



<b>SOP TITLE</b>	<b>Evaluation of Non-Governmental Accreditation Bodies (NGAB) for Accrediting Environmental Laboratories under Recognition by The NELAC Institute (TNI)</b>
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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 the 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 of National Environmental Laboratory Accreditation Program (NELAP) ABs that are part of governmental agencies.

This SOP 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 individuals 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

Term	Definition
<b>Completeness Review</b>	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.
<b>Evaluation</b>	The process used to measure conformance of an AB to the applicable TNI standards, policies, and procedures.
<b>Evaluation Coordinator (EC)</b>	An individual chosen to coordinate the evaluation process, to facilitate communications as needed between all involved parties, and to ensure that all steps of the evaluation are completed in a timely manner.

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<b>Evaluator</b>	An individual who performs an evaluation of an AB's accreditation program for meeting the requirements of a TNI standard, policy, or procedure.
<b>Finding</b>	Documented results of the collected evaluation evidence against established criteria. Findings can indicate either conformity or nonconformity with criteria or opportunities for improvement.
<b>Nonconformity</b>	A finding that shows failure to meet a requirement in a TNI standard, policy, or procedure.
<b>Recognition</b>	The determination that an AB meets the requirements of a TNI Standard and can accredit applicant organizations.
<b>Technical Review Checklist</b>	A TNI developed checklist required for use to record all findings during an evaluation.
<b>TNI Non-Governmental Accreditation Body Recognition Committee (TNRC)</b>	A group appointed by the TNI Board of Directors to recognize NGABs that accredit applicant organizations to the TNI Environmental Laboratory Standards.
<b>Witness(ing) (Evaluation)</b>	Observation of an assessment conducted by the applicant AB by an evaluator.

**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 must 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.

## 5.0 Personnel Qualifications, Responsibilities, Selection, and Operations

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

The TNRC must 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:

- 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.
- Are TNI Members in good standing.
- 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.
- Are knowledgeable and have experience with the TNI NELAP program and its standards and procedures.
- Have TNI-recognized training on this SOP.

### 5.2 TNRC Responsibilities

The TNRC is responsible for:

- Approving the evaluator(s) for each upcoming evaluation.
- Ensuring an evaluator receives copies of previous evaluation reports, recognition recommendations, and if requested, other retained records from previous evaluations.
- Reviewing the evaluator's report and related evaluation information.

- d) Voting on the recognition status of each NGAB. Providing an annual report to the TNI Board outlining any needed revisions to this evaluation SOP and any training needs for the evaluator(s).
- e) Provide direction in the event of a conflict between the duties of the EC and the evaluator.

### **5.3 TNRC Operations**

The TNRC performs the following operations:

- a) Reviews copies of the evaluation report, the witness of the laboratory(s) assessment (as appropriate), and copies of any corrective action responses and implementation plans submitted during the evaluation process.
- b) Examines the objective evidence of findings and ensures it is a) unbiased, b) demonstrates a consistent interpretation of the Standard, and c) complete, thus confirming whether the NGAB complies with all elements of TNI EL Volume 2 to ensure the NGAB can accredit laboratories according to the standards contained in TNI EL Volume 1.
- c) Decides whether the NGAB should be recognized as conforming to the TNI requirements and documents its decision.
- d) Notifies the EC of its decision in writing.
- e) Addresses disagreements with matters concerning recognition through TNI's General Complaint Resolution Process (SOP 1-106).
- f) Prepares a report for the EC, 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 Evaluator, and who:

- a) Is generally familiar with TNI's activities and laboratory accreditation and completes the evaluator training course.
- b) Has experience that includes one or more of these specifications:
  - i. At least two years of participation in one of the TNI consensus body committees, developing or implementing standards for use by ABs.
  - ii. At least 2 years of career experience related to laboratory accreditation or certification.
  - iii. Suitable equivalent experience approved by the TNI Board of Directors.

### **5.5 EC Responsibilities**

The EC is responsible for:

- a) Coordinating the evaluation process and ensuring its quality.
- b) Recommending the Evaluator, and any additional evaluators with needed expertise, for approval by the TNRC, ensuring evaluators meet the criteria for training and experience.
- c) Assisting the Evaluator and the TNRC with any questions related to the evaluation process.
- d) Ensuring all communication between the Evaluator, the NGAB, and the TNRC occurs in a timely manner. 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.
- e) Documenting the role and qualifications of each evaluator.
- f) Reporting to the TNRC on the status of the evaluation process and informing TNRC of any inconsistencies.
- g) 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.

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- h) Sending renewal letters to existing NGABs nine months before existing recognitions expire.
- i) Monitoring the Evaluator for compliance with the timelines established by this SOP.
- j) Reviewing the application for completeness.
- k) Preparing the recognition or renewal letter and delivering it to the NGAB.
- l) Ensuring all records defined in Section 8 are sent to the Secretary of the TNI Board of Directors for archiving.

## 5.6 Evaluator Qualifications

The Evaluator is a TNI staff member who may also serve as the Evaluation Coordinator, and who:

- a) Is knowledgeable about and applies the currently adopted TNI Environmental Laboratory Sector Standard (which may include any applicable results of the TNI Standards Interpretation Request process), the requirements of this SOP, and the policies and procedures of NELAP (where applicable), when reviewing the AB's implementation of the TNI Standard.
- b) Has successfully completed a TNI evaluator training course that is based on this SOP, the TNI Standard(s), and other materials, such as the Technical Review Checklist.
- c) Has experience that includes at least one of the following:
  - d) A person knowledgeable and experienced with the operations of an accreditation body.
  - e) An assessor for NELAP or an individual trained on or who has performed NELAP assessments.
  - f) A representative of a NELAP-recognized or internationally recognized NGAB.
  - g) A technical expert knowledgeable in the scope the NGAB accredits or intends to accredit.
  - h) A person with at least one year of experience managing a laboratory accreditation program.

## 5.7 Evaluator Selection

- 5.7.1 Some evaluations, such as an Initial Evaluation or an evaluation where a Scope extension has been applied for, may require an additional evaluator with expertise to perform a witness of an assessment of a laboratory with a specified Scope or to review the ABs ability to add a new technology to their Scope. These evaluators must complete a TNI training course that may be an abbreviated form of the required training for the primary evaluator. The training course must include this SOP, and any relevant portions of the TNI Standard(s) and the Technical Review Checklist.
- 5.7.2 The EC recommends an Evaluator (and any additional evaluators as needed) for approval by the TNRC.
- 5.7.3 The EC must notify the NGAB of the Evaluator selected (and any additional evaluators as needed) for concurrence with the selection.
- 5.7.4 Should the NGAB object to the Evaluator selected (or any additional evaluators as needed), the NGAB must notify the EC explaining the reason for the objection. The EC must bring up the matter to the TNRC for a determination. If the TNRC determines the objection is valid, it will direct the EC to recommend an alternative Evaluator(s) to the TNRC. If the TNRC does not find the objection valid, it must inform the NGAB of its decision and any options available to the NGAB.

## 5.8 Evaluator Responsibilities

The Evaluator is responsible for:

- a) Conducting the evaluation of the assigned NGAB in accordance with this SOP.

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- b) Planning and directing the activities of the evaluation, and any additional evaluators as needed, from the application, technical review, site visit, witness, report writing, and review of all responses to nonconformities.
- c) Coordinating all communications with the NGAB once the application is received.
- d) Recommending NGAB recognition status to the EC.
- e) Ensuring that all findings are recorded in the Technical Review Checklist which may include any Attachments as needed.
- f) Notifying the EC of an evaluation's progress.
- g) Providing the EC with the evaluation records for archiving as described in Section 8.

## **5.9 Quality Assurance (QA) Peer Reviewer Qualifications and Selection**

5.9.1 The QA peer reviewer is a NELAP AB evaluator that has been trained as per Section 5.6.1 -5.6.3 of this SOP.

5.9.2 The EC recommends a QA Peer Reviewer for approval by the TNRC.

NOTE: The QA peer reviewer is not an evaluator and does not participate in the on-site evaluation, on-site observation, or the final decision regarding recognition of the AB. The QA peer reviewer can, however, assist the Evaluator as another "pair" of eyes or ears as might be helpful or if the Evaluator needs a sounding board to discuss issues as they arise during the evaluation of the AB.

## **5.10 QA Peer Reviewer – Responsibilities**

### **5.10.1 Findings Review**

Concerns regarding an AB's compliance should be directed to the QA Peer Reviewer prior to the report being submitted. The QA Peer Reviewer may request additional input from other NELAP ABs and NGABs regarding the determination of compliance.

### **5.10.2 Report Review**

QA Peer Reviewer reads the final report to ensure findings were appropriately identified and the Evaluator has clearly communicated all observations.

### **5.10.3 Technical Review Checklist Review.**

The QA Peer Reviewer reviews the Technical Review Checklist and any available corrective action responses to ensure the requirements of this SOP were met.

## **5.11 Conflicts of Interest**

5.11.1 All evaluators must sign a conflict-of-interest attestation and provide it to the EC prior to engaging in the evaluation process. See Appendix D.

5.11.2 Should the EC believe that an unforeseen circumstance creates a conflict of interest for an evaluator; the EC must 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 evaluator and inform the NGAB following Sections 5.7.3 and 5.7.4.

## **6.0 Procedure**

### **6.1 Frequency and Scope of Evaluation**

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

6.1.2 The scope of this evaluation includes:

- a) A review of the documentation received and completion of the Technical Review Checklist in the application package.
- b) An evaluation, either on-site or virtual.

NOTE: An on-site evaluation may be conducted in coordination with a national or international recognition program acceptable to the Evaluator and Chair of the TNRC.

6.1.2.1 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. For existing ABs, the Evaluator determines if a witnessing of an assessment is necessary.

- a) Nationally or internationally recognized ABs may submit a copy of their ISO/IEC 17011 Recognition Certificate, respective evaluation report(s), and corrective action response. Where conformance to ISO/IEC 17011 is demonstrated, these sections of the Technical Review Checklist are not re-evaluated by the Evaluator.
- b) ABs without national or international recognition to ISO/IEC 17011 must be evaluated for conformance to ISO/IEC 17011.

6.1.2.2 ABs who demonstrate conformance to ISO/IEC 17011 through submission of their evaluation report must notify the EC a minimum of 90 days before their next ISO/IEC 17011 evaluation and provide:

- a) A copy of the evaluation reports and corrective action reports to the EC within two weeks of receipt or submission of the final decision on the evaluation.
- b) Any changes to the AB's recognition status must be submitted to the EC within two weeks of receipt.

6.1.3 An evaluation report with findings for both the evaluation and the witness observation, as required.

6.1.4 A recommendation to the TNRC regarding recognition or denial of recognition.

## 6.2 Application Process

This section describes two procedures: one for an initial application and one for a renewal application. Sections 6.3 through 6.17 describe 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

- a) The initial application form can be obtained from the TNI website or EC. The application must be signed and dated by the person having authority. By signing the application, this individual attests to their authority and the validity of the information contained within the application and its supporting documents.
- b) The application fee must be submitted to TNI at the same time the initial application is filed.

#### 6.2.1.2 Initial Application Submittal

The NGAB must 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 and corrective action, as applicable) to the EC, including a completed Technical Review Checklist with specific documentation references included. Upon receipt of the application and supporting documents, the EC or designee must send an acknowledgement to the NGAB.

#### 6.2.1.3 Application Communications

Once the application has been submitted to the EC, an Evaluator has been appointed and then accepted by the NGAB, all subsequent communications regarding the application must be between the Evaluator 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 Review 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 Review Checklist (in Word with specific 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 must 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, an Evaluator has been appointed and then accepted by the NGAB, all subsequent communications regarding the application must be between the Evaluator and the NGAB, with copies provided to the EC.

## 6.3 Review of Application and Supporting Documents

### 6.3.1 Application Completeness Review

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

6.3.1.2 If the information is not complete, the EC must send a "Completeness Report" to the Evaluator for review. The Evaluator must send the NGAB the "Completeness Report" in writing. The NGAB has 30 days from receipt of the Completeness Report to address how it will supply any missing information.

6.3.1.3 If the missing material was inadvertently not submitted, it should be transmitted. If the missing material does not exist, that fact must be highlighted to the Evaluator to be addressed during the on-site visit. Once the EC and

Evaluator determine that the application is complete or that it is acceptable expecting missing materials to be available subsequently, the Evaluator must notify the NGAB of this determination.

### 6.3.2 Application Document Review for Technical Conformance

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

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

- 6.3.2.2 The Evaluator must 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 Evaluator and notice to the NGAB of the materials that will be needed during the on-site evaluation. The Evaluator has 30 calendar days to conduct this review after the application is determined complete. The Evaluator must consolidate any review results and then notify the NGAB of any nonconformities.
- 6.3.3.3 If the NGAB chooses to respond to these nonconformities prior to the site visit, the NGAB must respond with applicable information within 30 days from when the notification to submit corrective actions was provided.
- 6.3.3.4 The Evaluator may elect to proceed with the site visit prior to receipt of the NGAB response to the technical conformance document review findings.
- 6.3.3.5 If the Evaluator determines with agreement from the QA Reviewer, that the application is so substantially deficient in technical conformance that the evaluation cannot reasonably proceed without the NGAB submitting additional information, the Evaluator must notify the NGAB. If the NGAB does not have or cannot produce the needed information on time, the Evaluator prepares a recommendation letter to the TNRC recommending denying recognition.

### 6.3.3 Review of NGAB Documents Prior to Site Visit

- 6.3.3.1 In many cases, it will be possible for the Evaluator to review NGAB documents prior to the actual site visit. The Evaluator can determine, in consultation with the 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.
- 6.3.3.2 To initiate this off-site review, the Evaluator 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 must be transmitted as a list to the NGAB.

- 6.3.3.3 NGAB documents must be submitted electronically as PDFs, Word or Excel files or any other format found acceptable to the Evaluator.

#### **6.4 Scheduling the On-Site Program Evaluation**

- 6.4.1 Once the Evaluator concludes the review of documents for technical conformance review, the Evaluator will contact the NGAB within 30 calendar days to schedule the on-site evaluation. An on-site evaluation must be conducted, at the mutual convenience of the Evaluator and the NGAB, within 90 calendar days of completing the application's 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.
- 6.4.2 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 and corrective action 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.
- 6.4.3 The Evaluator will send written confirmation to the NGAB of the logistics required to conduct the evaluation. The written confirmation must include, but is not limited to:
- a) The on-site evaluation date, and agenda or schedule of activities.
  - b) The names and titles of the NGAB staff that need to be available during the on-site evaluation.
- 6.4.4 If the site visit is performed remotely, additional items to consider in planning include:
- a) Evaluations should be held for no more than 4-5 hours per day unless the NGAB and the Evaluator are willing to go longer. Keep in mind that the time allotted should include time for breaks.
  - b) 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 Evaluator must conduct an opening meeting prior to the start of the evaluation and a debriefing of findings at a closing meeting.
- 6.5.2 The Evaluator must 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:
- a) Interviewing management and staff involved with the accreditation program.
  - b) Reviewing internal audits and management reviews to determine if they were completed as required, and if corrective actions were taken to address noted findings.
  - c) 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 DOEAP.
  - d) Reviewing forms submitted by laboratories giving feedback to the NGAB about assessments performed.
  - e) Examining records of resolution of complaints about or from laboratories, including disputes and appeals.
  - f) Reviewing resumes and training records of assessors.

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- g) 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.
- h) Determining whether previously identified missing or incomplete items from the Technical Review Checklist are available and satisfactory.
- i) 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 an evaluator 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:
  - i. How to plan, manage and facilitate remote assessments.
  - ii. How to complement traditional oversight techniques.
  - iii. 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).
- j) 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 Evaluator must determine whether the NGAB is in conformance with its internal management system documents.

6.5.4 The Evaluator must 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 Evaluator must select laboratory files to review representing a mix of varying fields of accreditation and assessors. The Evaluator must endeavor to select files from laboratories showing varying degrees of compliance with 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 Evaluator must review the following information in each selected laboratory file:

- a) Application.
- b) Conflict of interest verification for assigned assessors and correspondence regarding assessment team approval from the laboratory
- c) Checklists used for laboratory assessments.
- d) Proficiency testing (PT) results for compliance with TNI requirements.
- e) Opening and closing meeting attendance sheets.
- f) On-site assessment report.
- g) Corrective action report.
- h) Correspondence.
- i) Documents related to the accreditation decision made by the NGAB.
- j) Certificate and scope of accreditation document, if accreditation was granted.
- k) Assessment appraisal forms completed by laboratories.

6.5.6 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 by the Evaluator 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 is required.

6.5.7 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 Evaluator will review the AB's established procedures to ensure 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.

## **6.6 Scheduling the Witness of a Laboratory Assessment**

- 6.6.1 At least one appropriately qualified evaluator 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. The Evaluator may choose to send an additional evaluator with expertise to witness the assessment based on the assessment's scope, the number of NGAB assessors involved, and the availability, knowledge, and experience of the Evaluator. This witnessing must be performed before the NGAB's evaluation is considered complete.
- 6.6.2 For an NGAB's initial application for recognition, the procedure described in Section 6.12.3 for Interim Recognition is followed.
- 6.6.3 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 evaluators. A review of the site logistics between the Evaluator and the NGAB assessor must be completed at least one week prior to the evaluation assessment.
- 6.3.4 For a witness of an assessment performed remotely, if the Evaluator (or additional evaluator as needed) cannot determine if the NGAB's staff carries out laboratory assessments in accordance with the Standard, the Evaluator 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.
- 6.3.5 For renewal applications, should the Evaluator 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 Evaluator 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**

- 6.7.1 An evaluator(s) performing the observation is not to evaluate the assessors' competence directly, but should focus on determining whether the NGAB's documented procedures for conducting assessments are followed.
- 6.7.2 During witnessing of the laboratory assessment, the evaluator must:

- a) Witness the NGAB's laboratory assessment team perform opening and closing meetings, interviews of laboratory staff, data review, and quality management systems review.
- b) Limit their participation to witnessing the NGAB's laboratory assessors without actively participating in the assessment.
- c) Make every effort to witness as many aspects of the NGAB's assessment process as possible.
- d) 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**

The evaluator must complete the appropriate portions of the Technical Review Checklist and document their observations for inclusion in the evaluation report within 15 calendar days from completion of the witness.

#### **6.9 Documentation of Findings of the Evaluation**

- 6.3.1 The findings of the evaluation, including those of the witness of a laboratory assessment (if required), must be documented in a report providing sufficient detail to document the salient activities the Evaluator conducted to determine conformance to the TNI Standard.
- 6.3.2 The Evaluator has 30 days from completion of the evaluation to prepare its findings report for QA peer review as described in Section 5.9 and 5.10. 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.

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 or Interim Recognition can be discussed (see Section 6.12.3).

#### **6.10 Corrective Action Report (CAR)**

Upon receipt of the evaluation report, the NGAB must prepare a CAR describing how it either has addressed or plans to address the nonconformities 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**

- 6.11.1 The Evaluator must review the NGAB's response to the on-site evaluation report, including its proposed corrective actions. The Evaluator must respond to the NGAB in writing, within 30 calendar days of receipt of the NGAB CAR, summarizing the conclusions of the evaluation.
- 6.11.2 If the NGAB CAR does not address all nonconformities, the Evaluator must notify the NGAB by any method providing receipt confirmation that it must submit another CAR for the remaining nonconformities within 30 calendar days of receipt of the notification.
- 6.11.3 If the NGAB corrects all the nonconformities of the on-site evaluation report, the Evaluator must 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.
- 6.11.4 If the NGAB does not correct all nonconformities of the on-site evaluation report, the Evaluator must 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 to the TNRC**

- 6.12.1 The Evaluator must 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 Evaluator's and QA peer review of the NGAB's CAR.
- 6.12.2 Once the Evaluator provides a recommendation to the TNRC for granting or denying recognition, all subsequent communications regarding recognition must be between the EC and the NGAB, with copies given to the TNRC.
- 6.12.3 Interim Recognition for Initial Applications
  - 6.12.3.1 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 witnessing of a laboratory assessment, the Evaluator will recommend to the TNRC that the new AB receive Interim Recognition.
  - 6.12.3.2 Because an AB that is not TNI recognized cannot conduct assessments under the TNI Standard until recognition as a TNI Standard AB has been achieved, the Evaluator recommends to the TNRC 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 AB while providing an opportunity for requirements to be met which are not achievable until after the AB's program is fully operational.
  - 6.12.3.3 The AB must notify the Evaluator when the first laboratory assessment is scheduled after Interim Recognition is granted the assessment is used as the required witnessing.

Note: Witnessing of the laboratory assessment should be completed within 6 months of the granting of Interim Recognition to ensure the process for achieving full Recognition can be completed within the 1-year period allowed for Interim Recognition.
  - 6.12.3.4 Upon completion of the Witnessing requirement and corrective action as needed, the Evaluator recommends to the TNRC that the AB be given full recognition and issued a Certificate of Recognition. If the AB fails to achieve recognition within 1 year of receiving Interim Recognition, the Evaluator recommends to the AC that the AB's recognition be revoked.

## **6.13 Recognition Decisions by the TNRC**

- 6.13.1 The TNRC decides on the recognition of an NGAB after reviewing the recommendation, all evaluation documents, and any other documents requested to facilitate arriving at a decision.
- 6.13.2 The TNRC's decision must be submitted in writing to the NGAB, EC, Evaluator and the Executive Committee of the TNI Board of Directors.
- 6.13.3 Disagreements with matters concerning recognition must be addressed through the TNI General Complaint Resolution Process (SOP 1-106).

## **6.14 Issuance of Certificate of Recognition to the NGAB**

- 6.14.1 The TNI Executive Director must issue the 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.
- 6.14.2 Annually thereafter, NGABs are issued a Certificate of Recognition, 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**

- 6.15.1 NGABs have one year to complete the application process from application submittal through CAR approval.
- 6.15.2 If the TNRC is not able to make a recognition decision based on the available documented evidence, the NGAB's application expires. NGABs with expired applications wishing to be considered for recognition must re-initiate the application process, including submitting any applicable fees.
- 6.15.3 If delays lasting more than a year in the recognition decision are the result of actions or inactions by TNI, the NGABs application does not expire.

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

- 6.16.1 In the event that the Evaluator encounters an unexpected or unusual circumstance while performing an evaluation, the Evaluator seeks guidance from the TNRC or the QA Peer Reviewer and works with the Applicant to resolve the issue in a mutually acceptable manner
- 6.16.2 In the event that the Applicant encounters an unexpected or unusual circumstance while the evaluation is underway, the Applicant seeks guidance from the Evaluator and works with the Evaluator to resolve the issue in a mutually acceptable manner

#### **6.17 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.

##### **6.17.1 Review of Records**

The review of records should focus on those listed in the application as currently existing for future use. The Evaluator 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.

##### **6.17.2 Witness of the NGAB's Laboratory Assessment**

The Interim Recognition procedure as described in Section 6.12.3 is followed.

##### **6.17.3 Laboratory Assessment Reports**

The evaluation report may request that the NGAB forward to the Evaluator 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 Evaluators must use the most recent version of the TNI EL standards, policies, procedures, and EL checklists. Documents are available from the EC.

## **8.0 Records Management**

- 8.1 NGAB evaluation records must 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 must 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.
- 8.2 TNI retains a complete file of the NGAB evaluation. The Evaluator transmits all records to the TNI EC. The TNI Secretary, or his or her designee, is the ultimate custodian and repository of all NGAB evaluation records.
- 8.3 The following items constitute the formal record of evaluation documents:
- a) Application materials.
  - b) Conflict of Interest attestation (Appendix D) from any evaluators involved in the evaluation.
  - c) The Technical Review Checklist and any correspondence related to it.
  - d) Evaluation report, including the report of the witnessing of a laboratory assessment(s).
  - e) 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.
  - f) Transmittal letter of the Evaluator to the TNRC recommending a recognition decision.
  - g) TNRC's letter to the NGAB notifying it of the Committee's recognition decision.
  - h) Copy of the certificate or documents authorizing an NGAB to accredit laboratories to TNI Standard.

## **9.0 Quality Control**

- 9.1 The TNRC and evaluator(s), EC and QA peer reviewer must review this SOP whenever the TNI Standard is updated, or when other information that requires updating this process is received.
- 9.2 If this SOP is revised, the revisions are distributed to the individuals in the paragraph above.
- 9.3 If there are substantive changes to the SOP, refresher training is required for all evaluators.

Note: The author, or revisor, of this SOP is, by default, considered trained to this SOP.

## **10.0 References**

Checklist to Determine Accreditation Body Conformance (Technical Review Checklist)  
Non-Governmental Accreditation Body Application  
Policy 1-104, Management of Records  
SOP 1-102 The Voting Rules for TNI Committees  
SOP 1-104, Control of TNI Documents  
SOP 1-106, General Complaint Resolution Process  
TNI Standard for the Environmental Laboratory Sector, Volume 1, "Management and Technical Requirements for Laboratories Performing Environmental Analysis", latest revision  
TNI Standard for the Environmental Laboratory Sector, Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories", latest revision

## 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".
6.0	6/21/2025	Remove requirements of an Evaluation Team and specify the requirements for evaluators instead. Add QA Peer Reviewer process. Substitute "must" for "shall". Remove requirement to resend a Checklist when scheduling the dates for an evaluation. Remove requirement that additional information can only be requested from an NGAB once. Add Interim Recognition procedures. Expand on description of assessor review. Update references. Update Appendix A. Eliminate Mock Assessment options. Added Appendix D. Minor editorial changes.

## 12.0 Appendices

Appendix A – NGAB Application Process – Target Timeframes

Appendix B – Suggested Format for On-Site Evaluation Opening Conference Meeting

Appendix C – Suggested Format for On-Site Evaluation Closing Conference Meeting

Appendix D – Conflict of Interest Attestation

## APPENDIX A

### NGAB Application Process – Target Timeframes

Action	Expected time	Cumulative timeline
NGAB submit electronic version of completed application and supporting documents with fee to the EC <ul style="list-style-type: none"> <li>EC sends acknowledgement</li> <li>EC recommends an Evaluator</li> <li>Evaluator signs Conflict of Interest attestation (Appendix D)</li> <li>EC notifies NGAB of the Evaluator</li> </ul>		30 days
NGAB notifies EC of approval or objection of the Evaluator	7 days	
EC and TNRC Chair consider objection and appoint a different Evaluator if needed.	10 days	
EC reviews application for completeness and sends it to the Evaluator with notification of any missing items. If incomplete, Evaluator sends "completeness report" to NGAB.	30 days after receipt, concurrent with above	30 days
NGAB responds to completeness report if necessary.	30 days	60 days
Evaluator conducts review of application using Technical Review Checklist and notifies NGAB of any nonconformities	30 days	90 days
NGAB may respond to nonconformities (prior to evaluation or during)	30 days	120 days
Onsite/virtual evaluation scheduled	30 days	150 days
Evaluator notifies NGAB of onsite/virtual evaluation logistics	60 days prior	
Onsite/virtual evaluation conducted	60-90 days from completion of technical review	150 -- 180 days
Conduct witness of AB lab assessment as required		
Witness evaluator submits a report and completed Technical Review Checklist items to the Evaluator	15 days	165 – 195 days
Preparation of the final report	30 days from completion of evaluation and witness	195 -- 225 days
QA peer reviewer reviews report, Technical Review Checklist, and any corrective action responses and Evaluator addresses any recommendations.	15-30 days	225-255 days
Report sent to the NGAB and responds to the evaluation report.	30 days	255 – 285 days
Evaluator reviews and responds to CAR	30 days	285 --315 days
Notice to NGAB that additional corrective action is needed	ASAP	
NGAB sends 2 <sup>nd</sup> CAR	30 days	315 -- 345 days
Evaluator review of 2 <sup>nd</sup> response	15 days	345 -- 360 days
Response to NGAB and recommendation to TNRC	7 days	360 -- 367 days
TNRC votes on recommendation	30 days	367 – 397 days
Issuance of certificate as needed	10 days	397 -- 407 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.
- Introduction of evaluation personnel.
- Purpose: To verify compliance with TNI Standard
- Determine the accuracy of the documents submitted by the NGAB
- Determine if the NGAB's implementation of the standards conforms with the current TNI Standard and the material it has submitted.
- Conflicts of Interest
- Schedule/agenda: Provide schedule of tasks for the on-site review, e.g., interviews, review of records, and closing meeting, and approximate times.
- Present schedule for witness of NGAB laboratory assessment(s), if applicable.
- Briefly discuss next steps, i.e., closing meeting, evaluation report and NGAB'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 evaluation personnel can go within the facility.
- Workspace: Identify a room where the evaluation personnel can meet to conduct interviews and to deliberate to prepare findings.
- Questions: Ask if NGAB personnel have any questions before beginning the evaluation.

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**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)
- Thank staff for their cooperation and assistance.
- Presentation of findings and resolved issues.
  - a. Summarize any 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 which are not covered by the TNI standard).
- Discuss list of “next steps” with due dates.
  - If witnessing of the NGAB has not been completed (if required), set date(s) and location(s) and identify participants. Discuss Interim Accreditation for initial applications.
  - Set a due date for Evaluator to submit final report to NGAB.
  - State deadline for NGAB to submit corrective action report (CAR) to Evaluator – 30 days after receipt of final report.
  - Evaluator response to CAR
  - NGAB’s submittal of revised CAR (if necessary) – 30 days after Evaluator’s response to original CAR. Make sure NGAB knows that the revised CAR must be satisfactory.
  - Evaluator’s recommendation to TNRC for recognition (renewal) or denial (revocation) or Interim Recognition (as appropriate)
  - TNRC’s issuance of certificate (or notification of denial)
- Make certain that Evaluator and NGAB have all necessary contact information for each party and understand importance of keeping on schedule.
- Adjourn.

## **APPENDIX D:**

### **Evaluation Conflict of Interest Attestation**

Name:

Organization:

Date of NGAB Evaluator Training:

Name of Accreditation Body Being Reviewed:

I attest that I shall act impartially, and I shall not reveal information gained through evaluations and/or evaluation reports to anyone who does not have the right to access such information or who has not signed this statement.

Additionally, I attest that I do not have a conflict of interest with the parties involved in the activities that I shall conduct.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_