#### TABLE OF CONTENTS

# CHAPTER Env-C 300 LABORATORY ACCREDITATION PART Env-C 301 PURPOSE AND APPLICABILITY Section Env-C 301.01 Purpose Section Env-C 301.02 Applicability PART Env-C 302 DEFINITIONS Section Env-C 302.01 Assessor Section Env-C 302.02 Department Section Env-C 302.03 Denial Section Env-C 302.04 Field of Accreditation Section Env-C 302.05 Limited Inorganic Chemistry Section Env-C 302.06 Method Detection Limit (MDL) Section Env-C 302.07 New Hampshire Environmental Laboratory Accreditation Program (NH ELAP) Section Env-C 302.08 Person Section Env-C 302.09 Practical Quantitation Limit (PQL) Section Env-C 302.10 Primary Accrediting Authority Section Env-C 302.11 Program Manager Section Env-C 302.12 Quality System Section Env-C 302.13 Responsible Party of Record Section Env-C 302.14 Revocation Section Env-C 302.15 Secondary Accrediting Authority Section Env-C 302.16 Successful Participation Section Env-C 302.17 Successor in Interest Section Env-C 302.18 Suspension Section Env-C 302.19 Technical Director PART Env-C 303 APPLICATIONS FOR ACCREDITATION Section Env-C 303.01 Application for Primary Accreditation Section Env-C 303.02 Application Form for Primary Accreditation Section Env-C 303.03 Signatures Required Section Env-C 303.04 Additional Information Required for Primary Accreditation Section Env-C 303.05 Application Fee Section Env-C 303.06 On-Site Assessment Reimbursable Expenses Section Env-C 303.07 Mobile Laboratories; Individual or Remote Sites Section Env-C 303.08 Application for Secondary Accreditation Section Env-C 303.09 Application Form for Secondary Accreditation Section Env-C 303.10 Additional Information Required for Secondary Accreditation **Applications** Section Env-C 303.11 Out-of-State Laboratories Applying for Accreditation with NH ELAP as a Secondary Accrediting Authority Section Env-C 303.12 Out-of-State Laboratories Applying for Accreditation with NH ELAP as a Primary Accrediting Authority Section Env-C 303.13 Application Processing Section Env-C 303.14 Decision on Application Section Env-C 303.15 Basis for Primary Accreditation

Section Env-C 303.16 Basis for Secondary Accreditation

Section Env-C 303.17 Application for Renewal

i Env-C 300

# PART Env-C 304 PARTICIPATION IN NH ELAP; USE OF NECLAC NAME AND LOGO Section Env-C 304.01 Issuance of Certificate and Analyte Lists Section Env-C 304.02 Withdrawal from Accreditation; Return of Certificate and Analyte Lists Section Env-C 304.03 Transferring Accreditation Section Env-C 304.04 Use of NELAC/NELAP Name and Logo Section Env-C 304.05 Providing Information on Accreditation Status PART Env-C 305 REQUIREMENTS FOR ACCREDITATION IN CHEMISTRY Section Env-C 305.01 Accreditation Requirements Section Env-C 305.02 Personnel Section Env-C 305.03 Laboratory Facilities Section Env-C 305.04 Laboratory Equipment and Reference Materials Section Env-C 305.05 Analytical Methodology Section Env-C 305.06 Sample Collection, Handling, and Preservation Section Env-C 305.07 Quality Assurance Requirements Section Env-C 305.08 Calibration of Instruments Section Env-C 305.09 Records and Data Reporting Section Env-C 305.10 Action Response to Laboratory Results for Compliance Purpose Samples Section Env-C 305.11 Outside Support Services and Supplies Section Env-C 305.12 Complaints PART Env-C 306 REQUIREMENTS FOR ACCREDITATION IN MICROBIOLOGY Section Env-C 306.01 Accreditation Requirements Section Env-C 306.02 Personnel Section Env-C 306.03 Laboratory Facilities Section Env-C 306.04 Laboratory Equipment and Supplies Section Env-C 306.05 Analytical Methodology Section Env-C 306.06 Sample Collection, Handling, and Preservation Section Env-C 306.07 Quality Assurance Requirements Section Env-C 306.08 Records and Data Reporting Section Env-C 306.09 Action Response to Laboratory Results Section Env-C 306.10 Outside Support Services and Supplies Section Env-C 306.11 Complaints PART Env-C 307 REQUIREMENTS FOR ACCREDITATION FOR RADIOCHEMISTRY Section Env-C 307.01 Accreditation Requirements Section Env-C 307.02 Personnel Section Env-C 307.03 Laboratory Facilities Section Env-C 307.04 Laboratory Equipment and Reference Materials Section Env-C 307.05 Analytical Methodology Section Env-C 307.06 Sample Collection, Handling, and Preservation Section Env-C 307.07 Quality Assurance Requirements Section Env-C 307.08 Calibration of Instruments Section Env-C 307.09 Records and Data Reporting Section Env-C 307.10 Action Response to Laboratory Results for Compliance Purpose Samples Section Env-C 307.11 Outside Support Services and Supplies Section Env-C 307.12 Complaints PART Env-C 308 REQUIREMENTS FOR ACCREDITATION IN WHOLE EFFLUENT TOXICITY Section Env-C 308.01 Accreditation Requirements Section Env-C 308.02 Personnel Section Env-C 308.03 Laboratory Facilities Section Env-C 308.04 Laboratory Equipment and Reference Materials

Section Env-C 308.05 Analytical Methodology

ii Env-C 300

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES Section Env-C 308.06 Sample Collection, Handling, and Preservation Section Env-C 308.07 Quality Assurance Requirements Section Env-C 308.08 Calibration of Instruments Section Env-C 308.09 Records and Data Reporting Section Env-C 308.10 Action Response to Laboratory Results for Compliance Purpose Samples Section Env-C 308.11 Outside Support Services and Supplies Section Env-C 308.12 Complaints PART Env-C 309 PROFICIENCY TESTING Section Env-C 309.01 Participation in Scheduled and Supplemental Proficiency Testing Section Env-C 309.02 Reporting of PT Study Results Section Env-C 309.03 PT Study Record Retention Section Env-C 309.04 Proficiency Testing Study Results Review PART Env-C 310 QUALITY SYSTEMS MANUAL AND STANDARD OPERATING PROCEDURES MANUAL Section Env-C 310.01 Establishment Section Env-C 310.02 Quality Systems Manual Section Env-C 310.03 Standard Operating Procedures Section Env-C 310.04 Corrective Actions Section Env-C 310.05 Essential Quality Control Procedures PART Env-C 311 ASSESSMENTS Section Env-C 311.01 Routine Assessments Section Env-C 311.02 Unannounced Assessments Section Env-C 311.03 Follow-up Assessments

Section Env-C 311.04 Results of the Assessment

Section Env-C 311.05 Third Party Assessors

Section Env-C 311.06 Application for Approval of Third Party Assessor Organizations

Section Env-C 311.07 Approval of Third Party Assessor Organizations

Section Env-C 311.08 Review of Third Party Assessor Work

#### PART Env-C 312 DENIAL; SUSPENSION; REVOCATION

Section Env-C 312.01 Denial

Section Env-C 312.02 Suspension

Section Env-C 312.03 Revocation

Section Env-C 312.04 Action to Deny Application for Renewal for Renewal Accreditation or Suspend or Revoke Accreditation

Section Env-C 312.05 Successor in Interest Applying for Reaccreditation

Section Env-C 312.06 Requesting Reconsideration of Accreditation Status

iii Env-C 300

# CHAPTER Env-C 300 LABORATORY ACCREDITATION

Statutory Authority: RSA 485:44; RSA 485:46; RSA 485:47

### PART Env-C 301 PURPOSE AND APPLICABILITY

Env-C 301.01 <u>Purpose</u>. The purpose of the rules in this chapter is to implement the environmental laboratory accreditation program established by RSA 485:44 and RSA 485:46.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 301.02 Applicability. The rules in this chapter shall apply to:

- (a) Any laboratory that is required to be accredited in order to perform laboratory analyses that will be accepted by regulatory agencies for compliance purposes; and
- (b) Any laboratory that voluntarily desires to be accredited in order to perform laboratory analyses that will be accepted by regulatory agencies for compliance purposes.

Source. #9134, eff 4-19-08

#### PART Env-C 302 DEFINITIONS

Env-C 302.01 "Assessor" means an individual who performs on-site assessments of laboratories' capability and capacity for meeting National Environmental Laboratory Accreditation Conference (NELAC) standards by examining the records and other physical evidence for each one of the tests for which accreditation has been requested.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 302.02 "Department" means department of environmental services.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 302.03 "Denial" means the accrediting authority's refusal to accredit, in total or in part, a laboratory applying for initial or renewal accreditation.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 302.04 "Field of accreditation" means a matrix, method, and analyte combination for which NH ELAP offers accreditation.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 302.05 "Limited inorganic chemistry" means 6 or fewer inorganic analyses other than trace metals.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 302.06 "Method detection limit (MDL)" means the minimum concentration of a substance that can be measured and reported with 99% confidence that the substance is present in the sample being tested.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 302.07 "New Hampshire Environmental Laboratory Accreditation Program (NH ELAP)" means the program implemented by the department pursuant to RSA 485:44 to accredit laboratories in conformance with and consistent with NELAC accreditation standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 302.08 "Person" means "person" as defined in RSA 485:1-a, XIII, namely "any individual, partnership, company, public or private corporation, political subdivision or agency of the state, department, agency or instrumentality of the United States, or any other legal entity."

Source: #9134, eff 4-19-08

Env-C 302.09 "Practical quantitation limit (PQL)" means the lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions.

Source: #9134, eff 4-19-08

Env-C 302.10 "Primary accrediting authority" means the agency or department designated at the territory, provincial, state, or federal level as the authority recognized by the National Environmental Laboratory Accreditation Program (NELAP) with responsibility and accountability for granting NELAC accreditation for a specific field of testing.

Source: #9134, eff 4-19-08

Env-C 302.11 "Program manager" means the department employee who is responsible for implementing the NH ELAP.

Source: #9134, eff 4-19-08

Env-C 302.12 "Quality system" means "quality system" as defined in Chapter 1, Appendix A of the NELAC standards, namely "a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC)."

Source: #9134, eff 4-19-08

Env-C 302.13 "Responsible party of record" means the individual, regardless of title, who is responsible for supervising overall laboratory procedures and test result reporting for the laboratory as a whole.

Source: #9134, eff 4-19-08

Env-C 302.14 "Revocation" means the total or partial removal of a laboratory's accreditation by the accrediting authority.

Source: #9134, eff 4-19-08

Env-C 302.15 "Secondary accrediting authority" means an entity that grants accreditation to laboratories accredited by a primary accrediting authority.

Source: #9134, eff 4-19-08

Env-C 302.16 "Successful participation" or "successfully participate" means:

- (a) For analyses accredited on an analyte-by-analyte basis, receiving a score of "acceptable" or "check for error" on all available concentrations; or
- (b) For analytes accredited as a group of interdependent analytes as described in chapter 2, appendix C of the 2003 NELAC standards, receiving a score of "pass".

Source: #9134, eff 4-19-08

Env-C 302.17 "Successor in interest" means any laboratory that is owned or controlled by a majority of persons that owned or controlled a laboratory accredited under a previously-issued certificate.

Source: #9134, eff 4-19-08

Env-C 302.18 "Suspension" means the temporary removal of a laboratory's accreditation by the accrediting authority in part or in total for a defined period of time.

Source: #9134, eff 4-19-08

Env-C 302.19 "Technical director" means an individual, regardless of title, who is responsible for supervising laboratory procedures and test result reporting for a particular area of the laboratory.

Source: #9134, eff 4-19-08

#### PART Env-C 303 APPLICATIONS FOR ACCREDITATION

Env-C 303.01 Application for Primary Accreditation.

(a) In order to request initial or renewed primary accreditation pursuant to RSA 485:44, the applicant shall submit a complete application as specified in (b), below, to the department at the following address:

NH Department of Environmental Services Attn: Program Manager, NH ELAP P.O. Box 95 Concord, N.H. 03302-0095

- (b) A complete application for primary accreditation shall include:
  - (1) The information specified in Env-C 303.02 on an application form obtained and completed as specified in (c) through (e), below and signed as specified in Env-C 303.03;
  - (2) The additional information specified in Env-C 303.04;
  - (3) The results of successful participation in a proficiency test (PT) study as specified in chapter 2, appendix C of the 2003 NELAC standards; and
  - (4) The fee specified in Env-C 303.05.
- (c) The department shall provide, upon request, one application form in Microsoft Word® format to the applicant by e-mail or regular mail.
  - (d) The applicant shall complete the application form electronically.
- (e) In addition to the printed, signed application form, the applicant shall submit an electronic copy of the completed application form to the department.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

- Env-C 303.02 <u>Application Form for Primary Accreditation</u>. On the application form, the applicant shall provide the following information:
- (a) Whether the application is for a new laboratory, an update of a laboratory currently in the NH ELAP, or a renewal of a laboratory currently in the NH ELAP;
- (b) For a renewal or update application, the laboratory identification number previously assigned by the department;
- (c) The legal name, mailing address, street address, billing address, daytime telephone number, and fax number of the laboratory and, if available, the e-mail address and web site address of the laboratory;
  - (d) Whether the laboratory seeking accreditation is owned by a business entity or a government entity;
  - (e) If the laboratory is owned by a business entity, the following:
    - (1) The type of business entity, such as corporation, partnership, sole proprietorship, or other and the legal name of the business entity, if other than the legal name of the laboratory;
    - (2) The date the laboratory registered with the New Hampshire secretary of state;
    - (3) If the owner is a corporation, the date and state of incorporation; and
    - (4) The name and title of each principal official of the business entity, such as corporate officers or general partners;
- (f) If the laboratory is owned by a governmental entity, the name and primary mailing address of the federal, state, or local agency that owns the laboratory, if different from the information provided pursuant to (c), above;
- (g) The name, daytime telephone number, extension number, if applicable, and e-mail address of the individual at the laboratory who is the contact for purposes of the application;
- (h) The name and daytime telephone number including extension, if applicable, of the responsible party of record;
  - (i) The education and experience background of the responsible party of record;
- (j) The name and daytime telephone number including extension, if applicable, of the quality assurance officer;
- (k) The names and daytime telephone numbers including extensions, if applicable, of the lead technical director and of all other technical directors;
  - (1) The amount of fees due as specified by Env-C 303.05;
- (m) The type of laboratory, type of building housing the laboratory, floor plan space, utilities, and computer systems, including software;
- (n) A list of all general use laboratory equipment, including the name and description of the equipment, the manufacturer, the manufacturer's make and model, and the age and year purchased;
  - (o) Each matrix, method, and analyte for which accreditation is desired;
- (p) The analytical methodology and equipment used for each analyte, matrix, and method for which accreditation is desired;
  - (q) For a mobile laboratory, the vehicle identification number (VIN) or serial number; and

(r) Laboratory hours of operation.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### Env-C 303.03 Signatures Required.

- (a) The responsible party of record shall sign and date the application form.
- (b) The signature shall constitute certification that:
  - (1) The information provided is true, complete, and not misleading to the knowledge and belief of the signer; and
  - (2) The signer understands that any accreditation issued based on false, incomplete, or misleading information shall be subject to suspension or revocation.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 303.04 <u>Additional Information Required for Primary Accreditation</u>. The applicant shall provide the following to the department with the completed application form:

- (a) Transcripts of all college courses completed by each technical director, including graduate courses if applicable;
- (b) A paper and an electronic copy, in Excel®, Quattro Pro®, WordPerfect®, or Microsoft Word® format, of the quality system manual and standard operating procedures (SOPs) as specified in Env-C 310.02 and Env-C 310.03;
  - (c) A signed certificate of compliance as required by section 4.1.9 of the 2003 NELAC standards; and
- (d) Information regarding which of the methods allowed by Env-C 304.05 the laboratory intends to use to inform all prospective New Hampshire clients of which analytes or categories it is accredited by NH ELAP to test.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

New. #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### Env-C 303.05 Application Fee.

(a) A nonrefundable application fee shall accompany each application for a new, updated, or renewal accreditation.

- (b) For drinking water, non-potable water, and solid and chemical materials accreditation, the application fee shall be the sum of:
  - (1) A \$100 base fee; and
  - (2) All applicable amounts listed in Table 300-1 below, subject to the explanatory notes in (c), below:

Table 300-1 Additional Fees Included in Nonrefundable Fee

Accreditation Requested	A	В	C
Microbiology	\$100	\$125	\$150
Limited inorganic chemistry only	\$100	\$125	\$150
One or 2 metals only	\$100	\$125	\$150
Microbiology and limited inorganic chemistry	\$150	\$175	\$225
Microbiology and one or 2 metals	\$150	\$175	\$225
Microbiology, limited inorganic chemistry, and one or 2 metals	\$250	\$275	\$375
Metals, Inorganics, or both	\$400	\$500	\$600
Organic chemistry	\$400	\$500	\$600
Radiological chemistry	\$250	\$275	\$375
Whole Effluent Toxicity Testing	\$250	\$250	\$250
Radon analysis only	\$100	\$100	\$100
Each performance-based or laboratory-developed method	\$200	\$200	\$200

- (c) The following explanatory notes shall apply to Table 300-1:
  - (1) Column A shall apply to laboratories seeking accreditation for:
    - a. Drinking water matrix methods only;
    - b. Only non-potable water matrix methods other than SW-846 methods;
    - c. Non-potable water matrix SW-846 methods only;
    - d. A combination of a. and b., above; or
    - e. A combination of a. and c., above.
  - (2) Column B shall apply to laboratories seeking accreditation for:
    - a. Non-potable water matrix methods including SW-846 and non-SW-846 methods;
    - b. Solid and chemical material matrix methods only; or
    - c. Drinking water matrix methods or non-potable water matrix methods and solid and chemical material matrix methods.
  - (3) Column C shall apply to laboratories seeking accreditation for a combination of drinking water matrix methods, non-potable water matrix methods, and solid and chemical material matrix methods.
- (d) Accreditation shall not be granted if the correct application fee is not received by the department.

7

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 303.06 On-Site Assessment Reimbursable Expenses.

- (a) In addition to the nonrefundable fee, the laboratory shall reimburse the state in accordance with (b) through (f), below, for the following costs associated with a routine assessment or follow-up assessment:
  - (1) Department staff expenses, calculated as the time needed to perform the tasks listed in a. through e., below, multiplied by the hourly rate of the assessor plus employee benefits:
    - a. Review the application and documents supplied with the application;
    - b. Prepare the checklists used for the assessment;
    - c. Travel to and from the laboratory;
    - d. Assess the laboratory; and
    - e. Prepare the on-site assessment report;
  - (2) Meals and lodging while on out-of-state assessments or in-state assessments that require an overnight stay; and
  - (3) Costs of transportation, which for public transportation shall include all fares and which for non-public transportation shall include:
    - a. Mileage;
    - b. Tolls paid, if any; and
    - c. Parking fees, if any.
- (b) The department shall inform the laboratory of the costs associated with the assessment with the assessment report.
- (c) If accreditation is denied, revoked, or suspended based on the assessment, or if the laboratory withdraws its request for accreditation, the laboratory shall pay the costs of the assessment within 30 days of receiving the assessment report.
- (d) If accreditation is granted or renewed, the laboratory shall pay the costs of the assessment prior to receiving its accreditation certificate and analyte list.
- (e) Accreditation shall be revoked or suspended if the laboratory fails to pay the costs associated with an on-site assessment performed other than in conjunction with an application within 30 days of receiving the assessment report.
- (f) If payment is made by check or money order, the instrument shall be made payable to "Treasurer State of New Hampshire".

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

# Env-C 303.07 Mobile Laboratories; Individual or Remote Sites.

- (a) Pursuant to section 4.0 of the 2003 NELAC standards, NH ELAP shall deem a mobile laboratory not associated with a laboratory having a fixed base in New Hampshire to be a separate laboratory and so subject to the same application process, fees, assessments, and other requirements as any other environmental laboratory.
- (b) A mobile laboratory owned by an accredited fixed-based laboratory shall be considered an extension of the parent laboratory and so not require separate accreditation if it:

- (1) Operates under the same quality system as the fixed-based laboratory;
- (2) Performs a subset of analyses for which the parent laboratory is accredited; and
- (3) Analyzes samples exclusively from within the state in which the parent fixed-base laboratory is located.
- (c) A mobile laboratory owned by an accredited fixed-base laboratory shall be considered a separate laboratory requiring separate accreditation if it:
  - (1) Does not operate under the same quality system as the fixed-based laboratory;
  - (2) Performs analyses for which the fixed-base laboratory is not accredited; or
  - (3) Analyzes samples from outside of the state in which the parent fixed-base laboratory is located.
- (d) Individual or remote sites shall be subject to the same application process, fees, assessments, and other requirements as other environmental laboratories, subject to the following:
  - (1) A part of a laboratory that is in a building in proximity to the laboratory shall not be considered an individual or remote site; and
  - (2) A location that is only a sample collection site shall not be considered an environmental laboratory that is subject to the requirements of this chapter.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 303.08 Application for Secondary Accreditation.

(a) In order to request initial or renewed secondary accreditation pursuant to RSA 485:44, the applicant shall submit a complete application as specified in (b), below, to the department at the following address:

NH Department of Environmental Services Attn: Program Manager, NH ELAP P.O. Box 95 Concord, N.H. 03302-0095

- (b) A complete application shall include:
  - (1) The information specified in Env-C 303.09 on an application form obtained and completed as specified in (c) through (e), below and signed as specified in Env-C 303.03;
  - (2) The additional information specified in Env-C 303.10; and
  - (3) The fee specified in Env-C 303.05.
- (c) The department shall provide, upon request, one application form in Microsoft Word® format to the applicant by e-mail or regular mail.
  - (d) The applicant shall complete the application form electronically.

(e) In addition to the printed, signed application form, the applicant shall submit an electronic copy of the completed application form to the NH ELAP.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 303.09 <u>Application Form for Secondary Accreditation</u>. On the application form for secondary accreditation, the applicant shall provide the following information:

- (a) All information required by Env-C 303.02;
- (b) For the applicant's primary accrediting authority, the following:
  - (1) The name, mailing address, and main telephone number of the primary accrediting authority;
  - (2) The name, mailing address, and daytime telephone number and, if available, an e-mail address of an individual at the primary accrediting authority who can be contacted relative to the applicant; and
  - (3) The date the applicant's current primary certification or accreditation will expire; and
- (c) For each other accrediting authority that has accredited the applicant, the following:
  - (1) The name, mailing address, and main telephone number of the accrediting authority;
  - (2) The name, mailing address, and daytime telephone number and, if available, an e-mail address of an individual at the accrediting authority who can be contacted relative to the applicant; and
  - (3) The date the applicant's current certification or accreditation from the authority will expire.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

- Env-C 303.10 <u>Additional Information Required for Secondary Accreditation Applications</u>. The applicant shall provide the following to the department with the completed application form:
  - (a) All information required by Env-C 303.04; and
- (b) A copy of the most recent and valid certificate and analyte list from the primary accrediting authority or authorities.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

- Env-C 303.11 <u>Out-of-state Laboratories Applying for Accreditation with NH ELAP as a Secondary Accrediting Authority.</u>
- (a) Any laboratory located outside of New Hampshire applying for accreditation with NH ELAP as a secondary accrediting authority shall submit a complete application as specified in Env-C 303.09.
  - (b) The laboratory shall also submit the following with the application:
    - (1) A copy of the certificate and analyte list(s) from its primary accrediting authority with specific accredited analytes and methods noted and the expiration date clearly indicated;
    - (2) A copy of all on-site assessment report(s) not more than 2 years old, used to obtain the accreditation for each area accreditation is requested; and

- (3) A copy of the response to each on-site assessment report provided pursuant to (2), above.
- (c) NH ELAP shall recognize the analyte-specific accreditation granted by another primary accrediting authority for the same matrix-analyte-method analyses that NH ELAP accredits laboratories as a primary accrediting authority.
- (d) NH ELAP shall recognize the accreditation for groups of analytes granted by another primary accrediting authority only if the group is identical to a group that would be accredited by the NH ELAP as the primary accrediting authority.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

# Env-C 303.12 Out-of-state Laboratories Applying for Accreditation with NH ELAP as a Primary Accrediting Authority.

- (a) An out-of-state laboratory may request NH ELAP to be a primary accrediting authority only if:
  - (1) There is no NELAC-approved accrediting authority in the state or province in which the laboratory is located; or
  - (2) The primary accrediting authority in the state or province in which the laboratory is located does not offer the fields of accreditation sought by the laboratory.
- (b) Before applying for accreditation with NH ELAP as a primary accrediting authority, the out-of-state laboratory shall request in writing, by registered mail, an application from NH ELAP.
- (c) The request for the application shall be made by the laboratory's responsible party of record or quality assurance officer.
  - (d) The department shall process requests for applications in the order received by the NH ELAP.
  - (e) The program manager shall maintain a list of applicants in the order described in (d), above.
- (f) Any laboratory located outside of New Hampshire applying for accreditation with NH ELAP as a primary accrediting authority shall apply as specified in Env-C 303.01 through Env-C 303.07.

Source. #9134, eff 4-19-08

#### Env-C 303.13 Application Processing.

- (a) The application shall not be processed until a complete application is received.
- (b) Subject to (e) and (f), below, if the application is not complete when filed, the department shall notify the applicant in writing of what is needed to complete the application.
- (c) Upon notifying an applicant that the application is incomplete, the department shall suspend further processing of the application pending receipt of the information needed to complete the application.
- (d) No portion of the time between the date a notice of incompleteness is provided and the date the applicant responds shall be included in computing the time limits for processing the application specified in RSA 541-A:29.
- (e) The department shall notify the applicant by telephone in lieu of providing a written notice of incompleteness if:
  - (1) The anticipated time required of the applicant to correct the deficiency is less than the anticipated time required of the department to notify the applicant in writing; and

- (2) The department is able to contact the applicant by telephone.
- (f) If the department provides notice of incompleteness pursuant to (e) above, the department shall specify a reasonable time period for completing the application in the verbal notice, after which time written notice will be sent by the department in accordance with (b) above, if no response from the applicant is received by the department.
- (g) Upon determining that an application is complete, the department shall review it and proceed to make a decision on the application.

Source. #9134, eff 4-19-08

Env-C 303.14 <u>Decision on Application</u>. The department shall approve an application for accreditation only if:

- (a) The applicant has submitted a complete application as specified in Env-C 303.02 for primary accreditation or Env-C 303.09 for secondary accreditation, as applicable;
  - (b) The applicant has paid all additional reimbursable expenses pursuant to Env-C 303.06;
- (c) The criteria listed in Env-C 303.15 for primary accreditation or Env-C 303.16 for secondary accreditation, as applicable, have been met; and
  - (d) No grounds exist on which the accreditation would be denied, suspended, or revoked.

Source. #9134, eff 4-19-08

Env-C 303.15 Basis for Primary Accreditation.

- (a) In determining whether to approve an application for primary accreditation, the department shall consider:
  - (1) The results of successful participation in a proficiency test (PT) study as specified in chapter 2, appendix C of the 2003 NELAC standards; and
  - (2) The results of a routine assessment, follow-up assessment, or unannounced assessment as specified in Env-C 311.
- (b) Accreditation status shall be either "Accredited" for a laboratory meeting the 2003 NELAC standards, or "Not Accredited" for a laboratory not meeting the 2003 NELAC standards, based upon the criteria specified in (a), above.
- (c) If a laboratory completes all of the requirements for accreditation except for an on-site assessment because NH ELAP is unable to schedule the assessment and a third-party assessor as provided in Env-C 311.05 is not available, NH ELAP shall issue an interim accreditation. Such interim accreditation shall allow the 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 12 months.

Source. #9134, eff 4-19-08

Env-C 303.16 Basis for Secondary Accreditation.

- (a) In determining whether to approve an application for secondary accreditation, the department shall consider:
  - (1) The matrix and method or technology and analyte or analyte group listed on the analyte list of the primary accrediting authority;

- (2) The matrix and method or technology and analyte or analyte group combination that is available in the NH ELAP's fields of accreditation; and
- (3) The accreditation status information from the primary accrediting authority.
- (b) Accreditation status shall be either "Accredited" for a laboratory meeting the 2003 NELAC standards, or "Not Accredited" for a laboratory not meeting the 2003 NELAC standards, based upon the criteria specified in (a), above.

Source. #9134, eff 4-19-08

#### Env-C 303.17 Application for Renewal.

- (a) Any accredited laboratory wishing to renew its accreditation shall submit an application for renewal to the department in accordance with this section.
  - (b) The application for renewal of primary accreditation shall:
    - (1) Comply with Env-C 302.03; and
    - (2) Be submitted to NH ELAP:
      - a. Not later than 30 calendar days prior to the expiration date of the current accreditation if a routine assessment is not scheduled; or
      - b. Not later than 120 calendar days prior to the expiration date of the current accreditation if a routine assessment is scheduled.
  - (c) The application for renewal of secondary accreditation shall:
    - (1) Comply with Env-C 303.08; and
    - (2) Be submitted to NH ELAP not later than 30 calendar days prior to the expiration date of the current accreditation.

Source. #9134, eff 4-19-08

# PART Env-C 304 PARTICIPATION IN NH ELAP; USE OF NELAC NAME AND LOGO

Env-C 304.01 Issuance of Certificates and Analyte Lists.

- (a) Any accreditation issued by NH ELAP pursuant to Env-C 303 shall be valid for one year from the date of initial issuance unless suspended, revoked, or replaced in accordance with these rules.
- (b) A certificate or analyte list issued as a replacement certificate or analyte list shall be valid until the expiration date of the certificate or analyte list that it is replacing.
  - (c) Each certificate shall include the following:
    - (1) The name and address of the laboratory;
    - (2) A statement that continued accreditation depends on successful participation in NELAP;
    - (3) A statement requesting that customers verify the laboratory's accreditation status with NH ELAP;
    - (4) A certificate number; and
    - (5) An effective date and expiration date of the certificate.

- (d) The certificate shall be accompanied by one or more lists of the analytes for which the laboratory is accredited.
- (e) NH ELAP shall issue a new analyte list whenever changes in the laboratory's fields of accreditation are approved.
  - (f) The analyte list shall:
    - (1) List the name, address, and telephone number of the laboratory;
    - (2) Have each page numbered with the total number of pages indicated;
    - (3) Specify a unique analyte list number;
    - (4) List the effective date and expiration date of the analyte list; and
    - (5) List the matrix, method, or technology and analyte(s) or analyte group(s) for which accreditation is granted.
- (g) The laboratory shall post or display its most recent certificate and analyte list in a location within the laboratory where clients or potential clients visiting the laboratory would be most likely to see them.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### Env-C 304.02 Withdrawal from Accreditation; Return of Certificate and Analyte Lists.

- (a) An accredited laboratory that wishes to withdraw from the NH ELAP shall so inform the program manager in writing no later than 45 days prior to the end of the laboratory's accreditation year.
- (b) A laboratory accredited by NH ELAP shall return its original certificate and analyte list(s) to NH ELAP if:
  - (1) Accreditation is totally suspended, revoked, or denied;
  - (2) The request for accreditation is voluntarily withdrawn; or
  - (3) When a new analyte list is issued by another primary accrediting authority.
  - (c) A laboratory accredited by NH ELAP shall return its original analyte list(s) to NH ELAP if:
    - (1) Accreditation is partially suspended, revoked or denied; or
    - (2) Accreditation status is updated as a result of PT results.
  - (d) The laboratory shall not return expired certificate(s) or analyte list(s).

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

New. #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

# Env-C 304.03 <u>Transferring Accreditation</u>.

- (a) A laboratory's accreditation shall not be directly transferable when ownership, location, analytical instrumentation, the principal officers, or the local management of the laboratory changes.
- (b) Any change in ownership shall meet the conditions specified in section 4.1.8 of chapter 4 of the 2003 NELAC standards.
- (c) The laboratory director shall inform the department in writing within 30 calendar days as to whether the changes as specified in (a), above, will affect the day-to-day operations of the laboratory and, if so, how the day-to-day operations will be affected.
- (d) The laboratory shall reapply for accreditation as specified in Env-C 303 within 30 calendar days of the change if the change will affect the day-to-day operations of the laboratory.
- (e) NH ELAP shall reissue a new certificate and analyte list within 14 calendar days of receiving the application if there is a change in name or location. The expiration date of the new certificate and analyte list shall be the same as the expiration date on the certificate and analyte list before the change.
- (f) The department shall conduct an on-site assessment of a laboratory having NH ELAP as its primary accrediting authority within 60 calendar days if changes reported by the laboratory affect the day-to-day operations of the laboratory.
- (g) Before appointing a new technical director, the laboratory shall inform the department in writing of its intent to appoint a new technical director.
- (h) The notice provided pursuant to (g), above, shall include a copy of the college transcript of the proposed new technical director.
- (i) The proposed technical director shall meet the educational and experience requirement of 4.1.1.2 of the 2003 NELAC standards.
- (j) If a technical director is appointed by the laboratory without approval by the department and it is determined that the new technical director does not meet the requirements of 4.1.1.2 of the 2003 NELAC standards, accreditation of the affected area(s) shall be suspended based on Env-C 312.02 (a)(4).

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

# Env-C 304.04 Use of NELAC/NELAP Name and Logo.

- (a) An accredited laboratory shall provide only true, complete, and not misleading information regarding its NH ELAP fields of accreditation, methods, analytes, or accreditation status on any written, printed, or electronic document, including laboratory test reports, catalogs, advertising, business solicitations, quotations, or other materials, or on a website.
- (b) When a NH ELAP laboratory uses the NH ELAP name and/or the NELAC/NELAP logo on a website or in written, printed, or electronic laboratory test reports, catalogs, advertising, business solicitations, quotations, or other materials, the laboratory shall include the phrase "NELAP-accredited" and the laboratory's NH ELAP assigned 4-digit identification number.
- (c) The accredited laboratory shall use its NH ELAP certificate and analyte list(s), NH ELAP accreditation status, and the NELAC/NELAP logo only to show compliance with the 2003 NELAC standards.

- (d) A laboratory accredited by NH ELAP shall not use its NH ELAP certificate, NH ELAP accreditation status, or the NELAC/NELAP logo to imply endorsement by the accrediting authority.
- (e) If accreditation is denied, suspended, revoked, or withdrawn, the laboratory shall discontinue the use of all written, printed, or electronic laboratory test reports, catalogs, advertising, business solicitations, quotations, or other materials that contain any reference to the laboratory's past NH ELAP accreditation for the affected analyses, and shall delete any reference to the past NH ELAP accreditation for the affected analyses from its website.
- (f) If accreditation is suspended, revoked, or withdrawn, the laboratory shall return all copies and original certificates and analyte lists to NH ELAP as specified in Env-C 304.02(b) and (c).

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

# Env-C 304.05 Providing Information on Accreditation Status.

- (a) A laboratory shall inform all prospective New Hampshire clients of which analytes or categories it is accredited by NH ELAP to test by one of the following methods:
  - (1) Providing a copy of the laboratory's current certificate and analyte list(s) to prospective clients with all sample kits;
  - (2) Providing a list of tests for which the laboratory is accredited with all sample kits;
  - (3) Using an asterisk or other mark with the appropriate legend to indicate accreditation status next to the test on a price list or other literature supplied with all sample kits; or
  - (4) Providing the address of a website where the information is located.
- (b) The list of tests for which the laboratory is accredited by the NH ELAP to perform shall be indicated on or with the test report by one of the following:
  - (1) Using an asterisk or other mark next to the result or the name of the test with the appropriate legend to indicate accreditation status on the face of the report;
  - (2) Providing a copy of the laboratory's current certificate and analyte list with all test results;
  - (3) Providing a list of tests for which the laboratory is accredited with all test results; or
  - (4) Providing the address of a website where the information is located.
  - (c) A laboratory may choose to inform repeat clients of changes in accreditation status by:
    - (1) Sending a written notice;
    - (2) Sending a copy of the new certificate or analyte list, or both, at the time of the change instead of informing the client each time a sample kit is sent; or
    - (3) Providing the address of a website where the information is located.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### PART Env-C 305 REQUIREMENTS FOR ACCREDITATION IN CHEMISTRY

Env-C 305.01 <u>Accreditation Requirements</u>. To be accredited for chemistry, the laboratory shall meet all requirements specified in Env-C 305.02 through Env-C 305.12.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### Env-C 305.02 Personnel.

- (a) The laboratory shall have a responsible party of record.
- (b) The laboratory shall have one or more technical directors.
- (c) A responsible party of record or technical director shall be a full-time laboratory staff member and shall conduct actual day-to-day supervision of laboratory procedures and test result reporting.
  - (d) The duties of a responsible party of record or technical director shall include, but not be limited to:
    - (1) Monitoring standards of performance in quality control and quality assurance;
    - (2) Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data:
    - (3) Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and
    - (4) Providing educational direction to laboratory staff.
- (e) An individual shall not be the responsible party of record or technical director of more than one NELAP accredited environmental laboratory without written notification to the primary accrediting authority.
- (f) A responsible party of record or technical director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of responsible party of record or technical director to temporarily perform this function.
- (g) If a responsible party of record or technical director is absent exceeding 65 consecutive calendar days, the accrediting authority shall be notified in writing by the responsible party of record, the quality assurance officer, or the staff member temporarily performing the function.
- (h) A technical director of an environmental lab engaged in chemical analyses shall meet the following qualifications:
  - (1) A bachelor's degree in chemistry, environmental sciences, biological sciences, physical sciences, or engineering, with at least 24 college semester credit hours in chemistry;
  - (2) At least 2 years experience in the environmental analysis of representative inorganic or organic analytes for which the laboratory is seeking approval;

- (3) If the accredited laboratory is limited to inorganic chemical analyses, other than metals analysis, the educational requirement shall be at least an earned associate's degree in chemical, physical, or environmental sciences or 2 years of equivalent and successful college education with a minimum of 16 college semester credit hours in chemistry;
- (4) A full time employee of a drinking water or sewage treatment facility who holds an operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit;
- (5) A full time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit; and
- (6) An individual who does not meet the educational requirements set forth in (1) or (3), above, but possesses the requisite experience set forth in (2), (4), or (5), above, shall qualify as a technical director of a laboratory, subject to the conditions and requirements of section 4.1.1 of the 2003 NELAC standards.
- (i) A master's or doctoral degree may be substituted for one year of experience.
- (j) A laboratory shall have a quality assurance officer or person designated as accountable for data quality as specified in section 5.4.1.5.i of the 2003 NELAC standards.
- (k) The laboratory shall also meet all organizational and personnel requirements specified in section 5.4.1.5 and section 5.5.2 of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.03 <u>Laboratory Facilities</u>. The laboratory facilities shall meet the requirements as specified in section 5.5.3 of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.04 <u>Laboratory Equipment and Reference Materials</u>. The laboratory equipment and reference materials shall meet the requirements as specified in section 5.5.5 of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

New. #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.05 <u>Analytical Methodology</u>. The laboratory shall meet the analytical methodology requirements as specified in sections 5.5.4.1, 5.5.4.2.1.c, and 5.5.4.2.2 and chapter 5, appendix E of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.06 <u>Sample Collection, Handling, and Preservation</u>. The laboratory shall meet the sample collection, handling and preservation requirements as specified in section 5.5.8 of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

# Env-C 305.07 Quality Assurance Requirements.

- (a) The laboratory shall develop and implement a quality system, in accordance with chapter 5 of the 2003 NELAC standards, incorporating the essential quality control requirements specified in chapter 5, appendix D, section D.1 of the 2003 NELAC standards.
- (b) If the quality control requirements of chapter 5, appendix D, section D.1 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### Env-C 305.08 Calibration of Instruments.

- (a) The laboratory shall meet the instrument calibration requirements as specified in section 5.5.6 of the 2003 NELAC standards.
- (b) If the requirements in section 5.5.6 of the 2003 NELAC standards and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.09 <u>Records and Data Reporting</u>. The laboratory shall meet the records and data reporting requirements as specified in sections 4.3.3, 5.4.12 and 5.5.10.1 of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.10 <u>Action Response to Laboratory Results for Compliance Purpose Samples</u>. When action response as required in Env-Ws 322.11 is a designated laboratory responsibility, the proper authorities shall be promptly notified of exceedence results as required by Env-Ws 322.11(b)(3).

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.11 <u>Outside Support Services and Supplies</u>. The laboratory shall meet the outside support and supplies requirements as specified in section 5.4.6 of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 305.12 <u>Complaints</u>. The laboratory shall meet the requirements for handling complaints as specified in section 5.4.8 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

#### PART Env-C 306 REQUIREMENTS FOR ACCREDITATION IN MICROBIOLOGY

Env-C 306.01 <u>Accreditation Requirements</u>. To be accredited for microbiology, the laboratory shall meet all requirements specified in Env-C 306.02 through Env-C 306.11.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 306.02 Personnel.

- (a) The laboratory shall have a responsible party of record.
- (b) The laboratory shall have one or more technical directors.

- (c) A responsible party of record or technical director shall be a full-time laboratory staff member and shall conduct actual day-to-day supervision of laboratory procedures and test result reporting.
  - (d) The duties of a responsible party of record or technical director shall include, but not be limited to:
    - (1) Monitoring standards of performance in quality control and quality assurance;
    - (2) Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data;
    - (3) Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and
    - (4) Providing educational direction to laboratory staff.
- (e) An individual shall not be the responsible party of record or technical director of more than one NELAP approved environmental laboratory without written notification to the primary accrediting authority.
- (f) A responsible party of record or technical director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of responsible party of record or technical director to temporarily perform this function.
- (g) If a responsible party of record or technical director is absent exceeding 65 consecutive calendar days, the accrediting authority shall be notified in writing by the responsible party of record, the quality assurance officer, or the staff member temporarily performing the function.
- (h) A technical director engaged in microbiological or biological analyses shall meet the following qualifications:
  - (1) A bachelor's 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;
  - (2) At least 2 years experience in the environmental analysis of representative analytes for which the laboratory is seeking approval;
  - (3) An employee of a laboratory engaged in microbiological analyses limited to total coliform, fecal coliform, and standard plate count with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of 4 college semester credit hours in general microbiology and one year experience, shall be deemed to meet the educational and experience requirements of the technical director;
  - (4) A full time employee of a drinking water or sewage treatment facility who holds a valid plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements of the technical director within the scope of that facility's regulatory permit;
  - (5) A full time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision shall be deemed to meet the educational and experience requirements of the technical director within the scope of that facility's regulatory permit; and
  - (6) An individual who does not meet the educational requirements set forth in (1) or (3), above, but possesses the requisite experience set forth in (2), (4), or (5), above, shall qualify as a technical director of a laboratory, subject to the conditions and requirements of section 4.1.1 of the 2003 NELAC standards.
  - (i) A master's or doctoral degree may be substituted for one year of experience.

- (j) College education that includes at least 2 years of equivalent and successful education, including the microbiology requirement, may be substituted for the associate's degree.
- (k) A laboratory shall have a quality assurance officer or person designated as accountable for data quality as specified in section 5.4.1.5.i of the 2003 NELAC standards.
- (l) The laboratory shall also meet all organizational and personnel requirements specified in section 5.4.1.5 and section 5.5.2 of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 306.03 <u>Laboratory Facilities</u>. The laboratory facilities shall meet the requirements specified in section 5.5.3 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 306.04 <u>Laboratory Equipment and Supplies</u>. The laboratory equipment and supplies shall meet the requirements specified in sections 5.5.5 and 5.4.6 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 306.05 <u>Analytical Methodology</u>. The laboratory analytical methodology shall meet the requirements as specified in sections 5.5.4.1, 5.5.4.2.1.c, and 5.5.4.2.2 and chapter 5, appendix E of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 306.06 <u>Sample Collection, Handling, and Preservation</u>. The laboratory shall meet the sample collection, handling, and preservation requirements as specified in section 5.5.8 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 306.07 Quality Assurance Requirements.

- (a) The laboratory shall develop and implement a quality system, in accordance with chapter 5 of the 2003 NELAC standards, incorporating the essential quality control requirements specified in chapter 5, appendix D, section D.3 of the 2003 NELAC standards.
- (b) If the quality control requirements of chapter 5, appendix D, section D.3 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Source. #9134, eff 4-19-08

Env-C 306.08 <u>Records and Data Reporting</u>. The laboratory shall meet the records and data reporting requirements as specified in sections 4.3.3, 5.4.12 and 5.5.10.1 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 306.09 <u>Action Response to Laboratory Results</u>. When action response as required in Env-Ws 322.11 is a designated laboratory responsibility, the proper authorities shall be promptly notified of exceedence results as required by Env-Ws 322.11(b)(3).

Env-C 306.10 <u>Outside Support Services and Supplies</u>. The laboratory shall meet the outside support services and supplies requirements as specified in section 5.4.6 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 306.11 <u>Complaints</u>. The laboratory shall meet the requirements for handling complaints as specified in section 5.4.8 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

#### PART Env-C 307 REQUIREMENTS FOR ACCREDITATION FOR RADIOCHEMISTRY

Env-C 307.01 <u>Accreditation Requirements</u>. To be accredited for radiochemistry, the laboratory shall meet all requirements specified in Env-C 307.02 through Env-C 307.12.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 307.02 Personnel.

- (a) The laboratory shall have a responsible party of record.
- (b) The laboratory shall have one or more technical directors.
- (c) A responsible party of record or technical director shall be a full-time laboratory staff member and shall conduct actual day-to-day supervision of laboratory procedures and test result reporting.
  - (d) The duties of a responsible party of record or technical director shall include, but not be limited to:
    - (1) Monitoring standards of performance in quality control and quality assurance;
    - (2) Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data;
    - (3) Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and
    - (4) Providing educational direction to laboratory staff.
- (e) An individual shall not be the responsible party of record or technical director of more than one NELAP approved environmental laboratory without written notification to the primary accrediting authority.
- (f) A responsible party of record or technical director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of responsible party of record to temporarily perform this function.
- (g) If a responsible party of record or technical director is absent exceeding 65 consecutive calendar days, the accrediting authority shall be notified in writing by the responsible party of record, the quality assurance officer, or the staff member temporarily performing the function.
- (h) A technical director of an environmental lab engaged in radiochemical analyses shall meet the following qualifications:

- (1) A bachelor's degree in chemistry, physics, or engineering, with at least 24 college semester credit hours in chemistry;
- (2) At least 2 years experience in the radiological analysis of environmental samples;
- (3) If the accredited laboratory is engaged in the examination of radon in air only, the educational requirement shall be at least an associate's degree or 2 years of college with at least one year of experience in the measurement of radon and/or radon progeny;
- (4) A full time employee of a drinking water or sewage treatment facility who holds a valid plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements of the technical director within the scope of that facility's regulatory permit;
- (5) A full time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision shall be deemed to meet the educational and experience requirements of the technical director within the scope of that facility's regulatory permit; and
- (6) An individual who does not meet the educational requirements set forth in (1) or (3), above, but possesses the requisite experience set forth in (2), (4), or (5), above, shall qualify as a technical director of a laboratory, subject to the conditions and requirements of section 4.1.1 of the 2003 NELAC standards.
- (i) A master's or doctoral degree may be substituted for one year of experience.
- (j) A laboratory shall have a quality assurance officer or person designated as accountable for data quality as specified in section 5.4.1.5.i of the 2003 NELAC standards.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 307.03 <u>Laboratory Facilities</u>. The laboratory facilities shall meet the requirements as specified in section 5.5.3 of the 2003 NELAC standards.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 307.04 <u>Laboratory Equipment and Reference Materials</u>. The laboratory equipment and reference materials shall meet the requirements as specified in section 5.5.5 of the 2003 NELAC standards.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 307.05 <u>Analytical Methodology</u>. The laboratory shall meet the analytical methodology requirements as specified in sections 5.5.4.1, 5.5.4.2.1.c, and 5.5.4.2.2 and chapter 5, appendix E of the 2003 NELAC standards.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 307.06 <u>Sample Collection, Handling, and Preservation</u>. The laboratory shall meet the sample collection, handling, and preservation requirements as specified in section 5.5.8 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 307.07 Quality Assurance Requirements.

- (a) The laboratory shall develop and implement a quality system, in accordance with chapter 5 of the 2003 NELAC standards, incorporating the essential quality control requirements specified in chapter 5, appendix D, section D.4 of the 2003 NELAC standards.
- (b) If the quality control requirements of chapter 5, appendix D, section D.4 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Source. #9134, eff 4-19-08

Env-C 307.08 Calibration of Instruments.

- (a) The laboratory shall meet the instrument calibration requirements as specified in section 5.5.6 of the 2003 NELAC standards.
- (b) If the requirements in section 5.5.6 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Source. #9134, eff 4-19-08

Env-C 307.09 <u>Records and Data Reporting</u>. The laboratory shall meet the records and data reporting requirements as specified in sections 4.3.3, 5.4.12 and 5.5.10.1 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 307.10 <u>Action Response to Laboratory Results for Compliance Purpose Samples</u>. When action response as required in Env-Ws 322.11 is a designated laboratory responsibility, the proper authorities shall be promptly notified of exceedence results as required by Env-Ws 322.11(b)(3).

Source. #9134, eff 4-19-08

Env-C 307.11 <u>Outside Support Services and Supplies</u>. The laboratory shall meet the outside support and supply requirements as specified in section 5.4.6 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 307.12 <u>Complaints</u>. The laboratory shall meet the requirements for handling complaints as specified in section 5.4.8 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

PART Env-C 308 REQUIREMENTS FOR ACCREDITATION IN WHOLE EFFLUENT TOXICITY

Env-C 308.01 <u>Accreditation Requirements</u>. To be accredited for whole effluent toxicity, the laboratory shall meet all requirements specified in Env-C 308.02 through Env-C 308.12.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 308.02 Personnel.

- (a) The laboratory shall have a responsible party of record.
- (b) The laboratory shall have one or more technical directors.
- (c) A responsible party of record or technical director shall be a full time laboratory staff member and shall supervise laboratory procedures and test result reporting.
  - (d) The duties of a responsible party of record or technical director shall include, but not be limited to:
    - (1) Monitoring standards of performance in quality control and quality assurance;
    - (2) Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data:
    - (3) Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and
    - (4) Providing educational direction to laboratory staff.
- (e) An individual shall not be the responsible party of record or technical director of more than one NELAP accredited environmental laboratory without written notification to the primary accrediting authority.
- (f) A responsible party of record or technical director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of responsible party of record or technical director to temporarily perform this function.
- (g) If a responsible party of record or technical director is absent exceeding 65 consecutive calendar days, the accrediting authority shall be notified in writing by the responsible party of record, the quality assurance officer, or the staff member temporarily performing the function.
- (h) A technical director of an environmental lab engaged in whole effluent toxicity analyses shall meet the following qualifications:
  - (1) A bachelor's degree in chemistry, environmental sciences, biological sciences, physical sciences, or engineering, with at least 24 college semester credit hours in chemistry;
  - (2) At least 2 years experience in the environmental analysis of representative inorganic or organic analytes for which the laboratory is seeking approval;
  - (3) If the accredited laboratory is limited to inorganic chemical analyses, other than metals analysis, the educational requirement shall be at least an earned associate's degree in chemical, physical, or environmental sciences or 2 years of equivalent and successful college education with a minimum of 16 college semester credit hours in chemistry;
  - (4) A full time employee of a drinking water or sewage treatment facility who holds an operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements of the technical director within the scope of that facility's regulatory permit;
  - (5) A full time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision shall be deemed to meet the educational and experience requirements of technical director within the scope of that facility's regulatory permit; and
  - (6) An individual who does not meet the educational requirements set forth in (1) or (3), above, but possesses the requisite experience set forth (2), (4), or (5), above, shall qualify as a technical director of a laboratory, subject to the conditions and requirements of section 4.1.1 of the 2003 NELAC standards.

- (i) A master's or doctoral degree may be substituted for one year of experience.
- (j) A laboratory shall have a quality assurance officer or person designated as accountable for data quality as specified in section 5.4.1.5.i of the 2003 NELAC standards.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08; ss by #9134, eff 4-19-08

Env-C 308.03 <u>Laboratory Facilities</u>. The laboratory facilities shall meet the requirements as specified in section 5.5.3 of the 2003 NELAC standards.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 308.04 <u>Laboratory Equipment and Reference Materials</u>. The laboratory equipment and reference materials shall meet the requirements as specified in section 5.5.5 of the 2003 NELAC standards.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

Env-C 308.05 <u>Analytical Methodology</u>. The laboratory shall meet the analytical methodology requirements as specified in sections 5.5.4.1, 5.5.4.2.1.c, and 5.5.4.2.2 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 308.06 <u>Sample Collection, Handling, and Preservation</u>. The laboratory shall meet the sample collection, handling and preservation requirements as specified in 5.5.8 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 308.07 Quality Assurance Requirements.

- (a) The laboratory shall develop and implement a quality system, in accordance with chapter 5 of the 2003 NELAC standards, incorporating the essential quality control requirements specified in chapter 5, appendix D, section D.2 of the 2003 NELAC standards.
- (b) If the quality control requirements of chapter 5, appendix D, section D.2 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Source. #9134, eff 4-19-08

Env-C 308.08 Calibration of Instruments.

- (a) The laboratory shall meet the instrument calibration requirements as specified in section 5.5.6 of the 2003 NELAC standards.
- (b) If the requirements in section 5.5.6 of the 2003 NELAC standards and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Source. #9134, eff 4-19-08

Env-C 308.09 <u>Records and Data Reporting</u>. The laboratory shall meet the records and data reporting requirements as specified in sections 4.3.3, 5.4.12, and 5.5.10.1 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 308.10 <u>Action Response to Laboratory Results for Compliance Purpose Samples</u>. When action response as required in Env-Ws 322.11 is a designated laboratory responsibility, the proper authorities shall be promptly notified of exceedence results as required by Env-Ws 322.11(b)(3).

Source. #9134, eff 4-19-08

Env-C 308.11 <u>Outside Support Services and Supplies</u>. The laboratory shall meet the outside support and supplies requirements as specified in 5.4.6 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

Env-C 308.12 <u>Complaints</u>. The laboratory shall meet the requirements for handling complaints as specified in 5.4.8 of the 2003 NELAC standards.

Source. #9134, eff 4-19-08

#### PART Env-C 309 PROFICIENCY TESTING

Env-C 309.01 Participation in Scheduled and Supplemental Proficiency Testing.

- (a) Laboratories seeking to become accredited or to maintain accreditation shall perform analyses of proficiency testing (PT) samples for each field of accreditation for which NH ELAP accreditation is sought, as described in section 2.1.3 of the 2003 NELAC standards.
- (b) Prior to participating in a PT study, a laboratory shall have an Environmental Protection Agency (EPA) laboratory code, the EPA identification number the laboratory uses when reporting results to a NELAP-approved PT provider. A laboratory without an EPA laboratory code shall apply to the EPA for a code before requesting PT samples from a NELAP-approved PT provider.
- (c) The laboratory seeking or maintaining accreditation shall obtain scheduled and supplemental PT samples that meet the requirements of sections 2.4.1 and 2.7.3.1 of the 2003 NELAC standards from any PT provider as required by section 2.4 of the 2003 NELAC standards.
- (d) Each laboratory seeking or maintaining accreditation shall participate in at least 2 PT studies per year provided by a PT Provider as required by section 2.4 of the 2003 NELAC standards.
- (e) The laboratory shall successfully participate annually in at least one PT study for each drinking water method and analyte for which accreditation is sought.
- (f) Subsequent PT studies for initial or continuing accreditation shall be conducted in accordance with section 2.7.2 of the 2003 NELAC standards.
- (g) The laboratory's management and all analysts shall handle all PT samples in the same manner as client samples.
- (h) The laboratory shall use the same staff, procedures, equipment, facilities, and frequency of analysis for PT samples as for client samples.
- (i) There shall be at least 15 calendar days between the close of one study and the shipment of any subsequent study, whether scheduled or supplemental.
  - (j) Failure to meet the schedule specified in (f), above, shall be regarded as a failed study.
- (k) A failed study shall be counted as an attempted study for purposes of determining compliance with (q) or (r), below.
  - (l) An analyst employed at more than one laboratory shall:

- (1) Before analyzing any PT sample, inform the NH ELAP, in writing, that the analyst is employed at more than one laboratory;
- (2) Declare to the NH ELAP the date on which each laboratory plans to analyze the PT sample;
- (3) Analyze the PT sample in only one laboratory; and
- (4) Not analyze any PT sample for that round of testing after analyzing the first PT sample.
- (m) A laboratory shall not send any PT sample or portion of a PT sample to another laboratory for analysis or knowingly receive any PT sample or portion of a PT sample from another laboratory for analysis.
- (n) No personnel of an accredited laboratory or a laboratory seeking accreditation shall communicate with or otherwise attempt to exchange any information regarding PT sample results with anyone from another laboratory.
- (o) No personnel of an accredited laboratory or a laboratory seeking accreditation shall attempt to obtain the assigned value of any PT sample from the PT provider.
- (p) A laboratory may participate in a supplemental study for analyses missed or for meeting the PT requirements for a new analysis as allowed in section 2.7.3 of the 2003 NELAC standards.
- (q) A laboratory which seeks accreditation for a field of accreditation for which it has not been previously accredited shall successfully complete 2 PT studies for each requested field of accreditation out of the most recent 3 rounds attempted within the last 18 months.
- (r) In order to maintain accreditation, an accredited laboratory shall maintain a history of at least 2 successful PT studies out of the most recent 3 PT studies attempted within the last 18 months.
  - (s) The results of supplemental studies shall be included in (q) and (r) above.
- (t) A laboratory may withdraw from a PT study for an analyte(s) or for the entire study if the laboratory notifies both the PT provider and the NH ELAP before the closing date of the PT study. Such withdrawal shall not exempt the laboratory from participating in the semiannual PT study schedule.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### Env-C 309.02 Reporting of PT Study Results.

- (a) The laboratory shall analyze the samples and return the results to the PT study provider for scoring no later than 45 calendar days from the date of sample receipt.
- (b) The laboratory shall authorize the PT provider to release all accreditation and remediation results and acceptable/not acceptable status directly to the primary accrediting authority, the proficiency testing oversight body/proficiency test provider accreditor, and the laboratory.
- (c) NH ELAP shall evaluate only results received directly from the PT provider as specified in chapter 2, appendix B, section 5 of the 2003 NELAC standards.
- (d) The laboratory shall be responsible for accurately reporting results and the method and technology used in the analysis to the PT provider.

(e) Errors in reporting the proper method used in the analysis of the PT sample by the laboratory shall be graded as "not acceptable".

Source. #9134, eff 4-19-08

### Env-C 309.03 PT Study Record Retention.

- (a) The laboratory shall maintain copies of all written, printed, and electronic records pertaining to PT sample analyses for 5 years or for as long as is required by the applicable regulatory program, whichever is greater.
  - (b) Records retained pursuant to (a), above, shall include, but not be limited to:
    - (1) Bench sheets;
    - (2) Instrument strip charts or printouts;
    - (3) Data calculations;
    - (4) Data reports; and
    - (5) The PT study report forms used by the laboratory to record PT results.
- (c) The laboratory shall make all records retained available to assessors during on-site assessments of the laboratory.

Source. #9134, eff 4-19-08

#### Env-C 309.04 Proficiency Testing Study Results Review.

- (a) Laboratories shall review all "not acceptable" results received from PT sample analysis and determine what caused the error and what corrective action the laboratory shall take to correct the problem.
- (b) The laboratory shall document in its own records the causes and corrective action the laboratory has taken to correct the problem.
- (c) The laboratory shall submit the results of its own investigation and a corrective action report to NH ELAP within 30 calendar days of receiving the results.
  - (d) Laboratories shall submit a corrective action report before requesting a supplemental PT study.

Source. #9134, eff 4-19-08

# PART Env-C 310 QUALITY SYSTEMS MANUAL AND STANDARD OPERATING PROCEDURES MANUAL

#### Env-C 310.01 Establishment.

- (a) The laboratory shall establish and maintain a quality system, based upon the required elements found in chapter 5 of the 2003 NELAC standards, which shall be appropriate to the type, range, and volume of environmental testing activities it undertakes.
- (b) The elements of this quality system shall be documented in the organization's quality manual as specified in Env-C 310.02
  - (c) The quality systems documentation shall be available for use by all laboratory personnel.
- (d) The laboratory shall define and document its policies and objectives for, and its commitment to, accepted laboratory practices and quality of testing services.

- (e) Laboratory management shall ensure that these policies and objectives are documented in a quality systems manual and communicated to, understood, and implemented by all laboratory personnel by conducting:
  - (1) Internal audits as specified in sections 5.4.13.1 and 5.4.13.2 of the 2003 NELAC standards;
  - (2) Managerial reviews as specified in sections 5.4.14.1 and 5.4.14.2 of the 2003 NELAC standards;
  - (3) Audit reviews as specified in section 5.4.13.3 of the 2003 NELAC standards; and
  - (4) Performance audits as specified in section 5.5.9.1 of the 2003 NELAC standards.
  - (f) The quality assurance officer shall be responsible for maintaining a current quality systems manual.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by 9134, eff 4-19-08

#### Env-C 310.02 Quality Systems Manual.

- (a) The laboratory shall prepare and maintain a quality systems manual that meet the requirements specified in sections 5.4.2.1 and 5.4.2.3 of the 2003 NELAC standards.
- (b) The quality systems manual shall represent the laboratory's normal day to day operating procedures and policies.
- (c) The standard operating procedures may be recorded in a separate document referenced in the quality systems manual.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by 9134, eff 4-19-08

# Env-C 310.03 <u>Standard Operating Procedures</u>.

- (a) The laboratory shall prepare written standard operating procedures (SOPs) for all laboratory activities including, but not limited to, sampling, test methods, instrument operation, data generation, and corrective action.
- (b) The written SOPs shall accurately describe the laboratory's procedure for the analysis of client and quality control samples.
- (c) The written SOPs shall be consistent with EPA approved methodology. If the method allows modifications, the modification used by the laboratory shall be documented in the SOPs.
- (d) The laboratory shall maintain a record of SOP effective dates. A copy of the SOPs and the record of effective dates shall be maintained for the period of time that records of the data generated by those procedures are required to be maintained.

- (e) Copies of each written SOP shall be made available to all personnel engaged in laboratory activities to which a particular SOP is applicable.
- (f) Each written SOP shall bear the signature of the laboratory director, quality assurance officer, and supervisor of the area that prepares the SOP.
- (g) The analyst shall use only the applicable laboratory written SOP for all laboratory activities related to the analysis of compliance samples and any other sample analyses for which accreditation is required.
- (h) The laboratory shall maintain a record of samples not analyzed in accordance with the laboratory SOPs.
  - (i) The record required by (h), above, shall include:
    - (1) Laboratory sample identification traceable to client sample identification;
    - (2) Modification(s) to the SOP;
    - (3) Reason for the modification; and
    - (4) Client authorization or acknowledgment of the modification.

<u>Source.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by 9134, eff 4-19-08

# Env-C 310.04 Corrective Actions.

- (a) The laboratory shall implement general procedures to be followed when departures from documented policies, procedures, and quality control (QC) have taken place.
- (b) The laboratory shall document departures from documented policies, procedures, and QC and the corrective actions taken as specified in section 5.4.10.6 of the 2003 NELAC standards.
- (c) Where possible, the laboratory shall report data only if all QC measures are acceptable as specified in the laboratory's policies, procedure, and QC.
- (d) If a QC measure is found to be a departure from documented policies, procedures, and QC, and the data is to be reported, all samples associated with the failed QC measure shall be reported with appropriate data qualifier(s).

Source. #9134, eff 4-19-08

#### Env-C 310.05 Essential Quality Control Procedures.

- (a) All laboratories shall develop and implement protocols to monitor the QC as specified in section 5.5.9.2(a) of the 2003 NELAC standards.
- (b) All QC measures shall be assessed and evaluated on an on-going basis, and the laboratory's documented QC acceptance criteria shall be used to determine the usability of the data.
- (c) The laboratory shall develop and implement procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist.

Source. #9134, eff 4-19-08

#### PART Env-C 311 ASSESSMENTS

# Env-C 311.01 Routine Assessments.

- (a) When serving as the primary accrediting authority, the department shall not issue an initial accreditation prior to completion of an on-site assessment in accordance with section 3.3 and 4.1.2 of the 2003 NELAC standards.
- (b) In order to maintain NH ELAP accreditation, a laboratory for which NH ELAP is the primary accrediting authority shall be assessed for all fields of accreditation at least once every 2 years.
- (c) A routine assessment shall include review of the application for completeness and a technical review of the application, quality systems manual, SOP, and any other document submitted with the application.
- (d) Laboratory personnel shall allow duly authorized employees of the department to enter the premises of any laboratory accredited under these rules during the laboratory's normal business hours to determine compliance with the rules and with chapter 5 of the 2003 NELAC standards.
- (e) Assessors shall have access to interview any and all staff engaged in activities related to the areas for which the laboratory requests accreditation.
- (f) Arrangements for an assessment shall be made between the program manager and the responsible party of record.
- (g) Accreditation or renewal of laboratory accreditation shall be denied for refusing to allow an announced on-site assessment.
- (h) The NH ELAP assessment team shall use the 2003 NELAC approved checklist(s) and technical checklists prepared by NH ELAP to conduct the assessment.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

New. #7126, eff 10-29-99; ss by #9134, eff 4-19-08

# Env-C 311.02 <u>Unannounced Assessments</u>.

- (a) NH ELAP shall conduct an unannounced assessment of a laboratory for which it is the primary accrediting authority if the program manager receives a written complaint or other credible information indicating that:
  - (1) The laboratory is engaged in an improper, illegal, or deceptive practice; or
  - (2) Laboratory records could be destroyed or altered if prior notice is given.
  - (b) An unannounced assessment shall be conducted during the laboratory's normal business hours.
- (c) The NH ELAP shall use either a 2003 NELAC approved checklist or a checklist prepared by the assessor to evaluate the merits of the information or complaints received by the program manager that were relied upon to justify an unannounced assessment.
- (d) Assessments conducted to confirm that corrective actions were implemented after a previous assessment also shall be unannounced.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

# Env-C 311.03 Follow-up Assessments.

- (a) The NH ELAP shall conduct a follow-up assessment if:
  - (1) The deficiencies noted during a routine assessment are so numerous or serious that the laboratory no longer meets the requirements for accreditation of the laboratory in part or in whole;
  - (2) The laboratory's responses to a previous on-site assessment report and the follow-up assessment report were inadequate; or
  - (3) Any deficiency noted during a routine assessment was the same as a deficiency that had been noted during any previous assessment.
- (b) A follow-up assessment shall be completed and reported within 30 calendar days after receipt of the laboratory's corrective action plan if the deficiencies are of such severity as to possibly warrant revoking, suspending or withholding of the laboratory's accreditation.
- (c) A follow-up assessment to examine the laboratory facilities, records, and personnel shall take place in order to determine the merits of a formal appeal filed by the laboratory.
- (d) The NH ELAP shall use the 2003 NELAC approved checklist(s) and technical checklists prepared by NH ELAP to conduct the assessment.
- (e) The laboratory may request that follow-up assessments be canceled by withdrawing the request for accreditation for the affected field of accreditation.

#### Source. #9134, eff 4-19-08

#### Env-C 311.04 Results of the Assessment.

- (a) The accrediting authority shall issue an assessment report in both hard copy and electronic copy in Microsoft Word® format to the laboratory within 30 calendar days of the on-site assessment.
- (b) If deficiencies are identified in the assessment report, the laboratory shall, within 30 calendar days of receiving the assessment report, prepare and submit to the department a corrective action report that:
  - (1) Explains how each deficiency has been corrected or will be corrected; and
  - (2) Includes supporting documentation, where possible, to show how each deficiency was corrected or will be corrected.
- (c) The laboratory shall submit the corrective action report required by (b), above, in both hard copy format and electronic format, using Microsoft Word®, WordPerfect®, Excel®, or Quattro Pro® format.
- (d) Within 30 calendar days of receipt of the corrective action report, the NH ELAP shall inform the laboratory in writing if the report meets the 2003 NELAC standards or if the report, or a portion of the report, does not meet the 2003 NELAC standards.
- (e) The laboratory shall have 30 calendar days to submit a revised corrective action report if the report, or a portion thereof, is unacceptable.

(f) The results of any assessment, along with PT sample results and information submitted with the application, shall be used to determine whether accreditation will be granted, renewed, or denied.

Source. #9134, eff 4-19-08

### Env-C 311.05 Third Party Assessors.

- (a) The NH ELAP shall require a laboratory to use a third party assessor if:
  - (1) Based on available resources, NH ELAP will not be able to schedule an initial or routine 2-year on-site assessment within a reasonable period of time, because of the number and complexity of the field(s) of accreditation for which accreditation is sought; or
  - (2) NH ELAP staff lacks expertise in a field of accreditation requested by the laboratory.
- (b) NH ELAP shall notify the laboratory, in writing, of the need to use a third party assessor at the time the laboratory requests an application for initial accreditation or at the time an accreditation renewal application is sent to a laboratory, as applicable.
  - (c) The responsible party of record for a laboratory that receives a notice pursuant to (b), above, shall:
    - (1) Choose the third party assessor to conduct the on-site assessment from the list of approved third party assessors prepared by NH ELAP pursuant to Env-C 311.06; and
    - (2) Not later than one month prior to the scheduled onsite assessment, inform NH ELAP, in writing, which third party assessor the laboratory has chosen.
- (d) If the responsible party of record fails to comply with (c), above, the program manager shall inform the responsible party of record, in writing, that accreditation shall not be granted or renewed until the requirements of (c) have been met.
- (e) The laboratory shall pay all costs associated with a third party assessment directly to the third party assessor organization.

Source. #9134, eff 4-19-08

### Env-C 311.06 Application for Approval of Third Party Assessor Organizations.

(a) In order to be approved by NH ELAP, a third party assessor organization (TPAO) shall submit an application for approval, in writing, to NH ELAP at the following address:

NH Department of Environmental Services Attn: Program Manager, NH ELAP P.O. Box 95 Concord, N.H. 03302-0095

- (b) The application submitted pursuant to (a), above, shall include the following:
  - (1) The legal name, mailing address, street address, billing address, daytime telephone number, and fax number of the TPAO and, if available, the e-mail address and web site address of the TPAO;
  - (2) Whether the TPAO is a business entity or a government entity;
  - (3) If the TPAO is a business entity, the following:
    - a. The type of business entity, such as corporation, partnership, sole proprietorship, or other and the legal name of the business entity, if other than the legal name of the TPAO;

- b. The date the TPAO registered with the New Hampshire secretary of state;
- c. If the TPAO is a corporation, the date and state of incorporation; and
- d. The name and title of each principal official of the business entity, such as corporate officers or general partners;
- (4) If the TPAO is a governmental entity, the name and primary mailing address of the federal, state, or local agency that owns the laboratory, if different from the information provided pursuant to (b)(1), above;
- (5) The name, daytime telephone number, extension number, if applicable, and e-mail address of the individual at the TPAO who is the contact for purposes of the application;
- (6) The name, title, and qualifications of each individual assessor employed or otherwise used by the TPAO for laboratory accreditation assessments; and
- (7) Documentation that the TPAO meets the criteria specified in Env-C 311.07.

Source. #9134, eff 4-19-08

# Env-C 311.07 Approval of Third Party Assessor Organizations.

- (a) The NH ELAP shall approve a third party assessor organization (TPAO) to conduct accreditation assessments pursuant to Env-C 311.05 if the TPAO:
  - (1) Submits all information required by Env-C 311.07(b);
  - (2) Documents that it meets the requirements of an assessor as specified in section 3.2 of the 2003 NELAC standards;
  - (3) Has conducted at least 4 NELAC assessments using a qualified assessor;
  - (4) Agrees to conduct assessments that meet the assessment procedures as specified in section 3.4, 3.5, 3.6, and 3.7 of the 2003 NELAC standards;
  - (5) Agrees to use the quality systems checklist and technical checklists prepared by NH ELAP to conduct assessments;
  - (6) Agrees to provide to NH ELAP a copy of the checklists used for an assessment with all findings recorded in hard copy and electronic copy in Microsoft Word® format within one calendar week of the on-site assessment closing conference;
  - (7) Agrees to provide a hard copy of all handwritten notes and checklists used to prepare the checklists described in (6), above, above, to NH ELAP; and
  - (8) Agrees to proofread a draft of the on-site assessment report prepared by NH ELAP within 7 calendar days of receiving the report from NH ELAP.
- (b) NH ELAP shall notify an applicant for approval as a TPAO in writing of the approval or denial of its application. If the application is denied, the notice shall specify the reason(s) for the denial.
- (c) Upon being notified of its approval, the TPAO shall enter into a memorandum of understanding with NH ELAP by which it commits to meet the requirements of (a)(4) through (8), above, prior to conducting an accreditation assessment pursuant to Env-C 311.05.
- (d) NH ELAP shall maintain a list of approved TPAO and provide copies of such list upon request to any person.

Source. #9134, eff 4-19-08

# Env-C 311.08 Review of Third Party Assessor Work.

- (a) NH ELAP shall review all work performed by a third party assessor organization (TPAO) to determine compliance with Env-C 300 and the 2003 NELAC standards.
- (b) If the work performed by a TPAO does not comply with Env-C 300 and the 2003 NELAC standards, NH ELAP shall reject the work and:
  - (1) Return any work not in compliance to the TPAO with a written notice identifying the work that is not acceptable; and
  - (2) Inform each laboratory who used the TPAO in writing of any unacceptable work performed by the TPAO.
- (c) The department shall not grant accreditation for any field of accreditation for which the work of the TPAO has been rejected.
- (d) If the TPAO wishes to correct the unacceptable work, the TPAO shall resubmit its work to NH ELAP.
  - (e) NH ELAP shall review any resubmitted work from a TPAO in accordance with this section.

Source. #9134, eff 4-19-08

#### PART Env-C 312 DENIAL; SUSPENSION; REVOCATION

Env-C 312.01 Denial.

- (a) Reasons for NH ELAP to deny an application for initial or renewal accreditation shall include:
  - (1) Failure to submit a completed application within 60 days after notification of apparent errors or omissions:
  - (2) Failure of laboratory staff to meet the personnel qualifications as required by the 2003 NELAC standards including those related to education, training, and experience;
  - (3) Failure to successfully analyze and report proficiency testing samples as required by chapter 2 of the 2003 NELAC standards;
  - (4) 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, as required by Env-C 311.04(b).
  - (5) Failure to implement the corrective actions detailed in the corrective action report as required by Env-C 311.04;
  - (6) Failure to pay required fees;
  - (7) Failure to pass required on-site assessment(s) as specified in Env-C 311.04;
  - (8) Misrepresentation of any material fact pertinent to receiving or maintaining accreditation;
  - (9) Refusal to allow an assessor to enter during normal business hours for an on-site assessment; and
  - (10) Failure to implement a quality system as required by the applicable provision(s) of Env-C 305.07, Env-C 306.07, Env-C 307.07, and Env-C 308.07.

- (b) A laboratory shall have 2 opportunities to correct the deficient area(s) which resulted in a denial of accreditation as specified in Env-C 311.04.
- (c) If the laboratory is not successful in correcting the deficiencies, the laboratory shall wait at least 6 months before again reapplying for accreditation.
- (d) Upon reapplication, the laboratory shall again be responsible for all or part of the fees incurred as part of the application for accreditation.
- (e) A laboratory whose application for initial accreditation has been denied may request reconsideration. Any reconsideration request shall be filed in accordance with Env-C 206.
- (f) No laboratory's application for renewal accreditation shall be denied without opportunity for a hearing in accordance with Env-C 312.04.

<u>Source.</u> #4861, eff 7-6-90; ss by #5564, eff 1-28-93, EXPIRED: 1-28-99

New. #7035, INTERIM, eff 6-25-99, EXPIRES: 10-23-99

<u>New.</u> #7126, eff 10-29-99; ss by 9009, INTERIM, eff 10-29-07, EXPIRES: 4-26-08; ss by #9134, eff 4-19-08

#### Env-C 312.02 Suspension.

- (a) Reasons for NH ELAP to suspend an accreditation shall include:
  - (1) If the primary accrediting authority finds during the on-site assessment that public, safety or health requires emergency action;
  - (2) Failure to notify the primary accrediting authority within 30 calendar days of major changes in:
    - a. Laboratory ownership;
    - b. Location;
    - c. Key personnel named on the application; or
    - d. Analytical instrumentation;
  - (3) Failure to maintain a quality system as defined in Chapter 5 of the 2003 NELAC standards; and
  - (4) Failure of laboratory to employ staff that meet the personnel qualifications for education, training and experience as required by the 2003 NELAC standards.
- (b) A laboratory shall not be required to reapply for accreditation if the cause(s) for suspension are corrected within 6 months.
- (c) A laboratory shall not continue to analyze samples for clients who need analytical results from an accredited laboratory in the field(s) of testing accreditation for which its accreditation has been suspended.
- (d) If the laboratory is unable to correct the reason for the suspension, the laboratory's accreditation shall be revoked in total or in part.
- (e) No laboratory's accreditation shall be suspended without the opportunity for a hearing prior to the suspension as set forth in Env-C 312.04, except as provided in (f), below.

- (f) Accreditation shall be suspended for each affected field of accreditation where the laboratory fails 2 out of the most recent 3 PT studies until the laboratory has successfully participated in 2 out of the 3 most recent PT studies. The laboratory shall not be required to reapply for accreditation if the suspension is for failure on PT studies. The suspension shall take place upon the primary accrediting body's processing of the PT results, without a prior hearing.
  - (g) A suspension shall not exceed 6 months.
- (h) The laboratory shall retain accreditation for the fields of accreditation in which it continues to meet the requirements of the 2003 NELAC standards.
- (i) The laboratory's suspended accreditation status shall be changed to accredited when the laboratory demonstrates to the NH ELAP that the laboratory has corrected the cause of the suspension.

Source. #9134, eff 4-19-08

## Env-C 312.03 Revocation.

- (a) Reasons for NH ELAP to revoke an accreditation shall include:
  - (1) Failure to submit an acceptable corrective action plan, in response to an on-site assessment report;
  - (2) Failure to implement corrective action(s) related to any deficiencies found during a laboratory assessment after submitting 2 corrective action plans as specified in Env-C 311.04;
  - (3) Failure to respond to an on-site assessment report with a corrective action plan within 30 calendar days of the assessment report date;
  - (4) Failure to participate in the proficiency testing program as required by chapter 2 of the 2003 NELAC standards;
  - (5) Submittal of proficiency test sample results generated by another laboratory as its own;
  - (6) Misrepresentation of any material fact pertinent to receiving or maintaining accreditation;
  - (7) Refusal to allow an assessor to enter during normal business hours for an on-site assessment;
  - (8) Conviction of charges relating to the falsification of any report relating to a laboratory analysis;
  - (9) Failure to remit accreditation fees within the time limit established by NH ELAP; or
  - (10) Failure to implement corrective actions to correct deficiencies within the time period specified in the laboratory's corrective action plan.
- (b) Revocation of interim accreditation may be initiated for due cause as described in section 4.3.3 of the 2003 NELAC standards.
- (c) After correcting the cause for revocation, the laboratory may reapply for accreditation no sooner than 6 months from the official date of revocation.
- (d) No laboratory's accreditation shall be revoked without the opportunity for a hearing as set forth Env-C 312.04.

Source. #9134, eff 4-19-08

Env-C 312.04 <u>Action to Deny Application for Renewal Accreditation or Suspend or Revoke Accreditation.</u>

- (a) Whenever the department has reason to consider denial of an application for renewal accreditation or suspension or revocation of a laboratory's accreditation, it shall initiate an adjudicative proceeding in accordance with the applicable provisions of Env-C 200.
- (b) The laboratory shall be given an opportunity to be heard as provided in the provisions of Env-C 200 applicable to adjudicative proceedings prior to any final action being taken.
- (c) The department shall notify the laboratory of its decision in writing. If renewal accreditation is denied or if accreditation is suspended or revoked, the written decision shall specify the reason(s) for the decision.
- (d) The laboratory shall remain accredited with continued successful PT participation until it has been informed by registered mail of the results of the hearing process.

Source. #9134, eff 4-19-08

Env-C 312.05 <u>Successor in Interest Applying for Reaccreditation</u>. The revocation or suspension of accreditation shall operate to prohibit any successor in interest from applying for reaccreditation from NH ELAP until the end of the term for which the accreditation was revoked or suspended.

Source. #9134, eff 4-19-08

Env-C 312.06 <u>Requesting Reconsideration of Accreditation Status</u>. A request for reconsideration shall be made in accordance with Env-C 206.

Source. #9134, eff 4-19-08

#### **APPENDIX**

Rule	State Statute(s) Implemented
Env-C 301 - Env-C 302.18	RSA 485:44, II; RSA 485:47, I
Env-C 303.01 - Env-C 303.17	RSA 485:44, I; RSA 485:44, VII; RSA 485:46; RSA 485:47
Env-C 304.01 - Env-C 304.04	RSA 485:44, II; RSA 485:44 VII; RSA 485:44, X
Env-C 305.01 - Env-C 308.12	RSA 485:44, II; RSA 485:44 III; RSA 485:47
Env-C 309.01 - Env-C 309.02	RSA 485:44, II; RSA 485:44, III; RSA 485:47, I
Env-C 310.01 - Env-C 310.05	RSA 485:44, II; RSA 485:47, I
Env-C 311.01 - Env-C 311.07	RSA 485:44, II, RSA 485:47, I
Env-C 312.01 - Env-C 312.06	RSA 485:44, IX, RSA 485:47, III; RSA 541-A:16, I