



SOP TITLE:	TNI Accreditation Body Evaluation and Recognition Procedure used by the PT Program Executive Committee and NEFAP Executive Committee
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The NELAC Institute
 P.O. Box 2439
 Weatherford, TX 76086
www.nelac-institute.org

TNI Accreditation Body Evaluation and Recognition Procedure
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1.0 Purpose and Applicability

This document describes the procedures used by the National Environmental Field Activities Program (NEFAP) Executive Committee, henceforth, referred to as the NEFAP Executive Committee, and the TNI Proficiency Testing Program Executive Committee referred to as PT Program Executive Committee, to evaluate NEFAP Accreditation Bodies (AB) and Proficiency Testing Provider Accreditors (PTPA) for initial or continuing recognition. NEFAP ABs and PTPA's are collectively called ABs moving forward. This program is based on the current approved TNI Field Activities Volume 2, TNI Environmental Laboratory Sector Volume 4 Standards, and NEFAP and PT Program policies.

2.0 Summary

This document includes the procedures used to:

- Perform a completeness review of an AB's application and its attachments.
- Perform a document review of these materials.
- Perform an on-site evaluation of an AB, as applicable.
- Perform a witness assessment of the AB's assessor(s) performing an assessment.
- Complete the on-site evaluation report.
- Perform the review of and respond to the AB's corrective action plans and corrective action implementation.
- Prepare an evaluation report to the Recognition Committee (RC) for the scope of the evaluation.
- RC review and vote on the recognition of the AB and provide a recommendation letter to the TNI NEFAP Executive Committee and PT Program Executive Committee.
- Endorse the recognition by vote by the NEFAP Executive Committee and PT Program Executive Committee.
- Issue the Certificate of Recognition by each Executive Committee.

The evaluation of the systems, processes and procedures of the AB must provide a determination of the AB's conformance with the TNI standards, procedures and policies set forth by TNI and its capabilities to perform assessments in a consistent, uniform manner.

3.0 Related Documents

FSMO-V1-2014 Rev 2: General Requirements for Accrediting Field Sampling and Measurement Organizations (FSMO), or latest TNI adopted version.

FSMO-V2-2014 Rev 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations (FSMO), or latest TNI adopted version.

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EL-V3-2009: General Requirements for Environmental Proficiency Testing Providers, or latest TNI adopted version.

EL-V4-2009: General Requirements for an Accreditor of Environmental Proficiency Testing Providers, or latest TNI adopted version.

SOP 1-104: Control of TNI Documents

SOP 4-102: TNI Proficiency Testing Program Complaint, Appeal and Dispute Resolution Procedures

SOP 4-105: PT Program Executive Committee Voting Process

SOP 5-102: TNI NEFAP Executive Committee Voting Procedure for General Business and Field Activities Accreditation Matters,

SOP 5-104: TNI NEFAP Complaint, Appeal and Dispute Resolution Procedures

Application

Technical Checklist to Determine Accreditation Body Conformance (Technical Checklist)

4.0 Definitions

See International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17000 and the TNI Field Activities and PT Standards.

If conflicts in definitions or interpretations arise between the ISO/IEC and TNI Standards, the TNI Standards shall govern. It is understood that International Laboratory Accreditation Cooperation (ILAC)/ Asia Pacific Laboratory Accreditation Cooperation (APLAC) ABs must follow the more stringent requirements when compared to ISO/IEC 17011, ISO/IEC 17025 and ISO/IEC 17043.

Accreditation Body (AB):	For this SOP, PTPAs and NEFAP ABs are referred to as Accreditation Body (AB) for consistency.
Finding:	A conclusion of the evaluation process referenced to the TNI Standard (and/or ISO/IEC 17011 as appropriate) and supported by objective evidence. There are three types of findings: comments, concerns, and nonconformities.
Comment:	Finding about documents or AB's practices with a potential for improvement; but still fulfilling the requirements
Concern:	Finding where, in the opinion of the evaluation team, the AB's practice may develop into a nonconformity. The evaluated AB is not expected to respond to a concern but may do so if it wishes.
Nonconformity:	Finding where the AB does not meet a requirement of the applicable Standard (and/or ISO/IEC 17011 as appropriate), its own management system or the TNI agreement requirements in a way that discredits its competence or jeopardizes the quality of its work. The evaluated AB is expected to respond to any nonconformity by taking appropriate corrective action and providing the team with evidence of implementation.
Observation:	Witnessing of an assessment conducted by the applicant accreditation body by evaluation team member(s).
Organization:	PT Provider or FSMO.

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5.0 Personnel Qualifications, Selection and Responsibilities

5.1 Evaluation Team (ET)

- 5.1.1 All ET members must meet minimum requirements for training and professional qualifications as defined in this Section.
- 5.1.2 All ET members must successfully complete the appropriate TNI AB evaluator-training course.
- 5.1.3 All ET members must sign the conflict of interest statement. See Appendix A for the *Qualification and Conflict of Interest* form documenting freedom from any conflict of interest that would compromise acting in an impartial nondiscriminatory manner.
- 5.1.4 The ET has the responsibility to carry out the evaluation of the assigned AB in accordance with this SOP and consistently with the evaluations of other ABs.
- 5.1.5 All ET members shall have experience that includes at least one of the following:
 - 5.1.5.1 Certification as a lead assessor from an internationally recognized accreditation body;
 - 5.1.5.2 One year experience as a NEFAP or PT Program Assessor;
 - 5.1.5.3 One year experience implementing an AB accreditation program;
 - 5.1.5.4 One year experience developing or managing a laboratory, FSMO or PT Program accreditation program.
- 5.1.6 ETs must comply with the policies of TNI and the following criteria.

The ET shall:

 - 5.1.6.1 Have a technical expert knowledgeable in the scope the AB accredits or intends to accredit (this may be one or more) to complete the on-site observation of an AB assessment.
 - 5.1.6.2 Have representatives of a PT Program and/or NEFAP (as appropriate) recognized or internationally recognized Non-Governmental Accreditation Body (NGAB) or AB that is knowledgeable in the operations of an AB.
 - 5.1.6.3 Have a person with at least one year of experience developing and managing an AB accreditation program or developing and managing a laboratory, FSMO or PT Program accreditation program.
 - 5.1.6.4 At the discretion of the NEFAP Executive Committee or PT Program Executive Committee, some other combination of assessment experience and other related training may substitute for these qualifications; documentation of this discrepancy decision shall become part of the permanent record of the AB's evaluation. The NEFAP Executive Committee and PT Program Executive Committee will conduct a formal vote to accept alternative team qualifications for any team where deviations from these requirements are needed, with the motion being voted to include justification as well as the deviation accepted.
- 5.1.7 ET Selection
 - 5.1.7.1 The Evaluation Coordinator (EC) (see Section 5.3) and the Chair of the Recognition Committee (RC) (see Section 5.5) develop the ET with consideration of Sections 5.1.1 through 5.1.6. The size of the ET depends on the needs of the evaluation.
 - 5.1.7.2 All ET members work under the direction of the Lead Evaluator (LE) (see Section

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5.2).

5.1.7.3 The applicant/renewal AB is notified of the process for evaluation by the EC by sending this procedure and the names of the RC and selected ET (Appendix B includes an example letter for notification and for response from the AB).

5.1.7.4 The applicant/renewal AB has ten (10) calendar days after notification of the ET members (biographies submitted to AB) to submit a written objection with reason for the objection to the appointment of a LE or any team member(s). The EC and Chair of the RC or designee shall consider the objection within ten (10) calendar days and appoint other team members as appropriate.

5.1.7.5 The EC must document the role and qualifications of each evaluator selected. The documentation must demonstrate that the requirements of this procedure are met.

5.2 Lead Evaluator (LE)

5.2.1 The LE is under contract by TNI to lead evaluation activities. The LE is chosen by the TNI Executive Director in coordination with the NEFAP and PTP Program Administrator(s). The LE is responsible for planning activities. All members of the ET must be involved to ensure that the evaluation is well planned and consistent with the evaluations of other ABs.

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

5.2.2 The LE with input/assistance from the ET:

5.2.2.1 Conducts a review of the application and related material.

5.2.2.2 Facilitates off-site (remote) review using available resources such as video conferencing, teleconferencing, and web-based meetings, and providing information to the ABs as requested.

5.2.2.3 Submits Standards Interpretation Requests (SIRs) on behalf of the ET(s) when needed.

5.2.2.4 Performs on-site evaluations of the AB as applicable.

5.2.2.5 Provides input to the team assigned to conduct the observation portion of the AB's assessment.

5.2.2.6 Performs the review of and response to the AB's corrective action plans and corrective action implementation with input from the ET.

5.2.2.7 Obtains consensus of the ET in preparing the final recommendation to the RC (see Section 5.5).

5.2.2.8 Completes evaluation reports.

5.2.2.9 Reports any policy and procedure questions that arise during the evaluation as they occur to the EC who processes them through the Executive Committees (see Section 5.4.2).

5.3 Evaluation Coordinator (EC)

5.3.1 The EC is a TNI staff person who may also serve as the LE. The EC is chosen by the TNI Executive Director in coordination with the NEFAP and PTP Program Administrator(s).

5.3.2 The EC qualifications:

5.3.2.1 Is generally familiar with TNI's activities and accreditation, and completes the

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evaluator course.

5.3.2.2 Prior to appointment, must have experience that includes one or more of these specifications:

5.3.2.2.1 At least two years of participation in one of the TNI consensus body committees, developing or implementing standards for use by ABs.

5.3.2.2.2 At least 2 years of career experience related to accreditation or certification.

5.3.2.2.3 Suitable equivalent experience approved by both the PT Program Executive Committee and NEFAP Executive Committee.

5.3.3 EC responsibilities include:

5.3.3.1 Selects the LE and the ET Members with the assistance of the chair of the RC, and ensuring members meet the criteria for training and experience.

5.3.3.2 Coordinates the evaluation process.

5.3.3.3 Makes best effort to avoid an AB undergoing its evaluation at the same time its staff person is evaluating another AB.

5.3.3.4 Assists the LE with any questions regarding the evaluation process.

5.3.3.5 Assists the ET by ensuring all communication between the ET, AB and the RC occurs in a timely manner.

5.3.3.6 Tracks and documents that all aspects of AB evaluations are performed in a timely manner in conformance with this Standard Operating Procedure.

5.3.3.7 Reviews the AB application for completeness.

5.3.3.8 Reviews the evaluation reports for completeness and consistency according to the evaluation SOP and the TNI standards.

5.3.3.9 Provides final documents listed in 6.10.4.1 and 6.11.1 to the RC.

5.3.3.10 Reports monthly to the NEFAP Executive Committee and/or the PT Program Executive Committee on the status of the evaluation process when activities are underway.

5.4 Executive Committees

The NEFAP Executive Committee and PT Program Executive Committee formulate the RC to make decisions on AB evaluations.

5.4.1 These Executive Committees ensure that training for evaluators is available. Note: ET Members may be selected prior to the completion of training as long as a commitment is made by the member to obtain the necessary training requirements prior to performing an evaluation.

5.4.2 These Executive Committees assist the LE in the cases where policies and procedures are in question. This is processed through the EC to the Executive Committee in order to ensure handling of the item in a confidential manner.

5.5 Recognition Committee (RC)

A committee formulated and approved by the NEFAP Executive Committee and PT

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Program Executive Committee. The committee must be balanced to represent both NEFAP and PT Program interests.

5.5.1 RC Members

- 5.5.1.1 Must be a TNI member in good standing.
- 5.5.1.2 Must not be a NEFAP or PTP AB.
- 5.5.1.3 Must be impartial to the evaluation for recognition.
- 5.5.1.4 Must sign the conflict of interest statement. See Appendix A for the *Qualification and Conflict of Interest* form.
- 5.5.1.5 Do not have to be current member of either the NEFAP Executive Committee or PT Program Executive Committee but must have the following credentials:
 - a) Must be familiar with TNI NEFAP and PT programs and its standards and procedures by acknowledging having read the current documents.
 - b) Must have TNI training on the PT Program/NEFAP evaluation process with documentation of completing the training.
- 5.5.1.6 The Chair of the RC is elected from the members of the RC and by the members of the RC. In cases of a conflict of interest or other reason when the Chair cannot serve a function, the NEFAP Executive Committee and PT Program Executive Committee must agree on the appointment of a designee recommended by the RC.
- 5.5.1.7 The RC must be made up of at least five (5) members and no more than eight (8).
- 5.5.1.8 RC members serve for a period of four (4) years and the NEFAP Executive Committee and PT Program Executive Committee review the RC at the end of this period to determine whether there is a need for new membership based on willingness of members to serve another term. There is no limit on the number of terms of service for membership on the RC. The RC members serve at the discretion of the NEFAP Executive Committee and PT Program Executive Committee.
 - 5.5.1.8.1 Should a member no longer be able to serve on the RC, the Chair of the RC will work with the NEFAP Executive Committee and PT Program Executive Committee to replace the member. The new member must be approved by both the NEFAP Executive Committee and PT Program Executive Committee.
- 5.5.1.9 RC members are assigned the following tasks:
 - 5.5.1.9.1 Review the ET observations and objective evidence on the Evaluation performed of the designated AB.
 - 5.5.1.9.2 Vote on the recognition of the AB and provide a recognition letter to the TNI NEFAP Executive Committee and PT Program Executive Committee, as appropriate (procedures can be found in Section 6.11 and an example can be found in Appendix D).

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6.0 Procedures

6.1 Frequency and Scope of Evaluation

6.1.1 ABs are required to be evaluated initially and at a minimum of once every four (4) years thereafter to demonstrate compliance to ISO/IEC 17011 and the TNI Standards. This evaluation must include, unless otherwise noted below:

6.1.1.1 Completeness and technical reviews of the application/renewal package,

6.1.1.2 An on-site evaluation (this may be conducted in coordination with a national or international recognition program acceptable to the NEFAP Executive Committee and PT Program Executive Committee) as determined by the LE.

At a minimum all ABs (or applicant ABs) must undergo a document review and at least one observation assessment to ensure all elements of the appropriate TNI requirements are met. The LE reviews the application and documentation and determines the need for an on-site evaluation with input from the ET.

6.1.1.2.1 National or internationally recognized ABs may submit their respective evaluation report(s) to demonstrate conformance with ISO/IEC 17011. Where conformance to ISO/IEC 17011 is demonstrated in the report, these sections are not re-evaluated by the ET. Conformance to TNI requirements may be demonstrated through remote or on-site documentation evaluation as determined by the LE.

6.1.1.2.2 ABs without national or international recognition to ISO/IEC 17011 must be evaluated for conformance to ISO/IEC 17011 by the ET through review of documentation and during an on-site assessment.

6.1.1.3 Observation of the AB conducting an onsite assessment,

6.1.1.4 On-site evaluation report(s) with findings for both the on-site/remote evaluation (as applicable) and the observation, and

6.1.1.5 Evaluation report review by the RC to grant, maintain or deny recognition.

6.1.2 Once the ET provides the final evaluation report to the RC for granting, maintaining or denying recognition, all subsequent communications shall be between the EC and the AB, with copies given to the RC.

6.1.3 National or internationally recognized ABs who demonstrate compliance through submission of their evaluation report to the ISO/IEC 17011 Standard must notify the EC a minimum of 90 days before their next ISO/IEC 17011 evaluation.

6.1.3.1 A copy of the evaluation reports and corrective action reports must be submitted to the EC within two weeks of receipt or submission of the final decision on the evaluation.

6.1.3.2 Any changes to the AB's national or international recognition status must be submitted to the EC within two weeks of receipt.

6.2 Application/Renewal Process

6.2.1 Initial Application

6.2.1.1 Initial Application forms for recognition are obtained from the EC or TNI

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website.

6.2.1.2 The application must be signed and dated by an officer or authorized representative of the AB.

6.2.1.3 The completed application, Technical Checklist, and supporting documents shall be submitted to the EC. All columns of the Technical Checklist must be completed including document locations/references. If a question is not relevant, an "N/A" may be used and no reference needs to be included.

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

Note: All ABs pay an annual fee for each program.

6.2.1.5 Upon receipt of the application and supporting documents the EC shall send an acknowledgement to the AB. The EC must establish an ET.

6.2.2 Renewal Applications

6.2.2.1 Notification

The EC sends a letter with a renewal application form and a copy of the appropriate Technical Checklist(s) to the AB approximately 300 calendar days (10 months) prior to the expiration of the AB's current recognition. The letter includes a request for any changes since the previous application along with any updated documentation and a completed Technical Checklist(s) with documentation references included.

6.2.2.2 Renewal Submittal

6.2.2.2.1 The AB submits an electronic copy of the completed renewal application, Technical Checklist and any changes since the initial evaluation 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.

6.2.2.2.2 If the AB does not submit a renewal application or extension request within thirty (30) calendar days, the AB receives final notification from the EC by any method providing receipt confirmation that, if an application is not submitted within another fifteen (15) calendar days, the AB's recognition expires on the date of the current recognition certificate. Renewed recognition as an AB will require submission of an initial application (see 6.2.1).

6.2.2.3 Application Communications

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

6.2.3 Application/Renewal Completeness Review

6.2.3.1 Following receipt of the Application/Renewal information, the EC shall review it for completeness within (fifteen) 15 calendar days and report to the LE.

6.2.3.2 If the information is not complete, the EC sends a request for the missing information to the AB in writing. The ET members receive a copy of the request.

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- 6.2.3.3 The AB shall have fifteen (15) calendar days from receipt of the request to supply any missing information to the EC. If the missing material is not submitted, renewal will not proceed. Once the EC determines that the application is complete, he/she shall notify the AB and LE.
- 6.2.3.4 Extensions up to fifteen (15) calendar days may be granted by the EC.
- 6.2.4 Application Document Review
 - 6.2.4.1 The LE shall conduct a document review to verify that all required items have been addressed. The document review shall be divided among all ET members. The checklist, "Technical Checklist to Determine Accreditation Body Conformance" (Technical Checklist), shall be used to determine the ABs conformance to the TNI Standard (Field Standard Volume 2 and Volume 4 of the TNI Environmental Laboratory Standard, as applicable). Part of this review is to determine if there is a need for an on-site evaluation of the AB in order to evaluate conformance to the appropriate TNI standard.
 - 6.2.4.2 The ET shall review the application and all supporting documents to evaluate whether the AB's accreditation program requires its accredited organizations to meet the applicable TNI Standard(s).
 - 6.2.4.3 The document review shall follow the requirements of the TNI Standard. (An example "Technical Checklist" can be obtained from the EC.) The document review may be accomplished through review of electronic documents, conference calls, web-based records demonstrations, and any other means to efficiently review documents off-site.
 - 6.2.4.4 The ET has forty-five (45) calendar days to conduct this review after the application is determined complete. The LE may extend this period if needed, generally by no more than 30 days, to assure all opportunities for off-site review have been exhausted before determining the need for an onsite visit.
 - 6.2.4.4.1 The ET shall conduct thorough reviews of policies, procedures, documents, forms, processes, quality assurance measures, corrective actions and organization records in the course of the technical review. The ET shall interview program management, assessors, and any other accreditation program personnel to evaluate program knowledge and implementation of policies, procedures, and Standards. Off-site interviews will be conducted by telephone or using available electronic technology. The ET must endeavor to use technology and off-site evaluation to the greatest extent possible in order to eliminate or minimize the length of on-site review required to finalize the evaluation.
 - 6.2.4.4.2 During the technical review process, the ET may determine additional materials to be requested for review using available off-site technology.
 - 6.2.4.4.3 The content of the request for additional data for review, per AB, varies based on the documentation submitted with the initial application and Technical Checklist. Examples of additional documents requested may include evaluation forms, complaint records, internal assessments, organization files, etc.
 - 6.2.4.5 An example chronology follows:

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- 6.2.4.5.1 ET completes initial technical checklist review (based on documentation provided by the AB) with a series of noted questions for discussion and follow-up.
- 6.2.4.5.2 ET and AB have phone calls to discuss questions, open issues; ET notifies AB of list of additional items requested for review (e.g., lab files, corrective action plans, etc.) The procedures in Section 6.4 must be followed regardless of whether the information is reviewed off-site or on-site.
- 6.2.4.5.3 ET and AB have scheduled meetings (for example, phone calls or web-based meetings) for AB to provide access to requested information through such means as:
 - a. Technology-based access to electronic files (video conferencing, online meetings.)
 - b. Documents provided by AB in electronic format such as portable document format (pdf).
 - c. Staff interviews by telephone.
- 6.2.4.5.4 ET provides follow-up questions or document review requests after review of notes and an additional meeting(s) is scheduled to address additional questions or review additional records.
- 6.2.4.5.5 ET and LE review open items and determine whether the review is complete or an on-site will be needed (see Section 6.1.1.2.a.i).
- 6.2.4.5.6 An on-site visit to finalize the evaluation is scheduled if needed.
- 6.2.4.5.7 If an on-site visit is not scheduled and the review is complete, debriefing (closing) meeting is scheduled to review the findings prior to completion of the final report.

6.3 Scheduling the On-Site AB Evaluation

- 6.3.1 Once the LE determines that an onsite evaluation is needed, the AB is notified within fifteen (15) calendar days to schedule the on-site evaluation. If it is determined an on-site evaluation shall be conducted, it must occur within sixty (60) calendar days of completion of the application technical review and at the mutual convenience of the ET and the AB. The EC will coordinate the dates with the AB and the ET.
- 6.3.2 The LE, on behalf of the ET sends a written confirmation to the AB of the logistics required to conduct the evaluation, and to all of the ET members. The written confirmation shall include, but is not limited to:
 - 6.3.2.1 onsite evaluation date and agenda or schedule of activities;
 - 6.3.2.2 copies of the standardized evaluation checklist(s), as applicable;
 - 6.3.2.3 identification of files or records to have available for review;
 - 6.3.2.4 the names, titles, affiliations, and on-site responsibilities of the ET members, and
 - 6.3.2.5 the names and titles of AB staff that need to be available during the on-site evaluation, as applicable.

6.4 Conducting the On-Site/Off-Site AB Evaluation

- 6.4.1 The ET shall conduct an opening meeting prior to the start of the evaluation.

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- 6.4.2 The ET shall conduct a comprehensive evaluation of the AB's accreditation program to determine the accuracy of information contained in the AB application and the AB's conformance to the TNI Standards and relevant program requirements. The ET must do this by:
- 6.4.2.1 Interviewing AB management and technical staff (assessors – both contract and employee) and reviewing internal audits and management reviews to determine if they were completed as required, and if corrective actions were taken to address noted nonconformities (interviewing of technical staff may be performed remotely);
 - 6.4.2.2 reviewing a representative number of files adequate for the ABs program size from the list of TNI accredited organization(s) (more files should be reviewed if significant nonconformities warrant);
 - 6.4.2.3 reviewing evaluation forms submitted by the organization(s);
 - 6.4.2.4 reviewing records of the organizations' complaints, disputes and appeals;
 - 6.4.2.5 reviewing the training records and conducting interviews of AB staff designated as qualified assessors to evaluate their training, knowledge of assessment techniques, the TNI Standard, and the AB's own operating procedures;
 - 6.4.2.6 Reviewing evidence of the AB's monitoring of assessor performance of organization assessments and other assigned accreditation responsibilities. Note: The ET cannot request to see individual employee performance reviews or other confidential records.
 - 6.4.2.7 Determining that previously identified missing or incomplete items from the Technical Review Checklist are available and satisfactory;
 - 6.4.2.8 Observing the AB during its on-site assessment of an organization. The organization selected should hold sufficient fields of accreditation to allow the team to observe a comprehensive on-site assessment by the AB. A second organization assessment observation may be necessary if multiple fields of accreditation are not due for an AB assessment; and
 - 6.4.2.9 Reviewing any non-conformances, concerns or comments from the previous evaluation to confirm corrective actions have been continually implemented such that previous nonconformities did not recur (not applicable if this is a new application.)
 - 6.4.2.10 Referring to available NEFAP and/or PT Program guidance document(s) to assist with specific elements of an evaluation.
- 6.4.3 When selecting organization files to review, the ET selects those with varying fields of accreditation and different assessors as appropriate. The ET must include files from (i) an organization accredited by the AB that has lodged a complaint, if applicable; and (ii) an organization accredited by the AB that was subject to administrative action through severe quality system nonconformities, if applicable. At a minimum, the team reviews the following information in files from a representative number of organizations accredited by the AB:
- 6.4.3.1 Application
 - 6.4.3.2 Selection of assessors including review of conflict of interest
 - 6.4.3.3 Checklist(s) used for assessment, as applicable
 - 6.4.3.4 Proficiency testing (PT) results, if applicable
 - 6.4.3.5 Management qualifications review and approval

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- 6.4.3.6 Nonconformity report(s)
- 6.4.3.7 Corrective action report(s)
- 6.4.3.8 Correspondence
- 6.4.3.9 Opening and closing meeting attendance
- 6.4.3.10 Final report
- 6.4.3.11 Certificate, if granted
- 6.4.4 Before the conclusion of the evaluation, the ET shall assure that the ET has conducted a comprehensive evaluation of the AB's accreditation program using off-site and on-site review to determine the accuracy of information contained in the AB application and the AB's conformance to the applicable TNI Standard.
- 6.4.5 The ET conducts an exit debriefing to discuss all noted findings (nonconformities, concerns and comments). All findings are considered DRAFT until the Final Evaluation Report is completed. In general, the ET should follow the auditing principles as defined in ISO 19011. If any disputes or interpretations are identified, these are to follow the applicable program dispute resolution SOP.
- 6.5 Documentation of Findings from the Evaluation
 - 6.5.1 Findings include identification of nonconformities, concerns and comments.
 - 6.5.2 Documentation of the findings shall be delineated in the final report, along with the observations of the accreditation body's on-site assessment of an organization. The ET shall ensure that each nonconformity is clearly explained, including in what document, interview or observation the observation of the nonconformity was made and the reference to the Standard citation for this nonconformity. The ET may choose to request specific documentation as evidence of correction of the nonconformity.
- 6.6 Scheduling of the Witness/Observation Evaluation of an AB Assessment
 - 6.6.1 At least one member of the ET must observe the AB conducting an actual on-site assessment of an organization. This ET member must have the technical competence in the area being assessed by the AB. At the time of the scheduling of the on-site evaluation (or completion of the Technical Review if no onsite is needed), the LE should request from the AB a schedule of upcoming organization assessments. The LE uses this schedule to select the organization assessment which is observed during the on-site evaluation or other mutually agreed time. (Note: Although the observation can be conducted prior to the on-site AB evaluation, it should not take place until after the technical review issues have been resolved). The AB will make arrangements to have a representative from the AB's staff available during the witness/observation of the organization assessment. The AB staff will be the official point of contact for the ET.
 - 6.6.2 The EC, with the assistance of the LE (in consultation with the AB), may elect to send more than one member of the ET to witness/observe the assessment. This decision should be based on: (1) the scope of the organization assessment and the number of AB assessors involved, and (2) the availability of members of the ET.
 - 6.6.3 The number of witness/observation evaluations scheduled is based on the volume and type of activity conducted by the AB. The EC, LE and Chair of the RC or designee provides the rationale for the selection of the number and type of organization assessment(s) to be performed as part of the evaluation of the AB.
- 6.7 Conducting the Organization Witness/Observation Evaluation of an AB Assessment

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During the evaluation of the AB assessment, the ET member's role is to observe the AB's assessment team. The ET member(s) are not active participants in the assessment, thus, will not ask questions or make comments relative to the assessment. The ET member(s) must make every effort to observe as many aspects of the AB's assessment as possible and should make sure to concentrate on areas where the technical review may have revealed weaknesses in the AB's program. The ET member(s) must not discuss any evaluation information or concerns with the assessor unless the assessor is the AB representative from the AB's staff.

- 6.7.1 The appropriate sections of the Technical Checklist shall be completed.
- 6.7.2 Prior to the evaluation of the assessment, the evaluator must determine the need for specific safety training, safety equipment or other site-specific requirements (e.g. security, confidentiality and insurance). A review of the site logistics between the evaluator and the AB assessor must be completed at least one week prior to the evaluation assessment.
- 6.8 Documentation of Witness/Observation Evaluation of an AB Assessment
 - 6.8.1 Each member of the ET that participates in the witness/observation evaluation must discuss his/her comments, concerns and/or non-conformities with the AB staff representative to assure they understand the outcome of the witness/observation prior to the evaluator sending that information to the LE. A summary of the findings from the evaluation should be provided to the AB. The team member must transmit his/her observations to the LE for inclusion in the final evaluation report. The witness/observation evaluation report must be transmitted to the LE within fifteen (15) calendar days following the witness/observation.
- 6.9 Final Evaluation Report
 - 6.9.1 Following completion of the evaluation report by the LE and review by the ET, RC Chair and EC, the Final Evaluation Report shall be sent to the AB within 30 calendar days of completion of the on-site evaluation and the observation evaluation of an AB assessment. The report is sent to the AB by any method providing receipt confirmation.
 - 6.9.2 The AB is required to provide a corrective response to any cited nonconformities within thirty (30) calendar days from receipt of the Final Evaluation Report
- 6.10 Response to the AB Corrective Action Report (CAR)
 - 6.10.1 Each member of the ET must review the AB's response to the on-site evaluation report, including its corrective actions and objective evidence of correction, and transmit their review to the LE within ten (10) calendar days. The LE may schedule a conference call with the ET to review a DRAFT written response to the proposed corrective actions. The LE shall respond to the AB in writing within thirty (30) calendar days of receipt of the AB CAR.
 - 6.10.2 If the AB CAR does not address all nonconformities, the LE shall notify the AB by any method providing receipt confirmation that it must submit another CAR for the remaining nonconformities within fifteen (15) calendar days of receipt of this notification.
 - 6.10.3 If the ET determines the second response does not address the nonconformities, the LE shall document the unresolved non-conformities and report to the RC with the applicable documentation listed in Section 6.10.4.1.
 - 6.10.4 If the ET determines that the AB has corrected all of the nonconformities, the final report is submitted by the EC within thirty (30) calendar days of the ET determination to the RC.

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An example report format is included in Appendix C.

The following documentation shall be submitted with the report:

- 6.10.4.1 ET's Final Report with objective evidence observed of conformance or nonconformance to the TNI Standards.
- 6.10.4.2 AB's Final Report Corrective Action Response.
- 6.10.4.3 Completed Technical Evaluation Checklist with objective evidence observed of conformance or non-conformance to the appropriate TNI Standards.
- 6.10.4.4 Report on the ET's observation of an AB assessment.
- 6.10.4.5 Copy of Scope.
- 6.10.4.6 Example Certificate.

6.11 Recognition

- 6.11.1 Copies of the ET's final report, including the documents described in Section 6.10.4, are forwarded to the EC to forward to the RC for review. The EC shall also forward the following documentation:
 - 6.11.1.1 Qualifications of the ET (COI, training dates, etc.).
 - 6.11.1.2 AB application (without attachments).
- 6.11.2 The RC reviews the ET objective evidence of findings and (1) ensures it is unbiased, (2) demonstrates a consistent interpretation of the standard, and (3) it is complete (demonstrates all elements of the applicable TNI Standard(s) are performed by the AB). This review is handled expeditiously.
- 6.11.3 Upon review, the RC votes and prepares a recommendation letter (Appendix D) regarding the recognition of the AB for conformance to the TNI requirements. A 2/3 approval vote is required to move on to Section 6.11.4. If a 2/3 approval is not received, the RC will provide the EC with the reason(s) for its disagreement and allow the EC to work with the ET (as needed) to respond to those reasons with additional details. If resolution cannot be obtained, refer to Section 6.11.7.
- 6.11.4 This recommendation letter is submitted to the EC, NEFAP Executive Committee and PT Program Executive Committee as appropriate. (An example letter can be found in Appendix D.)
- 6.11.5 The NEFAP Executive Committee and PT Program Executive Committee independently review the recommendation letter from the RC and vote to endorse the recommendation and recognize the AB following the voting procedures outlined in each program's voting SOP (NEFAP: SOP 5-102 - TNI NEFAP Executive Committee Voting Procedure for General Business and Field Activities Accreditation Matters, PT Program: SOP 4-105 - PT Program Executive Committee Voting Process).
 - 6.11.5.1 The NEFAP Executive Committee and PT Program Executive Committee are provided with the following information when they receive the recommendation. The information provided gives each committee what it needs to determine whether the evaluation process was followed so that each committee can endorse the RC's recommendation.
 - A statement that the RC has completed the review of the ET's objective evidence of findings.

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- A statement that the process was unbiased, process was consistent with the Standard(s) and that the process was complete.
- A list of what was done during the assessment (review of application, on-site or off-site review, witness/observation, etc.).
- A list of the documentation that was reviewed.
- A list of the ET members, their role and a statement that the ET's records of qualifications met this SOP's requirements.
- A conclusion that once again summarizes the information in the bullet points above.
- A recommendation statement:
 - Such as: The RC recommends recognition of [AB] for conformance to the TNI NEFAP and PTP requirements effective [Month day, year] and expiring on [Month day, year].
 - Any additional comments as needed.

6.11.5.2 If either of the committees believes the RC did not follow the required process, a written statement is provided to the EC within fifteen (15) calendar days of the Executive Committee meeting to include the reasons for this concern and what the committee needs to resolve it. The EC reviews the statement with the RC. The RC will respond to the statement within thirty (30) calendar days of receipt of the statement with the information being requested so that the concern can be resolved. If the statement has validity and no additional information can be provided, the EC and RC will work to correct the concern with the ET and resubmit the recommendation.

6.11.6 Each Executive Committee notifies the TNI Board of Directors, in writing, of the recognition status of all new and renewed ABs. This can be handled through monthly updates provided by the Program Administrator or through email communication from the Executive Committee Chair or Program Administrator.

6.11.7 Disagreements with matters concerning recognition can be addressed through the TNI NEFAP Dispute Resolution Procedure (SOP 5-104) or TNI Proficiency Testing Program Complaint, Appeal and Dispute Resolution Procedure (SOP 4-102) as appropriate.

6.11.8 A new applicant AB has two years to complete the application process from application through resolution of corrective action. If recognition is not granted within two years of the application date the AB must reapply. Reapplication requires the resubmittal of the application package including any applicable fees.

Note: If delays are caused by TNI the re-application process does not apply.

6.12 Recognition - Issuance of Certificate of Recognition to the AB

The issuance of the Certificates of Recognition shall be the responsibility of the EC and shall be done in accordance with the requirements of this procedure. The renewal or dismissal letter and the certificate, if one is awarded, must be issued and mailed by the EC or Chair of the NEFAP Executive Committee or PT Program Executive Committee as appropriate. The Certificate is signed by the Chair of the respective Executive Committee.

7.0 Criteria, Checklists, Standards

7.1 All evaluators must ensure that they are using the correct version of the TNI standards and AB checklists based on the correct version.

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- 7.2 The complete TNI Standard must be available at the accreditation body. The checklist used by the accreditation body for the assessment of organizations must include all requirements found in FSMO-V1-2014 Rev 2 and EL-V3-2009.
- 7.3 The Technical Evaluation Checklist is presented in the order of the TNI standard and it must be used for the evaluation or an equivalent checklist may be used after approval by the EC. The relevant parts of the checklist are completed to provide objective evidence of conformance to the requirements.
- 7.4 Current editions of the evaluation and assessment checklists are available from the EC.

8.0 Records Management

- 8.1 Records associated with the evaluation of the ABs are deemed confidential information. The records are stored in accordance with the TNI procedure for records management (SOP 1-104).
- 8.2 The EC, under the direction of the LE, is responsible for submitting all documents as required in this procedure to the RC within thirty (30) calendar days of the ET's final recommendation.
- 8.3 The LE and ET members must submit all records to the EC within thirty (30) calendar days of the recognition decision. The LE and team members shall not retain records of the evaluation following the RC decision.
- 8.4 Final records are deemed confidential (Class V documents) and are to be stored in accordance with the TNI procedure for records management (SOP 1-104).
- 8.5 Records are stored for at least two (2) evaluation cycles.

9.0 Quality Control

- 9.1 The NEFAP Executive Committee and PT Program Executive Committee must review this SOP every two years. Input from applicant(s), recognized ABs, the RC and ETs must be requested in order to provide feedback on the evaluation and recognition process.
- 9.2 This review must be documented and any changes deemed necessary must be made following the TNI procedure.
- 9.3 If the document is revised, the revisions must be distributed to the appropriate stakeholders, including but not limited to applicant(s), recognized ABs, evaluators, and the RC members.

10.0 References

TNI FSMO Standards Volume 1 and 2, latest edition
TNI PT Standards – TNI ELS Volume 3 and 4, latest edition
ISO/IEC17000, 2004
ISO/IEC 17011, 2004
ISO/IEC 17025, 2005
ISO/IEC 17043, 2010
ISO 19011, 2011

11.0 SOP Approved Changes

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Revision No.	Date of Change	Description of Change
		New Document.

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APPENDIX A
Evaluation Team (ET) Qualification and Conflict of Interest (COI) Form

Name _____

Organization _____

Date of NEFAP/PT Program Evaluator Training Course _____

(Need one of the three below within last 5 years – keep what is applicable below and delete what is not. Delete this text in italics too. Ensure resume matches. RC members can delete this section.)

Additional Requirements:

- Certification as a lead assessor from an internationally recognized accreditation body;
- One year experience as a NEFAP or PT Program Assessor;
- One year experience implementing an AB accreditation program;
- One year experience developing or managing a laboratory, FSMO or PT accreditation program.

Name of Accreditation Body Being Reviewed _____

This statement shall be signed by the Lead Evaluator, team members, observers of an ET and members of the Recognition Committee (RC).

I declare 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.

(Pick one of the following statements to complete and delete the one not used. Delete this text in italics.)

Additionally, I declare that I do not have a conflict of interest with the parties involved in the evaluations or review of the evaluations that I shall participate in.

OR

Outside of the conflicts listed below, I declare that I do not have a conflict of interest with the parties involved in the evaluations or review of the evaluations that I shall participate in:

- Xxx
-

Signature _____

Date _____

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APPENDIX B

Example AB Notification Letter of Evaluation Team (ET) and RC

[DATE]

[AB]

[ADDRESS]

[AB CONTACT],

In accordance with TNI SOP 7-101, we are writing to determine your agreement to the ET to perform your evaluation. A copy of this SOP can be found on the TNI website (nelac-institute.org) to describe the evaluation process. With your assistance, the LE has committed to completing the document review by [DATE]. Need for an onsite evaluation will be reviewed and an observation/witness will be planned.

The following team has been selected to perform your evaluation and review documentation:

Lead Evaluator: [NAME]

TNI AB Evaluation Training: x/x/x

Evaluator(s): [NAME]

TNI AB Evaluator Training: x/x/x

(need one of the items below – keep what is applicable and ensure resume matches)

- Certification as a lead assessor from an internationally recognized accreditation body;
- One year experience as a NEFAP and/or PT Program Assessor (as appropriate);
- One year experience implementing an AB accreditation program;
- One year experience developing or managing a laboratory, FSMO or PT accreditation program.

Recognition Committee (RC): [NAMES]

Each ET includes:

- a technical expert knowledgeable in the scope the AB accredits or intends to accredit (this may be one or more) to complete the on-site observation of an AB assessment,
- a representative of a PT Program or NEFAP recognized or internationally recognized Non-Governmental Accreditation Body (NGAB) knowledgeable in the operations of an AB, and

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-
- a person with at least one year of experience developing and managing an AB accreditation program or developing and managing a laboratory, FSMO or PT Program accreditation program.

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

Please find attached, a copy of each evaluator's resume and a copy of their "Evaluation Team Conflict of Interest Form". You will also find copies of Conflict of Interest forms for the members of the RC.

We would also like to know if you have any objections to TNI sending the submitted documents to the lead evaluator and later designated technical evaluators via electronic mail.

You have ten (10) calendar days after receipt of this letter to submit a written objection with reason for the objection to the appointment of a Lead Evaluator or any team member(s). The Executive Committees shall consider the objection with ten (10) calendar days and appoint other team members as appropriate.

Please confirm your receipt of the letter and acceptance of the ET as soon as possible.

Sincerely,

The NELAC Institute
PT Program/NEFAP Evaluation Coordinator

Please check one selection from each box and sign - thank you

- | |
|--|
| <input type="checkbox"/> No objections to the lead or technical evaluators presented in this letter. Information will be forwarded to the AB within three (3) business days. |
| <input type="checkbox"/> We have objections to the listed evaluators for the reasons presented below (or in the attached) |

- | |
|---|
| <input type="checkbox"/> No objection to the use of electronic mail to distribute documents to the designated evaluators. |
| <input type="checkbox"/> We have objections to the use of electronic mail. We will use a secure site for distribution. |

Signed: _____

Date: _____

Title: _____

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APPENDIX C

Model Completion Letter to the RC from the Evaluation Team

EXAMPLE

[Date]

Final Report: [AB] Evaluation – TNI National Environmental Field Activities Program and TNI National Environmental Proficiency Testing Program

Lead Evaluator (LE): [Name]

To: RC

The evaluation team assigned to the [AB] evaluation has completed its evaluation of this Accreditation Body in accordance with *[insert TNI Standard References]* and with *[insert media-specific standard here if applicable]*. The evaluation consisted of the following: 1) a technical review of the [AB] application for renewal and its supporting documentation 2) an evaluation of the [AB] FSMO and PT accreditation programs *[as appropriate]*, and 3) a witness/observation evaluation of [AB] conducting an FSMO and PT Provider assessment *[as appropriate]*. Each of these parts of the evaluation is discussed below.

Evaluation Team members:

- *[insert Evaluation Team members]*

Application Completeness Review

The Evaluation Coordinator (EC) and LE completed an application review per TNI NEFAP SOP 7-101 and contacted the AB for any missing information on [DATE] *[or ... found that it was complete]*. Based on this review the [AB] application documentation appeared complete and approved for continuation to the document review phase of the evaluation procedure.

Document Review

The evaluation team completed its document review and issued a report detailing findings on [DATE]. In a response dated [DATE], [AB] provided a list of corrective actions taken to address any nonconformities noted. The team reviewed these corrective actions and determined that they adequately addressed the findings noted.

Evaluation

The team conducted an on-site *[or off-site]* evaluation of the [AB] NEFAP FSMO and PT accreditation programs on [DATE] *[as appropriate]*. team interviewed [#] [AB] staff members, reviewed FSMO and PT Provider files *[as appropriate]*, training files, complaint files, and PT records as applicable. The team documented [#] instances in which [AB] was determined to be in non-conformance with the TNI *[list appropriate standards]* Standards. A report was prepared and sent to [AB] on [DATE]. [AB] provided a corrective action plan for the [#] findings on [DATE]. The evaluation team has reviewed these corrective action responses and finds them to be acceptable.

(In some cases it may be appropriate to state the evaluation was conducted with another audit team such as a national or international team.)

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Witness/Observation Evaluation

The Technical Evaluator performed a witness/observation evaluation of [AB]'s assessment of [FSMO or PT Provider NAME] in [CITY, STATE] on [DATE] [list all FSMOs and PT Providers visited]. The conduct of this assessment was found to be in conformance with the TNI [list appropriate standards] Standards. No significant deviations were observed.

Summary

In accordance with TNI Procedure (SOP 7-101, effective [DATE]) and based upon the document review of the [AB] documentation, on-site evaluation [as appropriate] and onsite technical witness/observation evaluation of the [AB] accreditation process supporting compliance with FSMO-V2- [DATE]-Rev [#] [and or ELS-V3-[DATE]-Rev [#] – as appropriate] requirements, the AB has been found to be in conformance with the requirements of the TNI [list appropriate standards] Standards.

Please find copies of the following documents to support this conclusion (include as appropriate):

- 1) evaluation team's document review report,
- 2) [AB] document review report corrective action response,
- 3) evaluation team's report including the witness/observation of AB assessment of FSMO(s) [and/or PT Provider(s) – as appropriate], and
- 4) [AB] corrective action plan.
- 5) Copies of all checklists used in the evaluation.
- 6) Copy of Scope
- 7) [If applicable] Copy of national or international recognition documentation as meeting ISO/IEC 17011

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

[SIGNATURE]

[NAME]

[AFFILIATION]

Attachments

cc: Evaluation Coordinator

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APPENDIX D
Model Recommendation Letter to the TNI NEFAP Executive Committee
and/or PT Program Executive Committee

RC Recommendation

[Date]

To: [Name(s)]
Chair, National Environmental Field Activities Program Executive Committee (if appropriate)
Chair, National Environmental Proficiency Testing Program Executive Committee (if appropriate)

The evaluation team assigned to the evaluation of [AB] has completed its evaluation of this Accreditation Body (AB).

The RC has completed the review of the Evaluation Team's objective evidence of findings. We find the following as required by TNI SOP 7-101 Evaluation Procedure:

- (1) the process was unbiased
- (2) the process demonstrated a consistent interpretation of the Standard(s) (by the AB)
- (3) the process was complete (demonstrated all elements of TNI FSMO Volume 2 were performed by the AB for assurance of the FSMO implementation of TNI FSMO Volume 1 *and/or* all elements of the TNI ELS Volume 4 were performed by the AB for assurance of the PT Provider implementation of TNI ELS Volume 3.)

The evaluation consisted of the following: [Only include what was done in assessment] 1) a technical review of the [AB] application for recognition and its supporting documentation, 2) an on-site [or off-site] evaluation and 3) a witness/observation evaluation of an FSMO [and/or PT Provider] assessment. The RC reviewed the following documentation.

- 1) xx (List all documentation reviewed.)
- 2) xx
- 3) xx

The Evaluation Team members were:

- o xx, Lead Evaluator
- o xx, Technical Evaluator
- o etc

The evaluation teams records of qualifications met the requirements of the TNI SOP 7-101 Evaluation Procedure.

Conclusion

In accordance with SOP-7-101-Rev [X] – XX Evaluation Procedure, we have reviewed copies of the evaluation team's document review report, AB's document review report corrective action response, the evaluation team's evaluation report including the witness/observation evaluation of [AB]'s assessment of an applicant conformity

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assessment body (CAB), and documentation of [AB]'s corrective action implementation. We have reviewed the evaluation team's objective evidence of findings and are assured that it is 1) unbiased, 2) demonstrates a consistent interpretation of the standard, and 3) is complete (demonstrates that all elements of TNI FMSO Volume 2 are performed by [AB] for assurance of the CAB's implementation of TNI FMSO Volume 1 and/or demonstrates that all elements of the TNI ELS Volume 4 are performed by [AB] for assurance the CAB's implementation of TNI ELS Volume 3).

The RC recommends recognition of [AB] for conformance to the TNI NEFAP and PTP requirements effective [Month day, year] and expiring on [Month day, year].

[Include any additional comments as needed.]

Sincerely,

RC:

[List Members]

Copied:

[AB]

Evaluation Coordinator

TNI Board of Directors