-to-date (on-going) by the following:

   1) Evidence must be on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities.

   2) Training courses or workshops on specific equipment, analytical techniques or laboratory procedures shall all be documented.

   3) Analyst training shall be considered up to date if an employee training file contains a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure as defined by the laboratory document control system, 5.4.2.3.d) and documentation of continued proficiency by at least one of the following once per year:

      i. acceptable performance of a blind sample (single blind to the analyst). Note:

successful analysis of a blind performance sample on a similar test method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the test methods. The laboratory must determine the acceptable limits of the blind performance sample prior to analysis;

ii. an initial measurement system evaluation or another demonstration of capability;

iii. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory must determine the acceptable limits for precision and accuracy prior to analysis; or

iv. if i-iii cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.

d) documenting all analytical and operational activities of the laboratory;

e) supervising all personnel employed by the laboratory.

f) ensuring that all sample acceptance criteria (Section 5.5.8) are verified and that samples are logged into the sample tracking system and properly labeled and stored;

g) documenting the quality of all data reported by the laboratory; and

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

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

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ACCREDITING AUTHORITY

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i) County, municipal, and non-governmental laboratories shall not claim either primary or secondary accreditation by a federal agency, even if the laboratory is performing analyses under contract to that agency.

6.2.2 Where to Apply for NELAP Accreditation

a) All county, municipal and non-governmental laboratories seeking NELAP accreditation or renewal of NELAP accreditation must apply for such accreditation through their home state (the state in which the laboratory facility is located) accrediting authority.

b) Laboratories located in a territory or state that is not NELAP-recognized may seek NELAP accreditation through any NELAP-recognized state or territorial accrediting authority.

c) Except as noted in subsection 6.2.2 (g) below, state governmental laboratories seeking NELAP accreditation or renewal of NELAP accreditation may apply for such accreditation through their home state, home territory or through a NELAP-recognized federal accrediting authority.

d) Except as noted in subsection 6.2.2 (g) below, federal governmental laboratories located in a department or agency that is a NELAP-recognized federal accrediting authority shall follow that department or agency's policy regarding NELAP accreditation or renewal of NELAP accreditation.

e) Federal governmental laboratories located in a federal department or agency that is not a NELAP-recognized accrediting authority may seek NELAP accreditation through any NELAP-recognized federal or state accrediting authority, except where the relationship poses a conflict of interest.

f) Laboratories that are NELAP accredited by a state accrediting authority that has lost NELAP recognition may seek renewal of NELAP accreditation through any NELAP-recognized state accrediting authority. The laboratory's NELAP accreditation from an accrediting authority that has lost NELAP recognition shall remain valid throughout its current certificate of accreditation.

g) NELAP accredited laboratories whose home state becomes a recognized NELAP accrediting authority may retain their primary accreditation through the state that holds their current accreditation. The laboratory may retain their existing certificate of accreditation through to the date on the certificate, or until such time that they choose to renew. Depending on the regulations of their home state, the laboratory may still be required to apply for secondary accreditation from their home state until time for renewal for their primary accreditation. At the time of renewal, they must apply for their primary accreditation through their home state accrediting authority as applicable based on requested FOTs.

h) Governmental laboratories that are organizational units of the same department or agency in which the accrediting authority is located or have other institutional conflicts of interest shall:

   1) demonstrate by organizational structure that the laboratory's Technical Director and the environmental laboratory accreditation program manager do not report within the same chain-of-command; and

   2) demonstrate by policies and procedures that conflicts-of-interest do not exist; or

   3) apply for NELAP accreditation through any other NELAP-recognized accrediting authority.

i) In order that all laboratory applications for NELAP accreditation are treated equally, accrediting authorities shall initiate processing applications for NELAP accreditation in the chronological order that the applications are received.

e) The accrediting authority has the option to appeal a revocation or denial decision regarding NELAP recognition by the NELAP Director as set forth in Section 6.10 of this chapter.

6.7 CERTIFICATE OF RECOGNITION TO THE ACCREDITING AUTHORITY

a) The NELAP Director shall issue a certificate of NELAP recognition dated the day on which NELAP recognition is granted.

b) The certificate of NELAP recognition shall include the following items:

1) the name and address of the accrediting authority,

2) the fields of accreditation for which the accrediting authority is NELAP-recognized,

3) the date of the accrediting authority's most recent on-site evaluation,

4) the expiration date of the accrediting authority's NELAP recognition which shall not be more than three (3) years from the date of the most recent date granting NELAP recognition,

5) the signature of the NELAP Director,

6) a statement that the accrediting authority is in compliance with the NELAC standards,

7) a statement that the accrediting authority has been granted the authority to accredit environmental laboratories for the fields of accreditation for which the accrediting authority is NELAP-recognized,

8) a statement that continued NELAP recognition depends on compliance with the NELAC standards;

9) a seal incorporating the NELAP insignia; and

10) a unique designator, such as date of issuance and a serial or certificate number.

6.8 USE OF ACCREDITATION BY NELAP ACCREDITED LABORATORIES

a) The accrediting authority shall have requirements for controlling the ownership, use and display of the accrediting authority's NELAP accreditation documents and for controlling the manner in which an accredited laboratory may refer to its NELAP accreditation and/or use of the NELAC/NELAP logo. These arrangements shall include, but are not limited to requirements that:

1) NELAP accredited laboratories post or display their most recent NELAP accreditation certificate or their NELAP-accredited fields of accreditation in a prominent place in the laboratory facility;

2) NELAP accredited laboratories make accurate statements concerning their NELAP accreditation fields of accreditation and NELAP accreditation status;

3) NELAP accredited laboratories accompany the accrediting authority's name and/or the NELAC/NELAP logo with at least the phrase "NELAP accredited" and the laboratory's accreditation number or other identifier when the accrediting authority's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials; and

4) NELAP accredited laboratories not use their NELAP certificate, NELAP accreditation status and/or NELAC/NELAP logo to imply endorsement by the accrediting authority.

b) The accrediting authority shall have arrangements to ensure that NELAP accredited laboratories choosing to use the accrediting authority's name, making reference to its NELAP accreditation status and/or using the NELAC/NELAP logo in any catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, the NELAP accredited laboratory shall:

1) distinguish between proposed testing for which the NELAP-accredited laboratory is accredited and the proposed testing for which the NELAP accredited laboratory is not accredited;

2) include the NELAP-accredited laboratory's accreditation number or other identifier; and

c) The accrediting authority shall have arrangements to ensure that the NELAP-accredited laboratories upon suspension, revocation or withdrawal of their NELAP accreditation shall:

1) discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to their past NELAP accreditation status and/or display the NELAC/NELAP logo, and,

2) return any certificates for NELAP accreditation to the accrediting authority.

d) The accrediting authority shall have arrangements to take suitable actions, including legal action, when incorrect references to the accrediting authority's NELAP accreditation, misleading use of the laboratory's NELAP accreditation status and/or unauthorized use of the NELAC/NELAP logo is found in catalogs, advertisements, business solicitations, proposals, quotations, laboratory analytical reports or other materials.

6.9 REQUIREMENTS OF THE NELAP

a) The NELAP evaluation team shall submit all documents, letters, evaluation notes, checklists, etc. to the NELAP headquarters office within:

1) 30 calendar days of the final decision on the application by the NELAP Director, or

2) 30 calendar days after the final recommendation by the Accrediting Authority Review Board (AARB) as set forth in Section 6.10 of this chapter.

b) The NELAP Director shall maintain complete and accurate records of all documents relating to the application and on-site evaluation processes for each accrediting authority for a minimum of ten years or a longer period of time if required by contractual obligations or pertinent federal laws and regulations.

c) The NELAP Director shall maintain an electronic directory to display the status of all NELAP-recognized accrediting authorities, pending applications for NELAP recognition and currently scheduled announced on-site evaluations.

6.9.1 NELAP Evaluation Team

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

b) The NELAP evaluation team shall consist of at least one member who is an employee of the USEPA and at least one member who is an employee of a NELAP-recognized accrediting authority.