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.

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 yielding of PT data that are technically defensible on the basis of the type and quality of the PT samples provided;

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 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 The requirements of this standard apply to the responsibilities of the TNI-approved 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 PTPEC must approve them as applicable to TNI PT Provider accreditations.

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**)**:** 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 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 **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.

4.0 REQUIREMENTS FOR THE PROFICIENCY TESTING PROGRAM EXECUTIVE COMMITTEE (PTPEC)

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).

4.1 Selection of a PTPA(s)

The PTPEC shall approve an organization(s) to serve as PTPA(s). To accomplish this, the PTPEC shall:

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

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

c) Conduct appropriate evaluations of any organization seeking to be a PTPA at a minimum of every four (4) years..

4.2 Determining Evaluation Criteria

The PTPEC shall determine criteria for the PTPA(s)' ongoing monitoring of PT Provider activities.

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5.0 REQUIREMENTS FOR A PROFICIENCY TESTING PROVIDER ACCREDITOR

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 PTPEC that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider accreditation.

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

a) 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.

b) have, or have access to, technical expertise that conforms with ISO 17043 and/or ISO 17025 as appropriate, for the preparation and/or analysis of the types of proficiency testing materials being prepared by the PT Providers;

c) expertise in statistical applications used for interlaboratory comparison programs;

d) the capability to conduct on-site audits of PT Providers that are consistent with this Standard;

f) 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 PTPEC prior to use by a PTPA.

5.3 Development of Standard Operating Procedures and Forms

5.3.1 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.

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

5.3.3 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 Data Management System

5.4.1 The PTPA shall maintain a comprehensive PT data management system that contains 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 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

The PTPA shall maintain a list of accredited PT Providers and the FoPTs for which they are accredited. 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.

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 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.

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 Volume 3;

b) the sample designs used by the PT Provider for compliance with this Volume 3;

c) the PT analyte and sample scoring procedures used by the PT Provider for compliance with this 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.

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 Volume 1;

   ii the sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, accreditation to 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 staff qualifications and technical expertise necessary to produce acceptable PT samples;

b) a review of the sample manufacturing and analytical verification procedures, along with the study data, to ensure the requirements of Volume 3 are met;

c) 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;

d) a review of data reporting systems to ensure that the requirements of Volume 3 are met within the defined time periods.

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 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 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.

a) The determination of unacceptable quality shall use the same acceptance criteria that were used in the manufacture of the PT sample. .

b) 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:

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 open and close dates;
e) 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.