



SOP TITLE	Evaluation of Accreditation Bodies
SOP NO.	3-102
REVISION NO.	5.1
PROGRAM	NELAP

SOP Approval Dates

	Initial Approval	Revision Date	Review Date
Committee: LASEC		7/23/2020	
NELAP Program	12/15/2007	8/17/2020	
Policy Committee Review	12/15/2007	8/7/2020	
TNI Board of Directors Endorsement	12/15/2007	NA	
SOP Effective Date	12/15/2007	8/17/2020	

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Evaluation of Accreditation Bodies

1.0 Purpose

This document describes the procedures used by The NELAC Institute (TNI) National Environmental Laboratory Accreditation Program (NELAP) Accreditation Council (AC) to evaluate NELAP Accreditation Bodies (ABs) for initial or continuing recognition under the currently implemented version of the TNI Environmental Laboratory Sector Standard, which is the 2016 version as of the date of this SOP approval. The current revision of this document builds upon previous revisions developed by the EPA Evaluation Workgroup under NELAC, used during the years of the 2003 NELAC Standard. This 2016 revision further streamlines the evaluation process by maximizing opportunities for off-site review and video or teleconferencing in an effort to minimize travel expenses and accommodate travel constraints imposed by outside circumstances.

2.0 Applicability

This Standard Operating Procedure (SOP) is applicable to initial, renewal, or continual reviews of Federal, State, or Tribal ABs conducted by NELAP Evaluators. It is based on the policies of the NELAP AC and the currently adopted and implemented version of the TNI Environmental Laboratory Sector Standard (TNI Standard for the Environmental Laboratory Sector, Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories"), also referred to as "the Standard" in this document.

3.0 Summary/Scope

This document includes the procedures used to:

- Perform a technical review of the AB's application and its attachments.
- Perform an on-site evaluation of an AB.
- Perform an evaluation of the AB's assessment of laboratories and monitoring of assessors.
- Complete the evaluation report.
- Perform the review of and response to the AB's corrective action plans.
- Provide recommendations of the Evaluation Team (ET) to the NELAP AC.

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 NELAP AC and the AB's capabilities to perform laboratory assessments conforming to requirements of the TNI Standard and related policies.

4.0 Definitions

NOTE: Terms not defined in this Section may be found in the current TNI Environmental Laboratory Sector Standard Volume 2: **General Requirements for Accreditation Bodies Accrediting Environmental Laboratories**, Modules 1 (General Requirements), 2 (Proficiency Testing) or 3 (On-Site Assessment) or the normative references for those standards. Those same definitions will be found in the TNI Glossary, which may provide a more accessible reference.

Application of Standards: implementation of the accreditation standards by the AB and the ETs during an evaluation of an AB.

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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.

Certificate of Recognition: the document that officially designates a NELAP AB as being “approved” to accredit laboratories to the standard adopted by the NELAP AC. A certificate is valid for one year, issued at the beginning of the TNI fiscal year in October.

Date of Recognition: date the NELAP AC completes its vote to initially recognize an AB or approve an AB’s renewal of recognition at the end of an evaluation

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

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

Evaluation Coordinator (EC): an individual chosen by the NELAP AC (typically the NELAP Program Administrator) to coordinate the evaluation process, to facilitate communications as needed, and to assure that all steps of the evaluation are completed in a timely manner.

Evaluation Team (ET): a team comprised of the Lead Evaluator (LE), other State AB and/or EPA representatives, and any other technical evaluators approved by the NELAP AC to conduct a review of an AB for the purposes of granting NELAP recognition to the AB.

Evaluator: one who performs technical review and/or on-site evaluation of an AB’s accreditation program capability and capacity for meeting the requirements of the standard, by examining records and other evidence. This is generally either a state or federal government employee or an individual contracted to or employed by TNI for the purpose of conducting evaluations of ABs.

Finding: a conclusion of the evaluation process, referenced to the TNI Standard, and supported by objective evidence. There are three types of findings: comments, concerns, and nonconformities.

Comment: Finding about documents or AB’s practices with a potential for improvement, but still fulfilling the requirements.

Concern: Finding where, in the opinion of the ET, the AB’s practice may develop into nonconformity. The evaluated AB is not expected to respond to a concern but may do so if it wishes.

Nonconformity: Finding where the AB does not meet a requirement of the applicable standard, federal regulation, recognition requirements, or its own management system in a way that discredits its competence or jeopardizes the quality of its work. The evaluated AB is expected to respond to any nonconformity by taking appropriate corrective action and providing the team with evidence of implementation.

Interim Recognition: recognition granted to an initial applicant after having demonstrated that the AB has all procedures and personnel in place to operate a NELAP-compliant accreditation program but has not satisfactorily completed the on-site observation portion of the initial

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evaluation. The Interim Recognition period shall not exceed one year. An AB with Interim Recognition has all of the same rights and responsibilities of a NELAP AB holding NELAP Recognition.

Interpretation of Standards: an official explanation as to the meaning of a given TNI standard provided through the TNI established process (Standards Interpretation SOP 3-105, available on the TNI website).

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

Lead Evaluator (LE): the chosen member of the ET who provides direction for the ET and is responsible for issuing the written final recommendation regarding AB recognition, based on input from the entire team.

NELAP Accreditation Council (AC): the body within TNI's NELAP program comprised of representatives of each NELAP AB and holding final authority for implementation of the program for the accreditation of environmental laboratories.

NELAP Recognition: the determination by the NELAP AC that an AB meets the requirements of the NELAP and is recognized to grant NELAP accreditation to laboratories.

Primary Accreditation Body: as defined in V2M2 Section 3.3.

Recognition: see "NELAP Recognition" above.

Secondary Accreditation Body: as defined in V2M2 Section 3.12 and the NELAP Mutual Recognition Policy POL 3-100.

Technical Review: a detailed review of the materials required to be submitted by an AB as its application package for NELAP recognition. This review is part of the determination of whether the documentation and policies are acceptable according to the TNI Standard, and is typically performed with the help of a detailed checklist, Checklist to Determine Accreditation Body Compliance ("Technical Checklist"), available on the TNI website and submitted by the AB with its application.

5.0 Personnel Qualifications and Responsibilities

5.1 EPA Liaison

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

- At least 2 years of experience within EPA's quality system for environmental data operations.
- Have access to relevant decision making groups within EPA such as the Office of Groundwater and Drinking Water Technical Support Services Office and the Regional Science and Technology Directors.

5.1.2 The EPA Liaison has the responsibility to ensure that the EC has current lists of EPA regional contacts that need to receive notice of status changes for ABs.

5.2 Evaluation Coordinator (EC)

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The EC serves a coordinating function for the evaluation process. Although the role of EC may be performed by a member of the ET, the EC role is separate from the Team as defined by Section 5.3.

5.2.1 EC Qualifications:

The EC is generally familiar with TNI's activities and laboratory accreditation and shall complete the evaluator training course.

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

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

5.2.2 EC Responsibilities:

Recommends the ET compositions and bi-monthly schedule of evaluations to the NELAP AC for consideration and approval.

- ETs are designated at the beginning of an evaluation cycle such that each AB contributes an evaluator for one team. EPA evaluators are included in teams if the EPA regional office responsible for the state which the AB serves designates someone. The TNI staff member is automatically designated the "lead" for each team.
- Best efforts are made to avoid an AB undergoing its evaluation at the same time its staff person is evaluating another AB; partial overlaps are sometimes assisted by use of time extensions for scheduling.
- Personal and AB scheduling and travel preferences are accommodated to the extent possible, since AB evaluations occur on a predictable schedule.
- Only in exceptional circumstances would an AB's state evaluator be assigned to the same AB in consecutive cycles.

Assists the ET by assuring all communication between the ET and the AB, and between the ET and the NELAP AC, 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 AC 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 TNI Standard.

Reviews the evaluation reports for completeness and consistency according to the evaluation SOP, the Standard, and applicable federal regulations. Provides regular status reports to the NELAP AC.

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Identifies and designates the external quality assurance peer reviewer, a member of the NELAP AC or designated evaluator per Section 5.6 below.

5.3 The Evaluation Team (ET)

The size of the team may vary depending on the size of the AB, the number of laboratories the AB accredits and the number of assessors internal to the AB. Teams will generally include a TNI-assigned team member (may be a TNI staff member, contractor, or other mutually agreed upon individual who serves as LE) plus one state AB representative. Since only the LE will routinely be required to travel, it is expected that all ABs will provide the support of a participating team member on a rotating schedule.

The EPA region where the AB is located may provide an EPA staff person to participate on the team if the EPA region so chooses.

5.3.1 Member Qualifications

The members of the ET must be knowledgeable about and apply the currently adopted TNI Environmental Laboratory Sector Standard (ELSS, which may include any applicable results of the Standards Interpretation process), the requirements of this SOP, and the policies and procedures of the NELAP AC when reviewing the AB's implementation of the NELAP program.

All ET members must successfully complete a TNI NELAP evaluator training course that will be based on this SOP, the TNI Standard, and other materials such as the technical review checklist.

All ET members shall have 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 as a NELAP assessor;
- one year of experience implementing federal or state laboratory accreditation rulemaking; or
- one year of experience developing or managing a laboratory accreditation program.

Additionally, it is preferred for each ET to have at least one member who has successfully completed at least one of the EPA Drinking Water Certification Officer training courses.

At the discretion of the NELAP AC, 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 AC 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.

With the concurrence of the NELAP AC, an individual from an AB or a third party seeking to become involved with the NELAP evaluation process may participate in the ET as an "observer". This volunteer shall provide for his/her own expenses.

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- 5.3.2** The ET has the responsibility to carry out the evaluation of the assigned AB, in accordance with this SOP and consistently with the evaluations of other ABs.

5.4 The Lead Evaluator (Team Leader or LE)

The LE is normally a TNI staff member assigned by the TNI Executive Director or designee. Once assigned, this individual will serve as the team lead and generally is responsible for team leadership and planning, issuing correspondences on behalf of the ET, and communication with the EC, as well as conducting the on-site evaluation of the AB.

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 on-site visit, laboratory assessment observation (as applicable), evaluation report writing, and review of all corrective action responses to nonconformities.
- Reports to the EC and/or the NELAP AC any unresolved consistency problems with the evaluation as they occur.
- Provides a report to the NELAP AC at the completion of the evaluation cycle, or at other times requested by the AC.
- Ensures consistency among the ETs by documenting common findings from other ETs and presenting these findings in the summary to the AC.
- Conducts all ET communications with the AB once the application is received. NOTE: The TNI Logo and Arial 10 font are standard conventions for letters issued on behalf of the ET. Examples of the TNI Logo are found in the appendices to this SOP.
- Conducts the on-site evaluation on behalf of the ET. Additional team members may participate based on the ET's determination of the need for on-site review after completion of off-site reviews. EPA Regional participation in the on-site evaluation is welcome. However, any costs associated with EPA's participation are to be incurred by the EPA, not the AB.
- Provides direction to the ET throughout the evaluation process.
- Facilitates off-site review using available resources such as video conferencing, teleconferencing, and web-based meetings, and providing information to ABs as requested.
- Together with the assigned QA peer reviewer, provides a quality assurance function to ensure that all AB evaluations are conducted in a consistent manner.
- Obtains the QA peer review of the evaluation report before the report is finalized, in coordination with a NELAP AC member arranged by the EC per Section 5.6; communicates the reviewer's feedback to the ET.
- Obtains consensus of the ET in preparing the final recommendation of AB recognition status to the NELAP AC.
- Notifies the EC of all required communications and events.
- Informs the EPA Liaison and the EC of any issues which may affect EPA programs, particularly any concerns affecting the analysis of drinking water.
- Submits Standards Interpretation Requests (SIRs) on behalf of the ET(s) when needed.

5.5 The NELAP Accreditation Council (NELAP AC or AC)

The NELAP AC has the following responsibilities. The responsibilities may be performed by the AC as a whole (as applicable) or by the NELAP AC Chair or designee:

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- Appoint ET members for each upcoming evaluation.
- Prepare and send renewal letters to existing ABs, consistent with the approved schedule of evaluations.
- Provide the ETs with copies of previous evaluation report(s), the previous recommendation(s), and if requested, other retained records from the previous evaluation(s).
- Receive periodic updates on progress of the various evaluations from the EC.
- Receive and review the recommendations of the ETs and vote on the renewal status of each AB, according to SOP 3-101, “The NELAC Institute NELAP AC Voting Procedure for General Business and Laboratory Accreditation Matters”.
- Prepare renewal letters or initial recognition approval with a Certificate of Recognition. Deliver this correspondence to the AB, with copies to the EC for transmittal to appropriate staff in the relevant EPA Regional Office and the EPA Liaison, as well as to the LE. The renewal letter shall be delivered within 30 days of closing the AC vote on the renewal recommendation.

5.6 Quality Assurance (QA) Peer Review

In an attempt to add an additional level of consistency to the evaluations, the AC has implemented a Quality Assurance (QA) Peer Review process. Each NELAP AB will name a NELAP AB-qualified evaluator, as described in Section 5.3.1, to serve as a QA peer reviewer for one AB ET. The QA peer reviewer is not a member of the ET and does not participate in document review, on-site evaluation, on-site observation, or participate in the final decision of the ET regarding recognition of the AB. The QA peer reviewer can, however, assist the ET when another “pair” of eyes or ears might be helpful or if the ET needs a sounding board to discuss issues as they arise during the evaluation of the AB.

5.6.1 ET Findings Review

Concerns or lack of unanimous concurrence within an ET regarding an AB's compliance should be directed to the QA peer reviewer for the evaluation prior to the report being submitted for QA review. The QA peer reviewer may request additional input from other NELAP AC members regarding the determination of compliance.

5.6.2 ET Report Review

As a measure to promote objective review of the ET's final report, the LE will enlist a review of the report by the QA peer reviewer. The QA peer reviewer will read the final report to assure that findings have been assigned to the most fitting category (nonconformities, concerns, and comments) and to assure that the ET has clearly communicated its observations. This quality assurance measure is implemented to help ensure:

- clarity of communication,
- objectivity of observations,
- nonconformities to a written requirement, and
- consistency of implementation.

The expected timeline for report issuance allows 2 weeks for this review and for providing feedback to the ET.

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5.7 Conflict of Interest

All members of the ET, the EC, and the QA peer reviewer must sign the conflict of interest certification and provide it to the LE after the NELAP AC designates the ET members and QA peer reviewer and before commencing the technical review; the LE and the EC will coordinate to inform the NELAP AC if any conflicts exist. See Appendix A for the Conflict of Interest form.

6.0 Frequency and Scope of Evaluation

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

- technical reviews of the application package;
- an on-site evaluation;
- evaluation report with findings for both the off-site and on-site evaluation; and
- a recommendation to the NELAP AC regarding recognition or denial of recognition.

7.0 Application Process

7.1 Initial Application

Initial application forms can be obtained from the NELAP AC or directly from the TNI website.

The application must be signed and dated by the 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 day-to-day 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.

All NELAP ABs pay an annual fee that sustains the NELAP programmatic activities. A new applicant must consult with the NELAP AC Chair and/or the TNI Executive Director to establish the amount of the current fee, which will cover the full costs of the AB's initial evaluation. That fee shall be submitted to TNI at approximately the same time as the initial application. Once an AB is recognized, fees will be billed annually.

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 ET appointed (see also Appendix B).

7.1.1 Application Submittal

An electronic version of the completed application shall be submitted to the NELAP AC chairperson or designee. Copies of the completed application shall also be submitted to the EC. Where the ET is known in advance, copies of the electronic application and supporting documents shall be submitted to each team member with a copy provided to the EC. All TNI records are electronic.

Upon receipt of the application and supporting documents, the NELAP AC chairperson or designee shall send an acknowledgement to the AB and establish an ET with the approval of the NELAP AC. The EC will inform the applicant of the team composition, and will distribute the electronic application materials to the team.

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7.1.2 Application Communications

Once the ET is established by the NELAP AC and the application initially provided to the AC Chair and EC, all subsequent communications shall be between the LE and the AB, with copies provided to the EC. The LE or designee can respond to these communications as necessary.

7.2 Renewal Application Process

The NELAP AC Chair or designee will send a renewal notification letter to the AB in accordance with the approved schedule of evaluations, with copies sent to the EC and LE. In the letter, the NELAP AC will indicate that copies of the completed application and all supporting documentation shall be submitted directly to the EC, LE and other ET members; all team members will be identified in the letter. The letter is usually sent via e-mail. See Appendix C for a sample letter.

In the case of the AB represented by the Chair, the AC Vice Chair or designee will send the letter as well as fulfill other duties of the Chair during the evaluation process.

7.2.1 Application Submittal

The AB shall complete and submit The NELAC Institute NELAP Accreditation Body Application form (available on the TNI website). Copies of the completed application and any supporting documentation shall be submitted to the EC, LE and team members within 30 days of receipt of the renewal letter. Electronic submissions are required.

The AB may request an extension of the application due date for up to 30 days. This request shall be submitted to the AC Chair within twenty (20) days of receipt of the notification letter.

If the AB does not submit a renewal application within 30 days (or the extended due date, whichever is later), the AB will receive final notification from the NELAP AC or the EC that, if an application is not submitted within another 30 days, the AB's recognition will expire with the current NELAP Certificate of Recognition.

7.2.2 Application Communications

All 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 AC. The LE will respond to these communications as necessary.

8.0 AB Evaluation Process

8.1 Off-Site Technical Review

The technical review will be appropriately divided among all team members to complete the review. The applicant's completed Checklist to Determine Accreditation Body Compliance ("Technical Checklist", available on the TNI website) will be used as a guide to review and document AB compliance with the Standard. The ET shall review the application, Technical Checklist, and all supporting documents to evaluate whether the AB's accreditation program and the requirements for its laboratories meet the Standard.

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ET shall complete off-site portions of the technical review of the submitted application and supporting materials within 90 days of submission. This includes the ET's initial technical review and any subsequent conference calls, web-based records demonstrations, and other off-site reviews done in cooperation with the AB. The LE may extend this period if needed, generally by no more than 30 days, to assure that all opportunities for off-site review have been exhausted before planning the on-site portion of the review.

The ET shall conduct thorough reviews of policies, procedures, documents, forms, processes, quality assurance measures, corrective actions, and laboratory records in the course of the technical policy and records review. The ET shall interview program management, assessors, and any other accreditation program personnel to evaluate program knowledge and implementation of policies, procedures, and Standards. Off-site interviews will be conducted by telephone or using available videoconferencing technology. The ET will endeavor to utilize technology and off-site evaluation to the greatest extent possible in order to minimize the length of on-site review required to finalize the evaluation.

Appendix L contains a list of items generally reviewed by the ET during the course of the Technical Checklist review and review of associated records (either off-site or on-site).

During the technical review process, the ET may determine additional materials to be requested for review using available off-site technology to assure comprehensive review of the AB's quality system, procedures, and recordkeeping.

To initiate this off-site review, the ET would first identify documents (e.g., evaluation forms, complaint records, results of internal assessments, portions of laboratory files) for team review (See Appendix D and Appendix E for sample letters). These requests may be made in conjunction with communicating with the AB regarding Technical Checklist feedback. These communications are preliminary and are not a final report from the ET regarding findings. The content of the request for additional data for review, per AB, will vary based on the documentation submitted with the initial application and technical checklist.

The ET performs as much of the documentation review, coordination of questions and answers, even interviews of the AB staff and management in an attempt to assure as complete of a comprehensive evaluation off-site as possible. The following list includes the types of activities performed by the ET to ensure a comprehensive evaluation of the AB. Where access to these documents, records, or personnel are not available either by electronic submission, web-ex, video or teleconferencing, the ET will ensure that these activities are performed during the on-site AB evaluation (described in Section 8.3).

- Interview management and technical staff (AB lab assessors and other accreditation program staff) 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.
- Review a minimum of seven (7) NELAP laboratory files (for example: four Primary NELAP laboratory files and three Secondary NELAP laboratory files, if available) from the list of NELAP accredited laboratories (more files should be reviewed if significant nonconformities warrant). The number of files reviewed including the laboratory names and ID#s, as well as the number of laboratories accredited by the AB, shall be included in the evaluation report. When selecting laboratory files to review, the ET will select those with varying fields of accreditation and different assessors. If applicable, the ET will also include files

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from (i) a laboratory that has lodged a complaint, if available; (ii) a laboratory against whom a complaint was lodged, if applicable; and (iii) a laboratory that was cited for severe quality system deficiencies. At a minimum, the team will review the AB's records for each selected laboratory to verify that either the AB or the contract assessment provider maintains the following documentation:

- Application,
 - Conflict of interest verification,
 - Checklist(s) used for laboratory assessment, as applicable,
 - Proficiency testing (PT) results for compliance with methodological and EPA program requirements,
 - Technical Management qualifications review and approval,
 - Deficiency/Assessment report(s),
 - Corrective action report(s),
 - General Correspondence,
 - Opening and closing meeting attendance sheets,
 - Final determination of accreditation,
 - Evaluation forms for AB assessor (if returned by the laboratory), and
 - Certificate, if granted.
- Review customer feedback forms submitted by laboratories, if used by the AB.
 - Review records of resolution of complaints about laboratories, including disputes and appeals.
 - Review records of resolution of complaints from laboratories about the AB, including disputes and appeals.
 - Review the training records and conduct interviews of AB staff designated as qualified assessors to evaluate their training, knowledge of assessment techniques, the Standard, and the AB's own operating procedures.
 - Review evidence of the AB's monitoring of assessor performance of laboratory assessments and other assigned accreditation responsibilities. Note: The ET cannot request to see individual employee performance reviews or other confidential personnel records.
 - Determine that previously identified missing or incomplete items from the Technical Review (Compliance) Checklist are available and satisfactory.
 - Review the last NELAP evaluation report to assure that stated corrective actions (or revisions to the planned actions by the AB) have been continually implemented such that previous nonconformities did not recur (not applicable if this is a new application). It is often helpful to perform this review with AB management during the on-site visit.

The AB is responsible for working cooperatively with the ET to provide means for effective off-site review. The off-site review will be extended to replace one (1) or more days of review traditionally performed on-site with a team of evaluators. The AB and the ET should expect to schedule a series of teleconferences and/or web-based meetings in order to facilitate the off-site record reviews and interviews. An example chronology follows:

- ET completes initial technical checklist review with a series of noted questions for discussion or follow-up.
- ET and AB have telephone or email discussions of questions, open issues; ET notifies AB of list of additional items requested for review (e.g., lab files, corrective action plans, PT records).
- ET and AB have scheduled meetings if needed (for example, three subsequent phone calls or web-ex meetings) for AB to provide access to requested information through means such as:

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- Technology-based access to electronic files (video conferencing, online meetings),
- Documents provided by AB in scanned / portable document format (pdf), and
- Staff interviews by telephone.
- ET provides follow-up questions or document review requests after review of notes and an additional meeting(s) is scheduled to address additional questions or review additional records.
- ET reviews open items and determines that preponderance of review is completed and that remaining record review is preferably done on-site and can be completed in one-one-and-one-half working days by one evaluator.
- An on-site visit to finalize the evaluation is scheduled.

See SOP Section 8.3 for additional detail regarding technical review of documents and records which shall occur prior to the conclusion of the evaluation. Although the information to be examined off-site or on-site for each AB is determined on a case-by-case basis, information detailed in Section 8.3 is reviewed off-site, through the process described above, whenever possible.

8.2 Scheduling the On-Site AB Evaluation

Once the ET has exhausted opportunities for off-site review, 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 ET's off-site 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 ET 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, as applicable;
- identification of files or records to have available for review;
- the names, titles, affiliations, and on-site responsibilities of the NELAP ET members, as applicable; and
- the names and titles of AB staff that need to be available during the on-site evaluation, as applicable.

Below is a typical agenda for the on-site AB evaluation. The AB is given the option of flexibility.

Day 1 AM

Opening meeting

Review prior evaluation findings and corrective action implementation

Discuss potential findings and comments from technical checklist and lab records review

Review accreditation process

Day 1 PM

Review personnel training files

PT records and process

Records processing, filing and retention

Complaints

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Day 2 AM
Anything left over from Day 1
Closing meeting

8.3 **Conducting the On-Site AB Evaluation**

This portion of the evaluation may be conducted either in person or remotely using technologies that make video document-sharing and conversation available. The LE shall conduct a brief opening meeting prior to the start of the on-site evaluation. The opening meeting should cover the topics noted in Appendix H. To assure on-site efficiency, the LE should provide the AB with a list of materials for on-site examination in advance of the site visit.

The on-site evaluation is used to provide an additional opportunity for records review and interview including first-hand record review, particularly of files that are not allowed off-site. The on-site review supplements and completes the review initiated off-site and conducted by the ET. Members of the ET are encouraged to be available to participate in the on-site activities as appropriate and practical (e.g., opening and closing meetings, Day 1 discussions) by teleconference or other electronic means.

If the site visit is conducted in person and the LE determines that more than two overnight stays (one complete workday) for one evaluator is required during the on-site evaluation, the AB will be responsible for associated expenses (for additional evaluators and/or for additional days) paid as actual expenses and costs in accordance with the TNI SOP on Travel Procedures (SOP-1-119). This determination for additional on-site time may be based on the number or significance of nonconformities observed by the ET during off-site evaluation or may be based on insufficient access to AB records via off-site options. A new applicant's initial fee will include expected additional on-site assessment time in addition to the observation by a member of the ET of a laboratory assessment conducted by the applicant AB. (See Sections 8.5 and 8.6.)

The LE shall determine if the AB is in conformance to its own internal quality system documents.

The LE will assess the AB to ensure that the AB is in compliance with all NELAP AC policies and procedures, as well as existing interpretations of the TNI Standard. The Standard interpretations are posted on the TNI Website and may change over time.

Before the conclusion of the on-site evaluation, the LE shall assure that the full ET has conducted a comprehensive evaluation of the AB's accreditation program using off-site and on-site review to determine the accuracy of information contained in the AB application and the AB's conformance to the TNI Standard.

After the site visit, however performed, the LE will conduct an exit debriefing to discuss all noted deficiencies. Appendix I provides guidelines for this meeting. If time does not permit this debriefing to be done at the close of the on-site, the debriefing will be held as soon as practicable afterwards, and when additional members of the ET can participate along with the AB, using available technology such as teleconference or videoconference. The debriefing is an informal summary of potential nonconformities allowing for questions and brief discussion by the AB.

Additional items not discussed in the debriefing may appear on the report with appropriate justification. The LE, and possibly the whole ET, should make every effort to discuss any additional items in order to allow the AB to explain or resolve possible

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confusion regarding a perceived non-conformance that was not presented during the closing meeting prior to issuing the report. This explanation can be provided in the text of the email sent with the report.

8.4 Evaluation of the AB's Laboratory Assessors

NOTE: In former revisions of this SOP, the ET routinely performed an on-site observation of a laboratory assessment conducted by the AB's staff as part of all initial and renewal NELAP AB evaluations. The following text should guide an observation being done under the 2016 TNI ELSS. The NELAP AC anticipates a transition to a revised V2M1 at some point during the 2020-2022 evaluation cycle, and these references will need to be updated at that time.

Requirements of V2M3 sections 6.4.1, 6.7, 6.8, 6.9.1, 6.9.2, 6.10.1, 6.10.2, and 6.11.1 of the 2016 TNI Standard are specific to the assessment of laboratories by the AB. These requirements are reviewed and evaluated by the ET by examination of AB records and are supplemented with staff interviews. For initial applicants, the on-site observation of the AB's assessors performing a laboratory assessment described in Sections 8.5 and 8.6.3 is required.

V2M1 section 6.3 communicates a critical responsibility of the AB to have procedures to monitor and review the performance and competence of its personnel in order to identify training needs. The ET will review the AB's established procedures to assure that the AB has a process to observe the on-site performance of all assessors, including third party assessors, or evaluate by suitable alternative. The AB's evaluation shall ensure the appropriate performance and competence of all assessors working on behalf of the AB in accordance with requirements of V2M1 section 6.3. V2M1 section 6.3 communicates an expectation for on-site observation of each assessor on a regular schedule, normally every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently. For example, sufficient supporting evidence may include the AB management's participation in opening/closing on-site meetings by teleconference supplemented by a review of all records related to the assessment, when on-site observation is not practicable.

8.5 Observation of the AB's Laboratory On-Site Assessment

Should the ET find insufficient evidence through records review and/or interviews to determine that the AB's staff carries out laboratory assessments in accordance with the Standard, OR that the AB's Management has not adequately monitored all assessors in accordance with V2M1 section 6.3, the ET may determine that observation of an on-site assessment being performed by the AB's staff is required to confirm compliance to the Standard and/or the AB's quality system documents. The AB will be responsible for associated expenses for observation of an on-site laboratory assessment. The number of ET members needed for the observation will depend primarily on the size and scope of the laboratory being assessed and on the number of AB staff to be observed.

When the ET performs an observation of the laboratory assessment, the ET member(s):

- should observe the AB's laboratory assessment team perform opening and closing meetings, interviews of laboratory staff, data review, quality management systems review, etc.,
- are not active participants in the laboratory assessment,
- should make every effort to observe as many aspects of the AB's assessment as possible, and

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- should concentrate on areas where the technical review may have revealed weaknesses in the AB's program.

8.6 Adaptations for Evaluation of New (Prospective) ABs

The ET assigned to perform an evaluation of a new, not currently NELAP-recognized AB, will need to take into account the fact that the applicant AB does not operate an "active" NELAP accreditation program. Specifically, the "comprehensive evaluation" needs to take into account that the applicant AB will provide a "plan" of implementation or examples of documents, such as accreditation certificates, assessment reports, etc. since the applicant cannot provide actual real-world examples of these documents. For initial applicants, an in-person site visit is considered essential.

Some prospective ABs already will be operating in substantial conformance with the NELAP standards. This should be evident in the AB's statutes, regulations, and/or SOPs. If the ET through its records review determines this to be the case, the evaluation may proceed without the adaptations described here.

8.6.1 Interviews

The ET should interview assessors and managers to determine:

- their knowledge of the AB's quality management system and its associated procedures (as documented in its SOPs, forms, and other documentation) and
- their understanding of the current TNI Standard.

8.6.2 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 applicant AB shall provide real examples, or prototypes, if real examples are not available, of the on-site assessment reports, responses to corrective actions, proficiency testing review practices, associated correspondences to laboratories, etc., as part of the initial application package and associated documentation. These documents will provide the ET with information about the AB's implementation plan for its new program and provide opportunity for feedback to the new AB early in the implementation of its program so that any concerns or nonconformities arising from the review of the supplied records can be immediately addressed through the AB's own corrective action procedures.

The ET shall confirm that the applicant AB has performed at least one mock or actual internal audit and management review for ET review during the AB evaluation, either on or off site.

8.6.3 Observation of the AB's Laboratory Assessment

An observation of the AB performing an on-site laboratory assessment will be conducted by a member or members of the ET.

8.6.4 Evaluation Report(s)

The report of the evaluation shall include a request that the AB forward selected copies of actual assessment reports, internal assessments with associated corrective

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actions, and completed assessment appraisal forms from laboratory assessments completed over the first year of operation. These may help confirm implementation of a successful program. If there are concerns from later review of documents, as described in this Section, the LE should relay those concerns to the NELAP AC for consideration and possible action (as determined by the AC).

Because an observation of the AB's laboratory assessment cannot be completed before the AB is granted NELAP Recognition (full or interim), the ET prepares and issues a supplementary report describing the observation of the laboratory assessment. The ET's review of the AB's on-site laboratory assessment will include review of documentation associated with the assessment. The ET will issue its report within 30 days of the observation of the laboratory assessment or within 30 days of receipt of these assessment-related records (on-site report, corrective action reviews, etc.). The AB will be provided 30 days to provide a corrective action response to any nonconformity noted in the supplementary report.

8.6.5 Interim Recognition

After the AB has demonstrated compliance with all requirements of Volume 2 of the TNI Standard and all requirements of this SOP have been met, except those associated with the on-site assessment observation, the ET will recommend to the AC that the new AB receive Interim Recognition.

Because an AB that is not NELAP-recognized cannot conduct assessments under the NELAP program until recognition as a NELAP AB has been achieved, the ET will recommend to the AC that the AB be given Interim Recognition, for a period not to exceed one year, after other requirements for AB recognition have been met. Interim Recognition provides an AB with all rights and responsibilities of a fully-recognized NELAP AB while providing an opportunity for requirements to be met which are not achievable until after the AB's program is fully operational. (Note: It is recommended that the observation of the laboratory assessment be completed within 6 months of the granting of Interim Recognition to assure the process for achieving full Recognition can be completed within the 1-year period allowed for Interim Recognition.)

Upon completion of the observation requirement and corrective action as needed, the ET will recommend to the AC that the AB be given full NELAP Recognition and issued a Certificate of Recognition. If the AB fails to achieve full Recognition within 1 year of receiving Interim Recognition, the ET will recommend to the AC that the AB's recognition status be reduced to Not Recognized.

9.0 Reporting and Corrective Action Procedures

9.1 Final Evaluation Report

Documentation of the evaluation comments, concerns, and nonconformities shall be delineated in the final report presented by the ET. The LE will draft the report for review by the ET. The ET shall ensure that each nonconformity is clearly explained, including identifying the document, interview, or observation of an assessment in which the observation of the nonconformity was made and the reference to the Standard citation to which the nonconformity is a violation. The ET may choose to request specific documentation as evidence of correction of the nonconformity. (A sample report is provided in Appendix F.) The ET will request evidence of correction in all instances where a nonconformity is noted as a repeat or recurrence of a nonconformity cited during

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the previous evaluation.

The ET has 30 days from completion of the on-site portion of the evaluation to prepare its findings report for QA peer review as described in Section 5.6. The QA peer review should be completed within 15 days and the finalized report released to the AB as soon as practicable after QA review and finalization, typically 45 to 60 days from the date of the site visit.

9.2 **Corrective Action Report (CAR)**

The AB shall prepare a Corrective Action Report (CAR), describing how it either has addressed or plans to address the nonconformities from the evaluation report. The CAR must include a schedule for completion for any nonconformities not completed at the time of the CAR submission. The AB shall provide any requested documentation to the ET for review as part of the final CAR. Comments and concerns do not require a response in the CAR. The AB has 30 days from receipt of the evaluation report to submit this CAR.

9.3 **Response to the AB CAR**

Each member of the ET must review the AB's CAR, including its proposed corrective action and evidence of correction, and transmit his or her 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 nonconformities in a manner that brings the AB into timely compliance with the Standard, the LE shall notify the AB that it must submit a revised CAR within 30 calendar days of receipt of this notification. This notification should provide specific reasons why the CAR was determined to be not acceptable to meet the Standard, so that the AB can understand how to improve the CAR.

If the AB satisfactorily addresses the nonconformities in a revised CAR, the LE shall recommend to the NELAP AC that the AB be granted initial or continued NELAP recognition.

If the AB does not satisfactorily address the nonconformities in a revised CAR, the LE may recommend to the NELAP AC that the AB's NELAP Certificate of Recognition be revoked, initial or renewal recognition denied, or that provisional recognition be invoked (Issuance of Provisional Recognition of Accreditation Bodies, SOP 3-108). If the AB is a new applicant, the AB will not be recognized until the AB has addressed all nonconformities satisfactorily.

The LE must consider the AB's responses in preparing written recommendations to the NELAP AC (as discussed in Section 10.1).

10.0 **Recommendations to the NELAP AC and Determination of the AB's Recognition Status**

At the end of the evaluation process, a recommendation to the NELAP AC 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 ET, and, if requested by the AC, should be present (or designate a team member to be present if necessary) for the NELAP AC's discussion of the recommendation prior to its vote. Appendix G provides a sample of a recommendation letter

If the NELAP AC disagrees with the recommendation of the ET, it will notify the ET prior to the notification of the AB. The NELAP AC will provide the ET with the reason(s) for its

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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 will then be issued and mailed by the NELAP AC.

11.0 Evaluation of the Evaluation Process

The LE shall provide each team member as well as the manager of the AB with an electronic copy of the evaluation form provided in Appendix J, no later than with the transmission of the site report to the AB, and encourage all parties to complete this form and return it to the EC before the end of the evaluation process.

12.0 Standard Interpretation Process

If the ET has questions regarding the meaning of the Standard, the LE should first query the QA peer reviewer assigned to the evaluation, as described in Section 5.6. If the ET and QA peer reviewer cannot come to an agreement, the LE is to use the Standards Interpretation Request (SIR) submission 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 3-105.

Timelines are defined in SOP 3-105 for the NELAP AC Chair and LASEC Chair to act on the request. The LE 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 LE will be responsible for informing the ET as to the final interpretation of the standard.

Clear non-compliance to a Standard requirement is not subject to the interpretation process listed above but necessitates the documentation of nonconformities and corrective actions as listed in the Section 9.0. If the AB disagrees, it may utilize the dispute resolution process.

13.0 Exceptional Circumstances

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

13.1 Extensions

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

13.2 Appeal Process for Extended On-Site Review or On-Site Assessment Observation

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The affected AB may choose to appeal the ET's decision to extend the on-site evaluation of the AB or to observe the AB's assessors perform an on-site laboratory assessment. If the ET is making the recommendation for the on-site review to be extended beyond the customary time or number of reviewers or to observe a laboratory assessment, and if the ET making this recommendation is composed of at least three (3) members including an EPA representative, no appeal is applicable. In cases where the ET is comprised of the LE and the AB representative, the affected AB may choose to appeal this decision in writing (email is acceptable) with copies to both the EC and the NELAP AC Chair or designee. The written appeal must include clear explanation of the situation and justification as to why the AB does not agree with the ET's decision.

The NELAP AC Chair or designee will coordinate with the ET, the affected AB, and the QA peer reviewer to discuss the situation and hear both parties' arguments and will make a determination on the appeal.

13.3 **Dispute Resolution**

Disagreements with matters concerning recognition can be addressed through the NELAP Dispute Resolution Process (SOP 3-104) or through the TNI General Complaint Resolution Process (SOP 1-106), as applicable.

14.0 **Evaluation Process Funding**

Accreditation Body annual fees paid to TNI cover the generally expected expenses of the triennial assessment process. The generally expected expenses include on-site evaluation with two overnight stays for one evaluator and no on-site observation of a laboratory assessment.

Any additional labor or travel expenses necessary to conduct the evaluation are the responsibility of the AB, paid as actual costs and expenses in accordance with the TNI SOP on Travel Procedures (SOP 1-119) and for a TNI-appointed staff person serving as LE, as billable hours in accordance with normal TNI invoicing processes.

15.0 **Criteria, Checklists, Standards**

All evaluators must ensure that they are using the current, adopted version of the TNI Environmental Laboratory Sector Standard, as well as the most recent approved version of SOPs and checklists.

The reference documents (Section 18.0) may be found on the TNI website and under the "TNI Documents" button on the main page of the TNI website.

16.0 **Records Management**

Official records associated with the evaluation of the ABs shall be handled in accordance with TNI Policy POL 1-104 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 EC within 30 days of the ET's final recommendation. The EC ensures that the TNI Secretary knows where these records are located. The following items shall constitute the official record:

- the application materials;

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- conflict-of-interest forms from team members and EC;
- the final technical review (compliance) checklist as completed;
- the on-site report, to include the observation report (as applicable);
- the AB's CAR(s), if corrective actions are needed, and evidence that the corrective actions are complete;
- the letter of recommendation to the NELAP AC; and
- the NELAP AC's letter to the AB notifying them of the AC's decision. The status of the AB shall also be added to this permanent record by the EC.

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 AC. ET members should retain all working documents and evaluation notes for five years or submit them for archiving to the NELAP EC.

17.0 NELAP AB Evaluation SOP Review

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 AC's approval.

If the document is revised, the revisions will be posted to the TNI website.

18.0 References

- The TNI Environmental Laboratory Sector Standard 2016, Volume 2, Modules 1, 2 and 3
- TNI SOP for General Complaint Resolution, SOP 1-106
- TNI SOP for Travel Procedures, SOP 1-119
- NELAP SOP for Voting Procedure for General Business and Laboratory Accreditation Matters, SOP 3-101
- NELAP SOP for Dispute Resolution Process, SOP 3-104
- LASEC SOP for Standards Interpretation, SOP 3-105
- NELAP SOP for Issuance of Provisional Recognition of Accreditation Bodies According to the TNI Standard, SOP 3-108
- TNI Policy for Management of Records, POL 1-104
- Mutual Recognition Policy for NELAP-Recognized Accreditation Bodies POL 3-100
- NELAP Policy on Relationship of NELAP AB Certificates of Recognition and the NELAP Evaluation Process POL 3-102
- Other Policies and SOPs adopted by the AC, approved by the Policy Committee, and endorsed by the TNI Board of Directors

- Example evaluation tools – see the TNI website

- Evaluation Documents – see TNI website for current versions
 - AB Application for Renewal
 - Checklist for AB Compliance

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19.0 Revision History

Revision No.	Effective Date	Description of Change
1	12/15/2007	Change to new SOP format. Updated personnel list for Appendix A and B. Correct and format reference in Section 6.4
2	7/22/2009	Incorporated comments from evaluator training. Final version to incorporate provisions for evaluating new ABs: Added definition for Evaluator, Changes to Sections
3	10/3/2013	Incorporate changes to streamline evaluation process with review by NELAP evaluators workgroup. Minor edits to clarify that single contract LE will lead all ETs and to clarify that renewal cycle is 3 years from date of prior certificate expiration (not from AC vote to renew).
4	6/28/2016	Add flow charts of evaluation process. Add template letter for requesting documents for off-site review. Add evaluation form. Make text changes as requested by Policy Committee. Made changes to address two critical issues: (1) conflict of interest noted in previous round and (2) significant budget shortfalls noted in previous round. Made changes throughout SOP to reflect revisions for increased efficiency with focus on increased off-site view and minimal on-site review, AB burden to cover additional on-site expenses when needed, and removal of observation of on-site assessment by except for initial applicants. Additional minor changes, including reorganization of the SOP to more clearly delineate aspects of the evaluation, were made throughout the document to accommodate these edits and other readability, consistency, or clarity updates.
4.1	4/12/2017	Made minor revisions in response to Policy Committee comments. Replaced App A (COI form) with "Participation Form", approved by AC, that includes promise not to share materials outside of the evaluation process. Also clean-up headers of appendices and minor typos.
5	11/15/19	Update to accommodate the decoupling of certificates from evaluation cycle and incorporate changes based on another cycle's experience with version 4.1. Removed definition of "audit" as unnecessary.
5.1	8/17/ 20	Modify section 8.3 to allow for remote site visits, change NELAP AC Chair name in Appendices where needed

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

Appendix A



Evaluation Team Participation Agreement 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 TNI Environmental Laboratory Sector Standards adopted by the NELAP Accreditation Council. Additionally, I pledge to use the information that I review, as a member of this Evaluation Team, for its intended purpose only – evaluation of the NELAP Accreditation Body against the applicable standard and the relevant policies and procedures of the NELAP Accreditation Council.

Signature _____

Date _____

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Timeline for Evaluation Process – Part Two

Appendix B

Flow Charts of Application and On-Site Process plus
 Application Review Tracking Checklist – Target Timeframes

Timeline for Evaluation Process – Part One

Item	Expected Time (days)	Expected MAX timeline (total days elapsed, without extensions)
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	300 days prior to certificate expiration	Day 0
AB returns complete application	30	30
Application Technical Review, Off-site	90	120
Conduct On-Site AB Evaluation	(within 60 days)	180
Prepare Final Report	30	210
QA Review of Final Report	15	225
Send Final Report to AB	(after response to QA review)	240
AB response to Final Report	30 days from receipt of report	270
Evaluation team reviews response	30 days	300
Notice to AB that additional corrective action is required	ASAP	

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Timeline for Evaluation Process – Part Two

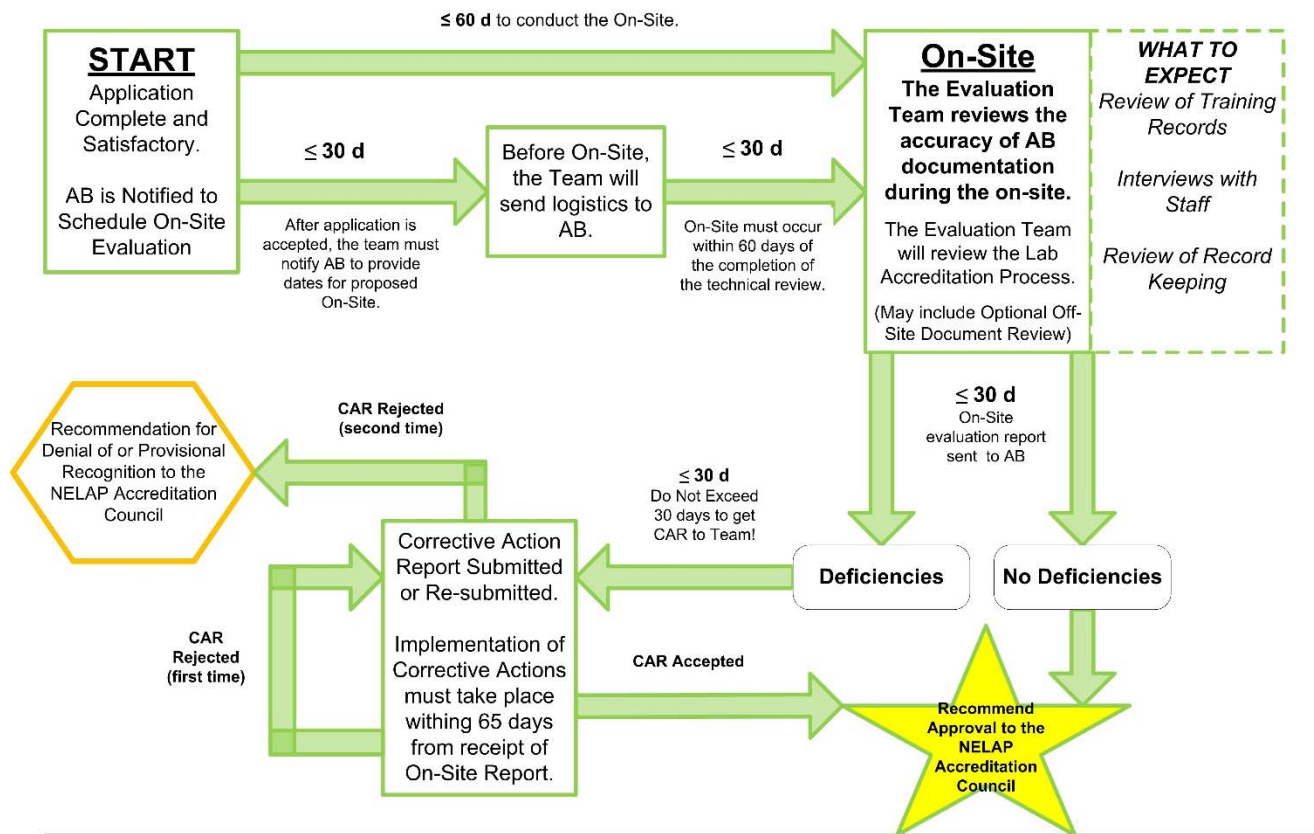
Item	Expected Time (days)	Expected MAX timeline (total days elapsed, without extensions)
AB 2 nd response to deficiencies	30 days	300+
ET review of second response	30 days	300+
Response to AB and Recommendation to NELAP AC	ASAP up to 2 weeks for AC meeting, up to 2 weeks for voting completion	300+
Renewal Letter and Certificate (or copy) sent to AB, LE, & Regional contacts	30 days	300+

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Timeline for Evaluation Process – Part Two

On-Site AB Program Evaluation Process

Purpose: to 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 NELAC Standards.



APPENDIX C



Sample Renewal Letter

_____(date)_____

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

Dear Dr. Yyyyyy,

Your recognition as a NELAP Accreditation Body will expire _____(date)_____. It is now time to submit the three-year renewal application to maintain recognition of the _____(AB's name)_____ Accreditation Program as a NELAP Accreditation Body.

Your application is due 30 days from receipt of this letter, approximately ___(date)_____. If additional time is needed, you must make a request within 20 days of receipt of this letter. Your completed application must include:

- A completed application form signed and dated by the highest ranking individual in the department or agency responsible for laboratory accreditation activities,
- and
- A completed Checklist to Determine Accreditation Body Compliance which will be used by the Evaluation Team.

All application materials should be submitted electronically using a standard software package, such as Adobe Acrobat, on a CD/DVD or by email; the checklists should remain in the Word format for ease of use by the team. Forms can be downloaded from the TNI website at www.nelac-institute.org on the NELAP Accreditation Council home page. Please send copies of your completed application package

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directly to each member of your assigned evaluation team and the Evaluation Coordinator and please request some form of confirmation that each individual has received the package.

Names and addresses of your team members are included as an Attachment at the end of this letter.

The NELAP Lead Evaluator for your renewal will be _____ (name/affiliation) _____. The Lead Evaluator will contact you at a later date to schedule your site visit. In addition, specific files will be requested identified for review, including some files regarding laboratories that have been assessed under your program.

If you have any questions, please contact _____ (LE) _____ at _____ (phone/email) _____. Our implementation of the NELAP program has been a great success and reflects your hard work and dedication. I look forward to the continuation of this cooperative venture.

Sincerely,

(name), Chair
NELAP Accreditation Council

cc: (name), Evaluation Coordinator
(name), Lead Evaluator

Attachment

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Attachment 1 – Evaluation Team Members

Lead Evaluator:

Add name, mailing address and FedEx/UPS delivery address, phone/fax and email

State AB Team Member:

Add name, mailing address and FedEx/UPS delivery address, phone/fax and email

EPA Team Members:

Add name, mailing address and FedEx/UPS delivery address, phone/fax and email

QA Reviewer:

Add name, mailing address and FedEx/UPS delivery address, phone/fax and email

Evaluation Coordinator:

Add name, mailing address and FedEx/UPS delivery address, phone/fax and email

APPENDIX D



Sample Letter for Technical Review Feedback

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

Dear Dr. Yyyyyy,

The National Environmental Laboratory Accreditation Program (NELAP) Evaluation Team (ET) assigned to the [insert state] Accreditation Body (AB) has completed preliminary technical review of the renewal application dated **month day, year**. 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 2016 TNI Standards. The ET review is based on the 2016 TNI Standard.

The ET has identified a number of potential nonconformities on the enclosed, "Checklist to Determine Accreditation Body Compliance." Items on the checklist which have been checked "No" are deficiencies based on materials submitted. 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. Additional information to clarify what has been provided is needed by the ET in order to make a final determination. Please note that while some items have been checked "Yes," the actual implementation of these requirements may be further assessed with additional record reviews. [DESCRIBE THE ET'S PLANS FOR NEXT STEPS – FOR EXAMPLE, A TELECONFERENCE TO DISCUSS ITEMS FROM TECHNICAL CHECKLIST, AN ATTACHED LIST OF ADDITIONAL MATERIALS TO BE REVIEWED USING OFF-SITE OPTIONS, ETC. SEE APPENDIX E.]

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

Sincerely,

Yyyy Y. Zzzzz

NELAP Lead Evaluator

cc: NELAP Evaluation Coordinator

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NELAP Evaluation Team

APPENDIX E



Sample Letter to Request Documents for Off-Site Review

_____ date _____

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

Dear Dr. Yyyyyy,

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**. A copy of the Technical Checklist is attached containing the ET's comments after initial review.

We would like to request the following additional items for off-site review. Per TNI SOP 3-102 Rev 4, the AB is financially responsible for on-site assessment labor and travel when the on-site assessment requires more than one day for one evaluator. As such, the ET desires to work with you to facilitate off-site review for the preponderance of records and for staff interviews and discussions. Please review the list of documents below which may be requested in our upcoming interviews and discussions. I will call you (or your representative) in a few days to discuss plans for the most efficient means to review these documents using off-site options such as video conferencing, web-based meetings, and teleconferencing and will gladly assist you by providing information to enable these resources.

[THE ET SHOULD CUSTOMIZE THIS LIST BASED ON ITEMS ALREADY SUBMITTED BY THE AB AND ITEMS REQUIRED TO COMPLETE THE TECHNICAL REVIEW]

REQUESTED RECORDS FOR REVIEW:

- Examples of Corrective Actions and Preventive Actions
- Complaint records
- Signed copies of SOPs and any remaining (or new) SOPs for the program
- Reports of assessment scheduling (time elapsed between assessments)

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- Reports of assessment reporting (time elapsed between site visit closure and issuance of on-site assessment report)
- All internal audits performed since the last evaluation
- All management reviews performed since the last evaluation
- Lists of assessors and specific qualifications per assessor
- Training records (may be examined on-site if linked to personnel files)
- Specific laboratory files selected by the ET [MINIMUM OF 3 IS REQUIRED]
 - Files selected should have varying fields of accreditation
 - Files selected should have varying assessors
 - Files selected should include at least 1 with notable or severe quality system deficiencies, if applicable (in most recent 3 years)
 - Files selected should include a lab with disputes or appeals, if applicable (in most recent 3 years)
 - Files selected should include a lab against whom a complaint was lodged, if applicable (in most recent 3 years)
 - Files selected should include a lab that has lodged a complaint, if applicable (in most recent 3 years)
- File review for a minimum of 3 labs will include verification of:
 - Application
 - Conflict of interest verification
 - Checklist(s) used for laboratory assessment
 - Proficiency testing (PT) results for compliance with methodological and EPA program requirements
 - Deficiency (on-site assessment) reports
 - Corrective action reports
 - Correspondence
 - Opening and closing meeting attendance sheets
 - Final determination of accreditation
 - Evaluation forms for AB assessor (if returned by the laboratory)
- Specific parts of laboratory files selected by the ET (e.g., correspondence records for a laboratory, checklists used in assessment, opening or closing meeting records, notification of AB staff members, conflict of interest signature statements, *etc.*).
- Laboratory files with specific situations (e.g., dual primary ABs, suspended Fields of Accreditation, appeals, disputes, secondary labs, *etc.*).
- Discussion / demonstration / documentation / records on PT management practices
- Copies of any/all reports from EPA regarding observation of on-site assessments [N/A FOR ABS NOT EVALUATING DRINKING WATER]
- Evidence of continued corrective action as indicated in previous NELAP AB Corrective Action Report

I look forward to speaking with you to plan the review of these records and will contact you in a few days. If you have any questions or require clarification regarding this request or any other aspect of the ET's communications, please feel free to contact me at (xxx)-xxx-xxxx.

Sincerely,

Yyyy Y. Zxxzz

NELAP Lead Evaluator
cc: NELAP Evaluation Team
NELAP Evaluation Coordinator

Appendix F



Sample of On-Site Report

NELAP ACCREDITATION BODY
REPORT of ON-SITE EVALUATION
According to the 2016 TNI Standard

[ORGANIZATION]

[LOCATION]

[Month] [Year]

Evaluation of Accreditation Bodies

TABLE OF CONTENTS

Team Composition X

Members of [Organization] InterviewedXX

Dates of On-Site Evaluation.....XXX

Background XXXX

Findings..... y

Summaryyy

[Appendices if warranted, should be included in the Index]..... yyyy

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Team Composition: (Members appointed by the NELAP Accreditation Council)

- [NAME], Lead Evaluator, [affiliation]
- [Name of Team member], [affiliation]
- [Name of Team member], [affiliation]
- others as appropriate

Members of [Organization] interviewed:

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

Dates of On-Site Evaluation: [Month] XX-YY, 20XX

Background:

The [organization] currently issues primary accreditation to [XX] laboratories. In (year of most recent evaluation), [organization]'s NELAP recognition was renewed following satisfactory completion of a comprehensive evaluation of the [organization]'s program. The 2016 TNI Environmental Laboratory Sector Standards (ELSS), Volume 2, applied to the previous evaluation. Renewals, which include on-site evaluations and laboratory assessment observations, are required every three years.

This evaluation is conducted under the 2016 TNI Environmental Laboratory Sector Standard, adopted by the NELAP Accreditation Council (AC) to become effective July 1, 2011. While not all ABs have been able to adopt the Volume 1 laboratory standards, all ABs are expected to modify their operations (where not codified in regulatory or legislative language) to comply with Volume 2, effective that date.

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, 20XX) and the application was accepted on [month] XX, 20XX.

The completed application technical review feedback was provided to [organization] on [month] XX, 20XX. (if appropriate) Additional data reviews, interviews, and discussions followed.

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

- Drinking water,
- Non-Potable Water,

Evaluation of Accreditation Bodies

- Solid and Chemical Materials,
Biological Tissue, 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:

- 2016 NELAP Standard, administered by the National Environmental Laboratory Accreditation Program (NELAP) Accreditation Council (AC) operating within The NELAC Institute (<http://www.nelac-institute.org>)
- Standard Operating Procedure For the Evaluation of Accreditation Bodies, Revision X.Y, date
- Checklists, however titled and URL where found
- Other items?

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

- renewal application;
- 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] (NOTE: some interviews may occur remotely);
- 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.

Please see DETAILS of FINDINGS below. Note that a corrective action response is required only for NONCONFORMITIES. A corrective action response for CONCERNS is at the discretion of the AB.

Definition of Finding: a conclusion of the evaluation process, referenced to the TNI Standard and supported by objective evidence. There are three types of findings: comments, concerns, and nonconformities.

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Nonconformity: Finding where the AB does not meet a requirement of the applicable standard, its own management system or the recognition requirements in a way that discredits its competence or jeopardizes the quality of its work. The evaluated AB is expected to respond to any nonconformity by taking appropriate corrective action and providing the team with evidence of implementation.

Concern: Finding where, in the opinion of the evaluation team, the AB's practice may develop into nonconformity. The evaluated AB is not expected to respond to a concern but may do so if it wishes.

Comment: Finding about documents or AB's practices with a potential for improvement, but still fulfilling the requirements.

Nonconformities: Each nonconformity includes a citation of the relevant section of the 2016 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. Note that technical review nonconformities not resolved prior to on-site should be included here).

1. **Citation(s):**

Nonconformity:

Discussion/Rationale (if desired):

2. **Citation(s):**

Nonconformity:

Discussion/Rationale (if desired):

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

Concerns:

1. **Citation(s):**

Concern:

Discussion/Rationale (if desired):

[Add numbers as needed.]

Comments:

1. **Citation(s) (if applicable):**

Comment:

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Discussion/Rationale (if desired):

[Add numbers as needed.]

Summary:

In order to continue the evaluation process, a written plan of corrective action for the above nonconformities must be submitted to each member of the evaluation team within 30 days of your receipt of this report. Concerns 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. Please refer to NELAP Standard Operating Procedure 3-102, [Evaluation of Accrediting Bodies] 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]

Appendix G



Sample 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 (ET) assigned to the XXXXX has completed its evaluation of this Accreditation Body (AB.) In accordance with the 2016 TNI Standard, the evaluation consisted of the following: 1) a technical review of the XXXXX application for renewal and its supporting documentation and 2) an on-site evaluation of the XXXXX lab accreditation program.

[IF ASSESSMENT OBSERVATION OF A LABORATORY WAS DONE, IT WOULD BE NOTED / DESCRIBED HERE]

Team members (appointed by the NELAP Accreditation Council):

- [insert Evaluation Team members]

The evaluation team completed its initial technical review and issued the technical checklist to the AB for review on ---date---. [BRIEFLY DESCRIBE MEETINGS HELD AND DATA REVIEWED FOR TECHNICAL DOCUMENT AND RECORD REVIEW SUCH AS: The ET and the AB worked cooperatively with meetings held XX, YY, and ZZ to facilitate off-site data review of documents records pertaining to the AB's implementation of its quality system and assessment of laboratories in accordance with the 2016 TNI Standard.]].

The ET conducted an on-site evaluation of the XXXXX laboratory accreditation program on ---dates---. The team interviewed XXXXX staff members, reviewed laboratory files, training files, complaint files, and PT records. The team documented XXX instances in which XXXXX was determined to be in non-conformance with the 2016 TNI Standard. A report was prepared and sent to XXXXX on ---date---. XXXXX provided a corrective action plan for the XX nonconformities on ---date---. The evaluation team has reviewed these corrective action responses and finds them to be acceptable.

Evaluation of Accreditation Bodies

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) technical checklist,
- 2) evaluation team's on-site evaluation report, and
- 3) 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 H

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

1. Distribute Agenda and Sign-In Sheet(s),
2. Introductions of personnel on the team:
 - a. Lead evaluator
 - b. Others as appropriate
3. Purpose: To verify compliance with 2016 TNI Standard (or other explicit scope of evaluation with a continuation of record review and/or interview – particularly if 2-tier program with EPA concurrently evaluating the non-NELAP portion)
 - 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 technical checklist)
 - b. Determine if the AB's implementation of the standards conforms with the 2016 TNI Standard and the material it has submitted
4. Conflicts of Interest: All team personnel have signed forms, and LE has copies on file.
5. 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. Request materials for review
6. Security IDs, restrictions: Determine if AB has any restrictions on where team can go within the facility.
7. Workspace for team: Identify a room where the team can meet to conduct interviews and to deliberate to prepare findings.
8. Questions: Ask if laboratory personnel have any questions before beginning the evaluation.

Appendix I

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

[This Meeting may be held remotely after the conclusion of the on-site evaluation if time does not permit an on-site meeting.]

1. Distribute Agenda and Sign-In Sheet(s)
2. Introductions (if needed).
3. Make sure that all AB staff that are supposed to attend are actually present.
4. Thank staff for their cooperation and assistance.
5. 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 TNI standard).
6. Discuss list of “next steps” with due dates.
 - a. Set due date for LE to submit **final report** to AB – 30 days after on-site.
 - b. State deadline for AB to submit **corrective action report (CAR)** to LE – 30 days after receipt of final report.
 - c. Evaluation team’s response to CAR – 30 days after receipt of CAR.
 - d. 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.**
 - e. ET’s recommendation to NELAP Accreditation Council for recognition (renewal) or denial (revocation).
 - f. NELAP Accreditation Council’s issuance of certificate (or notification of denial).
7. Make certain that ET and AB have all necessary contact information for each party and understand importance of keeping on schedule.
8. Adjourn.

Evaluation of Accreditation Bodies

APPENDIX J

Evaluator Feedback Form

Please return to the NELAP Evaluation Coordinator, evaluationcoordinator.nelap@gmail.com

Form Completed by (State AB staff or NELAP ET Member): _____

Date Completed: _____

Evaluator or Team Being Rated: _____

AB Evaluated: _____

	For each item, please provide rating with brief explanation	Rating from 1-5 (1-low, 5-high)					N/A	Explanation and additional comments
		1	2	3	4	5		
1	Communication with AB							
2	Communication with Evaluation Team							
3	Timeliness (time lines of SOP)							
4	Organizational skills --efficiency of performance, each phase of evaluation							
5	Knowledge of TNI SOP 3-102, Evaluation of NELAP ABs							
6	Knowledge of V2 of the TNI Standard (AB requirements)							
7	Knowledge of V1 of the TNI Standard (Laboratory Requirements)							

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	For each item, please provide rating with brief explanation	Rating from 1-5 (1-low, 5-high)						Explanation and additional comments
8	Knowledge of AB's program							
9	Management of evaluation records							
10	Evaluator's overall contribution to the completion of the review							
11	Overall rating of the AB's evaluation							
Other comments including suggestions for continuous improvement								

Appendix K

Sample Renewal Letter to AB

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

Dear Dr. Yyyyyy,

The National Environmental Laboratory Accreditation Program (NELAP) Accreditation Council (AC) voted on ___(date vote ended)___ to accept the recommendation of the Evaluation Team (ET) assigned to the Xxxx, that your recognition as a NELAP Accreditation Body be renewed until ___date of expiration)___

We are delighted that your evaluation was successfully completed and look forward to continuing to work with you on the AC.

Sincerely,

(name)

NELAP Evaluation Coordinator

Cc: Lead Evaluator

EPA Regional Contact(s) (as designated by EPA Liaison to the AC)

NELAP Accreditation Council Chair

Appendix L

ITEMS REVIEWED BY THE EVALUATION TEAM, EITHER OFF-SITE OR ON-SITE, INCLUDE:

NOTE TO EVALUATION TEAM: ITEMS REVIEWED SHOULD BE DOCUMENTED WITHIN THE TECHNICAL CHECKLIST OR IN THE REPORT NARRATIVE

1. Examples of Corrective Actions and Preventive Actions
2. Complaint records
3. Signed copies of SOPs and any remaining (or new) SOPs for the program
4. Reports of assessment scheduling (time elapsed between assessments)
5. Reports of assessment reporting (time elapsed between site visit closure and issuance of on-site assessment report)
6. All internal audits performed since the last evaluation
7. All management reviews performed since the last evaluation
8. Lists of assessors and specific qualifications per assessor
9. Training records (may be examined on-site if linked to personnel files)
10. Specific laboratory files selected by the ET [MINIMUM OF SEVEN IS REQUIRED]
 - a. Files selected should have varying fields of accreditation
 - b. Files selected should have varying assessors
 - c. Files selected should include at least 1 with notable or severe quality system deficiencies, if applicable (in most recent 3 years)
 - d. Files selected should include a lab with disputes or appeals, if applicable (in most recent 3 years)
 - e. Files selected should include a lab against whom a complaint was lodged, if applicable (in most recent 3 years)
 - f. Files selected should include a lab that has lodged a complaint, if applicable (in most recent 3 years)
11. File review for a minimum of 7 labs will include verification of:
 - a. Application
 - b. Conflict of interest verification
 - c. Checklist(s) used for laboratory assessment
 - d. Proficiency testing (PT) results for compliance with methodological and EPA program requirements
 - e. Deficiency (on-site assessment) reports
 - f. Corrective action reports
 - g. Correspondence
 - h. Opening and closing meeting attendance sheets
 - i. Final determination of accreditation
 - j. Evaluation forms for AB assessor (if returned by the laboratory)
12. Specific parts of laboratory files selected by the ET (e.g., correspondence records for a laboratory, checklists used in assessment, opening or closing meeting records, notification of AB staff members, conflict of interest signature statements, etc.).
13. Laboratory files with specific situations (e.g., dual primary ABs, suspended Fields of Accreditation, appeals, disputes, secondary labs, etc.).
14. Discussion / demonstration / documentation / records on PT management practices
15. Copies of any/all reports from EPA regarding observation of on-site assessments [N/A FOR ABs NOT EVALUATING DRINKING WATER]
16. Evidence of continued corrective action as indicated in previous NELAP AB Corrective Action Report
17. Any additional requests to help evaluate potential deficiencies noted in the initial technical review