

*Readopt with amendment Env-C 300, eff. 1-1-17 (doc. #12065), to read as follows:*

CHAPTER Env-C 300 N.H. ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

Statutory Authority: RSA 485:46, I; RSA 485:47, I-X

PART Env-C 301 PURPOSE; APPLICABILITY; INCORPORATED REFERENCE

Env-C 301.01 Purpose. The purpose of the rules in this chapter is to implement RSA 485:44 and RSA 485:46 relative to establishing an environmental laboratory accreditation program.

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;

(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 and that can be used for non-regulatory*** purposes; and

(c) Any third party assessor organization (TPAO) that seeks approval to conduct accreditation assessments under these rules.

Env-C 301.03 Incorporated Reference. For the purpose of this chapter, unless otherwise specified all references to the laboratory accreditation standards of The NELAC Institute (TNI standards) shall be to the ***2009-2016*** edition, available as noted in Appendix B.

PART Env-C 302 DEFINITIONS

Env-C 302.01 “Accreditation body” means “accreditation body” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.02 “Analyte list” means a list of the matrix/method/analyte combinations that a laboratory has been accredited to perform.

Env-C 302.03 “Applicant” means the entity seeking accreditation for a laboratory.

Env-C 302.04 “Assessor” means an individual who performs an assessment of a laboratory’s capability and capacity for meeting the TNI standards by examining the records and other physical evidence for each one of the tests for which accreditation has been requested.

Env-C 302.05 “Assessment” means “assessment” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.06 “Authorized agent” means the individual, regardless of title, who is responsible for supervising overall laboratory procedures and test result reporting for the laboratory as a whole.

Env-C 302.07 “Business entity” means any for-profit or non-profit organization. The term does not include any government or government agency.

Env-C 302.08 “Demonstration of capability” means “demonstration of capability” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.09 “Department” means department of environmental services.

Env-C 302.10 “Denial” means the accreditation body’s refusal to accredit, in total or in part, a laboratory applying for initial or renewal accreditation.

Env-C 302.11 “Extraordinary assessments” means those assessments conducted as a result of complaints or changes in ownership, key personnel, location, scope of accreditation, or other matters that may affect the ability of a laboratory to meet applicable accreditation requirements.

Env-C 302.12 “Field of accreditation” means “field of accreditation” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.13 “Follow-up assessment” means a type of assessment undertaken to verify effective implementation of corrective actions ***employed in response to an assessment.***

Env-C 302.14 “Initial assessment” means a type of assessment that is comprehensive and involves reviewing all key activities performed by a laboratory applying for accreditation for the first time.

Env-C 302.15 “Limited inorganic chemistry” means 6 or fewer matrix/method/analyte combination analyses for inorganic analytes other than metals.

Env-C 302.16 “Limited organic chemistry” means 6 or fewer matrix/method/analyte combination analyses for organic analytes.

Env-C 302.17 “Limit of quantitation (LOQ)” means the lowest concentration of a target variable that can be reported with a specific degree of confidence.

Env-C 302.18 “Method detection limit (MDL)” means the minimum ***measured*** concentration of a substance that can be ~~measured and reported~~ with 99% confidence that the ~~substance is present in the sample being tested~~ ***measured concentration is distinguishable from method blank results.***

Env-C 302.19 “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 TNI accreditation standards.

Env-C 302.20 “National Environmental Laboratory Accreditation Program (NELAP)” means the program established by TNI for the accreditation of environmental laboratories.

Env-C 302.21 “Person” means “person” as defined in RSA 485:1-a, XIII, as reprinted in Appendix C.

Env-C 302.22 “Primary accreditation body” means the agency or department designated at the territory, provincial, state, or federal level as the authority recognized by the NELAP with responsibility and accountability for granting NELAP accreditation for a specific field of testing.

Env-C 302.23 “Program manager” means the department employee who is responsible for implementing the NH ELAP.

Env-C 302.24 “Proficiency testing (PT)” means “proficiency testing” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.25 “Proficiency testing provider (PT provider)” means “proficiency testing provider” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.26 “Proficiency testing provider accreditor” means an organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.

Env-C 302.27 “Quality system” means “quality system” as defined in the TNI Standards Volume 1, Module 2, reprinted in Appendix D.

Env-C 302.28 “Reassessment” means a type of biennial assessment similar in scope to an initial assessments.

Env-C 302.29 “Revocation” means “revocation” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.30 “Secondary accreditation body” means an entity that grants accreditation to laboratories on the basis of accreditation granted by a primary accreditation body.

Env-C 302.31 “Successful participation” and any other verb form of the term such as “successfully participate” or “successfully participated” means receiving a score of “acceptable” or “check for error” on:

- (a) All available concentrations, for analyses accredited on an analyte-by-analyte basis; or
- (b) The entire group, for analytes accredited as a group of interdependent analytes as described in Volume 1, Module 1 of the TNI standards.

Env-C 302.32 “Successor in interest” means any laboratory that is owned or controlled by an entity in which the majority of officials also owned or controlled the laboratory accredited under a previously-issued certificate.

Env-C 302.33 “Surveillance assessment” means a type of assessment that is less comprehensive than an initial assessment or reassessment, and occurs as-needed between an initial assessment and a reassessment.

Env-C 302.34 “Suspension” means “suspension” as defined in the TNI standards, Volume 1, as reprinted in Appendix D.

Env-C 302.35 “Technical manager” means an individual, regardless of title, who is responsible for supervising laboratory procedures and test result reporting for a particular area of the laboratory.

Env-C 302.36 “Third party assessor (TPA)” means an assessor who is not affiliated with the department.

Env-C 302.37 “Third party assessor organization (TPAO)” means an organization that employs one or more assessors.

Env-C 302.38 “Unit cost” means the hourly rate of the department employee who conducts the work plus employee benefits and overhead.

Env-C 302.39 “Written notice” means a communication sent:

- (a) On paper via U.S. Postal Service first class mail or via private delivery service;
- (b) On paper sent by fax; or
- (c) Electronically via email.

## 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:

- (1) Electronically; ~~and-or~~
- (2) In hard copy, by mailing or otherwise delivering the application to:

NH Department of Environmental Services  
Attn: Program Manager, NH ELAP  
29 Hazen Drive  
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 303.03 on an Application For Laboratory Accreditation with NH ELAP as a Primary Accreditation Body form, NHDES-W-03-199, dated ~~2016-12-08-12-17-2019~~ and available at ~~http://des.nh.gov/organization/divisions/water/dwgb/documents/nhdes-w-03-199.docx~~ <https://onlineforms.nh.gov/?FormTag=NHDES-W-03-199>, that has been signed and dated as specified in Env-C 303.02;
  - (2) Information detailing each method/matrix/analyte combination for which accreditation is requested;
  - (3) The results of successful participation in a proficiency test (PT) study as specified in Volume 1, Module 1 of the TNI standards, submitted by the PT provider; and
  - (4) The fee specified in Env-C 303.08.

Env-C 303.02 Signatures Required.

- (a) The application form shall be signed and dated by the individual designated by the applicant pursuant to Env-C 303.04(c).
- (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:
    - a. Any accreditation issued based on false, incomplete, or misleading information shall be subject to denial, suspension, or revocation; and
    - b. The signer is subject to the penalties specified in New Hampshire law, currently RSA 641:3, for making unsworn false statements.

Env-C 303.03 Information for Primary Accreditation. An applicant for primary accreditation 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 and the EPA laboratory identification number;
- (c) The contact information specified in Env-C 303.04;
- (d) The ownership information specified in Env-C 303.05;
- (e) The laboratory operational information specified in Env-C 303.06; and
- (f) The additional information specified in Env-C 303.07.

Env-C 303.04 Required Contact Information. The contact information required by Env-Dw 303.03(c) shall be as follows:

- (a) 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;

- (b) 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;
- (c) The name and title of the individual authorized by the laboratory to sign the application form;
- (d) The name and daytime telephone number including extension, if applicable, of the authorized agent;
- (e) The name and daytime telephone number including extension, if applicable, of the quality assurance officer; and
- (f) The name and daytime telephone number including extension, if applicable, of the lead technical manager and of each additional technical manager.

Env-C 303.05 Required Ownership Information. The ownership information required by Env-Dw 303.03(d) shall be as follows:

- (a) Whether the laboratory seeking accreditation is owned by a business entity or a government entity;
- (b) If the laboratory is owned by a business entity, the following:
  - (1) The type of business entity, such as corporation, a limited liability corporation, a partnership, a sole proprietorship, or another type, which shall be identified;
  - (2) The legal name of the business entity, if other than the legal name of the laboratory;
  - (3) The date the laboratory registered with the New Hampshire secretary of state;
  - (4) If the owner is a corporation, the date and state of incorporation; and
  - (5) The name and title of each principal official of the business entity, such as corporate officers or general partners; and
- (c) 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 Env-C 303.04(a).

Env-C 303.06 Required Laboratory Operation Information. The laboratory operational information required by Env-C 303.03(e) shall be as follows:

- (a) The type of laboratory, type of building housing the laboratory, floor plan space, utilities, and computer systems, including software;
- (b) 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;
- (c) Each matrix/method/analyte combination for which accreditation is being sought;
- (d) The analytical methodology and equipment used for each analyte/matrix/method combination for which accreditation is being sought;
- (e) For a mobile laboratory, the vehicle identification number (VIN) or serial number;
- (f) Laboratory hours of operation; and
- (g) A demonstration of capability data for each new matrix/method/analyte combination for which accreditation is sought.

Env-C 303.07 Additional Information Required for Primary Accreditation. The additional information required by Env-C 303.03(e) shall be as follows:

- (a) The amount of fees due, calculated in accordance with Env-C 303.08;
- (b) The education and experience background of each technical manager;
- (c) Transcripts of all college courses completed by each technical manager, including graduate courses if applicable;
- (d) A resume for each technical manager that documents analytical laboratory experience;
- (e) A paper copy and an electronic copy of the quality system manual (QSM) and standard operating procedures (SOPs) as specified in Env-C 308.02 and Env-C 308.03;
- (f) Information regarding which of the methods allowed by Env-C 304.06 the laboratory intends to use to inform all prospective, current, and repeat New Hampshire clients of which analytes or categories it is accredited by NH ELAP to test; and
- (g) A Certificate of Compliance form, ***NHDES-W-03-265***, dated ~~09/2016~~ ***11/25/2020***, ***available at <https://onlineforms.nh.gov/app/#/formversion/bd65fb01-a733-4ffc-8475-f5946b82946d>***, that has been signed and dated by the authorized agent, each quality assurance officer, each technical manager, and the laboratory director, each of whom shall also type or print his or her name on the form, to constitute certification that each signer acknowledges that the laboratory is legally bound to:
  - (1) Fully comply with all applicable requirements of these rules and the TNI standards as incorporated into these rules;
  - (2) Provide ***NH ELAP administrative staff and assessors*** access to laboratory staff and to information, documents, and records as necessary for the assessment and maintenance of accreditation;
  - (3) Arrange the witnessing of laboratory services if requested in accordance with ***NH ELAP rules and*** the TNI standards;
  - (4) Claim accreditation only with respect to the ***latest*** scope of accreditation granted; and
  - (5) Pay fees as specified in ~~these rules~~ ***Env-C 303.08, Env-C 303.09, and Env-C 303.10***, as authorized by RSA 485:46, I.

Env-C 303.08 Fees for New or Renewal Applications.

- (a) A nonrefundable application fee shall accompany each application for a new or renewal accreditation for drinking water matrix methods, non-potable water matrix methods, solid and chemical materials matrix methods, tissue matrix methods, or air matrix methods, or any combination thereof.
- (b) The application fee required by (a), above, shall be the sum of:
  - (1) A ~~\$200~~ ***\$225*** base fee;
  - (2) A sample preparation method fee of ~~\$25~~ ***\$28*** per method;
  - (3) An additional fee for each non-standard performance-based or laboratory-developed method, as follows:
    - a. If column A applies, ~~\$100~~ ***\$112***;
    - b. If column B applies, ~~\$125~~ ***\$135***; and
    - c. If column C applies, ~~\$150~~ ***\$168***; and

- (4) 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

<b>Accreditation Requested</b>	<b>A</b>	<b>B</b>	<b>C</b>
Microbiology	<del>\$150</del> <b><i>\$168</i></b>	<del>\$175</del> <b><i>\$197</i></b>	<del>\$225</del> <b><i>\$253</i></b>
Pathogen analysis	<del>\$150</del> <b><i>\$168</i></b>	<del>\$175</del> <b><i>\$197</i></b>	<del>\$225</del> <b><i>\$253</i></b>
Limited inorganic chemistry only	<del>\$250</del> <b><i>\$281</i></b>	<del>\$275</del> <b><i>\$309</i></b>	<del>\$325</del> <b><i>\$365</i></b>
Limited organic chemistry only	<del>\$250</del> <b><i>\$281</i></b>	<del>\$275</del> <b><i>\$309</i></b>	<del>\$325</del> <b><i>\$365</i></b>
Limited inorganic chemistry	<del>\$150</del> <b><i>\$168</i></b>	<del>\$175</del> <b><i>\$197</i></b>	<del>\$225</del> <b><i>\$253</i></b>
Limited organic chemistry	<del>\$150</del> <b><i>\$168</i></b>	<del>\$175</del> <b><i>\$197</i></b>	<del>\$225</del> <b><i>\$253</i></b>
One or 2 metals <del>only</del>	<del>\$150</del> <b><i>\$168</i></b>	<del>\$175</del> <b><i>\$197</i></b>	<del>\$225</del> <b><i>\$253</i></b>
Microbiology and limited inorganic chemistry	<del>\$200</del> <b><i>\$225</i></b>	<del>\$225</del> <b><i>\$253</i></b>	<del>\$300</del> <b><i>\$337</i></b>
Microbiology and one or 2 metals	<del>\$200</del> <b><i>\$225</i></b>	<del>\$225</del> <b><i>\$253</i></b>	<del>\$300</del> <b><i>\$337</i></b>
Microbiology, limited inorganic chemistry, and one or 2 metals	<del>\$300</del> <b><i>\$337</i></b>	<del>\$325</del> <b><i>\$365</i></b>	<del>\$450</del> <b><i>\$506</i></b>
Metals	<del>\$425</del> <b><i>\$478</i></b>	<del>\$525</del> <b><i>\$568</i></b>	<del>\$650</del> <b><i>\$731</i></b>
Inorganic chemistry	<del>\$425</del> <b><i>\$478</i></b>	<del>\$525</del> <b><i>\$568</i></b>	<del>\$650</del> <b><i>\$731</i></b>
Metals and Inorganic chemistry	<del>\$500</del> <b><i>\$562</i></b>	<del>\$600</del> <b><i>\$675</i></b>	<del>\$725</del> <b><i>\$815</i></b>
Organic chemistry	<del>\$500</del> <b><i>\$562</i></b>	<del>\$600</del> <b><i>\$675</i></b>	<del>\$725</del> <b><i>\$815</i></b>
Radiological chemistry	<del>\$300</del> <b><i>\$337</i></b>	<del>\$325</del> <b><i>\$365</i></b>	<del>\$450</del> <b><i>\$506</i></b>
Whole Effluent or Sediment Toxicity Testing	<del>\$300</del> <b><i>\$337</i></b>	<del>\$300</del>	<del>\$325</del>
Whole Effluent and Sediment Toxicity Testing	<del>\$375</del>	<del>\$375</del> <b><i>\$506</i></b>	<del>\$400</del>
Radon in Water analysis <del>only</del>	<del>\$150</del> <b><i>\$168</i></b>	<del>\$150</del>	<del>\$175</del>

- (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. Non-potable water matrix methods other than SW-846 methods (non-SW-846 methods) only;
    - c. Non-potable water matrix SW-846 methods only;
    - d. Tissue matrix methods only;
    - e. Air matrix methods only; or
    - f. Solid and chemical materials matrix methods only.
  - (2) Column B shall apply to laboratories seeking accreditation for any 2 matrix ~~or~~ methods combinations listed in (1), above; and
  - (3) Column C shall apply to laboratories seeking accreditation for any combination of 3 or more matrix ~~or~~ methods combinations from (1), above.
- (d) Accreditation shall not be granted if the correct application fee is not received by the department.
- (e) The individual fees listed in Table 300-1 shall increase by 4%, rounded to the nearest whole dollar, on July 1 of each biennium beginning July 1, ~~2017~~ ***2023***.

Env-C 303.09 Fees for Requests to Modify Existing Accreditations.

(a) The fee for a request to modify ***either an primary accreditation or a secondary accreditation at a laboratory's request or based on a primary accreditation body's accreditation requirements*** shall be the sum of all applicable amounts listed in Table 300-2, below, or ~~\$300~~ ***\$337***, whichever is less:

Table 300-2: Fees for Requests to Modify Existing Accreditation

<b>Reason for Request:</b>	<b>Fee</b>
Update to latest revision or edition, Primary or Secondary Accredited Laboratories, one method; <b><i>previous accreditation remains.</i></b>	
Method with 1 to 5 analytes	<del>\$25</del> <b><i>\$28</i></b>
Method with 6 to 20 analytes	<del>\$35</del> <b><i>\$38</i></b>
Method with $\geq 21$ analytes	<del>\$45</del> <b><i>\$51</i></b>
<del>Request for</del> <b><i>Update to</i></b> latest revision or edition, Primary or Secondary Accredited Laboratories, multiple methods; <b><i>previous accreditation remains.</i></b>	
Method with 1 to 5 analytes	<del>\$15</del> <b><i>\$18</i></b>
Method with 6 to 20 analytes	<del>\$25</del> <b><i>\$28</i></b>
Method with $\geq 21$ analytes	<del>\$35</del> <b><i>\$38</i></b>
Additional new accreditation per method per request, Secondary Accredited Laboratories	
Method with 1 to 5 analytes	<del>\$15</del> <b><i>\$18</i></b>
Method with 6 to 20 analytes	<del>\$25</del> <b><i>\$28</i></b>
Method with $\geq 21$ analytes	<del>\$40</del> <b><i>\$46</i></b>
Additional new accreditation per method per request, Primary Accredited Laboratories	
Method with 1 to 5 analytes	<del>\$30</del> <b><i>\$33</i></b>
Method with 6 to 20 analytes	<del>\$50</del> <b><i>\$56</i></b>
Method with $\geq 21$ analytes	<del>\$80</del> <b><i>\$89</i></b>
Additional same-technology same-matrix accreditation per method per request, Primary or Secondary Accredited Laboratories	
Method with 1 to 5 analytes	<del>\$15</del> <b><i>\$18</i></b>
Method with 6 to 20 analytes	<del>\$25</del> <b><i>\$28</i></b>
Method with $\geq 21$ analytes	<del>\$35</del> <b><i>\$38</i></b>
Drop accreditation per method per request, Primary or Secondary Accredited Laboratories	
<del>Method <math>\geq 1</math> analyte</del>	<del>\$10</del>
<b><i>1 single Analyte Method</i></b>	<b><i>\$11</i></b>
<b><i>2 – 10 single Analyte Methods</i></b>	<b><i>\$18</i></b>
<b><i><math>\geq 11</math> single Analyte Methods</i></b>	<b><i>\$28</i></b>
<b><i>Multi-Analyte Method</i></b>	<b><i>\$18</i></b>

(b) The individual fees listed in Table 300-2 shall increase by 4%, rounded to the nearest whole dollar, on July 1 of each biennium beginning July 1, ~~2017~~ ***2023***.

(c) Fees for additional or updated accreditation shall be paid at the time of the request.

(d) Additional or updated accreditation requests shall not be processed until the applicable fee is received by the department.

Env-C 303.10 Reimbursable Expenses for Department Assessors.

(a) In addition to the nonrefundable application fee, the laboratory shall reimburse the department in accordance with ~~(b-d)~~ ~~(f-h)~~, below, for the following costs associated with the department's ~~review of TPAO~~ ***primary accreditation*** assessments ~~documentation~~, as applicable:



(1) Department staff expenses, calculated as the time needed to perform the tasks listed in a. through h., below, multiplied by the unit cost:

- a. Completeness review of the application and documents supplied with the application;
- b. Study of documents in preparation for the assessment;
- c. Preparation of the checklists used for the assessment;
- d. Communications with the applicant related to the assessment;
- e. Travel to and from the laboratory;
- f. Assessment of the laboratory;
- g. Preparation of the assessment report(s); and
- h. Review of any corrective action report(s) submitted per Env-C 309.04;

(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; ~~and.~~

*{(4) moved, renumbered as (c)}*

***(b) In addition to the nonrefundable application fee, the laboratory shall reimburse the department in accordance with (d) through (h), below, for the following costs associated with secondary assessments, calculated as the time needed to perform the tasks listed in (1) and (2), below, multiplied by the unit cost:***

***(1) Review of supporting documents related to additional or updated accreditation requests supplied by a laboratory; and***

***(2) Communications with the secondary accredited laboratory.***

~~(4c)~~ Department staff expenses for the following tasks incurred after a TPAO has conducted an assessment ***In addition to the nonrefundable application fee, the laboratory shall reimburse the department in accordance with (d) through (h), below, for the following costs associated with the department's review of TPAO assessment procedures and documentation, calculated as the time needed to perform the tasks listed in a-(1) through e-(5), below, multiplied by the unit cost:***

***(1) Review of supporting documents supplied by the applicant;***

~~a-(2)~~ Review of the draft checklist(s) and supporting documents supplied by a TPAO;

~~b-(3)~~ Review of the draft and final assessment reports and any corrective action report(s); ~~and~~

~~e-(4)~~ Communications with the applicant or the TPAO, or both, related to the assessment; ***and***

***(5) Quality control observations of TPAs performing on-site assessments, provided that if travel is required, the costs shall include costs identified in (a)(2) and (3), above, as applicable.***

~~(bd)~~ The department shall inform the laboratory of the costs associated with the assessment with the assessment report.

(~~ee~~) 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.

(~~ef~~) If accreditation is granted or renewed, the laboratory shall pay the costs of the assessment prior to receiving its accreditation certificate and analyte list.

(~~eg~~) Accreditation shall be denied, 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~~ ***any of the events covered by (a) through (c), above***, within 30 days of receiving the assessment report.

(~~eh~~) If payment is made by check or money order, the instrument shall be made payable to “Treasurer – State of New Hampshire”.

#### Env-C 303.11 Mobile Laboratories; Individual or Remote Sites.

(a) 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.

(b) A mobile laboratory owned by an accredited fixed-base laboratory shall be considered a separate laboratory requiring separate accreditation, subject to the same application process, fees, assessments, and other requirements as any other environmental laboratory, 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.

(c) 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.

#### Env-C 303.12 Application for Secondary Accreditation.

(a) In order to request initial or renewal secondary accreditation, the applicant shall submit a complete application as specified in (b), below, to the department:

- (1) Electronically; ~~and-or~~
- (2) In hard copy, by mailing or otherwise delivering the application to:

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

- (b) A complete application for secondary accreditation shall include:
- (1) The information specified in Env-C 303.13 on an Application For Laboratory Accreditation with NH ELAP as a Secondary Accreditation Body form, NHDES-W-03-200, dated ~~2016-12-08~~ ***12-17-2019*** and available at ~~<http://des.nh.gov/organization/divisions/water/dwgb/documents/nhdes-w-03-200.docx>~~ ***<https://onlineforms.nh.gov/?FormTag=NHDES-W-03-200>***, that has been signed and dated as specified in Env-C 303.02;
  - (2) Information detailing each method/matrix/analyte combination for which accreditation is requested; and
  - (3) The fee specified in Env-C 303.08.

Env-C 303.13 Application Information for Secondary Accreditation. An applicant for secondary accreditation shall provide the following information:

- (a) All information required by Env-C 303.03(a) - (d) and Env-C 303.06(c);
- (b) For the applicant's primary accreditation body, the following:
  - (1) The name, mailing address, and main telephone number of the primary accreditation body;
  - (2) The name, mailing address, and daytime telephone number and, if available, an e-mail address, of an individual at the primary accreditation body who can be contacted relative to the applicant; and
  - (3) The date the applicant's current primary accreditation will expire; and
- (c) For each other accreditation body that has accredited the applicant, the following:
  - (1) The name, mailing address, and main telephone number of the accreditation body;
  - (2) The name, mailing address, and daytime telephone number and, if available, an e-mail address, of an individual at the accreditation body who can be contacted relative to the applicant; and
  - (3) The date the applicant's current accreditation from that accreditation body will expire.

Env-C 303.14 Additional Information Required for Secondary Accreditation Applications. The applicant shall provide the following to the department with the completed application:

- (a) All information required by Env-C 303.07;
- (b) A copy of the most recent and valid certificate and analyte list from the primary accreditation body or accreditation bodies; ~~and~~
- (c) A certificate of compliance as required by Env-C 303.07(g); ***and***
- (d) ***Additional supporting documentation as necessary to verify laboratory compliance with applicable method, regulatory, or standards requirements.***

Env-C 303.15 Out-of-state Laboratories Applying for Accreditation with NH ELAP as a Secondary Accreditation Body.

- (a) Any laboratory located outside of New Hampshire applying for accreditation with the department as a secondary accreditation body shall submit a complete application as specified in Env-C 303.12.
- (b) The laboratory shall also submit the following with the application:
  - (1) A copy of the certificate and analyte list(s) from its primary accreditation body with each accredited method/matrix/analyte combination noted and the expiration date clearly indicated;
  - (2) A copy of any assessment report not more than 2 years old that was used to obtain the accreditation for each area accreditation is requested or was based on a complaint investigation;
  - (3) A copy of the response to each assessment report provided pursuant to (2), above, as applicable; and
  - (4) Copies of results from participation in proficiency test (PT) studies.
- (c) The department shall recognize the accreditation granted by another primary accreditation body for the same matrix/method/analyte combination that the department accredits laboratories as a primary accreditation body.
- (d) The department shall recognize the accreditation for groups of analytes granted by another primary accreditation body only if the group is identical to a group that would be accredited by the department as the primary accreditation body.

Env-C 303.16 Out-of-state Laboratories Applying for Accreditation with NH as a Primary Accreditation Body.

- (a) An out-of-state laboratory may request the department to be a primary accreditation body only if:
  - (1) There is no NELAP-approved accreditation body in the state or province in which the laboratory is located; or
  - (2) The primary accreditation body in the state or province in which the laboratory is located does not offer the fields of accreditation sought by the laboratory.
- (b) Any laboratory located outside of New Hampshire applying for accreditation with the department as a primary accreditation body shall apply as specified in Env-C 303.01.

Env-C 303.17 Application Processing.

- (a) The department shall not process an application until a complete application is received.
- (b) Subject to (e) and (f), below, if the application is not complete when filed, the department shall send the applicant written notice 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 telephone 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.

Env-C 303.18 Decision on Application. The department shall approve an application and grant accreditation only if:

- (a) The applicant has submitted a complete application as specified in Env-C 303.01 through Env-C 303.11 and Env-C 303.16, as applicable, for primary accreditation or Env-C 303.12 through Env-C 303.15 for secondary accreditation, as applicable;
- (b) The applicant has paid all additional reimbursable expenses pursuant to Env-C 303.10;
- (c) The criteria listed in Env-C 303.19 for primary accreditation or Env-C 303.21 for secondary accreditation, as applicable, have been met; and
- (d) No grounds exist on which the accreditation would be denied, suspended, or revoked.

Env-C 303.19 Basis for ~~Approving~~ ***Granting*** 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 PT study as specified in Volume 1, Module 1 of the TNI standards; ~~and~~
- (2) The results of an initial assessment, a reassessment, a surveillance, an extraordinary assessment, or a follow-up assessment, as applicable; ***and***
- (3) ***The results of the review of documentation submitted as part of the application process.***

(b) ~~Subject to Env-C 303.19,~~ Accreditation status shall be either “Accredited” for a laboratory meeting the TNI standards, or “Not Accredited” for a laboratory not meeting the TNI standards, based upon the criteria specified in (a), above, ***and Env-C 303.18.***

Env-C 303.20 Interim Status.

(a) If a laboratory completes all of the requirements for accreditation except for the on-site component of the assessment because the department is unable to schedule the on-site assessment and a third-party assessor is not available, the department shall issue an interim accreditation upon request by the laboratory.

(b) Interim status accreditation shall allow the laboratory to perform analyses and report results with the same status as an accredited laboratory until the on-site component of the assessment requirements have been completed, provided that interim accreditation status shall not exceed 12 months.

(c) Interim accreditation status may be ***denied, suspended, or*** revoked for just cause as described in Env-C 311.03.

Env-C 303.21 Basis for ~~Approving~~ ***Granting*** Secondary Accreditation.

(a) In determining whether to approve an application for secondary accreditation, the department shall consider:

- (1) The matrix/method/analyte combination listed on the analyte list of the primary accreditation body;
- (2) The matrix/method/analyte combination available in the department's fields of accreditation; ~~and~~
- (3) The accreditation status information from the primary accreditation body; ***and***
- (4) ***The results of the review of documentation submitted as part of the application process.***

(b) Accreditation status shall be either "Accredited" for a laboratory meeting the TNI standards, or "Not Accredited" for a laboratory not meeting the TNI standards, based upon the criteria specified in (a), above, ***and Env-C 303.18.***

Env-C 303.22 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 303.01; and
- (2) Be submitted to the department ***prior to the expiration date of the current accreditation.***

(c) The application for renewal of secondary accreditation shall:

- (1) Comply with Env-C 303.11 through Env-C 303.15; and
- (2) Be submitted to the department prior to the expiration date of the current accreditation ~~in accordance with the schedule specified in the renewal notification issued by the department, which schedule shall be based on:~~
  - a. ~~Whether the accreditation is primary or secondary;~~
  - b. ~~Whether an on-site assessment is needed; and~~
  - c. ~~The number of matrix/method/analyte combinations being accredited.~~

PART Env-C 304 ACCREDITATION ISSUANCE AND TRANSFERAL

Env-C 304.01 Issuance of Certificates and Analyte Lists.

(a) Any accreditation issued by the department pursuant to Env-C 303 shall be valid for one year from the date of initial issuance unless sooner suspended or revoked in accordance with Env-C 311.

(b) A certificate or analyte list issued as a replacement for an existing 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 compliance with these rules;
- (3) A statement requesting that customers verify the laboratory's accreditation status with the department;

- (4) A NH ELAP identification number; and
- (5) An effective date and expiration date of the certificate.
- (d) The certificate shall be accompanied by the laboratory's analyte list.
- (e) The department shall issue a new analyte list whenever any change in the laboratory's fields of accreditation is 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 each matrix/method/analyte combination for which the laboratory has been accredited.
- (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.

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 department in writing no later than 30 days prior to the end of the laboratory's accreditation year.
- (b) A laboratory accredited by the department shall return its original certificate and analyte list(s) to the department 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 accreditation body.
- (c) A laboratory accredited by the department shall return its original analyte list(s) to the department 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).

Env-C 304.03 Notification of Changes Required.

- (a) As required by RSA 485:44, X, a laboratory shall provide written notice to the department of any changes in ownership, location, personnel, methodology, or other factors significantly affecting the performance of analyses for which it is accredited within 5 business days of the change.
- (b) For purposes of this section, "other factors significantly affecting the performance of analyses for which it is accredited" means any circumstances that impede the performance of the analyses, including but not limited to damage to the laboratory's office(s) or equipment, or both, from fire or natural disasters.
- (c) ***A notification submitted pursuant to (a), above, for changes to the authorized agent, laboratory director, quality assurance officer, or technical manager positions shall include an updated application and certificate of compliance.***

Env-C 304.04 Transferring Accreditation: Name Change Only.

(a) If a laboratory changes its name but does not make any change identified in Env-C 304.05(a), the laboratory director shall:

- (1) Inform the department in writing of the new name within 30 calendar days of the change of name; and
- (2) Certify under penalties of false swearing that none of the changes identified in Env-C 304.05(a) are also being made.

(b) Within 10 business days of receipt of a notice pursuant to (a), above, the department shall issue a replacement certificate in the new name of the laboratory, provided it has no credible basis to believe that additional changes are being made.

Env-C 304.05 Transferring Accreditation: Changes Related To Capabilities.

(a) A laboratory's accreditation shall not be directly transferable when the ownership, the location, the analytical instrumentation, the principal officers, or the local management of the laboratory changes.

(b) The laboratory director shall provide written notice to the department as required by Env-C 303.03 of any change related to the laboratory's capabilities, as specified in Volume 2, Module 3, Section 7.0 of the TNI standards.

(c) The laboratory shall submit updated application information as specified in Env-C 303 for each change with the written notice required by (b), above.

(d) The department shall issue a new certificate and analyte list within 14 calendar days of receiving the application if there is a change in 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 being replaced.

(e) If the department is the primary accreditation body, the department shall conduct an assessment of the laboratory within 60 calendar days if changes reported by the laboratory affect the day-to-day operations of the laboratory.

(f) If a laboratory determines that it will be appointing a new technical manager, the laboratory shall inform the department in writing of its intent within 30 calendar days of making its determination.

(g) The proposed technical manager shall meet the educational and experience requirement of Volume 1, Module 2, Section 5.2.6 of the TNI standards.

(h) The notice provided pursuant to (e), above, shall include a copy of the college transcript and resume of the proposed new technical manager, if the individual has been selected at the time the notice is provided.

(i) If a technical manager is appointed by the laboratory without approval by the department and it is determined that the new technical manager does not meet the requirements of Volume 1, Module 2, Section 5.2.6 of the TNI standards, accreditation of the affected area(s) shall be suspended in accordance with Env-C 311.02.

Env-C 304.06 Use of NH ELAP Name and TNI/NELAP Logo.

(a) For purposes of this section, "business materials" means any written, printed, or electronic document, including but not limited to laboratory test reports, catalogs, advertising, business solicitations, quotations, or contracts, and any information provided on a website.



(b) 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 business materials.

(c) When an accredited laboratory uses the NH ELAP name or the TNI/NELAP logo on any business materials, the laboratory shall include the laboratory's NH ELAP assigned 4-digit laboratory identification number.

(d) The accredited laboratory shall use its department certificate and analyte list, department accreditation status, and the TNI/NELAP logo only to show compliance with the TNI standards.

(e) A laboratory accredited by the department shall not use its certificate, analyte list, accreditation status, or the TNI/NELAP logo to imply endorsement by the accreditation body ***or bring the accreditation body into disrepute.***

(f) If accreditation is denied, suspended, revoked, or withdrawn, the laboratory shall:

(1) Discontinue the use of all business materials that contain any reference to the laboratory's past NH ELAP accreditation for the affected analyses; and cast

(2) Delete any reference to the past NH ELAP accreditation for the affected analyses from its website.

(g) If accreditation is ***denied***, suspended, revoked, or withdrawn, the laboratory shall return all copies and original certificates and analyte lists to the department as specified in Env-C 304.02(b) and (c).

Env-C 304.07 Providing Information on Accreditation Status.

(a) A laboratory shall inform all prospective New Hampshire clients of which matrix/method/ analyte combination(s) it is accredited by the department to test using one of the following methods:

(1) Providing a copy of the laboratory's current certificate and analyte list 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 accreditation information is located.

(b) The list of tests for which the laboratory is accredited by the department to perform shall be indicated on or with the test report by one of the following methods:

(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 accreditation 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 new accreditation information is located.

#### PART Env-C 305 GENERAL REQUIREMENTS FOR ACCREDITATION

Env-C 305.01 Accreditation Requirements. To be accredited for specific analytes, the laboratory shall meet all requirements specified in Env-C 305.02 through Env-C 305.14, and the applicable educational requirements in Env-C 306.

##### Env-C 305.02 Personnel.

- (a) The laboratory shall have an authorized agent.
- (b) The laboratory shall have at least one technical manager who meets the educational requirements in Env-C 306 for each specific matrix/method/analyte combination of accreditation.
- (c) The laboratory shall have a quality assurance officer or individual designated as accountable for data quality as specified in Volume 1, Module 2, Section 4.1.7.1 of the TNI standards.
- (d) The laboratory also shall meet:
  - (1) All organizational and management requirements specified in Volume 1, Module 2, Section 4.0 of the TNI standards; and
  - (2) All organizational and personnel requirements specified in Volume 1, Module 2, Section 5.2 of the TNI standards.
- (e) ***The laboratory analytical staff shall:***
  - (1) ***Successfully perform an initial demonstration of capability for each matrix/method/analyte combination prior to using any method, and any time there is a change in instrument type, method, or any time that a method has not been performed by the analyst in a 12-month period; and***
  - (2) ***Once the initial demonstration of capability has been passed, successfully perform an ongoing demonstration of capability for each matrix/method/analyte combination on an annual basis.***

##### Env-C 305.03 Technical Manager Responsibilities and Qualifications.

- (a) A technical manager shall be a full-time laboratory staff member who conducts actual day-to-day supervision of laboratory procedures and test result reporting.
- (b) The duties of a technical manager shall include, but not necessarily 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.
- (c) An individual shall not be the technical manager of more than one NELAP-accredited environmental laboratory without providing written notification to the primary accreditation body.

(d) A technical manager who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of technical manager to temporarily perform this function.

(e) If a technical manager is absent for more than 65 consecutive calendar days, the quality assurance officer or the staff member temporarily performing the technical manager's functions shall notify the accreditation body in writing, by mail or electronically.

Env-C 305.04 Exceptions to Technical Manager Qualifications.

(a) In lieu of the educational requirements in the applicable sections of Env-C 306, the technical manager of an environmental laboratory for a drinking water or wastewater treatment facility may be a full time employee of the facility who:

- (1) Holds a valid operator's certificate appropriate to the nature and size of such facility within the scope of that facility's regulatory permit; and
- (2) Has not less than 2 years of experience testing the kind of samples required by the facility's permit.

(b) In lieu of the educational requirements in the applicable sections of Env-C 306, the technical manager of an environmental laboratory for an industrial waste treatment facility may be a full time employee of the facility who has not less than 2 years of supervised experience testing the kind of samples required by that facility's permit.

(c) Any individual who does not meet the applicable education requirements specified in Env-C 306 but who possesses the requisite experience shall qualify as a technical manager subject to the conditions specified in Volume 1, Module 2, Section 5.2.6.2(c) of the TNI standards.

Env-C 305.05 Laboratory Facilities. The laboratory facilities shall meet the requirements as specified in Volume 1, Module 2, Section 5.3 of the TNI standards.

Env-C 305.06 Laboratory Equipment, ***Calibration,*** and ~~Reference Materials~~ ***Measurement Traceability.***

(a) The laboratory equipment, ***including support equipment,*** ~~and reference materials~~ shall meet the requirements as specified in Volume 1, Module 2, Section 5.5 of the TNI standards.

***(b) The laboratory shall have reference standards and reference materials that meet requirements relative to measurement traceability as specified in Volume 1, Module 2, Section 5.6 of the TNI standards.***

Env-C 305.07 Analytical Methodology. The laboratory shall meet the analytical methodology requirements as specified in Volume 1, Module 2, Section 5.4 of the TNI standards.

Env-C 305.08 Sample Collection, Handling, and Preservation. The laboratory shall meet the sample collection, handling and preservation requirements as specified in Volume 1, Module 2, 5.7 and Module 2, Section 5.8 of the TNI standards.

Env-C 305.09 Quality Assurance Requirements.

(a) The laboratory shall develop and implement a quality system in accordance with Volume 1, Module 2 of the TNI standards that incorporates the essential quality control requirements specified in Volume 1, Modules 3 through 7 of the TNI standards.

(b) If the quality control requirements of Volume 1, Modules 2 through 7 of the TNI standards and the requirements in an approved method differ, the laboratory shall use the requirements that result in a higher level of confidence in testing results.

(c) The laboratory shall analyze ***laboratory*** control samples whenever whole volume material, concentrated material, or spiking solution material is available to create or otherwise prepare ***laboratory*** control samples.

***(d) An appropriate clean matrix material shall be used in laboratory reagent blank and laboratory control sample preparation associated with solid and chemical materials and biological tissue analytical procedures.***

Env-C 305.10 Calibration of Instruments.

(a) The laboratory shall meet the instrument calibration requirements specified in Volume 1, Module 2, Section 5.5 of the TNI standards.

(b) If the requirements in Volume 1, Module 2, Section 5.5 of the TNI standards and the requirements in an approved method differ, the laboratory shall use the requirements that result in a higher level of confidence in testing results.

(c) Prior to analyzing any samples, the laboratory shall verify all initial instrument calibrations with:

(1) A standard obtained from a manufacturer other than the one that produced the calibration standards used by the laboratory; or

(2) A standard obtained from the same manufacturer that produced the calibration standards but from a different lot that was independently prepared from different source materials.

***(d) If option (c)(2) is used, the laboratory shall maintain records from the manufacturer to document that the 2 lots were prepared independently from different source materials.***

Env-C 305.11 Records and Data Reporting.

(a) The laboratory shall meet the records and data reporting requirements specified in Volume 1, Module 2, Section 4.13 and 5.10 of the TNI standards.

***(b) All quality control and sample analytical results shall include the appropriate unit of measure.***

Env-C 305.12 Response to Laboratory Results for Compliance Purpose Samples. When a response required by Env-Dw 719.02 is a designated laboratory responsibility, the laboratory shall promptly notify the department of:

(a) Exceedance results as required by Env-Dw 719.02(c); and

(b) All other results in the time frame and format designated in Env-Dw 719.02.

Env-C 305.13 Outside Support Services and Supplies.

(a) The laboratory shall meet the outside support and supplies requirements as specified in Volume 1, Module 2, Section 4.6 of the TNI standards.

***(b) The laboratory shall meet the subcontracting of environmental tests requirements as specified in Volume 1 Module 2 Section 4.5 of the TNI standards.***

(c) ***When a laboratory subcontracts environmental tests, the laboratory shall:***

***(1) Be responsible to the customer for the subcontractor's work; and***

***(2) Communicate to the client any failure to meet the client's data quality objectives.***

Env-C 305.14 Complaints. The laboratory shall meet the requirements for handling complaints as specified in Volume 1, Module 2, Sections 4.8 and 4.11 of the TNI standards.

#### PART Env-C 306 SPECIFIC EDUCATION REQUIREMENTS FOR CATEGORIES OF TESTING

##### Env-C 306.01 Educational Requirement for Microbiology.

(a) To be accredited for microbiological or pathogen analysis, the technical manager shall have:

(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; and

(2) At least 2 years of experience in the environmental analysis of representative analytes for which the laboratory is seeking approval, provided that a master's degree or doctoral degree in one of the disciplines listed in (1), above, may be substituted for one year of experience.

(b) Subject to (c), below, an employee of a laboratory engaged in microbiological analyses limited to total coliform, fecal coliform, E. coli, and standard plate count who has 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 for a technical manager for microbiology.

(c) 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.

Env-C 306.02 Educational Requirement for Radiology. To be accredited for radiological analysis, the technical manager shall have:

(a) A bachelor's degree in chemistry, engineering, or environmental, biological, or physical sciences with at least 24 college semester credit hours in chemistry; and

(b) At least 2 years of experience in the radiological analysis of environmental samples, provided that a master's or doctoral degree in one of the disciplines listed in (a), above, may be substituted for one year of experience.

Env-C 306.03 Educational Requirement for Radon Testing. To be accredited for radon analysis, the technical manager shall have:

(a) An associate's degree or 2 years of college; and

(b) At least one year of experience in the measurement of radon or radon progeny, or both.

Env-C 306.04 Educational Requirement for Toxicity Analysis. To be accredited for toxicity analysis, the technical manager shall have:

(a) 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; and

(b) At least 2 years of experience in the environmental analysis of representative biological, physical science, inorganic or organic analytes for which the laboratory is seeking approval, provided that a master's or doctoral degree in one of the above disciplines may be substituted for one year of experience.

Env-C 306.05 Educational Requirement for Chemical Analysis. To be accredited for chemical analysis, the technical manager shall meet the following qualifications:

(a) A bachelor's degree in chemistry, environmental sciences, biological sciences, physical sciences, or engineering, with at least 24 college semester credit hours in chemistry; and

(b) At least 2 years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory is seeking approval, provided that a master's degree or doctoral degree in one of the disciplines listed in (a), above, may be substituted for one year of experience.

Env-C 306.06 Educational Requirement for Asbestos Analysis. To be accredited for microscopic examination of asbestos and/or airborne fibers, the technical manager shall have:

(a) For procedures requiring the use of a transmission electron microscope:

(1) A bachelor's degree in chemistry, environmental sciences, biological sciences, physical sciences, or engineering;

(2) Successful completion of a course in the use of the instrument; and

(3) One year of supervised experience in the use of the instrument.

(b) For procedures requiring the use of a polarized light microscope:

(1) An associate's degree or 2 years of college study in any of the areas listed in (a)(1), above;

(2) Successful completion of a formal course in polarized light microscopy; and

(3) One year of supervised experience in the use of the instrument, which shall include experience in the identification of minerals.

#### PART Env-C 307 PROFICIENCY TESTING (PT)

Env-C 307.01 Participation in Scheduled and Supplemental Proficiency Testing.

(a) Laboratories shall use proficiency testing (PT) providers approved by:

(1) TNI;

(2) The U.S. Environmental Protection Agency (EPA);

(3) Other proficiency test providers that are also accreditation bodies; or

(4) A proficiency testing provider accreditor.

(b) Laboratories seeking to become accredited or to maintain accreditation shall perform analyses of PT samples for each field of accreditation for which NH ELAP accreditation is sought, as described in Volume 1, Module 1 of the TNI standards.

(c) Prior to requesting PT samples or otherwise participating in a PT study, a laboratory shall obtain an EPA laboratory identification code, ***where applicable***, which is the EPA identification code the laboratory uses when reporting results to an approved PT provider.

(d) The laboratory seeking or maintaining accreditation shall obtain scheduled and supplemental PT samples that meet the requirements of Volume 1, Module 1 of the TNI standards from any PT provider as required by Volume 1, Module 1 of the TNI standards.

(e) Subject to (h), below, each laboratory seeking to become accredited or to maintain accreditation shall participate in at least 2 PT studies per year provided by a PT Provider as required by Volume 1, Module 1 of the TNI standards.

(f) The laboratory shall successfully participate annually in at least one PT study for each drinking water method and analyte for which accreditation is sought.

(g) Subsequent PT studies for initial or continuing accreditation shall be conducted in accordance with Volume 1, Module 1 of the TNI standards.

(h) Any laboratory seeking to obtain initial accreditation for whole effluent toxicity or to maintain such accreditation shall successfully participate in at least one discharge monitoring report-quality assurance (DMR-QA) study per year provided by a PT provider.

Env-C 307.02 PT Sampling Handling.

(a) The laboratory shall analyze PT samples in the same manner as is used for routine environmental samples using the same staff, sample tracking, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures, and acceptance criteria.

(b) There shall be at least ~~15-7~~ calendar days between the ~~analyses-closing~~ date(s) of PT samples that resulted in not-acceptable results and the ~~analyses-opening~~ date(s) of subsequent PT samples.

(c) A laboratory shall analyze:

- (1) Low level PT samples for low level method accreditation; and
- (2) Medium level PT samples for regular or standard method accreditation.

(d) A laboratory shall analyze a DMR-QA PT sample in place of a non-potable water PT when required by a wastewater program standard or a TNI standard. ***If this substitution is made, the quality control and corrective action requirements of the DMR-QA shall be met.***

Env-C 307.03 PT Study Deemed Not Acceptable.

(a) Failure to meet the schedule specified in Env-307.01 shall be regarded as a not-acceptable study.

(b) A laboratory may participate in a supplemental study for not-acceptable analyses, for missed analyses, or for meeting the PT requirements for a new analysis as allowed in Volume 1 Module 1, of the TNI standards.

Env-C 307.04 Employees and PT Sample Security.

(a) An analyst employed at more than one laboratory shall:

- (1) Before analyzing any PT sample, inform the department, in writing, that the analyst is employed at more than one laboratory;
- (2) Declare to the department 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.

(b) ~~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.~~ ***Laboratory personnel, including corporate personnel, shall meet the PT sample security requirements of Volume 1, Module 1, Section 4.1.5 of the TNI standards.***

~~(c) No personnel of an accredited laboratory or of a laboratory seeking accreditation shall communicate with or otherwise attempt to exchange any information regarding PT sample results with anyone from another laboratory.~~

~~(d) No member of the management or staff of a laboratory shall obtain or attempt to obtain the assigned value of any PT sample from their PT provider.~~

Env-C 307.05 New ***Initial and Continued*** Accreditation ***PT*** Samples.

(a) A laboratory that seeks accreditation for a field of accreditation for which it has not been previously accredited shall:

- (1) Successfully complete 2 PT studies for each requested field of accreditation out of the most recent 3 rounds attempted within the 18 months preceding the application; and
- (2) Maintain a PT study history for initial accreditation in accordance with Volume 1, Module 1 of the TNI standards during the application and accreditation process.

(b) 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~~.

(c) A laboratory may withdraw from a PT study for one or more analytes or for the entire study if the laboratory notifies both the PT provider and the primary accreditation body before the closing date of the PT study.

(d) Withdrawal from a PT study shall not exempt the laboratory from participating in the semiannual schedule required by Env-C 307.01(e).

***(e) Failure to meet the PT requirements shall result in a suspension of accreditation of the affected fields of accreditation. Failure to take the appropriate corrective action to address suspended accreditation due to PT failures shall result in a revocation of the affected fields of accreditation.***

Env-C 307.06 Reporting PT Study Results.

(a) After analyzing the PT samples, the laboratory shall:

- (1) Return the results to the PT study provider for scoring no later than 45 calendar days from the date of sample receipt;
- (2) Accurately and completely report the required matrix, technology key, method code, analyte code, and result information for each PT sample; and
- (3) Authorize the PT provider to release all accreditation and remediation results and acceptable/not acceptable status directly to the primary accreditation body, the proficiency test provider accreditor, and the laboratory.

(b) Errors in reporting the proper matrix, the method used, or the tested analytes in the PT study by the laboratory shall be graded as “not acceptable”.

(c) The department shall evaluate only results received directly from the PT provider as specified in Volume 1, Module 1 of the TNI standards.

Env-C 307.07 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; ***and***
- (6) The PT study report form that documents submitted results.***

(c) The laboratory shall make all records retained available to assessors during on-site assessments of the laboratory.

Env-C 307.08 Proficiency Testing Study Results Review. If a laboratory receives a “not acceptable” result for any PT sample, the laboratory shall:

- (a) Review each “not acceptable” result to determine:
  - (1) What caused the error; and
  - (2) What corrective action(s) the laboratory needs to take to correct the problem;
- (b) Document in its own records the cause(s) and corrective action(s) the laboratory has taken to correct each problem that caused or contributed to the “not acceptable” result;
- (c) Submit the results of its own investigation and a corrective action report to the department within 30 calendar days of receiving the results; and
- (d) ~~Submit~~ ***Initiate corrective action that is documented in*** a corrective action report ***submitted*** to the department before requesting a supplemental PT study.

#### PART Env-C 308 QUALITY SYSTEMS MANUAL AND STANDARD OPERATING PROCEDURES MANUAL

##### Env-C 308.01 Establishing and Documenting Quality Systems.

- (a) The laboratory shall define and document its policies and objectives for, and its commitment to, accepted laboratory practices and quality of testing services in a quality system that is:
  - (1) Based on the required elements found in Volume 1, Module 2 of the TNI standards;
  - (2) Appropriate to the type, range, and volume of environmental testing activities it undertakes; and
  - (3) Documented in the organization’s quality systems manual as specified in Env-C 308.02.
- (b) The laboratory’s quality assurance officer shall maintain the quality systems manual to ensure that it remains accurate and up-to-date.
- (c) The quality systems manual shall be available for use by all laboratory personnel.
- (d) Laboratory management shall ensure that the laboratory’s policies and objectives are communicated to, understood by, and implemented by all laboratory personnel, by conducting:
  - (1) Internal audits as specified in Volume 1, Module 2, 4.14 of the TNI standards;
  - (2) Managerial reviews as specified in Volume 1, Module 2, 4.15 of the TNI standards; and
  - (3) Data integrity investigations as specified in Volume 1, Module 2, 4.16 of the TNI standards.

##### Env-C 308.02 Quality Systems Manual.

- (a) The laboratory shall prepare and maintain a quality systems manual that meet the requirements specified in Volume 1, Module 2, Sections 4.2.8.3 and 4.2.8.4 of the TNI standards.

- (b) The quality systems manual shall:
  - (1) Represent the laboratory's normal day to day operating procedures and policies;
  - (2) State that all laboratory staff must follow all specified ~~quality control protocols~~ ***procedures and policies***;
  - (3) Describe ***or reference*** the procedures for the development of in-house limits for analytical method quality control standards when not defined by the reference method; and
  - (4) Describe ***or reference*** the procedures for reviewing and validating analytical method support activities, analytical results, and reported analytical results.
- (c) The quality systems manual shall either include the standard operating procedures (SOPs) or reference ~~the separate document~~ where the SOPs are ~~explained~~ ***maintained***.

Env-C 308.03 Documenting Standard Operating Procedures (SOPs).

- (a) The laboratory shall prepare:
  - (1) An SOP for preparing and implementing SOPs for laboratory activities, which shall include identifying the title of each position responsible for approving each SOP, known as the approving authority(ies); ~~and~~
  - (2) An accurate written SOP for each laboratory ***administrative*** activity, including but not limited to sampling, ~~test methods, instrument operation, data generation for client samples and quality control samples~~ ***sample receiving, employee training, reporting analytical results, verification of analytical results, internal audits***, and corrective actions; ***and***
  - (3) ***An accurate written SOP for each laboratory analytical activity, including but not limited to test methods, instrument operation, data generation and quality control sample analysis, and corrective actions.***
- (b) The ***analytical*** SOPs shall ~~be consistent with EPA approved methodology~~ ***meet the requirements specified in Volume 1, Module 2, Section 4.2.8.5 of the TNI standards***. If the ~~EPA approved~~ method allows modifications, the modification used by the laboratory shall be documented in the SOPs.
- (c) The laboratory shall maintain a copy of each SOP and a record of SOP effective dates for the same period of time that records of the data generated by those procedures are required to be maintained.
- (d) Copies of each current SOP shall be made available to all personnel engaged in laboratory activities to which a particular SOP applies.
- (e) Each official version of a SOP shall bear the signature(s) of the approving authority(ies).

Env-C 308.04 Implementing SOPs.

- (a) The analyst shall use only the official version of the applicable laboratory SOP or a controlled copy of the official version of the SOP for all laboratory activities related to the analysis of compliance samples and any other sample analyses for which accreditation is required.
- (b) The laboratory shall maintain a record of each sample that is not analyzed as required by the SOPs.
- (c) The records required by (b), above, shall include:
  - (1) Laboratory sample identification;
  - (2) For each deviation from the SOP, the following:
    - a. A description of the deviation;

- b. The reason(s) for the deviation; and
- c. Client authorization or acknowledgment of the deviation; and
- (3) An analytical report that identifies all quality control failure qualifiers.
- (d) In order to be properly evaluated against quality control limits, each analytical SOP shall require that:
  - (1) Quality control standard results are calculated and recorded as percent recovery or other applicable and valid statistical technique; and
  - (2) Duplicate samples are calculated and recorded as a relative percent difference or other applicable and valid statistical technique.

Env-C 308.05 Corrective Actions.

- (a) The laboratory shall implement general procedures to be followed when departures from documented policies, procedures, and quality control (QC) measures have occurred.
- (b) The laboratory shall document departures from documented policies, procedures, and QC measures and the corrective actions taken as specified in Volume 1, Module 2, Sections 4.9 and 4.11 of the TNI standards.
- (c) ***The laboratory's documented corrective action shall include a description of the nonconforming work or departure from a policy or procedure, a root cause analysis, a selection of corrective action, an implementation of corrective action, monitoring of corrective action, additional audits performed, and signed and dated approval of laboratory management.***
- (ed) Where possible, the laboratory shall report data only if all QC measures are acceptable as specified in the laboratory's policies; ***and*** procedures; ***have been followed*** and QC measures are acceptable.
- (de) If a QC measure is found to be a departure from documented policies, procedures, and QC measures and the data is to be reported, all samples associated with the failed QC measure shall be reported with appropriate data qualifier(s).

Env-C 308.06 Essential Quality Control Procedures.

- (a) All laboratories shall:
  - (1) ~~D~~Develop and implement protocols to monitor QC measures as specified in Volume 1, Module 2, Section 5.9 of the TNI standards;
  - (b2) ***Assess and evaluate a***All QC measures shall be assessed and evaluated on an on-going basis;
  - (e3) ~~Use t~~The laboratory's documented QC acceptance criteria shall be used to determine the usability of the data; ***and***
  - (d4) ~~The laboratory shall d~~Develop and implement procedures for the development of QC sample acceptance/rejection criteria where no method, data quality objective, or regulatory criteria exist.
- (eb) QC requirements for specific analytes shall be as specified in the TNI standard identified in table 300-3, below, and the reference method(s) upon which accreditation has been granted:

Table 300-3: Applicable QC Requirements

Type of Testing	TNI Standard
Asbestos	Volume 1, Module 3, Section 1.7.2
Chemical	Volume 1, Module 4, Section 1.7.3
Microbiology	Volume 1, Module 5, Section 1.7.3
Radiochemical	Volume 1, Module 6, Section 1.7.2
Toxicity	Volume 1, Module 7, Section 1.7.1
Pathogens	Volume 1, Module 5, Section 1.7.3

PART Env-C 309 ASSESSMENTS

Env-C 309.01 Initial Assessments, Reassessments, and Surveillance Assessments.

- (a) When serving as the primary accreditation body, the department shall not issue an accreditation prior to completion of an assessment in accordance with Volume 2, Module 3, Section 6.0 of the TNI standards.
- (b) In order to maintain NH ELAP accreditation, a laboratory for which the department is the primary accreditation body shall be assessed for all fields of accreditation at least once every 2 years ***plus or minus 6 months***.
- (c) An initial assessment or reassessment shall include an administrative review of the application for completeness and a technical review of the application, quality systems manual, SOPs, and any other document submitted with the application.
- (d) Surveillance assessments shall be performed to monitor a laboratory's ability to meet requirements of accreditation between an initial assessment or reassessment and a scheduled reassessment.
- (e) Laboratory personnel shall allow duly-authorized employees of the department or an approved TPAO to enter the premises of any laboratory accredited under these rules during the laboratory's normal business hours to determine compliance with the department's rules and with applicable TNI standards.
- (f) Assessors shall have access to interview any and all staff engaged in activities related to the areas for which the laboratory requests accreditation.
- (g) Arrangements for an assessment shall be made between the program manager or TPAO and the laboratory's authorized agent or contact person.
- (h) If a laboratory refuses to allow a scheduled assessment, the department shall:
- (1) Deny initial accreditation; or
  - (2) Initiate revocation proceedings to revoke or refuse to renew an existing accreditation.
- (i) The assessment team shall use the TNI quality systems checklist(s) and technical checklists prepared by the department to conduct the assessment.

Env-C 309.02 Extraordinary Assessments.

- (a) The department or TPAO shall conduct an extraordinary assessment of a laboratory for which the department is the primary accreditation body if the program manager receives a written complaint or other credible information indicating that:
- (1) The laboratory is not meeting the requirements of its accreditation under these rules or the TNI standards; or
  - (2) The laboratory is engaged in an improper, illegal, or deceptive practice.

(b) An extraordinary assessment shall be unannounced if laboratory records could be destroyed or altered if prior notice is given.

(c) An extraordinary assessment shall be conducted during the laboratory's normal business hours, to:

- (1) Confirm that corrective actions were implemented after a previous assessment; or
- (2) To determine whether reported changes in the laboratory's ownership, key personnel, location, scope of accreditation, or other matters have affected the ability of a laboratory to fulfill accreditation requirements.

(d) The assessor shall use either a TNI quality systems checklist or a checklist prepared by the department to evaluate the merits of the information or complaints received by the program manager that were relied upon to justify an extraordinary assessment.

Env-C 309.03 Follow-up Assessments.

(a) The department or TPAO shall conduct a follow-up assessment if:

- (1) The deficiencies noted during any 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 assessment report and the follow-up assessment report were inadequate; or
- (3) Any deficiency noted during an initial assessment or any deficiency identified during a reassessment was the same as a deficiency identified during any previous assessment.

(b) The 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) If the department issues a decision to suspend, revoke, or refuse to renew an accreditation that the laboratory appeals, the department shall conduct a follow-up assessment to examine the laboratory's facilities, records, and personnel to determine the merits of the appeal.

(d) The assessor shall use the TNI quality systems checklist(s) and technical checklists prepared by the department to conduct the follow-up assessment.

(e) The laboratory may request the follow-up assessment to be canceled by withdrawing the request for accreditation for the affected field of accreditation or the appeal, as applicable.

Env-C 309.04 Assessment Report; Corrective Action Report.

(a) The department or TPAO shall issue a written assessment report ~~in hard copy or~~ **electronically** ~~copy~~ to the laboratory within 30 calendar days of any 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 or TPAO as applicable based on who provided the assessment report to the laboratory, 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, ~~on paper and in~~ **electronically** ~~format~~, using a format that is compatible with that of the department or TPAO, as applicable based on who provided the assessment report to the laboratory.

- (d) If the laboratory wants additional time to submit the report required by (b), above, the laboratory shall:
- (1) Submit a written request to the department, on paper or electronically, prior to the original deadline, which explains why additional time is needed; and
  - (2) Negotiate in good faith to establish a new deadline.
- (e) Within 30 calendar days of receipt of the corrective action report, the department or TPAO, as applicable, shall:
- (1) Determine whether the submitted corrective actions are acceptable based on the applicable TNI standard(s), reference method(s), state rule(s), or federal regulation(s); and
  - (2) Notify the laboratory in writing of its determination, by sending:
    - a. A letter, if the submitted corrective actions are acceptable; or
    - b. A follow-up report, if the submitted corrective actions are not acceptable.
- (f) If the notice provided pursuant to (e), above, identifies any deficiency(ies) in the corrective action report, the laboratory shall submit a revised corrective action report, with supporting documentation as provided in (b), above, ~~on paper and in electronically format~~, within 30 calendar days of the date of the notice.
- (g) Within 30 calendar days of receipt of the revised corrective action report, the department or TPAO, as applicable, shall inform the laboratory in writing if the submitted revised corrective actions are acceptable or not based on the applicable TNI standard(s), reference method(s), state rule(s), or federal regulation(s).
- (h) The department shall base its decision to grant or deny initial accreditation or to suspend, revoke, or refuse to renew an existing accreditation based on its evaluation of the corrective action report, the revised corrective action report, if any, and PT sample results and information submitted with the application.

## PART Env-C 310 THIRD PARTY ASSESSOR ORGANIZATIONS; THIRD PARTY ASSESSORS

### Env-C 310.01 Mandatory Use of Third Party Assessor Organization (TPAO).

- (a) The department shall require an in-state or out-of-state laboratory to use a TPAO for part or all of an assessment if:
- (1) Based on available resources, the department will not be able to perform an on-site assessment within the required on-site time frame, for example because of the number and complexity of the field(s) of accreditation for which accreditation is sought;
  - (2) Based on available resources, the department will not be able to perform an initial or reassessment within the required 2 year plus or minus 6 months time frame; or
  - (3) The department staff lacks expertise in a field of accreditation requested by the laboratory.
- (b) The department shall notify the laboratory, in writing, of the need to use a TPAO within 30 days of receiving a laboratory's application for initial accreditation or at the time an accreditation renewal application is sent to a laboratory, as applicable.
- (c) The authorized agent for a laboratory that receives a notice pursuant to (b), above, shall:
- (1) Choose the TPAO to conduct the assessment from the list of approved TPAOs prepared by the department pursuant to Env-C 310.05(d); and

(2) Not later than one month prior to the scheduled onsite assessment, inform the department in writing of which TPAO the laboratory has contracted with.

(d) If the authorized agent fails to comply with (c), above, the department shall inform the authorized agent, in writing, that accreditation shall not be granted or renewed until the requirements of (c), above, have been met.

Env-Dw 310.02 Optional Use of TPAO.

(a) A laboratory may request the department to ~~approve~~***allow*** the use of a TPAO to conduct the assessment in lieu of the department by submitting a written request that:

- (1) Identifies the TPAO the laboratory wishes to use;
- (2) Explains why the laboratory wishes to have the TPAO conduct the assessment in lieu of the department; and
- (3) Provides sufficient information and documentation, which may take the form of a sworn affidavit from the laboratory director, that the criteria specified in (b), below, are met.

(b) The department shall approve a request to use a TPAO submitted pursuant to (a), above, if:

- (1) The TPAO chosen by the laboratory is on the list of approved TPAOs prepared by the department pursuant to Env-C 310.05(d);
- (2) The department is not aware of any complaints pending against the laboratory;
- (3) The laboratory has not made any changes in key personnel, major equipment, or laboratory location within the previous 6 months; and
- (4) If applicable, the laboratory has completed all corrective actions needed as a result of any prior assessment(s).

Env-C 310.03 Payment For TPAO Assessments.

(a) The laboratory shall pay all costs associated with a third party assessment directly to the TPAO.

(b) The laboratory shall pay all department expenses related to the review and processing of TPAO assessment support documentation, ***quality control observations***, ~~and~~ report(s), ***and laboratory corrective actions*** to the department per the fee schedule specified in Env-C 303.10.

Env-C 310.04 Application for Initial or Renewal Approval of TPAOs.

(a) In order to be approved by the department, a TPAO shall submit the information specified in (b), below, on a Third Party Assessor Organization Application for Approval form, NHDES-W-03-201, dated ~~2016-12-08-12-17-2019~~ and available at

<http://des.nh.gov/organization/divisions/water/dwgb/documents/nhdes-w-03-201.docx>

<https://onlineforms.nh.gov/?FormTag=NHDES-W-03-201>, to the department: ~~(1) Electronically; and~~

~~(2) In hard copy, by mailing or otherwise delivering the application to:~~

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

(b) A complete application for TPAO approval 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 website 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, general or limited partnership, sole proprietorship, or limited liability company, 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 and the business identification number assigned by the secretary of state's office;
  - 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 federal, state, county, or local agency, the name and primary mailing address of the agency, 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 and title of the individual authorized by the TPAO to sign the application;
- (7) The full legal name of each current and former affiliated and parent organization;
- (8) The geographic area(s) in which the TPAO provides service, both domestic and foreign;
- (9) The name, title, and qualifications of each individual TPA employed or otherwise used by the TPAO for laboratory accreditation assessments;
- (10) Documentation that the TPAO meets the criteria specified in Env-C 310.05(a);
- (11) An affidavit signed as specified in (12), below, that the TPAO:
  - a. Certifies that the statements regarding the TPAO's qualifications, systems, approved assessor lists, and supporting documentation provided on or with the application are true, complete, and not misleading to the best of the applicant's knowledge and belief;
  - b. Understands that application forms and supplemental application documentation and materials are considered public data;
  - c. Acknowledges receipt of a copy of the Tennessee Warnings provided with the application package and has read and understands the contents;-
  - d. Acknowledges that all current or former relationships, associations, or investments that may influence or appear to influence my judgment, discretion, or impartiality with laboratories applying to or accredited by the program have been disclosed, and that if a conflict of interest is confirmed, the TPAO will not knowingly access records of those laboratories for personal gain and will again declare the conflict of interest to the department if I am assigned duties where a conflict may be perceived to affect my judgment; and
  - e. Agrees to comply with all applicable requirements of the State of New Hampshire and the NH ELAP related to assessment of environmental laboratories and protection of the data obtained while preparing, performing or supervising the assessment activities; and
- (12) The affidavit required by (10), above, shall be:



- a. Signed by the individual authorized by the TPAO to sign the application; and
  - b. Notarized by a notary public in the jurisdiction in which the affidavit is executed.
- (c) The TPAO shall submit a renewal application prior to expiration of its existing approval.

Env-C 310.05 Approval of TPAOs.

- (a) The department shall approve a TPAO to conduct assessments if the TPAO:
- (1) Submits all information required by Env-C 310.04;
  - (2) Documents that each of its TPAs meets the requirements specified in:
    - a. Volume 2, Module 1, Sections 6.1.4 and 6.2.4 of the TNI standards; and
    - b. Volume 2, Module 3, Sections 4.2 through 4.4 of the TNI standards;
  - (3) *Submits copies of quality system documentation that describes the TPAO operations related to on-site assessments;***
  - ~~(34)~~ Agrees to conduct assessments that meet the assessment procedures specified in Volume 2, Module 3, Section 6.0 of the TNI standards;
  - ~~(45)~~ Agrees to use the quality systems checklist and technical checklists prepared by the department, or approved by the department as being equivalent to the department-prepared checklists, when conducting assessments;
  - ~~(56)~~ Agrees to provide to the department a copy of the checklists used for an assessment with all findings recorded in hard copy or electronic copy within one calendar week of the assessment closing conference;
  - ~~(67)~~ Agrees to provide a hard copy or electronic copy of all handwritten notes and documents used to prepare the checklists described in (6), above, to the department; and
  - ~~(78)~~ Agrees to provide a draft of the assessment report to the department within 7 business days of the assessment closing conference.
- (b) The department 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 written agreement with the department by which it commits to meet the requirements of (a)(4) through (7), above, prior to conducting an assessment pursuant to Env-C 310.01 or Env-C 310.02.
- (d) The department shall maintain a list of approved TPAOs on its website.
- (e) TPAO approvals shall be valid for one year unless sooner suspended or revoked per Env-C 311.03.

Env-C 310.06 Review of TPAO Work.

- (a) The department shall review all work performed by a TPAO to determine compliance with Env-C 300 and the TNI standards.
- (b) Disputes between a laboratory and a TPAO concerning issues raised during the assessment process shall be brought to the attention of the program manager.
- (c) If the work performed by a TPAO does not comply with Env-C 300 and the TNI standards, the department 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;
  - (2) Send written notice to each laboratory whose pending accreditation review relies on the assessment performed by the TPAO of any unacceptable work performed by the TPAO; and
  - (3) Provide the TPAO an opportunity to correct the unacceptable work within 30 days.
- (d) If the TPAO wishes to correct the unacceptable work, the TPAO shall resubmit its work to the department within 30 days of the date of the written notice provided pursuant to (b)(1), above.
- (e) The department shall review any resubmitted work from a TPAO in accordance with this section.
- (f) The department shall suspend the approval of a TPAO for any field of accreditation for which the work of the TPAO has been rejected and not corrected within 30 days.
- (g) The department shall not grant accreditation to a laboratory for any field of accreditation for which the work of the TPAO has been rejected and not corrected.
- (h) Department staff shall:***
- (1) Observe the physical on-site assessment procedure of the TPAO on an annual basis;***
  - (2) Notify a TPAO of any failure to meet the requirements of Env-C 310; and***
  - (3) Provide the TPAO an opportunity to correct any failure to meet the applicable regulation.***

#### PART Env-C 311 DENIAL, SUSPENSION, OR REVOCATION OF ACCREDITATION

##### Env-C 311.01 Denial.

- (a) Reasons for the department to deny a primary accreditation 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 TNI standards including those related to education, training, and experience;
  - (3) Failure to successfully analyze and report proficiency testing samples as required by Volume 1, Module 1 of the TNI standards;
  - (4) Failure to respond to an assessment report with a corrective action report within the required 30 calendar days after receipt of the assessment report, as required by Env-C 309.04(b);
  - (5) Failure to implement the corrective actions detailed in the corrective action report as required by Env-C 309.04;
  - (6) Failure to pay required fees;
  - (7) Misrepresentation of any material fact pertinent to receiving or maintaining accreditation;
  - (8) Refusal to allow an assessor to enter during normal business hours for an assessment; and
  - (9) Failure to implement a quality system as required by the applicable provision(s) of Env-C 308.
- (b) Reasons for the department to deny a secondary accreditation application for initial or renewal accreditation shall include:

- (1) Accreditation has been denied by the primary accreditation body;
  - (2) Failure to submit a completed application within 60 days after notification of apparent errors or omissions;
  - (3) Failure to pay required fees; and
  - (4) Misrepresentation of any material fact pertinent to receiving or maintaining accreditation.
- (c) A laboratory shall have 2 opportunities to correct the deficient area(s) that resulted in a denial of accreditation.
- (d) If the laboratory is not successful in correcting the deficiencies, the laboratory shall wait at least 6 months before again reapplying for accreditation.
- (e) Upon reapplication, the laboratory shall again be responsible for all or part of the fees incurred as part of the application for accreditation.
- (f) 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.
- (g) No laboratory's application for renewal accreditation shall be denied without opportunity for a hearing in accordance with Env-C 311.04.

Env-C 311.02 Suspension.

- (a) Reasons for the department to suspend a primary accreditation shall include:
- (1) The primary accreditation body finds during the assessment that emergency action is needed to protect public health or safety;
  - (2) Failure to notify the primary accreditation body 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 Volume 1, Module 2 of the TNI standards; and
  - (4) Failure of laboratory to employ staff that meet the personnel qualifications for education, training and experience as required by the TNI standards.
- (b) The department shall send written notice to the laboratory of the department's intent to suspend the laboratory's accreditation.
- (c) The notice sent pursuant to (b), above, shall:
- (1) Identify each reason for the proposed suspension and each field of accreditation that is proposed to be suspended; and
  - (2) Inform the laboratory that:
    - a. Its accreditation shall be suspended 10 days from the date of the written notice unless the laboratory sends a written request for a hearing to the department that is received by the department prior to the expiration of that time period;

- b. The accreditation shall remain suspended until the laboratory takes all corrective actions needed to address the reasons for suspension and submits proof that the corrective actions have been completed to the department; and
- c. If the laboratory does not take all corrective actions needed to address the reason(s) for suspension and submit proof that the corrective actions have been completed to the department within 6 months of the effective date of the suspension, the accreditation shall be revoked.

(d) Except as provided in (e), below, if a laboratory submits a request for a hearing as specified in (c)(2)a., above, then the laboratory's accreditation shall remain in effect until a decision is issued after a hearing is conducted in accordance with Env-C 200 as applicable to adjudicative proceedings.

(e) Accreditation shall be suspended for each affected field of accreditation where the laboratory fails 2 out of the most recent 3 PT studies. The suspension shall remain in effect 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 effect upon the primary accrediting body's processing of the PT results.

(f) After a laboratory's accreditation has been suspended, the laboratory shall not continue to analyze samples for clients who need analytical results from an accredited laboratory in the field(s) of testing for which the laboratory's accreditation has been suspended.

(g) A laboratory shall not need to reapply for accreditation if the cause(s) for suspension are corrected within 6 months of the effective date of the suspension.

(h) If the laboratory does not correct each basis for suspension within 6 months of the effective date of the suspension, the accreditation that had been suspended shall be revoked.

(i) The laboratory shall retain accreditation for the fields of accreditation in which it continues to meet the requirements of the TNI standards.

(j) The laboratory's suspended accreditation status shall be changed to accredited when the laboratory demonstrates to the department that the laboratory has corrected the cause of the suspension.

(k) Secondary accreditation shall:

- (1) Be suspended by the department if the accreditation granted by the primary accreditation body has been suspended; and
- (2) Remain suspended until accreditation is reinstated by the primary accreditation body.

Env-C 311.03 Revocation.

(a) Reasons for the department to revoke a primary accreditation, including an interim status accreditation, shall include:

- (1) Failure to submit an acceptable corrective action plan in response to an assessment report;
- (2) Failure to implement corrective action(s) related to any deficiencies found during an assessment after submitting 2 corrective action plans as specified in Env-C 309.04;
- (3) Failure to respond to an 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 Volume 1, Module 1 of the TNI 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 assessment;
- (8) Determination of civil or criminal liability by a court of competent jurisdiction for falsifying any report:
  - a. Relating to a laboratory analysis; or
  - b. Submitted to any government entity for an official purpose.
- (9) Failure to remit accreditation fees within the time limit established by the department; or
- (10) Failure to implement corrective actions to correct deficiencies within the time period specified in the laboratory's corrective action plan.

(b) After correcting the cause(s) for revocation, the laboratory may reapply for accreditation no sooner than 6 months from the effective date of the revocation.

(c) No laboratory's accreditation shall be revoked without the opportunity for a hearing as set forth Env-C 311.04.

(d) Secondary accreditation shall:

- (1) Be revoked by the department if the accreditation granted by the primary accreditation body has been revoked; and
- (2) Remain revoked until accreditation is reinstated by the primary accreditation body.

Env-C 311.04 Action to Deny Application for Renewal Accreditation or to Revoke Accreditation.

(a) Whenever the department has reason to consider denial of an application for renewal accreditation 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 Env-C 200 prior to any final action being taken.

(c) The department shall notify the laboratory of its decision in writing by certified mail, return receipt requested. If renewal accreditation is denied or if accreditation is revoked, the written decision shall specify the reason(s) for the decision.

(d) The laboratory shall remain accredited with continued successful PT participation until the department has issued a decision to revoke or refuse to renew the accreditation.

Env-C 311.05 Reconsideration of Accreditation Status.

(a) A laboratory whose accreditation has been revoked or refused renewal may request reconsideration of the decision.

(b) Any request for reconsideration shall be made in accordance with Env-C 206.

Env-C 311.06 Successor in Interest Applying for Reaccreditation. 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.

**APPENDIX A: STATE STATUTES IMPLEMENTED**

<b>Rule</b>	<b>State Statute(s) Implemented</b>
Env-C 301, Env-C 302	RSA 485:44, II; RSA 485:47, I
Env-C 303	RSA 485:44, I; RSA 485:44, VII; RSA 485:46; RSA 485:47
Env-C 304	RSA 485:44, II; RSA 485:44 VII; RSA 485:44, X
Env-C 305, Env-C 306	RSA 485:44, II; RSA 485:44 III; RSA 485:47
Env-C 307	RSA 485:44, II; RSA 485:44, III; RSA 485:47, I
Env-C 308	RSA 485:44, II; RSA 485:47, I
Env-C 309, Env-C 310	RSA 485:44, II, RSA 485:47, I
Env-C 311	RSA 485:44, IX, RSA 485:47, III; RSA 541-A:16, I

**APPENDIX B: INCORPORATED REFERENCE**

<b>Rule (Env-C)</b>	<b>Reference (Date/Edition)</b>	<b>Obtain From (Cost)</b>
301.03; 303.01(b)(3); 303.19(a)(1); 304.05(g)&(i); 305.02(c)&(d)(1)-(2); 305.05; 305.06; 305.07; 305.08; 305.09(a)&(b); 305.10(a)&(b); 305.11; 305.13; 305.14; 307.01(b), (d), (e), & (g); 307.03(b); 307.05(a)(2); 307.06(c); 308.01(a)(1)&(d)(1)-(3); 308.02; 308.05(b); 308.06(a)&(e); 309.01(e); 311.01(a)(3); 311.02(a)(3); 311.03(a)(4)	Laboratory Accreditation Standards, Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis ( <del>2009-2016</del> )	The NELAC Institute P.O. Box 2439 Weatherford, TX 76096 817-598-1624 Cost for <del>either volume: \$130 for</del> Single Use version; <del>\$320 for</del> <del>Network version</del> <b>Volume 1: \$290</b> <b>and Volume 2: \$250</b> ; TNI members can receive a discount based on the membership level (member, patron, sponsor, partner) Order on-line at:
301.03; 304.05(b); 309.01(a)&(e); 310.05(a)(2)&(3)	Laboratory Accreditation Standards, Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories ( <del>2009-2016</del> )	<a href="http://www.nelac-institute.org/content/CSDP/standards.php">http://www.nelac- institute.org/content/CSDP/standards.php</a>

**APPENDIX C: STATUTORY DEFINITIONS**

**RSA 485:1-a:**

XIII. “Person” means 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.”

**APPENDIX D: THE NELAC INSTITUTE VOLUME 1, MODULE 1 & 2 DEFINITIONS**

“Accreditation body” means the territorial, state or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation”.

“Assessment” means the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation).

“Demonstration of Capability” means a procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.

“Field of Accreditation” means those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

“Proficiency Testing (PT)” means a means of evaluating a laboratory’s performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

“Proficiency Testing Provider (PTP)” means a person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

“Quality System” means 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) activities.

“Revocation” means the total or partial withdrawal of a laboratory’s accreditation by an accreditation body.

“Suspension” means the temporary removal of a laboratory’s accreditation for a defined period of time, which shall not exceed six (6) months or the period of accreditation, whichever is longer, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.