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Standard Operating Procedure (SOP) 3 -- XX

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

1.0 Scope and Applicability

This document describes the procedures TNI uses to evaluate 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."

2.0 Summary

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

- 2.1 Check the completeness of an NGAB's application and its attachments.
- 2.2 Document the review of application materials.
- 2.3 Observe the NGAB assessors performing an on-site assessment.
- 2.4 Complete an evaluation report.
- 2.5 Review an NGAB's corrective action plan to the evaluation report, subsequent responses to the plan, and the implementation of correctives.
- 2.6 Forward documents to the TNI Non-Governmental Accreditation Body Recognition Committee (TNRC) needed to determine the recognition status of an NGAB.

3.0 Related Documents

TNI Standard for the Environmental Laboratory Sector, Volume 1, "Management and Technical Requirements for Laboratories Performing Environmental Analysis".

TNI Standard for the Environmental Laboratory Sector, Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories."

ISO/IEC 17000

ISO/IEC 17011

4.0 Definitions

Note: 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

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interpretations arise between the ISO/IEC and TNI Environmental Laboratory (EL) Standards, the TNI EL Standards shall govern.

Completeness Review: a review of the application package submitted by an NGAB for either new or renewal recognition to determine whether all required information and signatures are present.

Date of Recognition: the date that TNI and the NGAB enter into a written recognition agreement.

Evaluation: the process used to measure or establish the performance, effectiveness, capacity, and conformance of an NGAB to the TNI EL Standards

Evaluation Coordinator (EC): an individual who coordinates communications among the Evaluation Team, the NGAB, and the TNRC and facilitates all steps of the evaluation are completed in a timely manner. May need to re-visit

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 NGAB's capability and capacity for meeting the requirements of the standard, by examining records and other evidence.

Finding: a conclusion of the evaluation process, referenced to the TNI Standard and supported by objective evidence.

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| Comment: | Finding about documents or AB's practices with a potential of improvement; but still fulfilling the requirements |
| Concern: | Finding where, in the opinion of the evaluation team, the AB's practice may develop into a non-conformity. The evaluated AB is not expected to respond to a concern but may do so if it wishes. |
| Nonconformity: | Finding where the AB does not meet a requirement of the applicable standard (FMSO-v2-2008), its own management system or the Arrangement 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. |

Lead Evaluator (LE): a member of the Evaluation Team (ET) who leads the team and is responsible for the final report regarding NGAB recognition, after receiving input from the entire team.

Observation: witnessing of a laboratory assessment conducted by the applicant accreditation body by evaluation team member(s).

Recognition: the determination that an NGAB meets the requirements of the TNI EL Standard and is recognized to grant accreditation to applicant organizations.

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Technical Completeness Review: a detailed review of the materials required to be submitted by an NGAB 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.

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 by the TNI Board from representative groups of the program to ensure a balance of interest from the affected communities **to serve a three year term.**
- 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 Providing the ETs with 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.

5.3 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 evaluation of the

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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 – 104.
- 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, but not an ET Member, who coordinates the evaluation process and ensures its quality. The EC participates in site visits or observations at least once per year and at least once for each Lead Evaluator.

The EC:

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

Has experience preceding the appointment that includes:

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

5.5 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.

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- 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 agreements to the NGAB once final recognition is granted and obtaining a signature from the TNI Executive Director.
- 5.5.10 Maintaining final agreements and ensuring appropriate fees are paid.
- 5.5.11 Sending renewal letters to existing ABs nine months before existing recognitions expire.
- 5.5.12 Verifying how the ET completes an NGAB's application's technical review, on-site evaluation, and corrective action plan reviews to help assure all NGAB evaluations are performed in a consistent manner conforming to this SOP.
- 5.5.13 Informing the TNRC of any unresolved consistency problems as they occur.
- 5.5.14 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. 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, with the assistance of the TNRC, selects the ET for acceptance by the NGAB.

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- 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) Qualifications and Responsibilities

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

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, observation, 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

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

Note: After the first round of evaluations, the TNRC will review the three-year cycle for a possible change to a four-year cycle to coincide with NEFAP AB and other national and international evaluation cycles.

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, which may be conducted in coordination with another national or international evaluation acceptable to the TNRC.
- 6.1.3 An observation by an ET member of the NGAB conducting an on-site laboratory assessment.
- 6.1.4 An on-site evaluation report with findings for both the on-site evaluation and the observation.
- 6.1.5 A recommendation to the TNRC regarding recognition or denial of recognition.

Note: National or internationally recognized NGABs may submit their most recent respective evaluation report(s) to demonstrate compliance with ISO/IEC 17011. Where conformance to ISO/IEC 17011 is demonstrated in the report, these areas may not need to be re-evaluated with equal rigor by the NGAB ET.

6.2 Initial Application

6.2.1 Initial Application Forms, Application Fees, and Signatures

Initial application forms can be obtained from the TNI website. The application shall be signed and dated by the highest ranking NGAB individual, 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.

Note: All NGABs pay an annual separate fee that sustains TNI's accreditation program.

6.2.2 Application Submittal

The NGAB shall submit an electronic version of the completed application and supporting documents to the EC. 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.

6.2.3 Application Communications

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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.

6.2.4 Initial Application Timelines

Initial application timelines are summarized in Appendix A.

6.4 Review of Initial Application and Supporting Documents

6.4.1 Application Completeness Review

Following receipt of the application, the EC shall review it for completeness within 30 calendar days, using the “Application/Renewal Completeness Review Checklist” 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.

6.4.2 Initial Application Document Review for Technical Completeness

The LE shall coordinate a document review for technical completeness to verify that all required items have been addressed. The technical completeness document review shall be divided among all ET members. The checklist, “Technical Checklist to Determine Accreditation Body Compliance” (Technical Checklist) shall be used to determine the NGAB’s compliance with the TNI EL Standard. The review shall be performed by the same ET assigned to the on-site evaluation.

The ET shall review the application and supporting documents to evaluate whether the NGAB’s accreditation program and the requirements for its laboratories meet the Standard. In addition, the technical completeness document review should highlight items on the compliance 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. The ET has 30 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.

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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 completeness document review findings.

If the ET determines, by consensus, that the application is so substantially deficient in technical completeness that the evaluation cannot reasonably precede 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.

6.4.3 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.

6.5 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 60 to 90 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.

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:

- 6.5.1 The on-site evaluation date and agenda, or schedule of activities.
- 6.5.2 Copies of the standardized evaluation checklists.
- 6.5.3 The names, titles, affiliations, and on-site responsibilities of the ET members.

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6.5.4 The names and titles of the NGAB staff that need to be available during the on-site evaluation.

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

6.6.1 The LE shall conduct an opening meeting prior to the start of the evaluation and a debriefing of findings at a closing meeting.

The opening meeting should follow the following format:

- Distribute Agenda and Sign-In Sheet(s),
- 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 & technical checklists)
- Determine if the NGAB's implementation of the standards conforms with the 2009 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 observation(s) of NGAB laboratory assessments
 - 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.

Note: The outline for opening and closing meetings may need to go in an appendix or guidance documents.

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- 6.6.2 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:
- 6.6.2.1 Interviewing management and staff involved with the accreditation program.
 - 6.6.2.2 Appraising internal audits and management reviews to determine if they were completed as required, and if corrective actions were taken to address noted findings.
 - 6.6.2.3 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.
 - 6.6.2.4 Reviewing forms submitted by laboratories giving feedback to the NGAB about assessments performed.
 - 6.6.2.5 Examining records of resolution of complaints about or from laboratories, including disputes and appeals.
 - 6.6.2.6 Reviewing resumes and training records of assessors.
 - 6.6.2.7 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.
 - 6.6.2.8 Determining whether previously identified missing or incomplete items from the Technical Checklist are available and satisfactory.
 - 6.6.2.9 Observing 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 will grant accreditations.
 - 6.6.2.10 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.
- 6.6.3 The ET shall determine whether the NGAB is in conformance with its internal management system documents.
- 6.6.4 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.
- 6.6.5 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

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which a complaint was lodged. At a minimum, the ET shall review the following information in each selected laboratory file:

- 6.6.5.1 Application.
- 6.6.5.2 Conflict of interest verification for assigned assessors and correspondence regarding assessment team approval from the laboratory..
- 6.6.5.3 Checklists used for laboratory assessments.
- 6.6.5.4 Proficiency testing (PT) results for compliance with method and EPA program requirements.
- 6.6.5.5 Opening and closing meeting attendance sheets.
- 6.6.5.5 On-site assessment report.
- 6.6.5.6 Corrective action report.
- 6.6.5.7 Correspondence.
- 6.6.5.8 Documents related to the accreditation decision made by the NGAB.
- 6.6.5.9 Certificate and scope of accreditation document, if accreditation was granted.
- 6.6.5.10 Assessment appraisal forms completed by laboratories.

6.7 Scheduling the Observation of the Laboratory Assessment

At least one appropriately qualified member of the ET must observe the NGAB conducting an on-site laboratory assessment. The purpose of the laboratory observation is to evaluate the NGAB's conformance to the TNI Standard in performing laboratory assessments. At the time the on-site program 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 observed within the schedule of the on-site program evaluation or another mutually-agreed time. The LE may elect to send more than one member of the ET to observe the assessment based on the assessment's scope, the number of NGAB assessors involved, and the availability, knowledge, and experience of ET members.

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 observers. A review of the site logistics between the observer and the NGAB assessor shall be completed at least one week prior to the evaluation assessment.

6.8 Conducting the Laboratory Assessment Observation

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 laboratory assessment observations, the observing ET members shall:

- 6.8.1 Limit their participation to observing the NGAB's laboratory assessors without actively participating in the assessment.

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6.8.2 Make every effort to observe as many aspects of the NGAB's assessment process as possible.

6.8.3 Concentrate on areas where the technical review of the application may have revealed improvement opportunities in the NGAB's program.

6.9 Closing Meeting

The closing meeting should follow the following format;

- Distribute Agenda and Sign-In Sheet(s)
- 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 laboratory observation(s) has not yet been completed, set date(s) and location(s) and identify who will do them.
- Set due date for LE to submit final report to NGAB – 30 days after on-site or lab observation, 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.

6.10 Documentation of Findings of the Laboratory Assessment Observation

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

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6.11 Documentation of Findings of the On-Site Program Evaluation

The findings of the on-site program evaluation, including those of the laboratory assessment observation 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 observation, whichever is later, to prepare and send the evaluation report to the NGAB by any method providing receipt confirmation.

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

6.12 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 days from receipt of the on-site evaluation report to submit this CAR.

6.13 Response to the NGAB CAR

The ET shall review the NGAB's response to the on-site evaluation report, including its proposed corrective actions, in a timely manner. 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 program 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 program 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.

6.14 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.

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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.

6.15 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.

6.16 Issuance of Certificate of Recognition to the NGAB

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

6.17 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 caused by TNI, the NGABs application shall not expire.

6.18 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.

6.19 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.

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

The requirements outlined in Section 6.6 this SOP apply in principle to NGAB applicants that do not currently operate a laboratory accreditation program; 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

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adaptations are appropriate to evaluate NGABs that do not currently operate a laboratory accreditation program.

6.20.1 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.

6.20.2 Observation 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. Alternatively, the laboratory observation may be scheduled and performed within a year of the NGAB's application date.

6.20.3 Laboratory Assessment Reports

The program 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.

6.20 Renewal Application Process [ENTIRE SECTION RESERVED]

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.

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- 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 observation of laboratory assessments.
- 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.