



SOP TITLE	Evaluation of Non-Governmental Accreditation Bodies (NGAB) for Accrediting Environmental Laboratories under Recognition by The NELAC Institute (TNI)
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1.0 Scope and Applicability

This document describes the procedures TNI uses to evaluate Non-Governmental Accreditation Bodies (NGABs) for initial or continuing recognition based on their conformance to TNI Standard for the Environmental Laboratory Sector, Volume 2, “General Requirements for Accreditation Bodies Accrediting Environmental Laboratories.”

This SOP does not apply to the evaluation to National Environmental Laboratory Accreditation Program (NELAP) ABs that are part of governmental agencies.

This revision includes the option for remote site evaluations and witnessing using video or teleconferencing in an effort to minimize travel expenses, maximize staff resources, and accommodate travel constraints imposed by outside circumstances. The objective of a remote evaluation or witness is to maintain the same level of confidence in the NGAB’s accreditation program by direct (i.e., in-person) observations.

2.0 Summary

This document specifies the roles and responsibilities of persons involved in the NGAB evaluation. It also describes the procedures TNI uses to:

- 2.1 Ensure the completeness of an NGAB’s application and its attachments.
- 2.2 Document the review of application materials.
- 2.3 Perform an evaluation of the NGAB’s assessment of laboratories.
- 2.4 Complete an evaluation report.
- 2.5 Review an NGAB’s corrective action plan submitted in response to the evaluation report, subsequent responses to the plan, and the implementation of corrective actions.
- 2.6 Forward to the TNI Non-Governmental Accreditation Body Recognition Committee (TNRC) documents needed to determine the recognition status of an NGAB.

3.0 Related Documents

ISO/IEC 17000, 2004
ISO/IEC 17000, 2020
ISO/IEC 17011, 2004
ISO/IEC 17011, 2017
ISO 19011, 2018
SOP 3-102, Evaluation of Accreditation Bodies

4.0 Definitions

Note 1: Terms not defined in this section may be found in TNI Standard for the Environmental Laboratory Sector, Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories, Modules 1 (General Requirements), 2 (Proficiency Testing) 3 (On-Site Assessment), or the normative references for those standards. If conflicts in definitions or interpretations arise between the ISO/IEC and TNI Environmental Laboratory (EL) Standards, the TNI EL Standards shall govern.

Note 2: The acronym AB stands for Accreditation Body and is used in these definitions to be consistent with the TNI glossary. An NGAB is an AB.

Term	Definition
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Evaluation of Non-Governmental Accreditation Bodies (NGAB) for Accrediting Environmental Laboratories
 under Recognition by The NELAC Institute (TNI)

Comment	Finding about documents or AB's practices with a potential for improvement; but still fulfilling the requirements
Completeness Review	A review of the application package submitted by an AB for either new or renewal recognition to determine whether all required information and signatures are present.
Concern	Finding where, in the opinion of the evaluation team, the AB's practice may develop into a nonconformity. The evaluated AB is not expected to respond to a concern but may do so if it wishes.
Date of Recognition	The date that TNI and the AB enter into a written recognition agreement.
Evaluation	The process used to measure or establish the performance, effectiveness, capacity, and conformance of an AB to the applicable TNI Standards
Evaluation Coordinator (EC)	An individual who coordinates communications among the Evaluation Team, the AB, and the appropriate recognition committee and facilitates that all steps of the evaluation are completed in a timely manner. The evaluation coordinator may also serve as the lead evaluator.
Evaluation team	A team comprised of the LE and other technical evaluators approved by the TNRC to conduct a review of an AB for the purposes of granting TNI recognition to the AB.
Evaluator	An individual who evaluates an AB's capability and capacity for meeting the requirements of the applicable standard by examining records and other evidence.
Finding	A conclusion of the evaluation process referenced to a TNI Standard (and/or ISO/IEC 17011 as appropriate) or TNI Procedures and Polices and supported by objective evidence. There are three types of findings: comments, concerns, and nonconformities.
Gap Analysis	See "mock assessment".
Lead Evaluator (LE)	A member of the Evaluation Team (ET) who leads the team and is responsible for the final report regarding AB recognition, after receiving input from the entire team. The lead evaluator may also serve as the evaluation coordinator.
Mock Assessment	An on-site assessment of a volunteering laboratory performed to the TNI Standards by an AB that does not have TNI recognition to meet the requirements of a witness of an on-site assessment. In this SOP, mock assessment is synonymous with "gap analysis".
Nonconformity	Finding where the AB does not meet a requirement of the applicable Standard (and/or ISO/IEC 17011 as appropriate), its own management system or the TNI agreement 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.
Recognition	The determination that an AB meets the requirements of a TNI Standard and is recognized to grant accreditation to applicant organizations.
Technical Completeness Review	A detailed review of the materials required to be submitted by an AB in its application package for TNI recognition to determine whether the materials conform to the applicable TNI Standard.
TNI Non-Governmental Accreditation Body Recognition Committee (TNRC)	A group appointed by the TNI Board of Directors to recognize NGABs to accredit applicant organizations to the TNI Standards.

Witness(ing) (Evaluation)	Observation of an assessment conducted by the applicant accreditation body by evaluation team member(s).

5.0 Evaluation Personnel Qualifications, Responsibilities, Selection, and Operations

5.1 TNI Non-Governmental Accreditation Body Recognition Committee (TNRC) Composition and Qualifications

The TNRC shall be composed of five members elected by the TNI Board to grant the final decision on the recognition of NGABs. The TNI Board appoints the chair of the committee. TNRC members:

- 5.1.1 Are appointed to serve a three-year term by the TNI Board from representative groups to ensure a balance of interest from the affected communities.
- 5.1.2 Are TNI Members in good standing.
- 5.1.3 Declare potential or known conflicts of interest which are evaluated by the TNI Board to determine if the conflicts risk the impartiality of the process.
- 5.1.4 Are knowledgeable and have experience with the TNI NELAP program and its standards and procedures.
- 5.1.5 Have TNI-recognized training on this SOP.

5.2 TNRC Responsibilities

The TNRC is responsible for:

- 5.2.1 Approving the ET members for each upcoming evaluation.
- 5.2.2 Ensuring the ETs receive copies of previous evaluation reports, recognition recommendation, and if requested, other retained records from the previous evaluation.
- 5.2.3 Reviewing the ET report and related evaluation information.
- 5.2.4 Voting on the recognition status of each NGAB.
- 5.2.5 Providing an annual report to the TNI Board outlining any needed revisions to the evaluation SOP and any training needs for the ET.
- 5.2.6 Provide direction in the event of a conflict between the duties of the EC and the LE.

5.3 TNRC Operations

The TNRC performs the following operations:

- 5.3.1 Reviews copies of the ET's technical completeness review report, applicant's technical completeness review corrective action response, ET's on-site evaluation report, including the witness of the laboratory(s) assessment, and NGAB's corrective action implementation.
- 5.3.2 Examines the objective evidence of findings and assures it is unbiased, demonstrates a consistent interpretation of the standard, and is complete confirming whether all elements of TNI EL Volume 2 are performed by the NGAB to enable it to accredit laboratories according to the standards contained in TNI EL Volume 1.
- 5.3.3 Decides whether the NGAB should be recognized as conforming to the TNI requirements and documents its decision.
- 5.3.4 Notifies the EC of its decision in writing.
- 5.3.5 Addresses disagreements with matters concerning recognition through TNI's General Complaint Resolution Process SOP 1 – 106.
- 5.3.6 Prepares a report for the TNI Executive Committee appraising and offering improvement suggestions to the NGAB evaluation process.

5.4 Evaluation Coordinator (EC) Qualifications

The EC is a TNI staff member, who may also serve as the Lead Evaluator (LE), and who:

- 5.4.1 Coordinates the evaluation process and ensures its quality.
- 5.4.2 Is generally familiar with TNI's activities and laboratory accreditation and completes the evaluator training course.
- 5.4.3 Has experience preceding the appointment that includes one or more of these specifications:
 - 5.4.3.1 At least two years of participation in one of the TNI consensus body committees, developing or implementing standards for use by ABs.
 - 5.4.3.2 At least 2 years of career experience related to laboratory accreditation or certification.
 - 5.4.3.3 Suitable equivalent experience approved by the TNI Board of Directors.

5.5 EC Responsibilities

The EC is responsible for:

- 5.5.1 Selecting the LE and the ET Members, for the approval of the TNRC, ensuring members meet the criteria for training and experience.
- 5.5.2 Ensuring the ET size is based on the size of the NGAB, the number of laboratories the NGAB accredits, and the number of assessors employed or contracted by the NGAB.
- 5.5.3 Assisting the Lead Evaluator and the TNRC with any questions related to the evaluation process.
- 5.5.4 Assuring all communication between the ET, the NGAB, and the TNRC occurs in a timely manner.
- 5.5.5 Tracking and documenting that all aspects of NGAB evaluations are performed in a timely manner in conformance with this evaluation SOP and the applicable TNI Standards.
- 5.5.6 Documenting the role and qualifications of each evaluator selected demonstrating that the requirements of this SOP are met.
- 5.5.7 Reviewing evaluation reports for completeness and consistency with this SOP and the TNI Standards.
- 5.5.8 Reporting to the TNRC on the status of the evaluation process.
- 5.5.9 Submitting TNI contracts to the NGAB once final recognition is granted and obtaining a signature from the TNI Executive Director. This contract defines the scope of accreditations granted and delineates activities that each individual NGAB may perform under the aegis of TNI.
- 5.5.10 Maintaining final agreements and ensuring appropriate fees are paid.
- 5.5.11 Sending renewal letters to existing NGABs nine months before existing recognitions expire.
- 5.5.12 Monitoring the ET for compliance with the timelines established by this SOP.
- 5.5.13 Verifying that all NGAB applications' technical reviews, on-site evaluations, and corrective action plan reviews are performed in a consistent manner conforming to this SOP.
- 5.5.14 Informing the TNRC of any unresolved consistency problems as they occur.
- 5.5.15 Preparing the recognition or renewal letter and Certificate of Recognition for signature by the Chair of the TNRC and delivering both to the NGAB and the LE for publication and archives.

5.6 Evaluation Team (ET) Qualifications

All ET members shall successfully complete a TNI evaluator training course based on this SOP, the TNI Standard, and other materials such as the completeness and technical review checklists.

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At least one ET member shall be:

- 5.6.1 A person knowledgeable and experienced with the operations of an accreditation body.
- 5.6.2 An assessor for NELAP or an individual trained on or who has performed NELAP assessments.
- 5.6.3 A representative of a NELAP-recognized or internationally recognized NGAB.
- 5.6.4 A technical expert knowledgeable in the scope the NGAB accredits or intends to accredit.
- 5.6.5 A person with at least one year of experience implementing federal or state laboratory accreditation rulemaking or developing and managing a laboratory accreditation program.

5.7 ET Responsibilities

The ET is responsible for conducting the evaluation of the assigned NGAB in accordance with this SOP. All ET members work under the direction of the Lead Evaluator (LE).

5.8 ET Selection

- 5.8.1 The EC selects the ET for approval of the TNRC and acceptance by the NGAB.
- 5.8.2 The EC shall notify the NGAB of the members appointed to the ET for concurrence with the selection, or any changes made to the members appointed to the ET.
- 5.8.3 Should the NGAB object to the appointment of any member of the ET, the NGAB shall notify the LE explaining the reason for the objection. The LE will inform the EC about the objection and both will bring up the matter to the TNRC for a determination. If the TNRC determines the objection is valid, it will direct the EC to appoint an alternative member to the ET. If the TNRC does not find the objection valid, it shall inform the NGAB of its decision and any options available to the applicant.

5.9 Lead Evaluator (LE) Responsibilities

The LE may be a volunteer or is under contract by TNI to lead evaluation activities. The LE shall coordinate with all ET members to ensure that the evaluation is well planned and consistent with those of other ABs.

Note: The LE and the EC may be the same person.

The LE is responsible for:

- 5.9.1 Reviewing the NGAB application for completeness, with concurrence of the EC.
- 5.9.2 Planning and directing the activities of the team members, from application technical completeness review through site visit, witness, report writing, and review of all responses to non-conformities.
- 5.9.3 Sending the applicant NGAB this SOP, the names of the TNRC and the selected ET members.
- 5.9.4 Coordinating all communications with the NGAB once the application is received.
- 5.9.5 Obtaining consensus of the ET in preparing the final recommendation of NGAB recognition status to the TNRC.
- 5.9.7 Notifying the EC of an evaluation's progress and outcomes.

5.10 Conflicts of Interest

- 5.10.1 All members of the ET shall sign a conflict of interest certification and provide it to the EC prior to engaging in the evaluation process.
- 5.10.2 Should the EC believe that an unforeseen circumstance creates a conflict of interest for an ET member; the EC shall consult the TNRC and seek its advice on how to proceed.

If the TNRC determines a conflict of interest exists, it will instruct the EC to appoint a different member to the ET and inform the NGAB following clauses 5.8.2 and 5.8.3.

6.0 Procedures

6.1 Frequency and Scope of Evaluation

NGABs shall be evaluated before they are recognized, and after recognition at a minimum of once every three years.

The scope of this evaluation includes:

- 6.1.1 A completeness and a technical review of the application package.
- 6.1.2 An on-site evaluation (this may be conducted in coordination with a national or international recognition program acceptable to the LE and Chair of the TNRC).
 - 6.1.2.1 At a minimum, all ABs (or applicant ABs) must undergo a document review and, if an initial application, at least one witness of an assessment to ensure all elements of the appropriate TNI requirements are met. The LE reviews the application and documentation and determines the need for an on-site evaluation with input from the ET.
 - a) National or internationally recognized ABs may submit a copy of their ISO/IEC 17011 Recognition Certificate and their respective evaluation report(s) to demonstrate conformance with ISO/IEC 17011. Where conformance to ISO/IEC 17011 is demonstrated in the report, these sections are not re-evaluated by the ET. Conformance to TNI requirements may be demonstrated through remote or on-site documentation evaluation as determined by the LE.
 - b) ABs without national or international recognition to ISO/IEC 17011 must be evaluated for conformance to ISO/IEC 17011 by the ET through review of documentation and during an on-site assessment.
- 6.1.3 An witness by an ET member of an NGAB assessing a laboratory as outlined in Section 6.1.2.1
- 6.1.4 An evaluation report with findings for both the on-site evaluation and the witness as required.
- 6.1.5 A recommendation to the TNRC regarding recognition or denial of recognition. 6.1.6 National or internationally recognized ABs who demonstrate compliance through submission of their evaluation report to the ISO/IEC 17011 Standard must notify the EC a minimum of 90 days before their next ISO/IEC 17011 evaluation.
 - 6.1.6.1 A copy of the evaluation reports and corrective action reports must be submitted to the EC within two weeks of receipt or submission of the final decision on the evaluation.
 - 6.1.6.2 Any changes to the AB's national or international recognition status must be submitted to the EC within two weeks of receipt.

6.2 Application Process

This section describes two procedures for an initial and renewal application. Sections 6.3 through 6.17 describes the evaluation procedures after the application that apply to either type.

6.2.1 Initial Application

6.2.1.1 Initial Application Forms, Application Fees, and Signatures

Initial application forms can be obtained from the TNI website or EC. The application shall be signed and dated by the person having ultimate authority and responsibility for accreditation decisions and overseeing activities for which TNI recognition is sought. By signing the application, this individual attests to the validity of the information contained within the application and its supporting documents.

The application fee shall be submitted to TNI at the same time the initial application is filed.

6.2.1.2 Initial Application Submittal

The NGAB shall submit an electronic version of the completed application and supporting documents (including a copy of their ISO/IEC 17011 Recognition Certificate and most recent evaluation report, as applicable) to the EC, including a completed technical checklist. Upon receipt of the application and supporting documents, the EC or designee shall send an acknowledgement to the NGAB and appoint an ET with the approval of the TNRC.

6.2.1.3 Application Communications

Once an LE has been appointed all subsequent communications regarding the application shall be between the LE and the NGAB, with copies provided to the EC.

6.2.1.4 Initial Application Timelines

Initial application timelines are summarized in Appendix A.

6.2.2 Renewal Application

6.2.2.1 Notification

The EC sends a letter with a renewal application form and a copy of the appropriate Technical Checklist(s) to the AB approximately 270 calendar days (9 months) prior to the expiration of the AB's current recognition.

6.2.2.2 Renewal Submittal

- a) The AB submits an electronic copy of the completed renewal application, Technical Checklist (with documentation references included) and all supporting documentation to the EC within thirty (30) calendar days of receipt of the letter and renewal application. The renewal form identifies the information on file and requests any updates to this information. A thirty (30) day extension may be granted if requested.
- b) If the AB does not submit a renewal application or extension request within thirty (30) calendar days, the EC shall notify the AB by any method providing receipt confirmation that, if an application is not submitted within fifteen (15) calendar days, the AB's recognition expires on the date of the current recognition certificate. After this expiration, recognition as an AB will require submission of an initial application (see 6.2.1).

6.2.2.3 Application Communications

Once the renewal package is given to the EC, and the LE is assigned, all subsequent communications shall be between the LE and the AB, with copies provided to the EC. The LE must respond to these communications as necessary.

6.3 Review of Application and Supporting Documents

6.3.1 Application Completeness Review

Following receipt of the application, the EC shall review it for completeness within 30 calendar days and report his or her conclusions to the LE.

If the information is not complete, the EC shall send a "Completeness Report" to the LE for review. The LE shall send the NGAB and the ET the "Completeness Report" in writing. The NGAB shall have 30 days from receipt of the Completeness Report to address how it will supply any missing information to the EC and LE.

If the missing material was inadvertently not submitted, it should be transmitted. If the missing material does not exist, that fact shall be highlighted to the LE to be addressed during the on-site visit. Once the EC and LE determine that the application is complete or that it is acceptable expecting missing materials to be available subsequently, the LE shall notify the NGAB of this determination.

6.3.2 Application Document Review for Technical Conformance

The LE shall coordinate a document review for technical conformance to verify that all required items meet the TNI Standard. The technical conformance document review shall be divided among all ET members. The checklist, "Technical Checklist to Determine Accreditation Body Conformance" (Technical Checklist) shall be used to determine the NGAB's conformance with the TNI EL Standard. The review shall be performed by the same ET assigned to the on-site evaluation.

Note: If the applicant has submitted a copy their ISO/IEC 17011 Recognition Certificate and most recent complete evaluation report, only the TNI requirements on the checklist will be evaluated as noted in Section 6.1.2.1.a.

The ET shall review the application and supporting documents to evaluate whether the NGAB's accreditation program and the requirements for its laboratories meet the TNI Standard. In addition, the technical conformance document review should highlight items on the checklist for which NGAB implementation needs to be verified during the on-site program evaluation, providing a reminder to the ET and notice to the NGAB of the materials that will be needed during the on-site evaluation. The ET has 30 calendar days to conduct this review after the application is determined complete. The LE shall consolidate the review results from all team members and then notify the NGAB of any non-conformities.

If the NGAB chooses to respond to these non-conformities prior to the site visit, the NGAB shall have 30 days from notification to submit corrective actions.

The LE may elect to proceed with the site visit prior to receipt of the NGAB response to the technical conformance document review findings.

If the ET determines, by consensus, that the application is so substantially deficient in technical conformance that the evaluation cannot reasonably proceed without the NGAB submitting additional information, the LE shall notify the NGAB. If the NGAB does not have or cannot produce the needed information on time, the LE will prepare a recommendation letter to the TNRC recommending denying recognition.

6.3.3 Review of NGAB Documents Prior to Site Visit

In many cases, it will be possible for the ET to review NGAB documents prior to the actual site visit. The ET can determine, in consultation with the requesting NGAB, what types of

records might be reviewed before the visit. Personnel records or those containing laboratory confidential business information may need to be reviewed during the site visit to maintain confidentiality or to protect personal information.

To initiate this off-site review, the ET should first identify documents and records such as evaluation forms, complaint records, results of internal audits and management reviews and portions of laboratory files. This request shall be transmitted as a list to the NGAB as a single one-time request.

NGAB documents shall be submitted electronically.

6.4 Scheduling the On-Site Program Evaluation

Once the ET concludes the technical completeness review, the LE will contact the NGAB 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 NGAB, within 90 calendar days of completing the application's technical completeness review, realizing that more lead-in time may be required if making arrangements for evaluation of an on-site assessment of a laboratory is included with this visit.

This portion of the evaluation may be conducted either in person or remotely using technologies that make document-sharing, conversation and video available as needed. For an initial application, a nationally or internationally recognized NGAB must submit their most recent evaluation report to demonstrate compliance with ISO/IEC 17011. Where conformance to ISO/IEC 17011 is demonstrated in the report, the NGAB may be evaluated remotely. For all other applicants, a direct (in-person) evaluation is required for the initial application.

The LE will send written confirmation to the NGAB and the ET of the logistics required to conduct the evaluation. The written confirmation shall include, but is not limited to:

- 6.4.1 The on-site evaluation date, and agenda or schedule of activities.
- 6.4.2 Copies of the standardized evaluation checklists.
- 6.4.3 The names, titles, affiliations, and on-site responsibilities of the ET members.
- 6.4.4 The names and titles of the NGAB staff that need to be available during the on-site evaluation.
- 6.4.5 If the site visit will be handled remotely, additional items to consider in planning include:
 - 6.4.5.1 Evaluations should be held for no more than 4 hours a day unless the NGAB and ET members are willing to go longer. Allow for breaks.
 - 6.4.5.2 Testing of the technology to be used to share information remotely is recommended prior to the evaluation.

6.5 Conducting the On-Site Evaluation of NGAB Applicants that Currently Operate a Laboratory Accreditation Program

6.5.1 During the on-site evaluation, however performed, the LE shall conduct an opening meeting prior to the start of the evaluation and a debriefing of findings at a closing meeting.

6.5.2 The ET shall conduct a comprehensive evaluation of the NGAB's accreditation program to determine the accuracy of information contained in the NGAB's application and the NGAB's conformance to the latest approved or applicable TNI Standard by:

- 6.5.2.1 Interviewing management and staff involved with the accreditation program.

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- 6.5.2.2 Appraising internal audits and management reviews to determine if they were completed as required, and if corrective actions were taken to address noted findings.
- 6.5.2.3 Reviewing a minimum of three files from TNI accredited laboratories or, if none have been assessed, at least three files from laboratories accredited to a standard similar in scope to TNI's, such as DoD or DOECAP.
- 6.5.2.4 Reviewing forms submitted by laboratories giving feedback to the NGAB about assessments performed.
- 6.5.2.5 Examining records of resolution of complaints about or from laboratories, including disputes and appeals.
- 6.5.2.6 Reviewing resumes and training records of assessors.
- 6.5.2.7 Conducting interviews of designated qualified assessors to evaluate their training, knowledge of assessment techniques, knowledge of the NGAB's management system and its associated procedures, and the TNI Standard.
- 6.5.2.8 Determining whether previously identified missing or incomplete items from the Technical Checklist are available and satisfactory.
- 6.5.2.9 As applicable, witnessing one NGAB assessor during an on-site assessment of a laboratory or a combination of assessors and on-site assessments that allow the ET to witness the NGAB's ability to conduct assessments commensurate with the fields for which the NGAB grants accreditations. This is required for all initial evaluations and as needed for renewal evaluations. This portion of the evaluation may be conducted either in person or remotely using technologies that make document-sharing, conversation and video available as needed. If a witness is performed of an NGAB doing a remote assessment, the NGAB must have a procedure(s) for the following:
 - 6.5.2.9.1 How to plan, manage and facilitate remote assessments.
 - 6.5.2.9.2 How to complement traditional oversight techniques.
 - 6.5.2.9.3 How to handle a situation that does not allow the assessment to be completed (e.g., connectivity issues, time allocated, observation not possible when needed).
- 6.5.2.10 Reviewing recent reports of evaluations performed by other recognition organizations offered voluntarily by the NGAB, if those reports help establish the NGAB's capabilities for meeting the TNI Standard.
- 6.5.3 The ET shall determine whether the NGAB is in conformance with its internal management system documents.
- 6.5.4 The ET shall evaluate the NGAB to ensure it understands and is able to comply with TNI policies and procedures pertaining to environmental laboratory accreditation and existing official interpretations of the latest approved or applicable TNI Standard.
- 6.5.5 The ET shall select laboratory files to review representing a mix of varying fields of accreditation and assessors. The ET shall endeavor to select files from laboratories showing varying degrees of compliance with the TNI Standard or with an environmental accreditation standard similar in scope and rigor to the TNI Standard, including those from laboratories that have issued complaints against the NGAB or laboratories against which a complaint was lodged. At a minimum, the ET shall review the following information in each selected laboratory file:
 - 6.5.5.1 Application.
 - 6.5.5.2 Conflict of interest verification for assigned assessors and correspondence regarding assessment team approval from the laboratory.
 - 6.5.5.3 Checklists used for laboratory assessments.
 - 6.5.5.4 Proficiency testing (PT) results for compliance with method and EPA program requirements.

- 6.5.5.5 Opening and closing meeting attendance sheets.
- 6.5.5.6 On-site assessment report.
- 6.5.5.7 Corrective action report.
- 6.5.5.8 Correspondence.
- 6.5.5.9 Documents related to the accreditation decision made by the NGAB.
- 6.5.5.10 Certificate and scope of accreditation document, if accreditation was granted.
- 6.5.5.11 Assessment appraisal forms completed by laboratories.

6.6 Scheduling the Witness of a Laboratory Assessment (Mock Assessment)

At least one appropriately qualified member of the ET must observe the NGAB conducting an on-site laboratory assessment for all initial applications (see Section 6.5.2.9 – assessments may be performed remotely). The purpose of the laboratory witness is to evaluate the NGAB's conformance to the TNI Environmental Laboratory Standard in performing laboratory assessments. At the time the on-site evaluation is scheduled, the LE should request from the NGAB a schedule of upcoming laboratory assessments. The LE will use this schedule to select at least one laboratory assessment which will be witnessed within the schedule of the on-site evaluation or another mutually-agreed time. The LE may elect to send more than one member of the ET to witness the assessment based on the assessment's scope, the number of NGAB assessors involved, and the availability, knowledge, and experience of ET members.

For an NGAB's initial application for recognition, the NGAB, with approval of the ET, may arrange to perform a mock assessment or gap analysis of a volunteering laboratory. This assessment must be performed before the NGAB's evaluation is considered complete.

Prior to the observation, the NGAB must determine the need for specific safety training, safety equipment, or other site-specific requirements (e.g. security, confidentiality and insurance) for any ET members. A review of the site logistics between the ET member and the NGAB assessor shall be completed at least one week prior to the evaluation assessment.

For a witness of an assessment performed remotely, if the ET cannot determine if the NGAB's staff carries out laboratory assessments in accordance with the Standard, the ET may determine that a direct (in-person) witness of an on-site assessment by the NGAB's staff is required. The NGAB will be responsible for associated expenses for witness of an on-site laboratory assessment.

For renewal applications, should the ET find insufficient evidence through records review and/or interviews to determine that the NGAB's staff carries out laboratory assessments in accordance with the Standard, OR that the NGAB's Management has not adequately monitored all assessors in accordance with the Standard, the ET may determine that witness of an on-site assessment by the NGAB's staff is required to confirm compliance to the Standard and/or the NGAB's quality system documents. The NGAB will be responsible for associated expenses for witness of an on-site laboratory assessment.

6.7 Conducting the Witness of a Laboratory Assessment (Mock Assessment)

ET members performing the observation are not to evaluate assessors' competence directly, but should focus on determining whether the NGAB's documented procedures for conducting assessments are followed.

During witness of the laboratory assessment, ET members shall:

- 6.7.1 Witness the NGAB's laboratory assessment team perform opening and closing meetings, interviews of laboratory staff, data review, and quality systems review.
- 6.7.2 Limit their participation to witnessing the NGAB's laboratory assessors without actively participating in the assessment.

- 6.7.3 Make every effort to witness as many aspects of the NGAB's assessment process as possible.
- 6.7.4 Concentrate on areas where the technical review of the application may have revealed improvement opportunities in the NGAB's program.

6.8 Documentation of Findings of a Witnessing of a Laboratory Assessment (Mock Assessment)

Members of the ET that participate in a witness of a laboratory assessment shall transmit their observations to the LE for inclusion in the on-site evaluation report within 15 calendar days from completion of the witness, as determined by the LE.

6.9 Documentation of Findings of the On-Site Evaluation

The findings of the on-site evaluation, including those of the witness of a laboratory assessment (if required) shall be documented in a report providing sufficient detail to document the salient activities the ET conducted to determine conformance to the TNI Standard.

The ET has 30 calendar days from completion of the evaluation and the laboratory witness, whichever is later, to prepare and send the evaluation report to the NGAB by any method providing receipt confirmation.

Note: An initial NGAB evaluation is not considered complete until the on-site evaluation and laboratory assessment witness conclude. A draft report may be furnished to the NGAB if delays are encountered with scheduling the laboratory assessment witness.

6.10 Corrective Action Report (CAR)

Upon receipt of the evaluation report, the NGAB shall prepare a CAR describing how it either has addressed or plans to address the non-conformities from the evaluation report. The NGAB has 30 calendar days from receipt of the on-site evaluation report to submit this CAR.

6.11 Response to the NGAB CAR

The ET shall review the NGAB's response to the on-site evaluation report, including its proposed corrective actions. The LE shall respond to the NGAB in writing, within 30 calendar days of receipt of the NGAB CAR, summarizing the conclusions of the ET's review.

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

If the NGAB corrects all the non-conformities of the on-site evaluation report, the LE shall notify the NGAB and submit the report and the conclusions of the CAR review to the TNRC recommending that the NGAB's TNI recognition be granted.

If the NGAB does not correct all non-conformities of the on-site evaluation report, the LE shall notify the NGAB and submit the report and the conclusions of the CAR review to the TNRC recommending that the NGAB's TNI recognition be denied.

6.12 Recommendations of the ET to the TNRC

The LE shall submit the report and the conclusions of the CAR review to the TNRC recommending that the NGAB's TNI recognition be granted or denied based on the ET's review of the NGAB's CAR.

Once the ET provides a recommendation to the TNRC for granting or denying recognition, all subsequent communications regarding recognition shall be between the EC and the NGAB, with copies given to the TNRC.

6.13 Recognition Decisions by the TNRC

The TNRC decides on the recognition of an NGAB after reviewing the recommendation of the ET, all evaluation documents submitted by the LE, and any others upon request to facilitate arriving at a decision.

The decision to grant or deny recognition an NGAB is made by two-thirds majority vote of the entire TNRC.

The TNRC's decision shall be submitted in writing to the NGAB, EC, ET and the Executive Committee of TNI Board of Directors.

Disagreements with matters concerning recognition shall be addressed through the TNI General Complaint Resolution Process SOP 1 – 106.

6.14 Issuance of Certificate of Recognition to the NGAB

TNI shall issue initial Certificates of Recognition to NGABs awarded recognition bearing an effective date not earlier than the date of the affirmative decision made by the TNRC.

All NGABs will be issued a Certificate of Recognition annually, signed by the TNI Executive Director, contingent upon the most recent evaluation being satisfactory and assuming that the NGAB wishes to continue with the program.

6.15 Expiration of Application for Recognition

NGABs shall have one year to complete the application process from application submittal through CAR approval.

If the TNRC is not able to make a recognition decision based on the available documented evidence, the NGAB's application shall expire. NGABs with expired applications wishing to be considered for recognition must re-initiate the application process, including submitting any applicable fees.

If delays lasting more than a year in the recognition decision are the result of actions or inactions by TNI, the NGABs application shall not expire.

6.16 Handling of Unexpected Circumstances

In the event that the ET encounters an unexpected or unusual circumstance while performing an evaluation, the LE should seek guidance from the TNRC.

6.17 Standard Interpretation Process

If the ET has questions regarding the meaning of the Standard, the LE shall use the Standards Interpretation Request (SIR) form available on the TNI website to request an interpretation of a TNI Standard.

6.18 Conducting the Initial On-Site Evaluation of NGAB Applicants that Currently Do Not Operate a Laboratory Accreditation Program

The requirements outlined in Section 6.6 of this SOP apply in principle to all NGAB applicants; however, TNI understands that NGAB applicants in this category may not be able to comply exactly with the provisions of Section 6.6. Accordingly, the following adaptations are appropriate to evaluate NGABs that do not currently operate a laboratory accreditation program.

6.18.1 Review of Records

The review of records should focus on those listed in the application as currently existing for future use. The LE may request templates, prototypes or examples of required documents along with information on how the documents will be used to maintain future conformance with the TNI Standard.

6.18.2 Witness of the NGAB's Laboratory Assessment

The NGAB, with approval of the ET, may arrange to perform a mock assessment or gap analysis of a volunteering laboratory. This assessment must be performed before the NGAB evaluation is considered complete.

6.18.3 Laboratory Assessment Reports

The evaluation report may request that the NGAB forward to the LE any examples of documents that might be used to evaluate the implementation of a laboratory accreditation program that would comply with the TNI Standard.

7.0 Checklists, Standards, and Other Evaluation Documents

All ET members shall use the approved or applicable version of the TNI EL standards, policies, procedures, and EL checklists. Documents are available on TNI website at: www.nelac-institute.org.

8.0 Records Management

NGAB evaluation records shall be handled in accordance with TNI Policy 1 - 104, Management of Records, and TNI SOP 1 -104, Control of TNI Documents. All NGAB evaluation records shall be maintained electronically, preferably in portable document format (pdf). The EC is responsible for submitting all NGAB final evaluation records in electronic format to the TNRC.

TNI shall retain a complete file of the NGAB evaluation. The ET shall transmit all records to the TNI EC and shall not retain copies of confidential information submitted. The TNI Secretary, or his or her designee, is the ultimate custodian and repository of all NGAB evaluation records.

The following items shall constitute the formal record of evaluation documents:

- 8.1 Application materials.
- 8.2 Conflict of interest forms from ET members.
- 8.3 Correspondence about the completeness review and its checklist.
- 8.4 Correspondence about the technical completeness review and its checklist.
- 8.5 Evaluation report, including the report of the witness of a laboratory assessment(s).
- 8.6 NGAB's response to the evaluation report, a CAR with evidence that the corrective actions were completed, if corrective actions were needed, or documentation that a plan for achieving compliance was acceptable.
- 8.7 Transmittal letter of the LE to the TNRC recommending a recognition decision.
- 8.8 TNRC's letter to the NGAB notifying it of the Committee's recognition decision.
- 8.9 Copy of the certificate or documents authorizing an NGAB to accredit laboratories to TNI Standards.

9.0 Quality Control

The TNRC shall review this SOP whenever the TNI Environmental Laboratory standard is updated, or when other information that requires updating this process is received.

If this SOP is revised, the revisions shall be distributed to the appropriate stakeholders. If there are substantive changes to the SOP, refresher training may be required for all ET members.

10.0 References

- 3.1 TNI Standard for the Environmental Laboratory Sector, Volume 1, "Management and Technical Requirements for Laboratories Performing Environmental Analysis", latest revision
- 3.2 TNI Standard for the Environmental Laboratory Sector, Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories", latest revision
- 3.3 SOP 1-106 General Complaint Resolution Process
- 3.4 Non-Governmental Accreditation Body Application
- 3.5 Checklist to Determine Accreditation Body Conformance (Technical Checklist)

11.0 SOP Approved Changes

Revision No.	Effective Date	Description of Change
0	09/23/14	New SOP
1	01/13/16	Delete references to program, add TNRC responsibility to provide direction in the event of a conflict between duties of EC and LE, make it clear EC can serve as the LE, make it clear the completeness checklist and the technical checklist must be completed by the applicant as part of the application, and editorial changes.
2	7/10/19	Add application renewal procedures to SOP. Add References section to be consistent with TNI SOP format.
3	11/20/20	Added language to clarify that on-sites may be remote.
3.1	12/18/2020	Clarified use of remote evaluation for initial applications.
4.0	10/21/2022	Updated definitions; changed procedure for issuance of certificates
5.0	1/5/2024	Updated sections related to ISO/IEC 17011 recognized ABs (e.g., Sections 6.1.2.1, 6.2.1, 6.3.2), added updated ISO/IEC documents to Related Documents, removed the need for a Completeness Checklist to line up with SOP 3-102 and added "Mock Assessment" to section titles as appropriate. Definitions were updated and the term "witness" was substitute for "observation" where appropriate based on definition of "witness".

12.0 Tables, Figures, Diagrams, Charts, Examples, Checklists, and Appendices

APPENDIX A
NGAB Application Process – Target Timeframes

Action	Expected time (days)	Expected timeline (total days)
NGAB submit electronic version of completed application and supporting documents with fee to the EC <ul style="list-style-type: none"> • EC sends acknowledgement • EC appoints ET and LE w/ TNRC concurrence • EC notifies NGAB of LE and ET members 		30 days
NGAB notifies LE of approval or objection of ET member(s)	7 days	
EC and TNRC Chair consider objection and appoint new members of the evaluation team	10 days	
ET members sign conflict of interest forms		
EC reviews application for completeness and reports to LE <ul style="list-style-type: none"> • If incomplete, LE sends "completeness report" to NGAB and ET • NGAB responds to completeness report if necessary 	30 days after receipt, concurrent with above 30 days	30 days 60 days
LE and ET conduct technical review of application and notify NGAB of any non-conformities	30 days	90 days
NGAB may respond to non-conformities	30 days	120 days
Onsite evaluation scheduled	30 days	150 days
LE notifies NGAB of onsite evaluation logistics	60 days prior	
Onsite evaluation conducted	60-90 days from completion of technical review	150 -- 180 days
Conduct witness of AB lab assessment		
ET members submit witness of lab assessment to LE	15 days	165 – 195 days
Prepare final report	30 days from completion of evaluation and witness of lab	195 -- 225 days
NGAB responds to evaluation report	30 days	225 – 255 days
LE reviews and responds to CAR	30 days	255 --285 days
Notice to NGAB that additional corrective action is needed	ASAP	
NGAB sends 2 nd response to non-conformities	30 days	285 -- 315 days
ET review of 2 nd response	15 days	300 -- 330 days
Response to NGAB and recommendation to TNRC	7 days	307 -- 337 days
TNRC votes on recommendation	30 days	337 – 367 days
Issuance of certificate	10 days	347 -- 377 days

Appendix B:
Suggested Format for On-Site Evaluation Opening Conference Meeting
(Can be modified for Remote Site Evaluation as appropriate.)

The opening meeting should follow the following format:

- Distribute the opening meeting agenda and a sign-in sheet.
- Introductions of personnel on the team:
 - Lead evaluator
 - State team members
 - Others as appropriate
- Purpose: To verify compliance with 2009 TNI Standard (or other explicit scope of evaluation)
- Determine the accuracy of the documents submitted by the NGAB (i.e., the application for renewal, the QSM, the AB's responses in the completeness and technical checklists)
- Determine if the NGAB's implementation of the standards conforms with the current TNI Standard and the material it has submitted.
- Conflicts of Interest: All team personnel have signed forms, and LE has copies on file.
- Schedule/agenda: Provide schedule of tasks for the on-site review, e.g., interviews, reviews of records and closing meeting, and approximate times.
- Present schedule for witness of NGAB laboratory assessment(s)
- Briefly discuss next steps, i.e., closing meeting, evaluation report and lab's response(s), and recommendation to the TNRC. (This may be done at the closing briefing if desired.)
- Security IDs, restrictions: Determine if NGAB has any restrictions on where team can go within the facility.
- Workspace for team: Identify a room where the team can meet to conduct interviews and to deliberate to prepare findings.
- Questions: Ask if laboratory personnel have any questions before beginning the evaluation.

Appendix C:

Suggested Format for On-Site Evaluation Closing Conference Meeting (Can be modified for Remote Site Evaluation as appropriate.)

The closing meeting should follow the following format;

- Distribute closing meeting agenda and sign-In sheet
- Introductions (if needed)
- Make sure that all NGAB staff that are supposed to attend are actually present.
- Thank staff for their cooperation and assistance.
- 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).
- Discuss list of “next steps” with due dates.
 - If witness of laboratory assessment(s) has not yet been completed, set date(s) and location(s) and identify who will do it.
 - Set due date for LE to submit final report to NGAB – 30 days after on-site or witness of lab assessment, whichever occurs last.
 - State deadline for NGAB to submit corrective action report (CAR) to LE – 30 days after receipt of final report.
 - Evaluation team’s response to CAR – 30 days after receipt of CAR.
 - AB’s submittal of revised CAR (if necessary) – 30 days after ET’s response to original CAR. Make sure NGAB knows that the revised CAR must be satisfactory.
 - ET’s recommendation to TNRC for recognition (renewal) or denial (revocation)
 - TNRC’s issuance of certificate (or notification of denial)
- Make certain that ET and NGAB have all necessary contact information for each party and understand importance of keeping on schedule.
- Adjourn.