



<b>SOP TITLE</b>	<b>Evaluation of Accreditation Bodies</b>
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\* With the help of the regional evaluators

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## 1.0 Purpose

This document describes the procedures used by The NELAC Institute (TNI) National Environmental Laboratory Accreditation Program (NELAP) Accreditation Council, to evaluate NELAP Accreditation Bodies (ABs) for initial or continuing recognition. It is based on the SOP developed by the EPA Evaluation Workgroup under NELAC, and the SOP for the Evaluation of Accreditation Bodies, Rev. 2.0, 07-22-2009, used during the years that the 2003 NELAC Standard was in place.

## 2.0 Applicability

This Standard Operating Procedure is applicable to initial or continual reviews of Federal, State, or Tribal Accreditation Bodies conducted by NELAP Evaluators. It is based on the policies of the NELAP Accreditation Council and the 2009 TNI Standards. Unless otherwise noted, the applicable standards for this document are the 2009 TNI Standard for the Environmental Laboratory Sector, Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories." These will be referred to as "the Standard" in this document.

This document provides timelines for many of the required tasks. The overarching goal is for the process to be completed within 270 days, starting 270 days before expiration of the AB's current, valid Certificate of Recognition. Individual activities may vary from the recommended timeline (see Appendix B, and timeframes as noted in Section 6 of this document).

## 3.0 Summary/Scope

This document includes the procedures used to:

- Perform a completeness check of an AB's application and its attachments.
- Perform a technical review of these materials.
- Perform an on-site evaluation of an AB.
- Perform an observation of the AB's assessor(s) performing a laboratory assessment.
- Complete the on-site evaluation report.
- Perform the review of and response to the AB's corrective action plans.
- Provide recommendations of the evaluation team to the TNI NELAP Accreditation Council.

The examination of the systems, processes and procedures of the AB must provide a determination of the AB's compliance with the policies of the TNI NELAP Accreditation Council and its capabilities to perform laboratory assessments in a consistent, uniform manner that conforms to the 2009 TNI Standard.

## 4.0 Definitions

NOTE: Terms not defined in this section may be found in Volume 2: **General Requirements for Accreditation Bodies Accrediting Environmental Laboratories**, Modules 1 (General

Requirements), 2 (Proficiency Testing) or 3 (On-Site Assessment) of Volume II of the 2009 TNI Standard or the normative references for those standards.

**Application of Standards:** implementation of the accreditation standards by the AB and the Evaluation Teams during an evaluation of an Accreditation Body.

**Assessment Criteria:** the measures established by the Standard and applied in establishing the extent to which an applicant is in conformance with its requirements.

**Assessment Team:** the group of people authorized to perform the on-site inspection of a laboratory and evaluate proficiency testing data required to establish whether an applicant meets the criteria for NELAP accreditation.

**Audit:** a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.

**Completeness Review:** a review of the application package submitted by an AB for either new or renewal recognition. This review determines whether all required information and signatures are present. A checklist for “completeness review” may be found at [http://www.nelac-institute.org/cms/posts/1213771614.php#pab1\\_6](http://www.nelac-institute.org/cms/posts/1213771614.php#pab1_6)

**Critical Finding:** a finding or a combination of findings that results in a significant negative effect on data quality or defensibility, if not corrected.

**Date of Recognition:** date the NELAP Accreditation Council completes its vote to recognize an AB.

**Evaluation:** the process used to measure or establish the performance, effectiveness, and conformance of an organization as a NELAP Accreditation Body

**EPA Liaison:** a staff person designated by EPA to serve as liaison for the Agency to the NELAP Accreditation Council.

**Evaluation Coordinator (EC):** an individual, selected by the NELAP Accreditation Council, who coordinates all communications between the Evaluation Team and the AB, and assures all steps of the evaluation are completed in a timely manner. The Evaluation Coordinator (EC) reports directly to the NELAP Accreditation Council.

**Evaluation Team:** a team comprised of the LE, other State AB and/or EPA representatives, and any other technical evaluators approved by the NELAP Accreditation Council to conduct a review of an AB for the purposes of granting NELAP recognition to the AB.

**Evaluator:** one who performs on-site evaluation of accreditation bodies' accreditation program capability and capacity for meeting the requirements of the standard, by examining records and other evidence.

**Finding:** an assessment conclusion referenced to The TNI Standard and supported by objective evidence.

**Gap Analysis:** an assessment against a recognized standard, performed by an independent external party, typically used to identify items that require additional effort to be compliant with that standard.

**Interpretation of Standards:** an official explanation as to the meaning of a given TNI standard provided through the TNI established process.

**Laboratory Accreditation System Executive Committee:** the group within TNI that has responsibility for providing official interpretations of the standard in use, among other roles.

**Lead Evaluator (LE):** a state or EPA member of the evaluation team who provides direction for the evaluation team and is responsible for the final recommendation regarding AB recognition, based on input from the entire team.

**Mock Audit:** see Gap Analysis, above. In the context of this SOP, used to observe the assessors of a new applicant for AB recognition.

**NELAP Accreditation Council:** the body within TNI's NELAP program that has final authority for implementation of the program for the accreditation of environmental laboratories

**NELAP Recognition:** the determination by the NELAP Accreditation Council that an Accreditation Body meets the requirements of the NELAP and is recognized to grant NELAP accreditation to laboratories.

**Primary Accreditation Body:** the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting NELAP accreditation for a specified field of testing.

**Quality Assurance Officer (QAO):** an individual, selected by the NELAP Accreditation Council who participates on all AB assessments, performing a quality assurance function, and acting as a liaison between the NELAP Accreditation Council and the evaluation team. The QAO reports directly to the NELAP Accreditation Council.

**Recognition:** see "NELAP Recognition" above.

**Technical Review:** a detailed review of the materials required to be submitted by an AB as its application package for NELAP recognition. This review determines whether the documentation and policies are acceptable according to the 2009 TNI Standard, and is typically performed with the help of a detailed checklist at [http://www.nelac-institute.org/cms/posts/1213771614.php#pab1\\_6](http://www.nelac-institute.org/cms/posts/1213771614.php#pab1_6)

**Temporary Certificate:** in the event that an AB evaluation extends beyond the intended 270 days, a Temporary Certificate shall be issued (in increments of 3 months) to enable continued operation of the AB until such time as the evaluation process and voting by the NELAP AC are completed.

**Secondary Accreditation Body:** the Territorial, State or federal agency that grants NELAP accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accreditation Body. See also Recognition and Primary Accreditation Body.

## 5.0 Personnel Qualifications and Responsibilities

### 5.1 EPA Liaison

5.1.1 The EPA Liaison to the NELAP Accreditation Council shall have the following qualifications:

- At least 2 years experience within EPA's quality system for environmental data operations
- Has access to decision making groups within EPA (Regional Science and Technology Directors, Forum on Environmental Measurements, and the Quality Advisory Board Quality and Information Council)

5.1.2 The EPA Liaison has the following responsibility:

Ensures that the EC has current lists of EPA regional contacts that need to receive notice of status changes for ABs

## 5.2 Evaluation Coordinator

The EC is not a Team Member but serves a coordinating function for the evaluation process. The EC does not participate in site visits or observations.

5.2.1 The EC has the following qualifications:

Is generally familiar with TNI's activities and laboratory accreditation, and shall complete the evaluator training course.

Preferably has experience preceding the appointment that includes:

- at least two years of participation in one of the TNI consensus body committees, developing and implementing standards for use by ABs.
- at least 2 years of career experience related to laboratory accreditation or certification.
- Or suitable experience as approved by the NELAP AC

5.2.2 The EC has the following responsibilities:

Recommends the evaluation team compositions to the NELAP Accreditation Council for consideration

Assists the evaluation team by assuring all communication between the evaluation team and the AB, and between the evaluation team and the NELAP Accreditation Council occurs in a timely manner.

Ensures that EPA regional QA Managers and Certification Officers receive formal notification whenever the status of an AB is updated.

Coordinates with the EPA Liaison to the NELAP Accreditation Council to ensure that any potential negative impacts of changing AB status are communicated to the appropriate EPA Regional contacts.

Tracks and documents that all aspects of AB evaluations are performed in a timely manner in conformance with the evaluation SOP and the 2009 TNI Standard.

Reviews the AB application for completeness, with concurrence of the LE.

Reviews the evaluation reports for completeness and consistency according to the evaluation SOP and the Standard.

Provides regular status reports to the NELAP Accreditation Council.

### 5.3 QA Officer

The QAO is not a team member but does accompany the team for each site visit, and may participate in other team activities.

#### 5.3.1 The QAO has the following qualifications:

Has successfully performed assessments of laboratories or other organizations

Preferably has experience preceding the appointment that includes at least one of the following:

- certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;
  - one year of experience implementing federal or state laboratory accreditation rulemaking;
  - one year experience developing or participating at a managerial level in laboratory accreditation programs;
- Or suitable experience as approved by the NELAP AC

Has documentation that verifies freedom from any conflict of interest that would compromise acting in impartial nondiscriminatory manner.

#### 5.3.2 The QAO has the following responsibilities:

The QAO assures all AB evaluations are performed in a consistent manner in conformance with this Standard Operating Procedure for the Evaluation of Accreditation Bodies.

The QAO reviews the following aspects of the AB evaluation process:

- technical review of the AB application;
- on-site evaluation of the AB;
- review of the AB's corrective action plans;

Informs the NELAP Accreditation Council of any unresolved consistency problems as they occur and will provide a report to the NELAP Accreditation Council at the completion of each AB evaluation, or at times requested by the Council.

Notifies the LE of common findings from other Evaluation Teams and to highlight these findings in the summary to the LE and the TNI Board of Directors and NELAP Accreditation Council. The purpose of this communication is to ensure consistency among the ETs.

Is responsible for submitting standards interpretation requests on behalf of the Evaluation Team. The QAO is also responsible for notifying the Evaluation Team(s) as to the final interpretation of a standard.

### 5.4 The Evaluation Team (ET)

#### 5.4.1 Member Qualifications

The members of the ET must apply the 2009 TNI Standard and the requirements of this SOP when reviewing the Accreditation Body's implementation of the NELAP program.

All ET members must comply with the policies of the TNI NELAP Accreditation Council (<http://www.nelac-institute.org/cms/posts/1213771614.php>)

All ET members must successfully complete a TNI accreditation body evaluator training course that will be based on this SOP, the standard, and other materials such as the completeness and technical review checklists.

Additionally, the NELAP ET shall include:

- at least one member who is a NELAP assessor

And

- at least one member with experience that includes at least one of the following:

- certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;

- one year of experience implementing federal or state laboratory accreditation rulemaking; or

- one year of experience developing or managing a laboratory accreditation program.

Teams will include at least one state AB representative; the other member is preferred to be from the EPA region where the AB is located. If the EPA region does not provide a representative, then another EPA representative may be accepted, or else a second state AB representative (from a different AB) should be selected.

The evaluation team shall agree on one of its members being designated LE, and shall submit that person's name to the NELAP Accreditation Council for approval.

At the discretion of the NELAP Accreditation Council, some other combination of assessment experience and other related training may substitute for these qualifications; documentation of this discretionary decision shall become part of the permanent record of the AB's evaluation. The Accreditation Council will conduct a formal vote to accept alternative team qualifications for any team where deviations from these requirements are needed, with the motion being voted to include the justification as well as the deviation accepted.

5.4.2 The ET has the following responsibilities:

- Choose a leader from among its membership

- Carry out the evaluation of the assigned AB, in accordance with this SOP.

5.4.3 The size of the team shall be established based on the size of the AB, the number of laboratories the AB assesses and the number of assessors internal to the AB. For example an AB with three assessors and 40 laboratories may use two evaluators.

## 5.5 The Team Leader (Lead Evaluator or LE)

The LE is chosen from the team and generally is responsible for planning activities. All members of the evaluation team should be involved to ensure that the evaluation is well planned and consistent with the evaluations of other ABs.

5.5.1 The LE has the following additional responsibilities, beyond those of a team member:

Plans and orchestrates the activities of the team members, from technical review through site visit, observation, report writing and review of all responses to deficiencies or findings.

Conducts all communications with the AB once the application is received.

Provides direction to the evaluation team throughout the evaluation process.

Is responsible for obtaining consensus of the evaluation team in preparing the final recommendation of AB recognition status to the NELAP Accreditation Council.

Is responsible for notifying the EC and QAO of all required communications and events.

Is responsible for informing the EPA liaison of any issues which may affect EPA programs, particularly any concerns affecting the analysis of drinking water.

**5.6 The NELAP Accreditation Council**

5.6.1 The NELAP AC has the following responsibilities:

Identify Evaluation Team (ET) members for each upcoming evaluation.

Prepare and send renewal letters to existing ABs, nine months before existing recognition expires.

The NELAP Accreditation Council Chair or designee shall provide the ETs with copies of previous evaluation report, the previous recommendation, and if requested, other retained records from the previous evaluation.

Receive updates on progress of the various evaluations at its periodic teleconference meetings

Receive the recommendations of the ETs and vote on the renewal status of each AB, according to SOP 3-101, "The NELAC Institute NELAP Accreditation Council Voting Procedure for General Business and Laboratory Accreditation Matters."

Prepare renewal letter and Certificate of Recognition. Deliver both to the AB, the LE and the EC for transmittal to appropriate staff in the relevant EPA Regional Office and the EPA Liaison.

**5.7 Conflict of Interest**

Further, all members of the evaluation team, and the QAO and EC, must sign the conflict of interest certification and provide it to the LE after the NELAP Accreditation Council designates the evaluation team members and before commencing the technical review; the LE will inform the NELAP Accreditation Council if any conflicts exist. See Appendix A for the Conflict of Interest form.

## 6.0 Procedures

### 6.1 Frequency and Scope of Evaluation

Accreditation Bodies shall be evaluated initially and at a minimum of once every 3 years thereafter. This evaluation will include:

- Completeness and technical reviews of the application package,
- An on-site evaluation,
- Observation of the AB conducting an on-site laboratory assessment by an ET member,
- On-site evaluation report(s) with findings for both the on-site evaluation and the observation, and
- Recommendations to the TNI NELAP Accreditation Council regarding recognition or denial of recognition.

See section 5 for personnel qualifications and responsibilities.

### 6.2 Initial Application Process

#### 6.2.1 Initial Application

Initial application forms can be obtained from the NELAP Accreditation Council.

The application must be signed and dated by the highest ranking individual within the department or agency responsible for laboratory accreditation activities for which NELAP recognition is being sought. (This is the person that has the ultimate authority and responsibility for accreditation decisions.) By signature on the application, this individual must attest to the validity of the information contained within the application and its supporting documents

#### 6.2.2 Application Submittal

An electronic version of the completed application and supporting documents shall be submitted to the NELAP Accreditation Council chairperson or designee. Copies of the completed application and any supporting documentation shall also be submitted to the EC and QAO.

With prior arrangements, paper copies of application materials may be accepted. If paper is used, then once the ET is selected, the AB applicant becomes responsible for delivering paper copies to the ET members also.

Upon receipt of the application and supporting documents the NELAP Accreditation Council chairperson or designee shall send an acknowledgement to the AB and establish an evaluation team, with the approval of the NELAP Accreditation Council. The EC will distribute the application to the team, if electronic.

#### 6.2.3 Application Communications

Once the application is given to the EC, all subsequent communications shall be between the LE and the AB, with copies provided to the EC. The LE or designee will respond to these communications as necessary.

The timeline for a new application shall be equivalent to that for a renewal application, from the point at which the application is received and an evaluation team appointed (see also APPENDIX B.)

### **6.3 Renewal Application Process**

#### **6.3.1 Notification**

The NELAP Accreditation Council chairperson or designee will send a letter with an attached application to the AB at least 270 calendar days prior to the expiration of the AB's current NELAP recognition with copies sent to the EC and appropriate LE. In the letter, the NELAP Accreditation Council will indicate that copies of the completed application and all supporting documentation shall be submitted directly to the EC, LE, QAO, and other ET members; all team members will be identified in the letter. The letter shall be sent by any method providing receipt confirmation.

#### **6.3.2 Application Submittal**

Copies of the completed application and any supporting documentation shall be submitted to the EC, LE, QAO and team members within 30 days of receipt of the renewal letter.

If the AB does not submit a renewal application within 30 days, the AB will receive final notification from the NELAP Accreditation Council or the EC by any method providing receipt confirmation that, if an application is not submitted within another 30 days, the AB's recognition will expire with the current NELAP certificate of recognition.

#### **6.3.3 Application Communications**

Once the application is given to the EC, all subsequent communications shall be between the LE and the AB, with copies provided to the EC, until such time as the recommendation is submitted to the NELAP Accreditation Council. The LE will respond to these communications as necessary.

### **6.4 Review of Application and Supporting Documents**

#### **6.4.1 Application Completeness Review**

The AB will submit an application, using the application form that is available on the TNI website [http://www.nelac-institute.org/cms/posts/1213771614.php#pab1\\_6](http://www.nelac-institute.org/cms/posts/1213771614.php#pab1_6) Following receipt of a new or renewal application, the EC shall notify the AB and the evaluation team that the application has been received. The EC shall review it for completeness within 30 days, using the "Checklist for Application Completeness," [http://www.nelac-institute.org/cms/posts/1213771614.php#pab1\\_6](http://www.nelac-institute.org/cms/posts/1213771614.php#pab1_6) and will report to the LE.

If the application is complete, the LE will advise the AB, the ET, and the QAO that the application is complete.

If the application is not complete, the EC will send the completeness deficiency report to the LE for review. The LE will send the AB an Application Completeness Deficiency Report (Appendix C includes a possible example of a deficiency report letter) in writing. The NELAP Accreditation Council and ET will receive a copy of this Deficiency Report.

The AB shall have no more than 30 days from receipt of the Completeness Deficiency Report to supply any missing information to the EC and LE. If the missing material was inadvertently not submitted, it should be transmitted. If the missing material does not exist, that fact shall be highlighted to the LE to be addressed during the on-site visit. Once the EC and LE determine that the application is complete (or acceptable with deficiencies to be addressed during on-site,) the LE shall notify the AB and the NELAP Accreditation Council of this determination.

Extensions up to 30 days may be granted by the NELAP Accreditation Council.

#### 6.4.2 Application Technical Review

The ET shall then conduct a technical review to verify that all required items have been addressed. The applicant's completed TNI Standard Compliance Checklist [http://www.nelac-institute.org/cms/posts/1213771614.php#pab1\\_6](http://www.nelac-institute.org/cms/posts/1213771614.php#pab1_6) will be used as a guide to determine accreditation body compliance with the Standard. The review shall be performed by the same ET assigned to the on-site evaluation.

The ET shall review the application and supporting documents to evaluate whether the AB's accreditation program requires its laboratories to meet the Standard.

The evaluation team has 30 days to conduct this review after the application is determined complete and respond in writing to the AB. The ET will send, by any manner providing receipt confirmation, an application technical review deficiency report to the AB (see Appendix D.)

The AB will have 30 days to respond to any deficiencies with written corrective actions, clarifications, or revised documentation. The ET shall review and respond to the AB's corrective actions within 30 days of receipt. If the ET determines that substantial deficiencies remain in the application materials or are not addressed by the AB's corrective action plan, the application may be considered as "incomplete" by the LE and the evaluation will proceed from section 6.3.2 of this SOP.

Items not satisfactorily remedied by this opportunity for the AB to correct its deficiencies may be deferred to the on-site visit for further consideration. Deficiencies remaining after the on-site visit shall be included in the ET's report as Findings to be addressed by the AB's corrective action report (Section 6.12)

If the initial application as submitted contained no deficiencies or after the opportunity for corrective actions was provided, the evaluation process will continue and the NELAP ET shall schedule the on-site evaluation.

#### 6.5 Scheduling the On-Site Program Evaluation

Once the ET determines that the documentation is satisfactory and the application is accepted, the AB will be notified within 30 calendar days to schedule the on-site evaluation. An on-site evaluation shall be conducted, at the mutual convenience of the ET and the AB, normally within 60 days of completion of the application technical review.

The LE, on behalf of the ET, will send written confirmation to the AB of the logistics required to conduct the evaluation, and to all of the evaluation team members. The written confirmation shall include, but is not limited to:

- onsite evaluation date and agenda or schedule of activities
- copies of the standardized evaluation checklists,
- the names, titles, affiliations, and on-site responsibilities of the NELAP ET members and QAO, and
- The names and titles of AB staff that need to be available during the on-site evaluation.

#### 6.6 Conducting the On-Site AB Evaluation

The LE shall conduct an opening meeting prior to the start of the evaluation. The opening meeting should cover the topics noted in Appendix G.

The ET shall conduct a comprehensive evaluation of the AB's accreditation program to determine the accuracy of information contained in the AB application and the AB's conformance to the 2009 TNI Standard. The ET will do this by:

- interviewing management and technical staff (AB lab assessors) and reviewing internal AB audits and management reviews to determine if they were completed as required, and if corrective actions were taken to address noted deficiencies;
- reviewing a minimum of three files from the list of NELAP accredited laboratories (more files should be reviewed if significant findings warrant) or other accredited laboratories if this is a new NELAP application. The number of files reviewed, as well as the number of laboratories accredited by the AB, shall be included in the On-Site report.
- reviewing evaluation forms submitted by laboratories, if used by the AB;
- reviewing records of resolution of complaints about laboratories, including disputes and appeals;
- reviewing records of resolution of complaints from laboratories about the accreditation body, including disputes and appeals;
- reviewing the training records and conduct interviews of AB staff designated as qualified assessors to evaluate their training, knowledge of assessment techniques and the Standard; and
- observing the AB during its on-site assessment of a laboratory. The laboratory selected should hold sufficient fields of accreditation to allow the team to observe a comprehensive on-site assessment by the AB. A second laboratory assessment observation may be necessary if a laboratory performing work in sufficient fields is not due for an AB assessment. See Section 6.9 regarding purpose of observation.
- reviewing the last NELAP evaluation report (not applicable if this is a new application).

The ET shall determine if the AB is in conformance to their internal quality system documents.

The ET will assess the AB to ensure that the AB is in compliance with all NELAP Accreditation Council policies and procedures, as well as existing interpretations of the 2009 TNI Standard (that may have changed over time, posted to [\[URL here.\]](#))

When selecting laboratory files to review, the evaluation team will select those with varying fields of accreditation and different assessors. The ET will also include files from i) a laboratory that has lodged a complaint, ii) a laboratory against whom a complaint was lodged, if applicable; and (iii) a laboratory that was cited for severe quality system deficiencies, if applicable. At a minimum, the team will review the following information in each selected laboratory file:

- Application
- Conflict of interest verification
- checklist(s) used for laboratory audit
- Proficiency testing (PT) results for compliance with methodological and EPA program requirements
- Deficiency report(s)
- Corrective action report(s)
- Correspondence
- Opening and closing meeting attendance sheets
- Final report
- Evaluation forms for AB assessor (if used.)
- Certificate if granted

The LE will conduct an exit debriefing to discuss all noted deficiencies. (see Appendix H)

## **6.7 Adaptations for On-site Evaluation of New (Prospective) ABs (as compared to renewal evaluations in section 6.7)**

No modifications to opening meeting.

Comprehensive evaluation needs to take into account the lack of “active” program implementation.

### **6.7.1 Interviews**

The ET should interview assessors and managers to determine (a) their knowledge of the AB’s quality system and its associated procedures (as documented in its SOPs, forms, and other documentation,) and (b) their understanding of the current standards.

### **6.7.2 Review of Records**

The emphasis of the records reviews should focus on records which have been listed in the application as being in place. The ET shall include in its report a suggestion that the AB submit examples of assessment reports, follow-up reports, etc., to the LE. These documents would provide the LE with information about the AB’s implementation of its new program.

### **6.7.3 Observation of the ABs Laboratory Assessment**

This mandatory observation will be met by one of the following:

- The AB may arrange to perform a “mock audit” or “gap analysis” of a volunteering laboratory, possibly even the state’s own lab. This would provide valuable experience to the assessors, technical assistance to the laboratory and useful information to the ET.
- A laboratory observation may be scheduled and performed during the first year of AB operations.

### **6.7.4 On-site Assessment Report**

The report of the on-site visit shall request that the AB forward to the LE and/or the EPA Regional Office ET member such documents as examples of assessment reports, internal assessments and associated corrective actions and completed feedback evaluations from laboratory assessments completed over the first year of operation. These may help confirm implementation of a successful program and also provide affirmation to the EPA Regional Office that responsibilities of the AB to meet the Safe Drinking Water Act certification for labs are met. If there are concerns from later review of documents, as described in this section, the LE or EPA/ET member should relay those concerns to the NELAP Accreditation Council for consideration and possible action (as determined by the Council.)

## **6.8 Scheduling of the Observation of the Laboratory Assessment**

At least one member of the NELAP evaluation team must observe the AB conducting an actual on-site laboratory assessment. The purpose of the laboratory observation is to perform an evaluation of the AB’s conformance to the 2009 TNI Standard in performing laboratory assessments. The QAO may also be present at the on-site laboratory assessment. At the time the on-site evaluation is being scheduled, the LE should request from the AB a schedule of upcoming laboratory assessments. The LE will use this schedule to select the lab assessment which will be observed during the on-site evaluation or other mutually agreed time. (Note:

Although the observation can be conducted prior to the on-site AB evaluation, it should not take place until after the technical review issues have been resolved.)

The LE may elect to send more than one member of the evaluation team to observe the assessment. This decision should be based on: (1) the scope of the laboratory assessment and the number of AB assessors involved and (2) the availability of members of the evaluation team.

### **6.9 Conduct of the Laboratory Assessment Observation**

During the observation of the laboratory assessment, the evaluation team member's role is to observe the AB's laboratory assessment team. The evaluation team members are not active participants in the laboratory assessment. The evaluation team member(s) should make every effort to observe as many aspects of the AB's assessment as possible and should make sure to concentrate on areas where the technical review may have revealed weaknesses in the AB's program.

Within the AB Compliance Checklist [http://www.nelac-institute.org/cms/posts/1213771614.php#pab1\\_6](http://www.nelac-institute.org/cms/posts/1213771614.php#pab1_6), certain questions are considered to constitute the Observation checklist. These questions shall be completed during the observation (presently questions numbered 353 and 360-370.)

### **6.10 Documentation of Findings from the Laboratory Assessment Observation**

Each member of the ET that participates in the laboratory assessment observation must transmit his/her observations to the LE for inclusion in the on-site evaluation report. These findings must be transmitted to the LE in a timely manner. The exact due date shall be determined by consensus of the ET members to make sure that no deadlines are missed.

The ET member performing the observation is not expected to evaluate the assessor's competence during this observation, but rather to determine that documented procedures are followed. The ET should establish (during the technical review and on-site) whether the AB's quality system would detect an inability to meet the standard (e.g., capabilities).

The evaluation team has 30 days to prepare and send findings of the on-site evaluation to the AB by any method providing receipt confirmation. (Note: The AB evaluation is not considered complete until the on-site evaluation and laboratory assessment observation are complete.) (see Appendix F for template)

### **6.11 Documentation of Findings from the On-Site Program Evaluation**

Documentation of the findings shall be delineated in the final report, along with any findings from the observation of the accreditation body's on-site assessment of a laboratory.

### **6.12 Corrective Action Report**

The AB shall prepare a Corrective Action Report (CAR), describing how it either has or plans to address the findings from the On-Site report. The AB has 30 days from receipt of the On-Site Report to submit this CAR.

### **6.13 Response to the AB CAR**

Each member of the ET must review the AB's response to the on-site evaluation report, including its proposed corrective actions, and transmit their review to the LE in a timely manner. The LE shall respond to the AB in writing, within 30 calendar days of receipt of the AB CAR.

If the AB CAR does not address all deficiencies, the LE shall notify the AB by any method providing receipt confirmation that it must submit another CAR for the remaining deficiencies within 30 calendar days of receipt of this notification.

If the AB corrects all the deficiencies, the LE shall recommend to the NELAP Accreditation Council that the AB be granted NELAP recognition.

If the AB does not correct all deficiencies, the LE may recommend to the NELAP Accreditation Council that the AB's NELAP recognition be revoked, or that provisional recognition/approval be invoked [per SOP under development.]

The LE must consider the AB's responses in preparing written recommendations to the NELAP Accreditation Council (as discussed in Sec. 5.5.1).

#### **6.14 Recommendations to the NELAP Accreditation Council**

At the end of the evaluation process, a recommendation to the NELAP Accreditation Council regarding NELAP recognition shall be made. The LE shall be responsible for preparing the written recommendation with input from, and on behalf of, the entire evaluation team, and should be present (or designate a team member to be present if necessary) for the NELAP Accreditation Council's discussion of the recommendation prior to its vote. Appendix F provides a model recommendation letter. A copy of the team's recommendation shall also be sent to the QAO, all members of the ET, and the appropriate EPA contacts of that EPA region as provided by the EPA liaison if the team does not include a representative from that region.

If the NELAP Accreditation Council disagrees with the recommendation of the evaluation team, it will notify the evaluation team prior to the notification of the AB. The NELAP Accreditation Council will provide the ET with the reason(s) for its disagreement and allow the team to respond to those reasons with additional details. When the AB receives notification of this decision, the EPA Liaison shall be notified as well, so that the relevant EPA Regional Office will be notified.

The renewal or dismissal letter and the certificate, if one is awarded, will then be issued and mailed by the NELAP Accreditation Council.

#### **6.15 Issuance of Certificate of Recognition to the AB**

The issuance of Certificates of Recognition shall be the responsibility of the NELAP Accreditation Council.

Certificates will be awarded for a period not to exceed 3 years from the date of expiration of the prior evaluation's Certificate of Recognition.

A copy of the Certificate shall be sent to the EPA liaison for distribution to the EPA Regional Office, and also to the LE. ET members may request a copy from the LE if desired.

The Date of Recognition shall be included on the Certificate.

Should the evaluation process extend beyond the expiration date of the prior Certificate, a temporary certificate may be issued by the NELAP AC, until the recommendation of the ET is voted upon. That is, the "old" certificate remains in effect until the evaluation and voting processes are completed, but when a new Certificate is issued, the expiration date shall be three (3) years from the expiration of the prior certificate.

#### **6.16 Handling of Unexpected Circumstances**

In the event that the team encounters an unexpected or unusual circumstance, the LE should seek guidance from the QAO and the NELAP Accreditation Council. This will help ensure consistency in how such circumstances are handled.

#### 6.16.1 Standard Interpretation Process

If the ET has questions regarding the meaning of a standard, the Lead Evaluator is to convey the question/s to the QAO.

The QAO is to use the Standards Interpretation Request (SIR) form available on the TNI website to request an interpretation of a TNI Standard. Use of this form will ensure that the question is handled according to the SOP in place for SIRs. (TNI SOP for Standards Interpretation, SOP-5-101)

Timelines are defined in SOP 5-101 for the NELAP Accreditation Council Chair and LASC Chair to act on the request. The QAO is to follow progress and encourage more timely action given the tight schedule for AB evaluations. The rest of the evaluation should proceed normally, pending resolution of the SIR.

All parties involved in the SIR may be contacted and asked to expedite resolution of the request, due to the time-sensitive nature of the AB evaluation process.

Publication of the consensus resolution is then made to the affected parties via email and on the TNI web site. Also, the QAO will be responsible for informing the Evaluation Team as to the final interpretation of the standard.

Clear non-compliance to a standard is not subject to the interpretation process listed above but necessitates the documentation of findings and corrective actions as listed in the sections below. (If the AB disagrees, it may utilize the dispute resolution process.)

#### 6.16.2 Scheduling Conflicts

It should not occur that a renewing AB has no on-site laboratory assessments scheduled during the review period, since the AB will have known that its renewal was pending and when its application was submitted, thus ensuring at least half a year advance notice.

#### 6.16.3 Extensions

If extensions to timeframes are needed, the AB or LE should request an appropriate amount of time extension in writing, to the NELAP Accreditation Council Chair. Supporting justification must be provided, and multiple extensions will occur only in extraordinary circumstances.

#### 6.16.4 Dispute Resolution

Disagreements with matters concerning recognition can be addressed through the TNI Dispute Resolution Process (SOP 5-100).

## 7.0 Criteria, Checklists, Standards

All evaluators must ensure that they are using the current, adopted version of the 2009 TNI standards and checklists.

The reference documents may be found at [URL of the section of the TNI website for each of the reference documents]

## **8.0 Records Management**

Records associated with the evaluation of the ABs shall be handled in accordance with TNI Policy POL-104 Management of Records. All AB evaluation records shall be electronic, preferably in portable document format (pdf).

The LE is responsible for submitting all final documents, letters, checklists, etc., in electronic format to the NELAP Accreditation Council and the NELAP program administrator within 30 days of the team's final recommendation. These items shall constitute the formal record:

- the application materials
- conflict-of-interest forms from team members, QAO and EC
- correspondence about the completeness review and the completeness checklist
- correspondence about the technical review and the final checklist as completed
- the on-site report, to include the observation report
- the AB's response(s) to the on-site report, if corrective actions are needed, and evidence that the corrective actions are complete
- the letter of recommendation to the NELAP Accreditation Council
- the NELAP Accreditation Council's letter to the AB notifying them of the Council's decision and the status of the AB shall also be added to this permanent record by the Program Administrator, as shall a copy of the Certificate sent to the AB.

The LE and/or the EC, at his/her discretion, may retain a complete file of the AB evaluation. Members of the ET wishing to retain copies of the official record should make that known to the LE at the time the recommendation is sent to the NELAP Accreditation Council. Evaluation team members should retain all working documents and evaluation notes for five years or submit them for archiving to the NELAP Program Administrator.

## **9.0 Quality Control**

This SOP will be reviewed every three years or whenever the TNI standard is updated, whichever occurs first. The NELAP Program Administrator will initiate this review by contacting the appropriate committee.

This review will be documented and any changes deemed necessary will be made with the LAS EC and NELAP Accreditation Council's approval.

If the document is revised, the revisions will be distributed to the NELAP evaluators and the NELAP Accreditation Council.

## **10.0 References**

The TNI Standard 2009, Volume 2, Modules 1, 2 and 3

SOP 3-101, "The NELAC Institute NELAP Accreditation Council Voting Procedure for General Business and Laboratory Accreditation Matters"

TNI Records Policy 104

TNI SOP on Dispute Resolution (verify reference)

TNI SOP for Standards Interpretation, SOP-5-101

TNI SOP for Provisional Approval, SOP-X-YYY

URL for “example” evaluation tools – Jerry to provide when created

AB Application for Renewal [URL]

Checklist for AB Application Completeness [URL]

Checklist for AB Compliance [URL]

## 11.0 SOP Approved Changes

Original SOP

Approved by the NELAP Board: July 22, 2009

Reviewed by the Policy Committee:

Endorsed by the Board of Directors:

Prev. SOP No.	New SOP No.	Date of Change	Description of Change
Unknown		10/22/07	Updated personnel list for Appendix A and B.
		10/22/07	Editorial and formatting.
		10/23/07	Correct and format reference in Section 6.4
		11/06/07	Incorporated comments from EPA evaluators
001 Rev. 8.4	3-102 Rev 1	12/15/07	Change to new SOP format.
		02/15/08	Incorporated comments from evaluator training
3-102 Rev 1	3-102 Rev 2	7/22/2009	Final version to incorporate provisions for evaluating new ABs: Added definition for Evaluator, Changes to Sections
		4/9/2010	New language re interpretation/application
		4/16/2010	New language to address additional evaluator discussion
		5/13/2010	New language to address concerns from NELAP Board and individual evaluators
		6/3/2010	Formalize version control, make changes discussed in evaluator call 5/19/10
		6/22/2010	Make changes discussed in 6/9/10 evaluator call, add appendices for report template and closing meeting, fix page numbers in index, accept all changes and send to AB Cmte w/ cc to evaluators
		7/21/2010	Made changes per discussion on 7/20 Lab AB Committee teleconference, including major restructuring of the qualifications and responsibilities section so it is by role instead of quals, then duties. Rebecca Pierrot of ALS agreed to tackle sorting out the “outline” function that has become badly mangled during repeated edits from the old version for the NELAC standard.
		7/29/2010	Minor edits from further Lab AB committee review and one from the Task Force

Evaluation of Accreditation Bodies

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3-102 Rev 2	3-102 Rev 3	8/19/2010	Minor edits to remove comments and typos as LAB Committee finalizes its approval.
		11/23/2010	LAS EC approved edits plus one edit added by AC
		6/21/2011	edits to adapt ET selection to shortage of evaluators due to out-of-state travel restrictions and staffing shortages

Note: Earlier versions of this document showed a revision number of 9.0, dating back to an SOP developed by NELAC.

# Appendix A

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## Evaluation Team Conflict of Interest Form

Name \_\_\_\_\_

Agency \_\_\_\_\_

Date of NELAP Evaluator Training Course \_\_\_\_\_

Name of Accreditation Body Being Reviewed \_\_\_\_\_

I certify that I have no known relationship with the above Accreditation Body that would impair my objectivity in the performance of my responsibilities as described in the NELAC Standards.

Signature \_\_\_\_\_

Date \_\_\_\_\_

# Appendix B

## Application Review Tracking Checklist

Item	Days Allowed	Date Completed (total days elapsed)
Assignment of Evaluation Team	Completed before renewal letter is sent	Asap if new applicant
EPA Region proposes additional technical evaluators to NELAP Accreditation Council	ASAP once teams are agreed upon	
Application Renewal Notification	270 days prior to certificate expiration	Day 0
NELAP Accreditation Council sends out renewal letter	--	
AB returns complete application	30	30
NELAP Accreditation Council notifies AB of late application	30	30-60
Conflict of Interest forms submitted to LE	7	(30-during application prep time)
LE informs NELAP Accreditation Council of COI (Y/N)	3	(60-during application prep time and possibly completeness review period)
Application Completeness Review	--	
Evaluation team conducts review	30	60-90
LE notifies AB of deficiencies		
AB response to deficiencies	30	90-120
Application Technical Review	--	
Evaluation team conducts review	30	120-150
LE notifies AB of deficiencies		
AB response to deficiencies	30	150-180
Evaluation team reviews response		180-210
Schedule On-Site AB Evaluation	-- (within 60 days)	210-270
LE notifies AB of on-site review logistics		
Conduct on-site review		
Conduct Observation of AB Lab Assessment		210-270
Prepare Final Report		
Send Final Report to AB	30 days from end of total on-site	240-300
AB response to Final Report	30 days from receipt of Rpt.	270-330
Evaluation team reviews response	30 days	300-360

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Item	Days Allowed	Date Completed (total days elapsed)
Notice to AB that additional corrective action is required	ASAP	
AB 2 <sup>nd</sup> response to deficiencies	30 days	330-390
ET review of second response	30 days	360-410
Response to AB and Recommendation to NELAP Accreditation Council	ASAP	

## Appendix C

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### Model Letter for Application Completeness Review Deficiencies

#### EXAMPLE

Dr. Xxxxx N. Yyyyyyy  
Xxy State Dept. of Health  
P.O. Box XXX  
Xxxx, Xxx 45690

Dear Dr. Yyyyyyy,

The National Environmental Laboratory Accreditation Program (NELAP) Evaluation Team (ET) assigned to the Xxx Accreditation Body has completed its review of the renewal application dated November 21, 2003. As you are aware, a completeness review is conducted by the ET in order to determine whether or not the information and supporting documentation required by the application form and checklists.

The ET believes that the Xxx application is incomplete because:

[List deficiencies and reference 2009 TNI V2M1 Standard for each deficiency]

You have 30 days from receipt of this letter in which to provide the requested information. Thank you for your prompt attention to this matter. If you have any questions, please feel free to contact me at (xxx) yyy-zzzz.

Sincerely,

Yyyy Y. Zzzzz

NELAP Lead Evaluator

cc: NELAP Accreditation Council

# APPENDIX D

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## Model Letter for Technical Review Deficiencies

Dr. Xxxxx N. Yyyyyyy  
Xxy State Dept. of Health  
P.O. Box XXX  
Xxxx, Xxx 45690

Dear Dr. Yyyyyyy,

The National Environmental Laboratory Accreditation Program (NELAP) Evaluation Team (ET) assigned to the [insert state] Accreditation Body (AB) has completed its technical review of the renewal application dated **month day, year**. As you are aware, a technical review is conducted by the ET in order to determine whether or not the accreditation body's environmental laboratory accreditation program requires its accredited laboratories to meet the standards set forth in the 2009 TNI Standards. The ET review is based on the 2009 TNI Standard.

The ET has identified a number of findings on Attachment 2, "Checklist to Determine Accreditation body Compliance." Items on the checklist which have been checked "No" are deficiencies. Specific comments relative to each deficiency have been provided in the "Document Location/Comments" column. In addition to the items which have been checked "No," there are some items where we have included a "?" in either the Yes or No column. In these instances the ET could not determine if the requirement had been met or not. Additional information to clarify what has been provided is needed by the ET in order to make a final determination. This additional clarifying information should be provided in your response to this report. Please note that while some items have been checked "Yes," the actual implementation of these requirements cannot be assessed until the actual on-site assessment of the XYX AB program takes place later this month.

Per NELAP policy, you have 30 days in which to provide a corrective action response to this technical report. Please attach to your response any new or updated documents cited in your corrective action response.

If you have any questions or require clarification regarding any of our findings, please feel free to contact me at (xxx) xxx-xxxx.

Sincerely,

Yyyy Y. Zxxxz

NELAP Lead Evaluator

cc: NELAP Accreditation Council

# Appendix E

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Template for On-Site Report

**NELAP ACCREDITATION BODY**  
**REPORT of ON-SITE EVALUATION**  
**According to the 2009 TNI Standard**

**[ORGANIZATION]**

**[LOCATION]**

**[Month] [Year]**

## TABLE OF CONTENTS

Team Composition.....	x
Members of [Organization] interviewed.....	xx
Dates of On-Site Evaluation .....	xxx
Background.....	xxxx
Findings.....	y
Summary.....	yy
Attachment: Observation of On-site Laboratory Assessment .....	yyy
[Appendices if warranted, should be included in the Index] .....	yyyy

**Team Composition:** (Members appointed by the NELAP Accreditation Council; QAO accompanied but did not directly participate in, Evaluation Team)

- [NAME], Lead Evaluator, [affiliation]
- [Name of Team member], [affiliation]
- [Name of Team member], [affiliation]
- [Name], Quality Assurance Officer for the NELAP Accreditation Council of The NELAC Institute [if appropriate]

**Members of [Organization] interviewed:**

- [NAME], [title]
- [NAME], [title]
- [NAME], [title]
- [NAME], [title]
- continues as needed

**Dates of On-Site Evaluation:** [Month] XX-YY, 2008

**Background:**

The [organization] currently issues primary accreditation to [XX] laboratories. [It was one of the ten original NELAP accrediting authorities granted recognition in 1999.] In \_\_{year of most recent evaluation}\_\_, [organization]'s NELAP recognition was renewed following a satisfactory completion of a comprehensive evaluation of the [organization]'s program. The following NELAC Standards applied to the [year] evaluation: June 2003 (Constitution and Bylaws; Program, Policy, and Structure; Proficiency Testing; Accrediting Authority) and May 2001 (On-site Assessment; Accreditation Process; Quality System). The June 2003 version of the NELAC Standards extended the interval between evaluations to three years. Additionally, NELAP gave accreditation bodies due for renewal a one-year extension, due to the shift of the NELAP program from EPA to the NELAC Institute (TNI). Renewals which include on-site evaluations and laboratory assessment observations are required every three years.

This evaluation is conducted under the 2009 TNI Standard, adopted by the NELAP Accreditation Council to become effective July 1, 2011.

In [month, year], [organization] submitted its renewal application along with required documentation, including its regulations, rules and standard operating procedures, and the NELAP checklists. This documentation was reviewed for completeness (completed [month] XX, 200XX) and an application technical review report was sent to [organization] on [month] XX, 200XX. The technical review was completed and the application was accepted on [month] XX, 200XX.

[Organization] has requested that the following areas of accreditation be maintained:

- Drinking water,
- Non-Potable Water,
- Solid and Chemical Materials, and
- Air and Emissions.

[modify this section as appropriate for the organization]

Please refer to Attachment 1 for a complete listing of all [organization] fields of accreditation for which recognition is being sought.

### **Evaluation Process:**

This evaluation was conducted according to the following standards and procedures:

- 2009 NELAP Standard, available at \_\_\_\_\_URL\_\_\_\_\_ administered by the National Environmental Laboratory Accreditation Program Accreditation Council operating within the NELAC Institute (<http://www.nelac-institute.org>)
- Standard Operating Procedure For the Evaluation of Accreditation Bodies, Revision X.Y, date, \_\_\_\_\_URL\_\_\_\_\_
- Checklists, however titled and URL where found
- Other items?

The evaluation team reviewed the following materials: **modify as appropriate**

- renewal application;
- NELAP completeness checklist;
- NELAP Technical Review Checklist;
- statutes authorizing [organization]'s program;
- current and proposed [organization] rules;
- standard operating procedures comprising the [organization] quality system;
- various [organization] applications and checklists;
- laboratory assessment schedules and program reviews; and
- the complete program files, covering the period since the last NELAP renewal, for [laboratory names here].

During the on-site evaluation, the team: **modify as appropriate**

- interviewed both [organization] assessors and the program's supervisor, [name];
- received a detailed description of the steps a laboratory must take to become accredited, including the materials each prospective applicant receives;
- reviewed the program's system for tracking proficiency testing (PT) data and adjusting its laboratories' accreditation; and
- discussed its findings from the technical review and on-site evaluation with the [organization] assessors and their supervisor.

One member of the team also observed a(n) [organization] laboratory assessment; the report of this observation is attached.

**Findings:** Each finding includes a citation of the relevant section of the 2009 NELAP Standard and/or the [organization's] Quality Manual. In addition we have provided a recommended corrective action which [organization] may consider during the development of its corrective action response.

**(These will typically be multiple lines, not expected to be limited to the single line required for the heading.)**

1. **Finding:**

**Citation(s):**

**Discussion/Rationale (if desired):**

**Recommended Corrective Action:**

2. **Finding:**

**Citation(s):**

**Discussion/Rationale (if desired):**

**Recommended Corrective Action:**

**[Add numbers as needed. Consider grouping the results to avoid redundant writing. For example, if several findings concern the same issue, list them together as 1a, 1b, 1c, etc.].**

**Observations (optional):** Observations are written when there is insufficient evidence to clearly write a finding or failure to follow the standard. These will not carry forward into the final recommendation to the Board.

1. **Observation:**

**Citation (to standard):**

**Discussion/Rationale (if desired):**

**Recommended Corrective Action:**

[Add numbers as needed. Consider grouping the results to avoid redundant writing. For example, if several findings concern the same issue, list them together as 1a, 1b, 1c, etc.].

**Summary:**

In order to continue the evaluation process, a written plan of corrective action for the above findings must be submitted to each member of the evaluation team within 30 days of your receipt of this report. Observations need not be addressed but may be used for quality improvement. If such corrective actions have not been completed at the time of your response, please include a schedule for their completion. All corrective actions must be satisfactorily completed within XX calendar days of the receipt of this letter. Please refer to NELAP Standard Operating Procedure X.Y [the evaluation SOP] for further details regarding the requirements and deadlines for renewal of recognition.

[should there be no need for corrective actions, this paragraph can say so, and that a positive recommendation will be forwarded to the NELAP Accreditation Council.]

**Date of Report:** [insert date report is finalized]

**Signature of Lead Evaluator:**

*[Johnna Evaluator]*

[insert signature block, with title and affiliation, here]

**Observation of On-site Laboratory Assessment:**

Assessment Performed by: [organization]

Laboratory Name: [identity of laboratory being assessed]

Dates of Observation: [Month day, year]

Name of Observer: [Name(s) of Team member(s) performing observation]

Assessors Observed:

- [name], Lead Assessor
- [name] [specialty field(s), e.g., GC, wet chemistry]
- [name] etc as needed

[Summary of observations about opening conference.]

[Summary of observations about attitude, effectiveness, and techniques of assessors.]

Laboratory areas assessed during this observation included:

[Example areas that might be observed follow; customize this list for your Team's observation(s)]

- Pesticide, PCB and Semi-volatile organic analyses by Gas Chromatography,
- Wet Chemistry analyses by auto analyzer,
- Volatile Organic Analyses by Gas Chromatography/Mass Spectrometry
- Semi -volatile Organic Analyses by Gas Chromatography/Mass Spectrometry
- Microbiological Methods
- Quality Systems

[Summary of observations about closing conference.]

[Summary indication of acceptability of overall assessment.]

# Appendix F

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## Model Recommendation Letter to the TNI NELAP Accreditation Council

Recommendation for Renewal of Recognition of XXXXX as a NELAP Accreditation Body

[insert name and title]

Chair

National Environmental Laboratory Accreditation Program Accreditation Council (NELAP Accreditation Council)

The National Environmental Laboratory Accreditation Program (NELAP) evaluation team assigned to the XXXXX has completed its evaluation of this Accreditation body. In accordance with the 2009 TNI Standard, the evaluation consisted of the following: 1) a technical review of the XXXXX application for renewal and its supporting documentation 2) an on-site evaluation of the XXXXX lab accreditation program, and 3) an observation of XXXXX conduct of an on-site laboratory assessment. Each of these parts of the evaluation discussed below.

Team members (appointed by the NELAP Accreditation Council):

- [insert Evaluation Team members]

### Technical Review

The evaluation team completed its technical review and issued a report detailing findings on April 12, 2004. In a response dated April 28, 2004 XXXXX provided a list of corrective actions taken to address the deficiencies noted. The team reviewed these corrective actions and determined that they adequately addressed the findings noted.

### On-Site Evaluation

The team conducted an on-site evaluation of the XXXXX laboratory accreditation program on April 19 - 21, 2004. The team interviewed 19 XXXXX staff members, reviewed laboratory files, training files, complaint files, and PT records. The team documented 11 instances in which XXXXX was determined to be in non-conformance with the 2009 TNI Standard. A report was prepared and sent to XXXXX on May 27, 2004. XXXXX provided a corrective action plan for the 11 findings on June 23, 2004. The evaluation team has reviewed these corrective action responses and finds them to be acceptable.

### Observation

The Regional Lead Evaluator performed an observation of XXXXX's on-site assessment of XYZ Laboratories (Edison, NJ) on May 18-20, 2004. The conduct of this assessment was found

to be in compliance with the 2009 TNI Standard, V2M1. No significant deviations were observed.

#### Recommendation

The evaluation team recommends that NELAP recognition of XXXXX's Accreditation Program be continued for all the fields of accreditation in the attached list.

For your consideration and for the permanent record, attached please find copies of the following documents:

1) evaluation team's technical report, 2) XXXXX technical report corrective action response, 3) evaluation team's on-site evaluation report, and 4) XXXXX on-site evaluation corrective action plan.

If you have any comments or questions, please contact me at (xzx) zzz-yyyy.

[insert signature block, with title and affiliation, here]

#### Attachments

cc: XXXXX, XXXXX

## Appendix G

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### **DRAFT Recommended Discussion Topics for Opening Meetings at On-Site Evaluations of ABs**

Additions agreed to in the NELAP revision should be transferred here when adopted.

1. Introductions of personnel on the team:
  - a. Lead evaluator
  - b. State & EPA team members
  - c. Observer: Paul Ellingson, the NELAP Accreditation Council's QAO
2. Purpose: To verify compliance with 2009 TNI Standard
  - a. Determine the accuracy of the documents submitted by the AB (i.e., the application for renewal, the QSM, the AB's responses in the completeness & technical checklists)
  - b. Determine if the AB's implementation of the standards conforms with the 2009 TNI Standard and the material it has submitted?
3. Conflicts of Interest: All team personnel have signed forms, and LE has copies on file.
4. Schedule/agenda:
  - a. Provide schedule of tasks for the on-site review, e.g., interviews, reviews of records and closing meeting, and approximate times.
  - b. Present schedule for observation(s) of AB laboratory assessments
  - c. Briefly discuss next steps, i.e., closing meeting, evaluation report and lab's response(s), and recommendation to NELAP Accreditation Council. (This may be done at the closing briefing if desired.)
5. Security IDs, restrictions: Determine if AB has any restrictions on where team can go within the facility.
6. Workspace for team: Identify a room where the team can meet to conduct interviews and to deliberate to prepare findings.
7. Questions: Ask if laboratory personnel have any questions before beginning the evaluation.

## Appendix H

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### Recommended Items for Closing Meeting at On-Site Evaluations of ABs

1. Introductions (if needed.)
2. Make sure that all AB staff that are supposed to attend are actually present.
3. Thank staff for their cooperation and assistance.
4. Presentation of findings and resolved issues.
  - a. Summarize findings from interviews, record reviews, etc.
  - b. Summarize questions which were unresolved prior to the on-site which have been satisfactorily answered during the on-site.
  - c. Summarize suggestions for improvement (observations of things which are not covered by the NELAP standard).
5. Discuss list of “next steps” with due dates.
  - a. If **laboratory observation(s)** has not yet been completed, set date(s) and location(s) and identify who will do them.
  - b. Set due date for LE to submit **final report** to AB – 30 days after on-site or lab observation, whichever occurs last.
  - c. State deadline for AB to submit **corrective action report (CAR)** to LE – 30 days after receipt of final report.
  - d. Evaluation team’s response to CAR – 30 days after receipt of CAR.
  - e. AB’s submittal of revised CAR (if necessary) – 30 days after ET’s response to original CAR. Make sure AB knows that the revised CAR **must** be satisfactory.
  - f. ET’s recommendation to NELAP Accreditation Council for recognition (renewal) or denial (revocation).
  - g. NELAP Accreditation Council’s issuance of certificate (or notification of denial).
6. Make certain that ET and AB have all necessary contact information for each party and understand importance of keeping on schedule.
7. Adjourn.