SOP TITLE:	**Evaluating Proficiency Test Provider Accreditors**
SOP NO.:	4-104
REVISION NO:	2 (Provisional)

Committee:	PT Program Executive Committee	**Approved Date:**	3-17-11
Program Executive Committee:	PT Program Executive Committee	**Approved Date:**	3-17-11
Policy Committee Reviewed Date:			[Enter date here]
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SOP Effective Date:			3-17-11

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1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) delineates the functions and operations of The NELAC Institute's (TNI) Proficiency Testing Executive Committee (PT Program Executive Committee) in performing an assessment of an organization seeking to become a Proficiency Testing Provider Accreditor (PTPA) for TNI. The policies and procedures through which this is accomplished are outlined in this SOP. The PTPA ongoing recognition biennial evaluation process and procedures are also outlined in this SOP.

2.0 Summary

Organizations seeking to become a designated PTPA for TNI shall apply using the application form on the TNI website and shall submit a completed application form along with the required supporting quality system documentation to the TNI PT Program Executive Committee. Currently approved PTPAs must also re-apply every two years using the same procedure. The PT Program Executive Committee appoints an evaluation team to perform a completeness review of the application materials and to perform a technical review of the applicant's quality system. The evaluation team also conducts an on-site visit at the applicant's office facilities, and it may also observe the applicant perform an on-site assessment of a PT Provider. The evaluation team uses the checklist given in Attachment 1 of this SOP, which is based on Volumes 3 and 4 of TNI's Environmental Sector Standards and on Modules of the Stationary Source Audit Sample Standards.

The evaluation team forwards its checklists, the applicant's responses and corrective actions, and its recommendations regarding the applicant's conformance to the applicable TNI Standards and designation as PTPA to the PT Program Executive Committee. The PT Program Executive Committee has the final vote for recognizing the applicant as PTPA for TNI, and for delineating the scope of the PT Program for which the PTPA may accredit and approve PT Providers for the TNI PT Program.

3.0 Related Documents

None.

4.0 Definitions

None.

5.0 PT Program Executive Committee Qualifications and Responsibilities

Volume 4, Section 4.2 of The NELAC Institute's Standards in the Environmental Sector require the PT Program Executive Committee to select an organization or organizations to serve as a PTPA. To accomplish this, the PT Program Executive Committee shall:

- Assure that the prospective PTPA meets all requirements in Section 5 of Volume 4.

- Approve all policies and procedures used by the PTPA for the purposes of accreditation and oversight of PT Providers. This shall include approval of any additional (non-TNI) requirements from the PTPA that are related to their policies for compliance with ISO/IEC 17011 and international agreements.

- Conduct appropriate biennial on-site assessments of any organization seeking to be a PTPA.

Volume 4, Section 4.3 requires that the PT Program Executive Committee determine criteria for ongoing oversight of PT Provider activities, including activities and objectives for the PTPA review consistent with the TNI Standards. The PT Program Executive Committee shall have arrangements to

develop and maintain a database for oversight of PT Providers. The database shall include the following:

a) data on verification, homogeneity and stability testing;

b) summary information about each study, including

i. means and standard deviations;
ii. number of results;
iii. information about unacceptable rates;
iv. any other information requested by the PTPA to meet the requirements of Section 6.3.

The PT Program Executive Committee is also responsible to serve as final arbiter for complaints about the PTPA that come from Accreditation Bodies or from PT Providers and for any disputes between PTPA's.

Based on these evaluations, the PT Program Executive Committee forwards its recommendations to the TNI Board of Directors for the final disposition regarding the organization's designation as a PTPA for the TNI PT Program.

Each PT Program Executive Committee member appointed to evaluate a prospective or current PTPA is required to acknowledge that he/she has read, understands, and agrees to follow this SOP and to agree that all candidate PTPAs will be assessed in a professional, consistent, and comprehensive manner as required by the TNI Standards.

The PT Program Executive Committee will organize and perform each evaluation of an applicant PTPA according to the highest standards of professionalism and integrity possible. At a minimum, a member of the PT Program Executive Committee will serve as the lead evaluator for the team assigned to perform the evaluation. The evaluation team will consist of at least two members. Each team member will sign a statement acknowledging that he or she has no conflict-of-interest that might influence the results of a PTPA evaluation. The objectives of the PT Program Executive Committee and the evaluation team in conducting the evaluation are to:

1. Be impartial;

2. Be responsible for:
    a. performing the evaluation of the applicant PTPA (evaluation team);
    b. delivering the contents of the reports of a PTPA evaluation to the PT Program Executive Committee (evaluation team);
    c. formulating any policy decisions necessary during an evaluation and documenting the decision for consistency in implementation (PT Program Executive Committee);
    d. reporting assessment findings and making recommendations to the prospective PTPA (or designated PTPA in the case of a renewal) possible remedies to the findings (evaluation team); and
    e. overseeing all PTPAs, once recognized (PT Program Executive Committee);

3. Follow this SOP, the NELAC Institute's Bylaws, and Volumes 3 and 4 of the TNI Environmental Sector Standards; and

4. Ensure that activities of a prospective or designated PTPA do not conflict with the duties for a PTPA as described in the TNI Standards.

6.0 Application Process for a PTPA

Any organization may apply to become a PTPA provided that it meets the applicable requirements in Volume 4 of the TNI Environmental Laboratory Sector Standards and/or Module 2 of the Stationary

Source Audit Sample (SSAS) standards. An organization seeking to become a PTPA shall complete and submit the application form along with required supporting quality system documentation that shows how the TNI Standards are fulfilled. The PTPA application form is available on the TNI website.

The following supporting documentation is required to be supplied to the PT Program Executive Committee along with a completed application form:

1) Statement of Qualifications
2) Proposal for operating as a TNI PTPA
3) Quality Manual relevant and referenced to sections in Volumes 3 & 4 of the TNI Standards
4) Conflict of interest policy
5) National and International accreditations held by your organization
6) Financial resources available to operate a TNI PTPA program
7) Database services available to operate a TNI PTPA program
8) Proficiency Test Provider (PTP) application
9) PTP on-site assessment checklist
10) A copy of the PTPA Evaluation Checklist (Attachment 1) that has been filled out completely by the applicant. The applicant is to reference a policy or procedure from their quality system that addresses each checklist item.

The application must contain information demonstrating that the applicant organization:

1. has technical expertise sufficient to implement and operate a national program of PT Provider evaluation and oversight;

2. has administrative capacity sufficient to implement and operate a national program of PT Provider evaluation and oversight; and

3. has financial resources sufficient to implement and operate a national program of PT Provider evaluation and oversight

The applicant will submit the application and supporting documentation to the TNI PT Program Executive Committee Chair. One electronic copy and one hard copy of the application and supporting documentation must be submitted. The TNI PT Program Executive Committee Chair will distribute the application and supporting documentation to all TNI PT Program Executive Committee members for review.

An organization functioning within The NELAC Institute as a PTPA will assess and verify that participating providers of proficiency test samples or stationary source audit samples (SSAS) meet the TNI Environmental Sector Standards in Volume 3 and/or the SSAS Standards. A PTPA will also provide information to the PT Program Executive Committee in order for the PT Program Executive Committee to include this information in its report to The NELAC Institute's membership.

The PT Program Executive Committee may require that the organization provide additional information necessary to determine conformance with relevant national, international, and TNI Standards for PTPAs. The PT Program Executive Committee will provide any necessary explanations to organizations seeking to become a PTPA when the desired scope of designation is related to a specific program, such as a sample matrix related to United State Environmental Protection Agency (US EPA) regulatory programs (e.g., the US EPA Safe Drinking Water Act) or scientific disciplines (e.g., Toxicity testing).

7.0 Assessment Process for a PTPA

The detailed description of the evaluation procedures for a candidate or renewing PTPA is contained within this SOP. The evaluation will be documented on the checklist given in Attachment 1. The checklist

will be provided to an organization seeking to become a PTPA. The flowchart for the evaluation process of candidate PTPA is given in the flowchart in Attachment 2.

7.1 Appointment of the PT Program Executive Committee Evaluation Team

The TNI PT Program Executive Committee will appoint at least two of its members to serve as the evaluation team for the candidate PTPA (where necessary, a contractor or other TNI members having experience in auditing and familiarity with the TNI requirements for a PTPA may also be appointed to the evaluation team). To avoid conflict-of-interest, no appointed evaluation team member may be an employee or paid representative of a PT Provider, the candidate PTPA, or another PTPA. The applicant PTPA may provide written comment to the PT Program Executive Committee requesting that a specific PT Program Executive Committee member recuse oneself from the PTPA application evaluation process due to a potential conflict of interest (see also section 5.7). Each appointed evaluation team member, who accepts appointment, must provide the applicant and PT Program Executive Committee chair the following statement in writing:

"I hereby certify that I have no conflict of interest with (insert applicant here), or with any other organization participating in TNI, that would compromise my ability to conduct an objective appraisal of your quality system and your ability to meet the TNI Standards for PTPA designation."

The applicant PTPA may object to the appointment of a particular PT Program Executive Committee member to serve on the evaluation team. Such objections must be made to the PT Program Executive Committee in writing, along with the reasons for the objection. If the objection and the documented reasons are found to have merit, another PT Program Executive Committee member may be appointed to replace the team member in question. However, the PT Program Executive Committee and the TNI Board of Directors reserve the right to limit the number of appeals that may be made by the applicant.

7.2 Application Review for Completeness

The evaluation team shall review the application and supporting documentation for completeness. Completeness means that the application form is completely filled out and that the submitted information contains all the required supporting documentation listed in Section 6.0 of this SOP, so that a technical review may proceed. The completeness review should be conducted within 30 days of the PT Program Executive Committee's appointment of an evaluation team. The applicant shall be informed of the results of this review in writing, and the applicant shall submit the materials that are identified as needed to make the application "complete." If the application is complete, then the evaluation proceeds to the technical review phase.

7.3 Technical Review of the Application

The evaluation team shall review the application and supporting documentation for technical content and adherence to the applicable TNI Standards in SSAS and in Volumes 3 and 4 of the Environmental Sector. The checklist in Attachment 1 is used for this purpose. The evaluation team shall determine if any checklist items are "Not Applicable" or if some checklist items are to be reserved for the on-site assessment portion of the evaluation. The evaluation team should complete this first technical review within 60 days after the applicant has been notified that the application has been determined "complete" to do the technical review.

The applicant shall be informed of the results of the technical review in writing, plus any deficiencies that must be corrected. When the revised quality documentation, responses, and/or other information is submitted from the applicant, the evaluation team shall do a second technical review, which should be conducted within 30 days. If there are still deficiencies, the applicant has

one more chance to submit the required quality system documentation to satisfy the technical review. Any third technical review should be conducted within 15 days of receiving the requested documentation. If the technical review of the application is not satisfied upon the third technical review, the evaluation will be put on hold and the evaluation team will inform the PT Program Executive Committee regarding the issues remaining with the technical review of the application. The PT Program Executive Committee will then decide whether to continue to work through the remaining issues with the applicant or reject the application.

Once the technical review has been satisfied, the PT Program Executive Committee evaluation team shall contact the applicant PTPA and schedule the on-site assessment.

7.4 Preparations for the On-Site Assessment of the PTPA

The PT Program Executive Committee's plan for its on-site assessment activities consists of reviewing the candidate PTPA organization's statement of qualifications and quality system, plus the checklist in Attachment 1 that has been completed to date as a result of the technical review. At the PT Program Executive Committee's or the evaluation team's discretion, the on-site assessment may, in addition to the on-site inspection performed at the organization's facilities, elect to observe the organization conducting its on-site assessments at a PT Provider's facilities. It is a requirement for biennial renewal applications that the PT Program Executive Committee evaluation team observe the applicant organization conducting an on-site assessment at a PT Provider's facilities. The evaluation team is authorized to interview the organization's personnel and to examine the applicant organization's records as necessary to determine that the organization meets the applicable TNI Standards to be recognized as a PTPA, and to determine that the organization's PT Provider approvals and/or SSAS Provider approvals are made in conformance with the TNI Standards.

The assessment team's plan and the date of the on-site assessment will be made with the mutual agreement of assessment team and the candidate PTPA organization. Since the mandate to assess candidate PTPA organizations on-site is clearly defined in the TNI Standards, all organizational personnel should already be familiar with this mandate. The assessment team will evaluate the organization's structure, policy & procedures, confirm compliance with TNI requirements with respect to approving PT Providers and SSAS Providers, and confirm its implementation of procedures so as to give confidence in the approvals it bestows to these Providers.

The applicant organization is responsible for reimbursing the evaluation team members for the travel costs associated with conducting the on-site assessment.

7.5 Assessment of a PTPA

The assessment team will evaluate the candidate PTPA organization's services covered by the requested scope of approval for TNI Fields of Proficiency Testing against the relevant TNI Standards. The organization's application and submitted documentation will be reviewed to determine adherence to as many checklist items as possible.

Checklist items that could not be confirmed as complied with during the technical review will be assessed during the on-site assessment at the candidate PTPA organization's management headquarters. A representative portion (at least 10%) of the checklist items identified as compliant during the technical review will also be examined on-site at the organization to confirm adherence to the documented quality system elements. The assessment team shall have the authority to interview the organization's personnel and to review records as necessary to determine compliance with the TNI Standards.

If the evaluation team also observes the on-site assessment of a PT Provider or SSAS Provider by the organization, the evaluation team shall not participate in the on-site assessment. Instead, the evaluation shall observe and record the extent of the applicant organization's compliance with the TNI Standards in approving the Provider. The assessment team shall be available to answer questions but will not provide undue influence or consultancy.

7.6 Assessment Reports for a PTPA

The evaluation team will meet with representatives of the candidate PTPA at the conclusion of the on-site assessment, at which time the evaluation team will provide a verbal report of the findings of the evaluation and indicate areas of non-conformance (deficiencies) with the TNI Standard. The candidate PTPA organization's personnel may ask questions about the findings and deficiencies and the basis for the findings and deficiencies.

The evaluation team will prepare a written report of the findings and deficiencies as to the candidate PTPA organization's conformity with the relevant TNI Standards for approving PT Providers and/or SSAS Providers. This report will be issued within 30 calendar days of the closing date of the on-site assessment to the candidate PTPA organization. The report will identify deficiencies that must be corrected in order to comply with the TNI Standards. The report will contain the dates of the on-site assessment, names of the PT Program Executive Committee evaluation team members involved in the on-site assessment and responsible for the report, names and addresses of all sites evaluated on behalf of the candidate PTPA, comments on the conformity with the relevant TNI Standards and comparisons with the results of previous on-site assessments of the organization, where applicable, and an explanation of any differences in the information presented to the candidate PTPA organization's personnel at the closing meeting.

The candidate PTPA organization personnel shall provide corrective action responses including objective evidence demonstrating that the deficiencies have been addressed within 30 calendar days of receipt of the on-site report. The evaluation team will notify the candidate PTPA organization's management whether a full or partial re-assessment is needed or whether a written declaration of corrective actions and estimated completion dates are needed to show correction of the deficiencies cited. Deficiencies that the candidate PTPA cannot fully implement shall be responded to with a corrective action plan that includes the proposed actions and timelines for implementation. The evaluation team shall review these corrective action plans and determine either to approve of the actions or require full corrective action responses including objective evidence prior to recommending approval.

7.7 Recognition of the PTPA

After the evaluation team evaluates the submitted corrective action responses and any re-assessment to demonstrate compliance with the TNI Standards, the evaluation team will deliver to the PT Program Executive Committee a copy of all proposed corrective actions and/or re-assessment reports and a written recommendation for final status of the organization as a PTPA. Associate committee members (other than the applicant or associate members who may be part of the evaluation team) are not provided copies of applicant documents reviewed during the assessment without the prior written consent of the applicant

The PT Program Executive Committee will evaluate all materials submitted from its appointed evaluation team. PT Program Executive Committee members having a conflict of interest will recuse themselves from part or all of the evaluation and voting process, as needed. The PTPA applicant may provide written comment to the PT Program Executive Committee requesting that a specific PT Program Executive Committee member recuse oneself from the PTPA application evaluation process due to a specified known or potential conflict of interest. The PT Program Executive Committee chair may also ask a PT Program Executive Committee member to recuse

oneself for part or all of the PTPA applicant evaluation and voting process due to a known or potential conflict of interest, as deemed necessary.

Upon evaluation of the materials submitted to the PT Program Executive Committee by the evaluation team, the PT Program Executive Committee may determine that further corrective action response by the applicant is necessary to satisfactorily address a finding by the evaluation team. If additional corrective action response is necessary, the evaluation team will contact the applicant and the applicant will have 15 days to provide further corrective action response. If the evaluation team approved the use of a corrective action plan in lieu of a full corrective action response to a deficiency(ies), than the PT Program Executive Committee shall determine if this plan is adequate.

Upon completion of the review of all materials submitted by the evaluation team, the PT Program Executive Committee members will conduct a formal vote as to whether the applicant shall be recognized or be denied recognition as a PTPA. The PT Program Executive Committee shall develop and send a written recommendation to the TNI Board of Directors concerning the recognition or denial of the candidate organization as a PTPA.

The final report from the PT Program Executive Committee will take into consideration:

1. qualifications, experience, and authority of the applicant's staff encountered;

2. adequacy of the applicant's internal organization and procedures to give confidence in the quality of its approvals bestowed to PT Providers and/or SSAS Providers; and

3. actions that the applicant has taken to correct identified deficiencies (including those deficiencies identified during the on-site assessment(s))

4. status of corrective action plans and approval thereof; including a statement that recognition of this candidate PTPA will be contingent upon the corrective action plans being implemented within the agreed timeframe of the PT Program Executive Committee..

7.8 Subsequent Evaluations of the PTPA

The TNI Standards provide for the PTPA organization to be assessed on a regular basis to verify that the organization continues to comply with the TNI Standards. The PT Program Executive Committee's procedures for subsequent assessments of PTPA organizations are consistent with the initial first-time assessment unless this SOP or the relevant TNI Standards for proficiency testing or stationary source audit samples are revised. The minimum frequency for such assessments is biennially (every two years). Additional assessments may be conducted for cause. An example may be when the PTPA seeks to expand the scope of Fields of Proficiency Testing over which it exercises oversight of PT and SSAS Providers.

The procedures and checklist to use during the biennial evaluations of the PTPA shall be the same as previously described in Sections 4.0 through 5.7 above. In addition, the evaluation team shall review the findings and report from the previous evaluation of the PTPA and ensure that the PTPA has corrected the cited findings.

During the biennial evaluations of the PTPA, the PT Program Executive Committee's evaluation team shall also witness the on-site assessment activities of the PTPA organization's assessors during the evaluation of a PT or SSAS Provider. The evaluation team will observe the on-site assessment activities conducted on behalf of the PTPA, will not interfere with the assessment activities of the Provider, and will evaluate if the on-site activities are conducted in accordance with the TNI Standards and with the PTPA's quality system.

7.9 Responsibilities of the Designated PTPA

The PTPA organization shall inform the TNI PT Program Executive Committee and the TNI Board of Directors within 30 days of any changes in its operations that affect its legal or organizational status, organization and management, policies, procedures, premises, personnel, equipment, facilities, working environment, or other resources and that may have a significant or potentially significant impact on the ability of the organization to perform as a PTPA for TNI. The PTPA organization must also inform the PT Program Executive Committee of any other matters that may affect its capability, scope of recognized activities, or conformance with the TNI Standards for approving PT or SSAS providers.

When a PTPA wishes to expand the scope of TNI PT programs for which it is formally approved by TNI, the PTPA must submit a formal request for scope expansion to the TNI PT Program Executive Committee. The PT Program Executive Committee will evaluate the PTPA request to determine if an audit of the PTPA or additional documentation is required to meet the requirements of the applicable PT Program. When the PT Program Executive Committee is satisfied that the PTPA meets the requirements of the requested PT program, the PT Program Executive Committee will make a formal recommendation to the TNI Board of Directors that the PTPA's oversight should be expanded to cover the requested PT program.

7.10 On-Going Monitoring of Approved PT and/or SSAS Providers by the PTPA

The PTPA must demonstrate that it is conducting the on-going oversight of its approved PT Providers according to Volume 4, Section 6.3 of the TNI Environmental Sector Standards. The oversight shall include at a minimum:

- Review of sample verification and PT study data to assure that every PT sample meets criteria defined in the TNI Standards, to include:

(a) assurance that concentrations are distributed throughout the specified analyte ranges;

(b) confirmation of the required minimum number of analytes included in groups such as volatiles, semi-volatiles, herbicides, etc;

(c) approval of documentation for any change in the initial assigned value during a study;

(d) confirmation of the correct calculation of assigned values and acceptance limits as appropriate per analyte;

(e) verification of the prepared or assigned value;

(f) appropriate homogeneity testing prior to the study;

(g) appropriate stability testing.

- Investigating any situation where a PT Provider's pass/fail rate for any analyte or overall is statistically different from the national average at a 95% level, as determined by appropriate statistical techniques.

- When necessary, using an accredited referee laboratory to verify the assigned values of the concentrations when monitoring indicates that the PT Provider's sample is of unacceptable quality.

- Verification of the PT Provider's adherence to the appropriate standards for:

(a) correct and complete analyte lists as per PT provider accreditation;
(b) a process for handling complaints;
(c) compliance with defined nomenclature (codes) for methods, analytes and technologies;
(d) appropriate study lengths, including announced start and stop dates;
(e) timeliness of reports to customers, Accreditation Bodies and the PTPA.

- Review of critical operational parameters of the PT Provider, such as changes in ownership or senior management, and the evidence of internal audits and management review.

- Biennial on-site assessments of the PT Provider; review and monitoring of critical operational parameters of the PT Provider (examples: sale of the company, change in senior management).

- On-site inspections of the PT Provider for cause.

The TNI PT Program Executive Committee will make every effort to provide the necessary on-going monitoring criteria to be used by the PTPA. At a minimum, the PTPA should have the following documents available for review by the PT Program Executive Committee:

(a) Selection process for PT Provider samples to be tested, selection process for the Fields of Proficiency Testing to be tested, number or percentage requirements of the total number of PT samples to be tested to ensure representativeness, the evaluation criteria to be used, and the selection process of any referee laboratory(ies) to be used in the verification of analyte concentrations in randomly selected PT Provider samples.

(b) Procedures for examining the Assigned Values, robust laboratory participant means, robust laboratory participant standard deviations, lower and upper acceptance criteria, number of laboratory participants, number of participant laboratories producing unacceptable results, results of tests made to verify the Assigned Value, and results of tests made to verify the Homogeneity and Stability for each Field of Proficiency Testing in each PT study. The PT providers should be willing to provide this general, summary information to the PTPA as a condition of maintaining approval to provide PT and audit samples for the NELAP and SSAS Programs.

8.0 Criteria, Checklists, and Other Standards to be Applied

The checklist for the evaluation of an applicant organization, seeking either to become a TNI-recognized PTPA or to maintain their current recognition as a TNI PTPA, is given in Attachment 1 of this SOP. The criteria for evaluation are taken from Volumes 3 and 4 of the TNI Environmental Sector Standards.

The principal areas to be evaluated require specific expertise including formulations of proficiency test samples, statistical analyses for setting acceptance criteria, verification of analyte assigned values, PT sample homogeneity studies, and PT sample stability studies. The PT Program Executive Committee evaluation team members should demonstrate knowledge necessary to assess whether the applicant PTPA conforms with the minimum criteria in Volumes 3 and 4 of the TNI Environmental Sector Standards. The candidate PTPA should be able to explain in qualitative, simplified, scientific terms to the PT Program Executive Committee evaluation team the statistical methods and criteria used to ensure that the PT Provider's and/or the SSAS Provider's samples comply with the technical requirements of the TNI Standards.

9.0 Records Management

The official records will be formulated, copied, distributed, and maintained by the TNI PT Program Executive Committee's evaluation team members until such time as the PT Program Executive Committee sends a written recommendation to the TNI Board of Directors concerning the recognition or

denial of the applicant organization as a PTPA. After the TNI Board of Directors is contacted by the PT Program Executive Committee, the evaluation team forwards all official records of the assessment to the NELAC Institute (TNI) program offices. The official records will be maintained by the NELAC Institute (TNI) program offices for 5 years after the date that organizational PTPA assessments are made. The records to be maintained include the following:

1. the completed application form for each candidate PTPA;
2. the supplementary information and documentation provided in the organization's quality system;
3. the completed evaluation checklist for each candidate PTPA;
4. report of the on-site evaluation issued to each candidate PTPA;
5. the candidate's responses to any deficiencies cited;
6. the letter of recommendation to the TNI PT Program Executive Committee for the organization to be recognized as a PTPA;
7. the currently applicable TNI Standards; and
8. information about the evaluation process, as contained in this SOP and its attachments.

10.0 Quality Control

This SOP will be reviewed every three years or whenever the PTPEC requires, whichever occurs first. The TNI PT Program Administrator will initiate this review. This review must be documented and any changes deemed necessary must be made with the vote of the PTPEC. If the document is revised, the revisions will be posted on the TNI website.

11.0 References

ISO/IEC 17011:2004(E), "General Requirements for Assessment and Accreditation of Certification/Registration Bodies"

The NELAC Institute Environmental Laboratory Sector Volume 3, General Requirements for Environmental Proficiency Test Providers, EL-V3-2009.

The NELAC Institute Environmental Laboratory Sector Volume 4, General Requirements for an Accreditor of Environmental Proficiency Test Providers, EL-V4-2009.

National Standards for Water Proficiency Testing Studies Criteria Document, US EPA, December 30, 1998, NERL-Ci-0045

12.0 SOP Approved Changes

Original SOP
Approved by the PT Board: May 3, 2007

Prev. SOP Revision	New SOP Revision	Date of change	
0	0.1	2/21/08	
0.1	1.0	7/2/10	Reformatted to SOP template; Updated to reflect TNI Volume 3 & 4 requirements; Clarified records management; Added conflict of interest language;

			Listed supporting documentation requirements in section 4, Removed application example and referenced TNI website for application
1.0	2.0	3/24/11	Revised flowchart; Clarified language in 5.6 on deficiencies; Added language in section 5.9 on PTPA scope expansion procedures; Added clarification language in section 5.7 regarding applicant document distribution and corrective action plans

13.0 Attachments

Attachment 1: PTPA Evaluation Checklist
Attachment 2: Flowchart for PTPA Evaluation Process

ATTACHMENT 1:

PTPA EVALUATION CHECKLIST

PTPA APPLICANT ORGANIZATION: _____

Primary Contact: _____

Physical Address: _____

_____

Mailing Address: _____
(if different from above)

_____

Telephone Number: _____ Facsimile Number: _____

E-mail address: _____

EVALUATED BY: (Name) (Affiliation)

_____ _____

_____ _____

_____ _____

_____ _____

EVALUATION DATES: _____ (Completeness Review)

_____ (Quality System Technical Review)

_____ (PTPA On-Site Evaluation)

PTPA ORGANIZATIONAL DIRECTORS AND MANAGEMENT:
(Name) (Title)

_____ _____

_____ _____

_____ _____

_____ _____

INTRODUCTION:

The checklist is organized in a manner to facilitate the administrative review of the application, the technical review of the application, and the on-site inspection of the Proficiency Test Provider Accreditor (PTPA) candidate and/or renewal process.

The numbers in **BOLD** on the checklist reference the citation from The NELAC Institute's (TNI's) Environmental Sector Standard indicating where the requirement may be found. Although not specifically listed, analogous requirements are also found in the Stationary Source Audit Sample Standards.

GENERAL INSTRUCTIONS:

After each item check (with a check mark or "X") either "Yes", "No", or "N/A.

Mark "**YES**" if the PTPA meets the NELAC Standard referenced.

Mark "**NO**" if the NELAC Standard is not met and the PTPA must devise an acceptable Plan of Correction and estimated completion date.

Mark **"N/A" only** if the TNI Standard is not applicable because of the nature of the applicant's business mission, or outside the scope of Fields of Proficiency Testing with which the applicant wants to accredit PT Providers.

The evaluation team should also cite with objective evidence the citations or sections from the applicant's quality system that justifies a "YES" response. Objective evidence may also include noting specific documentation examples observed which support the applicant's compliance with TNI requirements.
Reasons and/or objective evidence for "NO" responses are required to be documented in the checklist.
Reasons for "N/A" should also be provided.

The TNI Standard reference for all "NO" responses, for which corrective action is required, must be cited in the on-site evaluation report.

THIS CHECKLIST IS ONLY A TOOL, NOT THE REQUIREMENTS OF THE NELAC INSTITUTE'S STANDARDS.

IF THERE IS A DISAGREEMENT BETWEEN THIS CHECKLIST AND THE NELAC INSTITUTE STANDARDS, THE NELAC INSTITUTE'S STANDARDS SHALL PREVAIL.

THE NELAC INSTITUTE (TNI), ENVIRONMENTAL LABORATORY SECTOR
VOLUME 4 – OVERSIGHT OF PROFICIENCY TESTING

Section 5 – Requirements for Approval of a Proficiency Testing Provider Accreditor

Section 5.1 – Technical and Administrative Qualifications

(V4, 5.1.1) Has the applicant organization documented technical expertise sufficient to implement and operate a national program of PT Provider accreditation and oversight?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.1) Has the applicant organization documented an administrative system sufficient to implement and operate a national program of PT Provider accreditation and oversight?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.1) Has the applicant organization documented that it has the financial resources sufficient to implement and operate a national program of PT Provider accreditation and oversight?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.2) Is the applicant organization recognized by a national or international cooperation of accrediting bodies for the accreditation of environmental laboratories?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.2(a)) Does the organization demonstrate compliance with ISO/IEC 17011: *General requirements for accreditation bodies accrediting conformity assessment bodies?*

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.2(b)) Does the organization have, or have access to, technical expertise that conforms with ISO Guide 34 and/or ISO 17025 as appropriate, for the preparation and/or analysis of the types of reference materials being prepared by the PT Providers?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.2(c)) Does the organization have, or have access to expertise in statistical applications used for inter-laboratory comparison programs?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.2(d)) Does the organization have documented processes to conduct on-site audits of PT Providers that are consistent with this Standard?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.1.2(e)) Does the organization have documented processes to conduct technical reviews of initial applications?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

Section 5.2 – Responsibilities Regarding Assessment of PT Providers

(V4, 5.2.1) Do the organization's oversight and assessment activities of PT Providers include the requirements specified in Volume 3 and in Volume 4, Section 6 of TNI's Environmental Laboratory Sector standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.2.2) Has the organization obtained approval from the TNI PT Program Executive Committee for any variations from these requirements or additions to these requirements prior to use?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.3 – Development of Standard Operating Procedures (SOPs) and Forms

(V4, 5.3) Has the organization developed procedures for conducting the PT Provider evaluation?

Yes ____ No ____ N/A ____
Objective Evidence/Comments:

(V4, 5.3) Are these procedures based upon the requirements of the TNI Environmental Laboratory Sector (and Stationary Source Audit Sample) Standard?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.1(a)) Do these procedures include the initial application submittal and review process?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.1(b)) Do these procedures include the on-site assessment?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.1(c)) Do these procedures include the accreditation process?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.1(d)) Do these procedures include the submittal of oversight information to the organization as PTPA?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.1(e)) Do these procedures include revoking a PT Provider's accreditation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.1(f)) Do these procedures include appealing accreditation determinations?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.2) Has the organization developed procedures for the initial application process to be followed by PT Providers applying for accreditation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.2) Does the application include information about the qualifications of the PT Provider seeking accreditation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.3) Does the organization's procedures require acceptance of other accreditations, recognitions, calibrations, etc., if they are current and are issued by organizations that have a mutual recognition agreement with the organization for that activity, product or characteristic?

NOTE: To the extent feasible, the PTPA shall not assess those activities that are so recognized; however, by mutual recognition agreement, the PTPA is allowed to find non-conformances in activities that have recognized accreditation.

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.4) Has the organization developed procedures for conducting consistent and effective on-site assessments of PT Providers?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.4) Does the organization's SOP include a description of the circumstances for conducting any additional assessments or unannounced assessments?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.3.5) Has the organization developed standard, consistent, and unambiguous checklists to be used during all assessments of PT Providers?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.4 – Development and Maintenance of a Comprehensive PT Database

(V4, 5.4.1) Has the organization developed and maintained a comprehensive PT database that contains summaries of participant results and results of all verification, homogeneity, and stability data?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.4.2) Does the organization have instructions for PT Providers on procedures for submitting data to the database?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.5 – List of Accredited PT Providers

(V4, 5.5.1) Does the organization maintain a list of accredited PT Providers and the Fields of Proficiency Testing (FoPTs) they are accredited to provide?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.5.1) Is the list of accredited PT Providers and their FoPTs maintained on a continuing basis, on an electronic bulletin board or similar means?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.5.1) Is the list readily available to laboratories seeking accreditation, Accreditation Bodies, and other interested parties?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.5.2) Does the organization ensure that approved PT Providers abide by the provisions of the TNI PT Program Executive Committee and itself regarding the advertising and marketing of their accreditation approval status?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.6 – PTPA Ethics

(V4, 5.6.1) Does the organization have processes to evaluate PT Provider information objectively and to use this information to make sound determinations regarding a provider's accreditation status?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.6.2) Does the organizations policies address that it is free of any organizational or financial conflict-of-interest that would prevent it from complying with the requirements of the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.6.3) Does the organization's policy address unbiased evaluation of information gathered and received including assessment reports, referee sample results, complaints, and any other information obtained regarding a PT Provider?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.6.4) Does the organizations process evaluate all information about a PT Provider related to providing PT programs, and determine which information is relevant to the PT Provider's accreditation status?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.6.4) Does the organization make available information used for determining PT Provider approval status to the appropriate parties, consistent with all confidentiality agreements?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.7 – Confidentiality

(V4, 5.7.1) Does the organization agree to maintain the confidentiality of proprietary information provided to it by the PT Providers?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.7.2) Does the organization treat all PT study data, sample formulation process information, analysis techniques, and other proprietary information as confidential and not accessible to any other entity; except as described in the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 5.7.2) Does the organization have a policy on release of confidential information without prior written permission from the PT Provider?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6 – Requirements for Accreditation of PT Providers

(V4, 6.0) Does the organization repeat the accreditation process of PT Providers every two years, which includes all stages of initial review, on-site assessment, and oversight?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.0) Do the organization's timelines for application review, conducting assessments, and follow-up activities not cause undue delay in processing a request for accreditation?

Note: These timelines will be consistent with the organization's internal policies, as approved by its mutual recognition partners.

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6.1 – Initial Application Review

(V4, 6.1(a)) Does the organization review the initial application documents for compliance with PT Provider qualifications described in the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.1(b)) Does the organization review the sample designs used by the PT Provider for compliance with the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.1(c)) Does the organization review the PT analyte and sample scoring procedures used by the PT Provider for compliance the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.1(d)) Does the organization review the procedures used by the PT Provider to validate that new PT sample formulations are fit for their intended purpose, prior to use of such material in a PT scheme?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

NOTE: This review shall ensure, at a minimum, that samples have assigned values within the specified ranges for every technology used to report results.

(V4, 6.1(e) Does the organization review the adequacy of data processing and analysis techniques used by the PT Provider, including statistical procedures used on sample sets with fewer than 20 laboratories?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.1(f)(i)) Does the organization confirm the PT Providers' absence of conflicting interests with subscribing laboratories, including any financial interest in a laboratory seeking or having accreditation to the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.1(f)(ii)) Does the organization confirm the PT Providers' absence of conflicting interests with subscribing laboratories, including the sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, accreditation to the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.1(g)) Does the organization provide to the PT Provider the checklists to be used during the inspection as part of the initial application process?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

NOTE: The checklist shall include all requirements that may be necessary for the PTPA to comply with their own policies and external agreements.

Section 6.2 – On-Site Assessment

(V4, 6.2.1) Does the organization perform an on-site inspection of the PT Provider after the initial application review?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

V4, 6.2.1(a)) Does the on-site assessment include a review of the PT Provider's quality management system for adherence to the requirements of the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.2.1(b)) Does the on-site inspection include a review

Yes ____ No ____ N/A ___

of staff qualifications and technical expertise necessary to produce acceptable proficiency testing samples?	Objective Evidence/Comments:
(V4, 6.2.1(c)) Does the on-site inspection include a review of the sample manufacturing and analytical verification procedures, along with the study data, to ensure that the requirements of TNI Standards are met?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.1(d)) Does the on-site inspection include a review of the procedures in place to ensure that all personnel are aware of and abide by the standards of conduct for PT Providers and confidentiality of assigned values and participant results?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.1(e)) Does the on-site inspection include a review of data reporting systems to ensure that the requirements of the TNI Standards are met within the defined time periods?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.1(f)) Does the organization conduct an exit meeting with the PT Provider following the on-site inspection?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.1(f)) Does the exit meeting include a discussion of all assessment findings?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.1(f)) Does the organization deliver the written final report from the assessment to the PT Provider during the exit meeting?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.2) Does the final inspection report contain only discrepancies and findings identified during the on-site assessment and discussed during the exit meeting, as defined by the organization's procedures?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.3) Does the organization allow the PT Provider to submit its response to the report?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.2.3) Does the organization require that the PT	Yes ____ No ____ N/A ___

Provider's response include a description of corrective actions necessary to meet the criteria of the TNI Standards and, as appropriate, objective evidence of successful implementation of any corrective action?

Objective Evidence/Comments:

(V4, 6.2.4) Does the organization follow its procedures and utilize the appropriate final report and associated documents submitted by the PT Provider for determining accreditation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6.3 – Responsibilities for Ongoing Monitoring of PT Providers

(V4, 6.3.1) Does the organization conduct ongoing monitoring of all accredited PT Providers, which includes a review of sample verification and PT study data to assure that every PT sample meets criteria defined in the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.1(a)) Does this monitoring include review of concentrations in PT samples to ensure they are distributed throughout the specified analyte ranges?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.1(b)) Does this review include confirmation that PT samples include the required minimum number of analytes in groups such as volatiles, semi-volatiles, herbicides, etc.?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.1(c)) Does this review include approval of documentation for any change in the initial assigned value during a PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.1(d)) Does this review include confirmation of the correct calculation of assigned values and acceptance limits as appropriate per analyte?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.1(e)) Does this review include verification of the prepared or assigned value?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.1(f)) Does this review include appropriate homogeneity testing prior to the respective PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.1(g)) Does this review include appropriate stability testing of PT samples during providers' PT studies (and any quick-response PT samples)?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.2) Does the organization investigate any situation where a PT Provider's pass/fail rate for any analyte or overall is statistically different from the national average at a 95% level, as determined by appropriate statistical techniques?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.3(a)) If the organization uses an accredited referee laboratory to verify the assigned values of the concentrations of PT samples, when on-going monitoring indicates that the PT Provider's sample is of unacceptable quality, does the determination of unacceptable quality use the same acceptance criteria that were used in the manufacture of the PT sample (for example, 1 standard deviation for verification or the approved criteria for homogeneity and stability)?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.3(b)) If the organization uses an accredited referee laboratory to verify the assigned values of the concentrations of PT samples, when on-going monitoring indicates that the PT Provider's sample is of unacceptable quality, does the organization provide each PT Provider with a report describing the results for any required referee analyses?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.4(a)) Does the organization's on-going monitoring of accredited PT Providers provide verification of the PT Provider's adherence to the appropriate standards for the correct and complete analyte lists as per PT Provider's accreditation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.4(b)) Does the organization's on-going monitoring of accredited PT Providers provide verification of the PT Providers' having a process for handling complaints?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.3.4(c)) Does the organization's on-going monitoring

Yes ____ No ____ N/A ___

of accredited PT Providers provide verification of the PT Providers' adherence to the appropriate standards for compliance with defined nomenclature (codes) for methods, analytes, and technologies?	Objective Evidence/Comments:
(V4, 6.3.4(d)) Does the organization's on-going monitoring of accredited PT Providers provide verification of the PT Providers' adherence to the appropriate standards for appropriate PT study lengths, including announced start and stop dates?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.3.4(e)) Does the organization's on-going monitoring of accredited PT Providers provide verification of the PT Providers' adherence to the appropriate standards for timeliness of reports to customers, Accreditation Bodies, and the organization?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.3.5) Does the organization's on-going monitoring include review of critical operational parameters of the PT Provider, such as changes in ownership or senior management, and the evidence of internal audits and management review?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.3.6) Does the organization fully document the causes and resolution for any unscheduled on-site assessments of PT Providers?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.3.7) Does the organization discuss first with the PT Provider any possible problems indicated by the on-going monitoring?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.3.7) Does the organization maintain complete records of all contacts and responses from the PT Provider during on-going monitoring?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:
(V4, 6.3.8) Does the organization assess whether a PT Provider's accreditation status should be suspended or withdrawn based upon the results of its on-going monitoring and its internal appeals process?	Yes ____ No ____ N/A ___ Objective Evidence/Comments:

Section 6.4 – Complaints and Corrective Action

(V4, 6.4.1) Does the organization evaluate all complaints that it receives regarding accredited or candidate PT Providers?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.4.1) Does the organization notify the PT Provider of the complaint if the organization determines that a complaint warrants investigation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.4.1) Does the organization consider the complaint unresolved until the PT Provider resolves the complaint to the satisfaction of the organization?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.4.2) Does the organization provide to the TNI PT Program Executive Committee a summary of all PT Provider complaints received the previous year?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.4.3(a)) Does the organization review a written summary of all complaints regarding the technical aspects of the PT studies and the resulting corrective actions?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.4.3(b)) Does the organization review all complaints that are unresolved after ninety days?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.4.4) Does the organization review any complaints about PT Providers received from Accreditation Bodies, and work with the PT Provider, the Accreditation Body, and the TNI PT Program Executive Committee to resolve the complaints?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6.5 – Suspension or Revocation of PT Provider Accreditation

(V4, 6.5.2) Does the organization formal written notice to a PT Provider of any action to revoke or suspend the PT Provider's accreditation for any reason?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.5.3) Does the organization inform the PT Provider of the reasons for proposed revocation or suspension and the procedures for appeal of such a decision?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V4, 6.5.4) Does the organization respect the due process rights of the PT Provider during any revocation or suspension proceedings, including the PT Provider's right to appeal the decision to the TNI PT Program Executive Committee after completion of the organization's appeals process?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

VOLUME 3 – PROFICIENCY TESTING (PT) PROVIDER REQUIREMENTS

Section 4 – PT Provider Accreditation

(V3, 4.1) Does the organization accredit PT Providers for every TNI FoPT which they will offer in their PT programs?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 4.2) Does the organization ensure that PT Providers comply with the requirements of the TNI Standards for any analyte in any FoPT during on-site audits and on-going oversight?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 4.3) Does the organization subject PT providers to biennial onsite audits conducted by their chosen TNI-approved PTPA, which may include unannounced audits for cause?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 4.4) Does the organization require PT providers to submit data from each of their accredited PT studies to it for review to determine compliance with the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 4.4.1) Does the organization determine the information required in these submittals, including the format and frequency/timing?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 4.4.2) Does the organization ensure that the PT providers not identify any participant laboratory to the organization without the expressed written consent of the

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

laboratory?

(V3, 4.5) Can the organization require the PT Provider supply, at no charge, specific PT samples included in the PT Provider's scope of accreditation, to the organization for submission to a referee laboratory?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 4.6) In conflicts between the PT Provider and itself, does the organization require the PT provider to follow the organization's appeals process?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 4.7) Does the organizations process require that unresolved conflicts between PT Providers and itself be submitted to the TNI PT Program Executive Committee?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5 – Management Requirements

Section 5.1 – Quality System Requirements

(V3, 5.1.1) Does the organization ensure that the PT Provider's quality management system meets ISO 9001 requirements for the design, production, testing, and distribution of PT samples and the evaluation of PT results?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.1.2) Does the organization ensure that PT Provider's manufacturing system meets the requirements of ISO Guide 34 (Quality System Guidelines for the Production of Reference Materials)?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.1.3) Does the organization ensure that ILAC G 13 requirements are fulfilled for the design and operation of the PT Provider's proficiency testing program?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.1.4) Does the organization ensure that ISO 17025 requirements (General Requirements for the Competence of Calibration and Testing Laboratories) are fulfilled for the testing facilities used to support the verification, homogeneity, and stability testing required by the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.1.5) Does the organization assess and make determinations related to the PT Provider's conformance to these requirements, even though the PT provider may hold

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

specific accreditations related to any of the requirements in ISO 9001, ISO Guide 34, ILAC G-13, and ISO 17025 above?

(V3, 5.1.6) Does the organization require PT Providers to retain all records related to each PT study for a minimum of 5 years after the close of the PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.2 – Provider Conflict of Interest and Confidentiality

(V3, 5.2(a)) Does the organization require PT Providers to document and certify that they are free of any conflicts of interest with any laboratory that may participate in their PT programs?

Note: Such a conflict of interest could take the form of a financial interest or sharing of personnel, facilities or equipment with any laboratory that may participate in the provider's PT studies.

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.2(b)) Does the organization ensure that PT Providers inform all internal and contractual personnel of their obligation to report personal and organizational conflicts of interest to the organization?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.2(c)) Does the organization ensure that PT Providers have continuing obligations to identify and report any actual or potential conflicts of interest arising during the performance of work in support of PT programs?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.2(d)) Does the organization ensure that PT Providers immediately make full disclosure to it of any identified actual or potential organizational conflicts of interest? *(Such disclosure includes a description of any action that the PT Provider has taken or proposes to take, after consultation with the organization, to mitigate, avoid, or neutralize the actual or potential conflict of interest.)*

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.2(e)) Does the organization require the PT Provider to have systems in place to ensure that the confidentiality

of data associated with PT samples and programs are not compromised?

(V3, 5.2(f)) Does the organization ensure that the PT Provider do not release the assigned values or acceptance limits of any PT sample prior to the conclusion of the study, except to the organization?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.2(g)) Does the organization ensure that the PT Provider only release participant laboratories' PT study results and/or evaluations to a designated contact at the laboratory and to laboratory accreditation bodies and/or other entities as specifically designated by the laboratory?

NOTE: PT providers may release, at the conclusion of a PT study, without permission of participant laboratories, summaries of participant laboratory results that do not identify individual laboratories.

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.3 – Provider Facilities and Personnel

(V3, 5.3.1) Does the organization require the PT Provider to have appropriate facilities, equipment, and analytical instrumentation in place for producing, analytically verifying, distributing, and providing data analyses and reporting functions for every PT sample for which it wishes to obtain or maintain accreditation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.3.2) Does the organization require the PT Provider employ sufficient technical and support staff to design, produce, analyze, distribute, and provide data evaluation and reporting functions for every PT sample for which it wishes to obtain or maintain accreditation?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.3.3) Does the organization ensure that the PT Provider maintain direct control of all portions of the design, production, testing, distribution, data collection,

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

data evaluation, and data reporting functions for each PT study?

NOTE: *"Direct Control" in this sense means that* these functions are performed in the PT provider's facilities by the PT provider's staff, or these functions are sub-contracted by means of a written agreement with defined PT provider supervision to ensure that all requirements of the TNI Standards are met.

(V3, 5.3.4) Does the organization assess any and all subcontracted functions related to design, production, testing, distribution, data collection, data evaluation, or data reporting to ensure that they meet the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.4 – Complaint Handling

(V3, 5.4.1) Does the organization ensure that PT providers have written procedures for handling both written and verbal complaints from PT study participants and laboratory accreditation bodies who receive PT study reports?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.4.2) Does the organization require the PT Provider to record all complaints received concerning its PT studies, including any remedial or corrective actions taken, and to provide this record to the organization upon request?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 5.4.3) Does the organization require the PT Provider to refer to it all complaints that remain unresolved after 90 days?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 5.5 – Notification of Sample Integrity

(V3, 5.5) Does the organizations procedure ensure that, if any sample or analyte used in a PT study is found to not meet any of the requirements of the TNI Standards, the PT provider has notified all affected laboratories and their designated accreditation bodies and the organization within 7 calendar days of the discovery of the non-compliance?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6 – PT Sample Design and Manufacture

Section 6.1 – Design Review

(V3, 6.1(a)) Does the organization ensure that the PT Provider's sample designs and manufacturing processes permit proficient laboratories, conforming to the calibration and quality control requirements of the analytical method(s) for which the sample was designed, to generate results that fall within the PT sample acceptance limits defined in the TNI Fields of Proficiency Testing Tables?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.1(b)) Does the organization ensure that the PT Provider's sample designs and manufacturing processes provide equivalent challenge to all participant laboratories?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.1(c)) Does the organization verify that the PT Provider's sample designs and manufacturing processes result in laboratory pass/fail rates that are consistent with historical norms?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6.2 – Sample Matrices

(V3, 6.2.1) Does the organization ensure that PT Provider's matrices for all PT samples, to the extent possible, resemble the matrices which participant laboratories routinely analyze?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.2.2) Does the organization ensure that the PT Provider's matrix for soil PT samples is well-characterized natural soil that does not contain greater than 90% sand by mass?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6.3 – Sample Analytes

(V3, 6.3.1) Does the organization ensure that PT providers prepare samples that are compliant with the criteria defined by the TNI PT Program Executive Committee and published in the TNI FoPT Tables on the TNI website?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.2) Does the organization ensure that, when the TNI PT Program Executive Committee makes changes to the PT sample design criteria, PT providers comply with the revised requirements per the PT Program Executive Committee's implementation schedule?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.3(a)) Does the organization ensure that, for those multi-analyte categories designated in the TNI FoPT tables as not requiring all analytes to be spiked, the PT Providers include all analytes in PT samples that are to be scored for 1-10 analytes?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.3(b)) Does the organization ensure that, for those multi-analyte categories designated in the TNI FoPT tables as not requiring all analytes to be spiked, the PT Providers include at least 10 analytes or 80%, whichever is greater, in PT samples that are to be scored for 10-20 analytes?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.3(c)) Does the organization ensure that, for those multi-analyte categories designated in the TNI FoPT tables as not requiring all analytes to be spiked, the PT Providers include at least 16 analytes or 60%, whichever is greater, for PT samples that are to be scored for over 20 analytes?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.3(d)) Does the organization ensure that, for those multi-analyte categories designated in the TNI FoPT tables as not requiring all analytes to be spiked, the PT Providers always round UP fractions to the next whole number for all percentages that contain fractions?

NOTE: For example: 16 analytes × 0.80 = 12.8 = 13 analytes in the sample.

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.4) Does the organization ensure that the PT Providers use a random selection process shall be used to determine which analytes will be spiked and unspiked within any given PT sample?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.4.1) Does the organization permit the PT providers to make modifications to randomly-selected analyte lists only when there are technical (i.e. compatibility, interference) issues?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.4.2) Does the organization require the PT Providers to document all modifications to randomly-determined analyte lists?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.5) Does the organization require PT Providers set the assigned value for unspiked analytes <PTRL?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.6) Does the organization ensure that, if the PT provider spikes analytes not on the TNI FoPT Tables in their PT samples, the PT provider ensures, to the organization's satisfaction, that these additional analytes do not interfere with laboratory performance for the required analytes?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.3.6) Does the organization ensure that, if the PT provider spikes analytes not on the TNI FoPT Tables in their PT samples, the PT provider does not use these analytes in the count toward the minimum analyte requirements of Section 6.3.3?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 6.4 – Assigned Values

(V3, 6.4.1) Does the organization require the PT providers to use a random process to determine the target assigned values for their PT samples?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.1.1) Does the organization permit PT providers to make modifications to randomly-selected assigned values only when there are technical (i.e. solubility, compatibility, interference) issues?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.1.2) Does the organization require the PT Providers to document any modifications to randomly-selected assigned values?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.2(a)) Does the organization require that the PT Providers' assigned values for aqueous, non-microbiological analytes that are measured (chemical concentrations, isotope activities, etc.) be equal to the made-to values of the analytes based on gravimetric and volumetric measurements of a starting material of known concentration?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.2(b)) Does the organization require that the PT Providers' assigned values for aqueous, non-microbiological analytes that are measured (chemical concentrations, isotope activities, etc.) be presented as three significant figures?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.3(a)) Does the organization require that the PT Providers' assigned values for quantitative microbiology analytes be equal to the mean of the assigned value verification and/or homogeneity testing conducted per Sections 7.1 and 7.2 of the TNI Environmental Laboratory Sector Volume 3 Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.3(b)) Does the organization require that the PT Providers' assigned values for quantitative microbiology analytes be presented as a whole number with no more than three significant figures?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.4(a)) Does the organization require that the PT Providers' assigned values for solid and chemical matrix analytes be equal to the natural (background) concentration as analytically determined by the PT provider, plus the made-to concentrations of any spiked analytes based on gravimetric and volumetric measurements of a starting material of known concentration?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.4(b)) Does the organization require that the PT Providers' assigned values for solid and chemical matrix analytes be presented as three significant figures?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 6.4.5) Does the organization require that the PT Providers' assigned values for qualitative analytes be represented as "Present" or "Absent"?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 7 – PT Sample Testing

Section 7.1 – Verification of Assigned Value

(V3, 7.1.1) Does the organization ensure that the PT Provider analytically verify the assigned values of all analytes in all PT samples prior to use in a PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.2) Does the organization require PT Providers to verify the assigned value by direct analysis against a calibration standard made from, or traceable to, a primary reference material (e.g. National Institute of Standards and Technology (NIST), United States Pharmacopeia (USP), etc) if available?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.3) Does the organization require that, if a primary reference material is not available, that PT Providers perform verifications against an independently prepared calibration material?

Note: An independently prepared calibration material is one prepared from a raw material source independent of the source used to prepare the PT sample or one prepared and documented by a source external to the provider.

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.4) Does the organization require that the assigned value verification analytical event by the PT Provider also include the analysis of a second source reference material from a source independent of the calibration standard and the PT sample being verified?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.5) Does the organization require that the PT provider have documented criteria for the acceptance of the results of the second source reference material?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.6) Does the organization require that the analytical method used by the PT provider for assigned value verification have a repeatability relative standard deviation of not more than one-sixth of the acceptance limits for the participant laboratories?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.7) Does the organization require that the relative

Yes ____ No ____ N/A ___

standard deviation of the PT provider's verification method be established by a method validation study for each method and instrument?

Objective Evidence/Comments:

(V3, 7.1.8) Does the organization require that PT Providers consider the assigned value of aqueous chemistry analytes verified only if the mean of the provider's verification analyses is within one-third of the laboratory acceptance limits, to a maximum of 10%, as calculated per Volume 3, Section 10.2, of either

(a) the assigned value, if an unbiased verification method is used; or

(b) the expected mean value for the analyte, if a biased method is used?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.9) Does the organization require that PT Providers consider the assigned value of solid matrix and microbiology analytes verified only if the mean of the provider's verification analyses is within one-half of the laboratory acceptance limits, as calculated per Volume 3, Section 10.2, of either

(a) the assigned value, if an unbiased verification method is used; or

(b) the expected mean value for the analyte, if a biased method is used?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.10) Does the organization require that the PT Provider's standard deviation of the verification analyses be less than one standard deviation as calculated for the participant laboratories?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.11) Does the organization require the PT Provider to verify all unspiked analytes analytically to ensure that they are not present at or above one-half the PTRL?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.1.12) Does the organization ensure that PT Providers not use any PT sample that fails to meet the requirements of Volume 3, Section 7.1 in a PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 7.2 – Homogeneity Testing

(V3, 7.2.1) Does the organization require that the PT Provider analytically verify that all analytes in all PT samples within a packaging event are sufficiently homogenous prior to their use in a PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.2.2) Does the organization ensure that the PT Provider verify the homogeneity of PT samples using the procedure outlined in Appendix A to Volume 3 of the TNI Environmental Laboratory Sector Standards, or a procedure with an equivalent ability, as determined by the organization, to verify that differences between samples will not impact the laboratory evaluations?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.2.3) Does the organization ensure that PT Providers perform homogeneity testing on a representative selection of samples randomly selected from each final packaged PT sample batch, prior to shipment to participant laboratories?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.2.4) Does the organization ensure that PT Providers not use samples that fail to pass the homogeneity testing criteria in a PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 7.3 – Stability Testing

(V3, 7.3.1) Does the organization ensure that the PT Providers, after the closing date of the PT study but prior to the issuance of final reports, verify that all analytes in all PT samples remained stable during the course of the study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.3.2) Does the organization ensure that PT providers retain samples of the original PT study material until the close of the study, for use in post-study analytical verification?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.3.3) Does the organization ensure that PT sample stability assessments are based on analytical data

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

comparing the mean of a series of random samples analytically tested before the start of a study to the mean of a series of random samples analytically tested after the study close date?

NOTE: If the difference between the two means cannot be shown to affect an evaluation, then the analyte can be considered stable for the study period.

(V3, 7.3.4) Does the organization approve PT Provider's procedure used for stability verification?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.3.5) Does the organization ensure that post-study stability verification include ensuring that unspiked analytes are still below one-half the PTRL?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.3.6) Does the organization ensure that providers follow procedures which require that PT samples or analytes which fail to meet the criteria for stability verification are invalidated in the PT study and described in the study discussion report?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 7.4 – Verification, Homogeneity, and Stability Testing Reporting

(V3, 7.4.1) Does the organization ensure that PT Providers, upon request and after issuance of final evaluation reports, make available the results of their sample assigned value verification, stability, and homogeneity testing to the participating laboratories?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.4.2) Does the organization ensure that PT Providers, upon request and after issuance of final evaluation reports, make available the results of their sample assigned value verification, stability, and homogeneity testing to laboratory accreditation bodies for which results were submitted to that laboratory accreditation body?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.4.3) Does the organization ensure that PT Providers, upon request and after issuance of final evaluation reports, make available the results of their

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

sample assigned value verification, stability, and homogeneity testing for any PT study sample / analyte to the TNI PT Program Executive Committee?

(V3, 7.4.4) Does the organization ensure that PT Providers supply to the organization the results of their sample assigned value verification, stability, and homogeneity testing for all PT samples / analytes included in each PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 7.4.5) Does the organization ensure that the PT providers follow its format and schedule for submittal of this verification, homogeneity, and stability data?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 8 – Provision of PT Samples

Section 8.1 – Study Duration

(V3, 8.1) Does the organization ensure that PT Provider PT study closing dates are no more than forty-five calendar days after the opening date of the study or as specified by the TNI PT Program Executive Committee?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 8.2 – Study Instructions

(V3, 8.2.1(a)) Does the organization ensure that PT Providers provide instructions to each laboratory participant describing how to dilute or otherwise prepare the PT sample?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.2.1(b)) Does the organization ensure that PT Provider instructions to participants include how to report their data to the PT provider?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.2.1(c)) Does the organization ensure that PT Provider instructions to participants include the close date of the PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.2.1(d)) Does the organization ensure that PT Provider instructions to participants include a warning that the TNI standard requires PT samples to be analyzed like

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

"real" samples utilizing the same analysts, methods, and quality control procedures?

(V3, 8.2.2(a)) Does the organization ensure that PT Providers not provide inappropriate assistance to the participant laboratories nor encourage the non-routine analysis of PT samples?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.2.2(b)) Does the organization ensure that PT Providers not suggest or direct laboratories to use additional quality control samples or quality control samples designed specifically for a given PT sample, in conjunction with any PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.2.2(c)) Does the organization ensure that PT Providers not provide excessive volume of any PT sample that may encourage multiple, non-routine analyses?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

NOTE: The organization in consultation with the TNI PT Program Executive Committee can determine what constitutes excessive volume based on method requirements and common PT provider practices within the industry.

Section 8.3 – Regularly Scheduled PT Studies

(V3, 8.3.1) Does the organization ensure that regularly scheduled PT studies consist of PT sample lots (or batches) that have not been provided, in any form or by any entity, to actual or potential participant laboratories prior to the opening date of the study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.3.2) Does the organization ensure that the assigned values for regularly scheduled PT samples are not released to any entity outside of the PT provider, other than the organization, prior to the closing date of the PT study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 8.4 – Supplemental PT Studies

(V3, 8.4.1(a)) Does the organization ensure that the PT

Yes ____ No ____ N/A ___

Providers, for supplemental PT samples, select a batch of PT samples that has been shown to meet all of the requirements of Sections 6 and 7 of Volume 3 of the TNI Standards?

NOTE: Supplemental PT samples may be from lots that have been previously used in a PT study.

Objective Evidence/Comments:

(V3, 8.4.1(b)) Does the organization ensure that PT Providers conduct stability testing at the close of the supplemental PT study or have data showing, to the satisfaction of the organization, that the sample was stable during the time period of the supplemental study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.4.1(c)) Does the organization ensure that PT Providers have documented procedures and systems in place to track all lots and assigned values of samples received by laboratories that may be used as supplemental PT samples?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.4.1(d)) Does the organization ensure that PT Providers not supply a supplemental PT sample to a laboratory that has received that sample in a previous PT study, or in any other form, or has had access to the assigned values for that sample?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.4.1(e)) Does the organization ensure that PT Providers remove the original lot number, study number, and/or tracking ID number of each supplemental PT sample and assign a unique identifier?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.4.2) Does the organization ensure that, if the laboratory informs the PT provider that a supplemental PT sample is being used for corrective action purposes for a specific quantitative analyte or analytes, the PT provider supplies a supplemental PT sample that contains the specified analyte(s) spiked into the sample [i.e. the sample does not have an assigned value of zero or <PTRL for the laboratory-specified analyte(s)]?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.4.3) Does the organization ensure that, if the laboratory informs the PT provider that a supplemental PT sample is being used for corrective action purposes for a specific qualitative (presence/absence) test, the PT Provider

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

randomly determines whether the analyte of interest is spiked into the sample so that the laboratory will not automatically know that it is present or not?

(V3, 8.4.4) Does the organization ensure that the PT Provider considers the closing date of a supplemental PT study to be the date that the participant(s) has reported study data for the required analytes?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 8.4.5) Does the organization ensure that the PT Provider considers the closing date of supplemental PT studies to be no more than forty-five days after the opening date of the study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 9 – System for Reporting by Participants

(V3, 9.0(a)) Does the organization ensure that the PT Providers have procedures and systems in place to ensure the accurate, timely and secure transmission of PT data from participant laboratories to the PT provider?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 9.0(b)) Does the organization ensure that PT Providers have a reporting mechanism that ensures that the results received by the PT provider are consistent with those submitted by the participant laboratory?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 9.0(c)) Does the organization ensure that PT Providers not delay or lose the results reported by participant laboratories because of the provider's reporting mechanism?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 9.0(d)) Does the organization ensure that PT Providers keep participant laboratory data secure and that they are not subject to unauthorized dissemination either during or after the data have been reported to the PT provider?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 10 – PT Study Data Analysis

Section 10.1 – Data Review

(V3, 10.1.1) Does the organization ensure that PT Providers examine all PT study data sets for bimodal and multi-modal distributions and/or situations where results from a given method have disproportionately large failure rates or reporting anomalies?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.1.2) Does the organization ensure that PT Providers evaluate results on a method-specific basis if a multi-modal distribution is found related to analytical method and acceptance criteria are calculated using robust statistical analysis of participant data?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.1.3) Does the organization ensure that PT providers review all PT study data sets for disproportionately high or low failure rates compared to historical norms?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 10.2 – Acceptance Limit Determination

(V3, 10.2.1) Does the organization ensure that PT Providers calculate acceptance limits per the requirements defined in the TNI Fields of Proficiency Testing Tables?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.2.2) Does the organization ensure that, if there are discrepancies between the PT acceptance limits as determined from the TNI Fields of Proficiency Testing Tables and the requirements in Volume 3, Section 10.2 of the TNI Standards, the analyte- or study-specific evaluation criteria defined in the TNI Fields of Proficiency Testing Tables supersede the criteria in this Section?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.2.3) Does the organization ensure that PT Providers represent acceptance limits following the same significant figure rules as defined for assigned values in Volume 3, Section 6.4 of the TNI Standards?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.2.4) Does the organization ensure that, for acceptance limits calculated using only the PT provider's assigned value (i.e. a fixed percentage limit around the assigned value, regression equation using the assigned value to determine an estimated mean and estimated standard deviation, etc.), the PT provider uses its assigned value and calculate the acceptance limits defined in the TNI Fields of Proficiency Testing Tables?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.2.5) Does the organization ensure that, for acceptance limits calculated using the actual study mean, the PT provider uses the mean as calculated by the following procedures:

(a) for samples sizes of 20 or more values: the biweight mean (per Karen Kafadar, "A Biweight Approach to the One-Sample Problem," *Journal of the American Statistical Association*, Vol. 77, No. 378, June, 1982, pp. 416-424) using 15 iterations with c=4 and c_o=6?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(b) for samples sizes of 7 to 20 values: the arithmetic mean after outlier testing using the T test (see ASTM E178) or other organization-accepted outlier testing procedure, with no more than 20% of the values in any set treated as outliers?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(c) sample sizes of less than 7 values are only evaluated using a statistical procedure approved by the organization?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.2.6) Does the organization ensure that, for acceptance limits calculated using the actual study standard deviation, the PT provider uses the standard deviation as calculated by the following procedures:

(a) for samples sizes of 20 or more values: the biweight standard deviation (per Karen Kafadar, "A Biweight Approach to the One-Sample Problem," *Journal of the American Statistical Association*, Vol. 77, No. 378, June, 1982, pp. 416-424) using 15 iterations with c=4 and c_o=6?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(b) for samples sizes of 7 to 20 values: the standard deviation after outlier testing with the T test (see ASTM E178) or other organization-accepted outlier testing procedure, with no more than 20% of the values in any set treated as outliers?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(c) sample sizes of less than 7 values are only evaluated using a statistical procedure approved by the organization?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.2.7) Does the organization ensure that, for acceptance limits calculated using the actual study median, the PT provider uses the median calculated from all properly reported data points, as defined by the PT Program Executive Committee, in the data set?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 10.3 – Evaluation of Individual Participant Results

(V3, 10.3.1) Does the organization ensure that, if the Assigned Value is greater than "0," the PT Provider evaluates the participant's reported numerical value as "Acceptable" if it is within the established acceptance limits, and evaluates it as "Unacceptable" if the reported value is outside the established acceptance limits or if the numerical value is reported with a less-than sign (<) and the numerical value is less than the lower acceptance limit?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

NOTE: As an example, if the Assigned Value is "10.0", the lower acceptance limit is "5.00" and the upper acceptance limit is "15.0":

(a) Any reported numeric value between 5.00 and 15.0 is evaluated "Acceptable"

(b) Any reported numeric value greater than 15.0 is evaluated "Not Acceptable".

(c) Any reported numeric value less than 5.00 is evaluated "Not Acceptable".

(d) Any numeric value reported with a less than sign (<) is evaluated "Acceptable" if the reported numeric value associated with the less than sign is equal to or greater than the lower acceptance limit. In this example, a reported value of '<5.00' shall be evaluated as "Acceptable" because 5.00 is equal to the lower acceptance limit.

(e) Any numeric value reported with a less than sign (<) is evaluated "Not Acceptable" if the reported numeric values associated with the less than sign is less than the lower acceptance limit. In this example, a reported value of '<4.99' shall be evaluated as "Not Acceptable" because 4.99 is less than the lower acceptance limit.

(V3, 10.3.2) Does the organization ensure that, if the Assigned Value is set to the Proficiency Test Reporting Limit (PTRL) with a less than sign (<) or set to "0", the PT Provider scores the participant's numeric value that is reported with a less than sign (<), a reported value of "0", or a reported numeric value less than the PTRL as "Acceptable"?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

NOTE: As an example, if the assigned value is set to "<2.50" and 2.50 is the PTRL associated with a less-than sign (<):

(a) Any reported numeric value reported with a less than (<) sign is evaluated "Acceptable".

(b) A reported value of zero "0" is evaluated "Acceptable".

(c) A reported numeric value between "0" and 2.50 is evaluated "Acceptable".

(d) A reported numeric value greater than 2.50 is evaluated "Not Acceptable".

(V3, 10.3.3) Does the organization ensure that the PT Provider evaluates a participant's result as "No Evaluation" if it cannot be evaluated (e.g., alpha characters for a quantitative test)?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.3.4) Does the organization ensure that the PT Provider evaluates analytes not reported by the laboratory, but included in a PT sample received from the PT provider, as "Not Reported"?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 10.3.5) Does the organization ensure that, if the PT Provider invalidates an analyte in a PT study, all evaluations for data reported for that analyte are "No Evaluation" and a discussion of the situation leading to the invalidation is included in the final report to participant laboratories and Abs?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 11 – Generation of Study Reports

Section 11.1 – Schedule

(V3, 11.1.1) Does the organization ensure that PT Providers submit the reports defined in Volume 3, Sections 11.2 and 11.3 of the TNI Standards to the required parties no later than twenty-one days after the close of the study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 11.1.2) Does the organization ensure that the PT Providers submit the reports to participant laboratories and laboratory-requested accreditation bodies within the same 24-hour period?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 11.2 – Final Evaluation Report

(V3, 11.2.1) Does the organization ensure that PT Providers submit final evaluation reports to all participant laboratories?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 11.2.2) Does the organization ensure that PT providers submit final evaluation reports to all laboratory accreditation bodies that have been requested by the laboratories to receive reports?

NOTE: Final evaluation reports may be submitted in hardcopy or electronic form.

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 11.2.3) Does the organization ensure that the PT

Providers include the following information in the final evaluation reports:

(a) PT Provider Name?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(b) PT Provider accreditation number?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(c) Participant laboratory name?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(d) Participant laboratory physical address?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(e) Name, title and telephone number of laboratory point of contact, as provided?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(f) Participant laboratory's primary accreditation body ID, as provided?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(g) Study type and study number?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(h) Opening and closing dates of the study?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(i) Date report was prepared?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(j) Date report was amended, if applicable?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(k) Study discussion including any pertinent information which addresses unusual details of the study (e.g., need to change an assigned value or delete an analyte from evaluation)?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 11.2.4) Does the organization ensure that PT

Providers include the following information for each PT sample / analyte in the final evaluation report:

(a) Lot or study number? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(b) Analyte name? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(c) Analyte code defined in the TNI FoPT Tables? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(d) Identification of those analytes included and not included in the PT provider's accreditation? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(e) Assigned value? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(f) Acceptance limits? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(g) Laboratory value, as reported? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(h) Method description, as reported? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(i) Analysis dates as reported by the participating laboratory? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(j) Evaluation, per Volume 3, Section 10.3 of the TNI Standards? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(k) Mean calculated from all study participant data? Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(l) Standard deviation calculated from all study participant Yes ____ No ____ N/A ___

data?

Objective Evidence/Comments:

(V3, 11.2.5) Does the organization ensure that each page of the PT Provider's final evaluation report shall include an indication of the length of the report, presented by either "Page X of Y" or the total number of pages with each page consecutively numbered?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

Section 11.3 – Study Failure Rate Report

(V3, 11.3.1) Does the organization ensure that, upon request by either a participant laboratory or a laboratory accreditation body, the PT provider
makes available a report listing the total number of participating laboratories and the number of laboratories scoring "Not Acceptable" for those analytes reported by the laboratory?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, 11.3.2) Does the organization ensure that the PT Providers not disclose specific laboratory results or evaluations to any parties without a written release from the laboratory?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

(V3, Appendix A.1) Does the organization ensure that PT Providers, in order to satisfy the requirements for the repeatability of test methods used to validate PT samples, determine this repeatability at two or more levels?

Yes ____ No ____ N/A ___
Objective Evidence/Comments:

ATTACHMENT 2: FLOWCHART FOR PTPA EVALUATION PROCESS

(timeframes are approximate only)