

VOTING DRAFT STANDARD

VOLUME 4

GENERAL REQUIREMENTS FOR AN ACCREDITOR OF ENVIRONMENTAL PROFICIENCY TEST PROVIDERS

Description

This Voting Draft Standard is a proposed revision of the 2009 standard (EL-V4-2009). It has been prepared by the TNI Proficiency Testing Expert Committee.

Note. The tracking shows proposed changes from the 2009 standard (EL-V4-2009)

VOLUME 4

GENERAL REQUIREMENTS FOR AN ACCREDITOR OF ENVIRONMENTAL PROFICIENCY TEST PROVIDERS

1.0 INTRODUCTION, SCOPE, AND APPLICABILITY

1.1 Introduction

This Volume provides the requirements for a person or an organization to function as a TNI-approved Proficiency Testing Provider Accreditor (PTPA).

1.2 Scope

The Proficiency Testing (PT) program includes the following elements:

- a) the production and supply of PT samples that challenge the critical components of each analytical procedure, from initial sample preparation to final data analysis;
- ~~b) the production and supply of PT samples that are as similar to real-world samples as are reasonably possible and representative of materials analyzed for environmental regulatory programs, agencies and communities;~~
- b) the yielding of PT data that are technically defensible on the basis of the type and quality of the PT samples provided; ~~and~~
- c) the preparation of PT samples which pose equivalent difficulty and challenge regardless of the manner in which the PT samples are designed and manufactured by the PT providers; ~~and~~
- ~~d) the approval of the PTPA(s) by the Proficiency testing Program Executive Committee (PTPEC)~~

1.3 Applicability

1.3.1 This Volume is applicable to any person or organization seeking to function as a TNI-approved PTPA.

~~1.3.2 Included in this Volume are some of the responsibilities of the TNI PT Board regarding the determination of fields of proficiency testing (FoPT), PT program content, evaluation criteria, and oversight. The PTPEC reviews and approves the PTPA(s) according to documented procedures. The PTPEC also maintains written procedures that describe its responsibilities regarding the determination of fields of proficiency testing (FoPT), PT program content, and evaluation and oversight of the PT program .~~

~~1.3.3 This is not intended as a complete set of requirements or procedures for the PT Board; rather, it is intended to assure (1) that these functions are controlled by the TNI consensus process, and (2) that there is an impartial selection process for the PTPA.~~

1.3.3 These requirements also of this standard apply to the responsibilities of the TNI-approved Accreditation Body (or bodies). ~~These requirements assume that monitoring is an essential part of accreditation, and so the accreditation and monitoring functions are seen as part of the same process. It is also recognized that~~ PTPA(s) to accredit and monitor their respective PT providers to ensure the requirements listed in Volume 3 are consistently met. ~~The~~ PTPA(s) may have other

requirements and mutual recognition agreements that may need to be included in the TNI PT Provider accreditation process. These requirements are outside the TNI consensus process, except that the ~~PT Board~~PTPEC must approve them as applicable to TNI PT Provider accreditations. ~~In addition, these recognitions allow TNI PT providers to offer their services in regions where TNI accreditation may not be recognized.~~

1.3.4 This volume is based on ISO/IEC 17011: 2004(E) Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies. This volume uses the language from ISO/IEC 17011 as written and provides additional requirements unique to the TNI PT Program. The reader must have a valid copy/license of ISO/IEC 17011 to see the entire text.

2.0 NORMATIVE REFERENCES

Not Applicable.

3.0 TERMS AND DEFINITIONS

For the purpose of this Standard, the relevant terms conform with *ISO/IEC 17011:2004(E), Clause 3* and *ISO/IEC 17025:2005(E), Clause 3*, and ISO/IEC 17043:2010. Additional relevant terms are defined below.

- 3.1 Field of Proficiency Testing (FoPT):** ~~Analytes for which a laboratory is required to successfully analyze a PT sample in order to obtain or maintain accreditation, collectively defined as: matrix, technology/method, analyte. Matrix, technology/method, analyte combinations for which the composition, spike concentration ranges and acceptance criteria have been established by the PTPEC.~~
- 3.2 Proficiency Testing (PT):** A means to evaluate a laboratory's performance, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.
- 3.3 Proficiency Testing Program (PT Program):** The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of results and the collective demographics and results summary of all participating laboratories.
- 3.4 Proficiency Testing Provider (PT Provider):** A person or organization accredited as a Conformity Assessment Body by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.
- 3.5 Proficiency Testing Provider Accreditor (PTPA):** ~~A person or~~ organization that is approved by ~~TNI the PTPEC~~ to accredit and monitor the performance of proficiency testing providers.
- 3.6 Proficiency Testing Sample (PT Sample):** A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.
- ~~**3.7 Proficiency Testing Study (PT Study):** A single complete sequence of circulation of proficiency testing samples to all participants in a proficiency test program.~~
- 3.7 Study (or PT Study):** This term refers to a scheduled PT Study or a Supplemental PT Study.
- a) Scheduled Proficiency Testing Study (Scheduled PT Study): A single complete sequence of circulation and scoring of proficiency testing samples to all participants in a

proficiency test program. The study must have the same pre-defined opening and closing dates for all participants.

- b) **Supplemental Proficiency Testing Study (Supplemental PT Study):** A PT sample that may be from a lot previously released by a PT provider that meets the requirements for supplemental PT samples given in this standard but that does not have a pre-determined opening and closing date.

~~3.8 **TNI PT Board (PT Board):** A board consisting of TNI members or affiliates, appointed by the TNI Board of Directors, which is responsible for the successful implementation and operation of the TNI Proficiency Testing Program. The duties of the TNI PT Board are defined in the TNI PT Board Charter.~~

4.0 **REQUIREMENTS FOR ~~PROFICIENCY TESTING BOARD OVERSIGHT OF PT PROGRAMS~~ THE PROFICIENCY TESTING PROGRAM EXECUTIVE COMMITTEE (PTPEC)**

4.1 ~~Fields of Proficiency Testing~~

~~The PT Board shall determine the content of approved PT programs and performance expectations for laboratories. These determinations shall be based on sound technical, professional, and statistical judgment. Content of PT programs, concentration ranges, expected values, and evaluation criteria shall, where appropriate, be consistent with public health needs and best international practices. The purpose of this section is to ensure that the PTPA(s) understand the PTPEC roles and that the PTPEC maintains written procedures describing the requirements of the PTPEC review and approval of the PTPA(s).~~

To this end, the PT Board shall:

4.1.1 ~~Determine the areas to be covered by PT studies, and define all requirements for content, including:~~

- ~~a) the appropriate matrix;~~
- ~~b) measurement technologies;~~
- ~~c) analytes or classes of analytes;~~
- ~~d) required concentration range;~~
- ~~e) proficiency testing reporting limit (PTRL) for each analyte.~~

4.1.2 ~~Determine acceptance limits for each analyte. The tables containing all analyte acceptance limits established by the PT Board shall be publicly available.~~

4.1.3 ~~Review PT data and the acceptance limits at least biennially to revise existing evaluation criteria and establish new criteria, as needed.~~

4.12 **Selection of a PTPA(s)**

The ~~PT Board~~PTPEC shall ~~select~~approve an organization(s) ~~or organizations~~ to serve as a PTPA(s). To accomplish this, the ~~PT Board~~PTPEC shall:

4.2.1a) Assure that the prospective PTPA meets all requirements in Section 5 of this Volume.

4.2.2b) Approve all policies and procedures used by the PTPA for the purposes of accreditation and ~~oversight~~monitoring 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.

~~4.2.3c)~~ Conduct appropriate ~~biennial on-site assessments~~ evaluations of any organization seeking to be a PTPA at a minimum of every four (4) years..

4.32 Determining Evaluation Criteria for Oversight

~~4.3.1~~ The ~~PT Board~~ PTPEC shall determine criteria for the PTPA(s)' ongoing ~~oversight monitoring~~ of PT Provider activities, ~~including activities and objectives for the PTPA review consistent with this Standard.~~

~~4.3.2~~ The PT Board 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.~~ assigned values
 - ~~ii.~~ means and standard deviations
 - ~~iii.~~ number of results
 - ~~iv.~~ information about unsuccessful rates
 - ~~v.~~ any other information requested by the PTPA to meet the requirements of Section 6.3.

~~4.3.3~~ The PT Board shall serve as final arbiter for:

- ~~a)~~ complaints about the PTPA that come from Accreditation Bodies or from PT Providers;
- ~~b)~~ disputes between PTPAs.

5.0 REQUIREMENTS FOR ~~APPROVAL OF~~ A PROFICIENCY TESTING PROVIDER ACCREDITOR

~~These requirements apply to the approval of the accreditation and oversight body. The requirements in this Section can serve as guidance for PT Board procedures for those functions, or as requirements that the PTPA shall meet in order to be approved. The requirements in this Section can serve as guidance for PTPEC procedures for those functions, or as requirements that the PTPA shall meet in order to be approved.~~

5.1 Technical and Administrative Qualifications

5.1.1 An organization shall demonstrate to the ~~PT Board~~ PTPEC that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider accreditation ~~and oversight.~~

5.1.2 The organization shall be recognized by ~~a national or an~~ international cooperation of ~~accrediting accreditation~~ bodies for conformance with ISO/IEC 17011:2004(E) General requirements for accreditation bodies accrediting conformity assessment bodies for the accreditation of ~~environmental~~ laboratories, and shall demonstrate the following:

- a) ~~compliance with ISO/IEC 17011: General requirements for accreditation bodies accrediting conformity assessment bodies;~~ is a signatory of the International Laboratory Accreditation Cooperation (ILAC) or the Asia Pacific Laboratory Accreditation Cooperation (APLAC) mutual recognition arrangement for ISO/IEC 17025, ISO Guide 34 and ISO/IEC 17043.

- bb) have, or have access to, technical expertise that conforms with ISO ~~Guide 3417043~~ and/or ISO 17025 as appropriate, for the preparation and/or analysis of the types of ~~reference proficiency testing~~ materials being prepared by the PT Providers;
- ec) expertise in statistical applications used for interlaboratory comparison programs;
- ed) the capability to conduct on-site audits of PT Providers that are consistent with this Standard;
- ef) the capability to conduct technical reviews of initial applications.

5.2 Responsibilities Regarding Assessment of PT Providers

- 5.2.1 The assessment and monitoring activities of the PTPA shall be designed to ensure that any accredited PT Provider meets the requirements specified in Volume 3 of this Standard.
- 5.2.2 Any variations from these requirements or additions to these requirements shall be approved by the ~~PT Board~~PTPEC prior to use by a PTPA.

5.3 Development of Standard Operating Procedures and Forms

~~The PTPA shall develop procedures to conduct the PT Provider evaluation. These documents shall be based upon the requirements of this Standard.~~

~~5.3.1 The PTPA shall develop and implement procedures including, but not limited to:~~

- ~~a) the initial application submittal and review process;~~
- ~~b) on-site assessment;~~
- ~~c) accreditation process;~~
- ~~d) submittal of oversight information to the PTPA;~~
- ~~e) revoking a PT Provider's accreditation;~~
- ~~f) appealing accreditation determinations.~~

~~5.3.2 The PTPA shall develop procedures for the initial application process to be followed by PT Providers applying for accreditation. The application shall include information about the qualifications of the organization seeking accreditation.~~ 5.3.13 The PTPA's procedures shall 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 PTPA for that activity, product or characteristic. To the extent feasible, the PTPA shall not assess those activities that are so recognized.

~~NOTE:5.3.2~~ By mutual recognition agreement, the PTPA is allowed to find non-conformances in activities that have recognized accreditation.

~~5.3.4 The PTPA shall develop procedures for conducting consistent and effective on-site assessments of PT Providers. The procedures shall include a description of the circumstances for conducting any additional assessments or unannounced assessments.~~

5.3.53 A PTPA shall develop standard, concise and unambiguous checklist(s) to be used during all assessments of PT Providers.

5.4 Development and Maintenance of a Comprehensive PT ~~Database~~Data Management System

5.4.1 The PTPA shall maintain a comprehensive PT ~~database~~data management system that contains ~~summaries of participant results~~PT Study summary data and results of all verification, homogeneity, and stability determinations. ~~The system shall allow for collection, storage, analysis and reporting of the PT Study summary data.~~

- 5.4.2 The PTPA shall instruct PT Providers on procedures for submitting data to the ~~database~~PTPA for ongoing monitoring.
- ~~5.4.3 PTPAs shall verify that PTPs have the means to provide (or upload) data to the TNI server, upon PTPEC's request.~~
- ~~5.4.4 PTPAs shall verify that PTPs comply with PTPEC's request for data.~~

5.5 List of Accredited PT Providers

- ~~5.5.1~~ The PTPA shall maintain a list of accredited PT Providers and the FoPTs for which they are accredited ~~to provide~~. The list shall be maintained on a continuing basis, on an electronic bulletin board or similar means, and shall be readily available to laboratories seeking accreditation, Accreditation Bodies, and other interested parties.

~~5.5.2 The PTPA shall ensure that all accredited PT Providers abide by the provisions of the PT Board and PTPA regarding the advertising and marketing of their accreditation approval status.~~

~~5.6 PTPA Ethics~~

~~5.6.1 A PTPA shall serve as an impartial body designed to objectively evaluate information about PT Providers and use this information to make sound determinations regarding a provider's accreditation status.~~

~~5.6.2 A PTPA shall be able to demonstrate to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of this Standard.~~

~~5.6.3 A PTPA shall remain unbiased in evaluating information gathered and received including assessment reports, referee sample results, complaints, and any other information obtained regarding a PT Provider.~~

~~5.6.4 The PTPA shall evaluate all information about a PT Provider related to providing PT programs, determine which information is relevant to the PT Provider's accreditation status, and provide that information to the appropriate parties, consistent with all confidentiality agreements.~~

~~5.7 Confidentiality~~

~~5.7.1 A portion of the information provided to a PTPA by the PT Provider in the course of its assessment and oversight activities shall be proprietary in nature. A PTPA shall agree to maintain the confidentiality of proprietary information provided to it by the PT Providers.~~

~~5.7.2 The PTPA shall treat all 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 this Standard. This information shall not be released without prior written permission from the PT Provider.~~

6.0 REQUIREMENTS FOR ACCREDITATION OF PT PROVIDERS

In addition to ISO 17011 the following are requirements for the PTPAs.

The accreditation process shall be repeated at a minimum of every ~~two~~ four (4) years, and shall include all stages of initial review, on-site assessment and monitoring.

Timelines for application review, conducting assessments, and follow-up activities shall not cause undue delay in processing a request for accreditation.

PTPAs shall upon request (by PTPEC) conduct a presentation at the PTPEC meeting during one of TNI's semi-annual forums.

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

6.1 Initial Application Review

The PTPA shall conduct the reviews described in this Section for the applications from any candidate or renewal PT Provider. This review shall include:

- a) the initial application documents for compliance with the PT Provider qualifications described in ~~this Standard~~ this Volume 3;
- b) the sample designs used by the PT Provider for compliance with ~~this Standard~~ this Volume 3;
- c) the PT analyte and sample scoring procedures used by the PT Provider for compliance with this ~~Standard~~ Volume 3;
- d) shall have procedures used to validate that new PT sample formulations are fit for their intended purpose within the specified ranges per the approved TNI FoPT tables for the relevant technologies, prior to use of such material in a PT scheme. ~~This review shall ensure, at a minimum, that samples have assigned values within the specified ranges for every technology used to report results;~~
- e) the adequacy of data processing and analysis techniques, including statistical procedures used on sample sets with fewer than 20 laboratories;
- f) confirmation of the absence of conflicting interests with subscribing laboratories, including:
 - i any financial interest in a laboratory seeking or having accreditation to ~~this Standard~~ Volume 1;
 - ii the sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, accreditation to ~~this Standard~~ Volume 1.
- g) providing PT Providers with checklist(s) to be used during the assessment as part of the initial application process. The checklist shall include all requirements that may be necessary for the PTPA to comply with their own policies and external agreements.

6.2 On-Site Assessment

6.2.1 An on-site assessment of the PT Provider shall follow the initial review and shall include, at a minimum:

- ~~a) a review of the quality management system for adherence to the requirements of this Standard;~~
- ba) a review of staff qualifications and technical expertise necessary to produce acceptable PT samples;

- ~~eb)~~ a review of the sample manufacturing and analytical verification procedures, along with the study data, to ensure the requirements of ~~this Standard~~Volume 3 are met;
- ~~ec)~~ a review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for PT Providers and confidentiality of assigned values and participant results;
- ~~ed)~~ a review of data reporting systems to ensure that the requirements of ~~this Standard~~Volume 3 are met within the defined time periods; ~~and~~

~~f) an exit meeting, which shall include delivery of the final report from the assessment and a discussion of all assessment findings.~~

~~6.2.2 The PTPA shall provide a written final report to the PT Provider during the exit briefing. The final report may only contain findings identified during the on-site assessment and discussed during the exit briefing, as defined in the PTPA's procedures.~~

~~6.2.3 The PTPA shall allow the PT Provider to submit its response to the report. In order for the PT Provider's response to be considered acceptable, it shall include a description of any corrective actions necessary to meet the criteria of this Standard, and, as appropriate, objective evidence of successful implementation of any corrective action.~~

~~6.2.4 A PTPA shall follow its procedure for determining accreditation. This procedure shall include use of the appropriate final assessment report and associated documents submitted by the PT Provider.~~

6.3 Responsibilities for Ongoing Monitoring of PT Providers

6.3.1 A PTPA shall conduct ongoing monitoring of all accredited PT Providers. This shall include a review of sample verification and PT study data to assure that every PT sample meets criteria defined in ~~this Standard~~ this Volume 3. The review shall also include:

- ~~a) assurance that concentrations are distributed throughout the specified analyte ranges; the evaluation of the distribution of the study concentrations to identify potential bias in the manufacturing process and the assigned values are within the specified analytical 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.

~~6.3.2 The PTPA shall 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. The PTPA shall monitor pass/fail rates per the PTPEC. The PTPA shall investigate pass/fail rates that deviate from criteria established by the PTPEC. The~~

PTPA shall notify the PT Provider of pass/fail rate deviations and monitor associated corrective actions taken by the PT provider.

- 6.3.3 The PTPA may use 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.
- The determination of unacceptable quality shall 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).~~ .
 - The PTPA shall provide each PT Provider with a report describing the results for any required referee analyses.
- 6.3.4 The monitoring shall provide verification of the PT Provider's adherence to the appropriate standards for the following:
- correct and complete analyte lists as per PT provider accreditation;
 - a process for handling complaints;
 - compliance with defined nomenclature (codes) for methods, analytes and technologies;
 - appropriate study lengths, including announced open and close dates;
 - timeliness of reports to participants, Accreditation Bodies and the PTPA.
- 6.3.5 PTPA monitoring shall 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.
- 6.3.6 Unscheduled on-site assessments of the PT Provider may be conducted for exceptional circumstances, such as persistent complaints from participants or Accreditation Bodies, failure to adequately respond to inquiries from the PTPA, or other evidence of persistent non-conforming activity. The causes and resolution of exceptional visits shall be fully documented.
- 6.3.7 Any possible problems indicated by the monitoring shall be discussed first with the PT Provider. Complete records shall be maintained of all contacts and responses from the PT Provider.
- 6.3.8 Based upon the results of its ongoing monitoring and its internal appeals process, the PTPA may determine that a PT Provider's accreditation status should be suspended or withdrawn.

~~6.4 — Complaints and Corrective Action~~

~~6.4.1 — The PTPA shall evaluate all complaints that it receives regarding accredited or candidate PT Providers. If the PTPA determines that a complaint warrants investigation, it shall notify the PT Provider of the complaint. The PT Provider is required to resolve the complaint to the satisfaction of the PTPA.~~

~~6.4.2 — The PTPA shall provide to the PT Board a summary of all PT Provider complaints received the previous year.~~

~~6.4.3 — Complaints made to PT Providers and the resultant corrective actions shall be reviewed by the PTPA in the following manner:~~

~~—— a) ——— review of a written summary of all complaints regarding the technical aspects of the studies and the resulting corrective actions; and~~

~~—— b) ——— review of all complaints that are unresolved after ninety (90) days.~~

~~6.4.4 — The PTPA shall review any complaints about PT Providers received from Accreditation Bodies, and work with the PT Provider, the Accreditation Body, and the PT Board to resolve the complaints.~~

~~6.5 — Suspension or Revocation of PT Provider Accreditation~~

~~6.5.1 — Based on their review of study data, onsite assessments and corrective actions associated with complaints or other non-conformances, the PTPA may determine that a PT Provider fails to meet the requirements of this Standard on a continuing basis.~~

~~6.5.2 — The PTPA shall provide formal written notice to a PT Provider of any action to revoke or suspend the PT Provider's accreditation for any reason.~~

~~6.5.3 — The PTPA shall inform the PT Provider of the reasons for proposed revocation or suspension and the procedures for appeal of such a decision.~~

~~6.5.4 — The PTPA shall 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 PT Board after completion of the PTPA's appeals process.~~