TNI STANDARD

VOLUME 4

GENERAL REQUIREMENTS FOR AN ACCREDITOR OF ENVIRONMENTAL PROFICIENCY TEST PROVIDERS

July 2016

Description

This Final TNI Standard has been taken through all of the voting stages and has received consensus approval by the TNI membership.

Shown through tracking are the final changes made as a result of persuasive voters' comments on the Interim Standard.

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 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) per PTPEC requirements document.

1.3 Applicability

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

1.3.2 The PTPEC reviews and approves the PTPA 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 to accredit and monitor its respective PT Provider(s) to ensure the requirements listed in Volume 3 are consistently met. The PTPA 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 17011:2004 (E) ~~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 17011:2004(E) 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 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):** An 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 where the study has 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 Volume 3 of 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)

4.1 Selection of a PTPA

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

a) ensure that the prospective PTPA meets all requirements in Section 5 of this Volume;

b) evaluate conformance of the PTPA's documented procedures to the requirements set forth in this Volume and the relevant requirements of ISO/IEC 17011; and

c) conduct appropriate evaluations of any organization seeking to be a PTPA at a minimum of every four (4) years. Timelines for application review, conducting assessments, and follow-up activities shall not cause undue delay in processing a request for accreditation.

4.2 Determining Evaluation Criteria

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

5.0 Requirements for a Proficiency Testing Provider Accreditor

In addition to ISO/IEC 17011:2004 (E) ~~ISO 17011~~ the following are requirements for the PTPA.

5.1 Technical and Administrative Qualifications

5.1.1 The PTPA 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 17025:2005, ISO Guide 34, and ISO/IEC 17043;

b) has expertise in statistical applications used for interlaboratory comparison programs; and

c) has the capability to conduct on-site audits of PT Providers that are consistent with this Standard.

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 A PTPA shall develop a standard, concise and unambiguous checklist(s) to be used by the PTPA 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 the PT Provider on procedures for submitting data to the PTPA for ongoing monitoring.

5.4.3 The PTPA shall verify that the PT Provider has the means to provide (or upload) data to TNI upon PTPEC's request and that such requests are being met per Section 5.10.4 of Volume 3.

5.5 List of Accredited PT Providers

The PTPA shall maintain a list of its accredited PT Providers and each FoPT for which they are accredited.

5.6 Additional Requirements

The PTPA shall, upon request by PTPEC, conduct a presentation at the PTPEC meeting during TNI forums.

a) The presentation, at a minimum, shall include:

i. list of PT Providers – additions, withdrawals, renewal status;

ii. number of complaints received – status (still open, closed, in progress), complaint type or category (e.g., deliverables, TAT, responsiveness, etc.);

iii. summary of fail rates for PT studies – a list of PTs that have historical (past 2-3 years) fail rates of >10%, including a discussion of possible biases to fail rates such as PT studies with low numbers of participants.

b) Upon request by PTPEC, such presentation shall be submitted to PTPEC.

6.0 PTPA Requirements for Assessment and Accreditation of PT Providers

In addition to ISO/IEC 17011:2004 (E) the following are requirements for the PTPA.

PT Provider assessments and accreditations shall occur approximately every 2 years, with an annual quality systems surveillance assessment between on-site assessments.

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

6.1 Initial or Renewal 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 Volume 3;

b) 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; and

c) providing the PT Provider with checklist(s) to be used during the assessment as part of the initial or renewal application process. The checklist shall include all requirements that may be necessary for the PTPA to comply with its own policies and external agreements.

6.2 During Document Review and/or On-Site Assessment

In addition to the ISO/IEC 17011:2004 (E) ~~ISO 17011~~ requirements, the document review and/or the on-site assessment shall include a review of the following:

a) staff qualifications and technical expertise necessary to produce acceptable PT samples;

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

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

d) the PT analyte and sample scoring procedures used by the PT Provider for compliance with Volume 3;

e) procedures used to validate that new PT sample formulations are fit for their intended purpose, and are manufactured within the specified ranges per the approved TNI FoPT tables, prior to use in a PT scheme;

f) the adequacy of data processing and analysis techniques, including statistical procedures used on sample sets with fewer than 20 laboratories;

g) the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for the PT Provider and confidentiality of assigned values and participant results; and

h) 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 ensure that every PT sample meets criteria defined in 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) verification of the appropriate documentation and technical reasoning applied to adjustments to the initial assigned values;

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 The causes and resolution of extraordinary on-site assessments of the PT Provider shall be fully documented.

6.3.6 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.

6.3.7 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.