

Draft Final Standard

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Description

The Interim Standard was published for voting through August 21, 2015. It has now been modified in response to persuasive comments from voters to become the Final Standard.

The changes from the Interim Standard, in response to persuasive comments, are shown through tracking.

This standard is in draft form pending formatting and any minor editing that will not result in substantive changes to the standard.

VOLUME 2, MODULE 2

Proficiency Testing

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VOLUME 2, MODULE 2

Proficiency Testing

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

1.1 Introduction

Volume 2, Module 2 provides the requirements for a Primary Accreditation Body (AB) to ensure an accredited laboratory or a laboratory seeking accreditation meets the proficiency testing requirements set forth in this Standard.

1.2 Scope

The purpose of the TNI Proficiency Testing program (PT Program) is to provide a means for a primary AB to evaluate a laboratory's performance, under specified conditions relative to given set of criteria in a specific area of testing, through analysis of proficiency testing (PT) samples provided by an external source.

1.3 Applicability

1.3.1 Volume 2, Module 2 is applicable to any accreditation body (AB) that uses this Standard as the basis for accreditation of laboratories regardless of the number of personnel or the extent of testing performed by that laboratory.

1.3.2 This standard applies only to fields of accreditation (FOA) that are associated with fields of proficiency testing (FoPT) designated by the TNI Proficiency Testing Program Executive Committee (PTPEC).

2.0 NORMATIVE REFERENCES

Not applicable.

3.0 TERMS AND DEFINITIONS

For the purpose of this Standard, the relevant terms and definitions conform to *ISO/IEC 17011:2004* and *ISO/IEC 17025:2005*. Additional relevant terms are defined below.

3.1 Accreditation Body: The organization having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program.

3.2 Field of Accreditation: Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

3.3 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 Proficiency Testing Program Executive Committee.

3.4 Primary Accreditation Body (Primary AB): The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

- 3.5 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.
- 3.6 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.
- 3.7 Proficiency Testing Provider (PT Provider):** A person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.
- 3.8 Proficiency Testing Provider Accreditor (PTPA):** An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.
- 3.9 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.
- 3.10 PT Study Closing Date:**
- **Scheduled PT Study:** The calendar date by which all laboratories must submit analytical results for a PT sample to a PT Provider
 - **Supplemental PT Study:** The calendar date a laboratory submits the results for a PT sample to the PT Provider.
- 3.11 PT Study Opening Date:**
- **Scheduled PT Study:** The calendar date that a PT sample is first made available to all participants of the study by a PT provider.
 - **Supplemental PT Study:** The calendar date the PT Provider ships the sample to a laboratory.
- 3.12 Revocation:** The total or partial withdrawal of a laboratory's accreditation by an Accreditation Body.
- 3.13 Secondary Accreditation Body (Secondary AB):** An accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of accreditation from a Primary Accreditation Body for the same field of accreditation.
- 3.14 Study (or PT Study):** This term refers to a Scheduled PT Study or a Supplemental PT Study.
- **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.
 - **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 date and closing date.

- 3.15 Suspension:** The temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six (6) months or the period of accreditation, whichever is ~~shorter~~**longer**, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.

4.0 ACCREDITATION BODY REQUIREMENTS

4.1 Primary Accreditation Body (Primary AB)

- 4.1.1 The Primary AB shall require laboratories to meet the proficiency testing requirements as specified in Volume 1 Module 1 of this Standard.
- 4.1.2 The Primary AB shall review the evaluation report issued by a PT Provider to verify the laboratory has met the PT requirements set forth in this Standard within sixty (60) calendar days of receipt of the report from the PT Provider.
- 4.1.3 The Primary AB shall only accept PT Study reports that come directly from the PT Provider as directed by the environmental laboratory.
- 4.1.4 The Primary AB shall accept only those PT Study results that meet the requirements of Volume 1 Module 1 and Volume 3 of this Standard.
- 4.1.5 The Primary AB shall have procedures in place to:
- a) receive final evaluation reports from any PTPA-accredited PT Provider;
 - b) assess a laboratory to ensure that the analysis of PT samples is performed in accordance with the requirements set forth in this Standard;
 - c) evaluate final evaluation reports as specified in this Standard;

Note: "Acceptable" PT study scores from a PT Provider do not automatically result in a successful evaluation of a PT study by an AB. For example, failure to report an analytical method or reporting of an incorrect method, failure to provide the PT Provider with a release of results to the AB before the close of the study, failure to report results to the PT Provider before the closing date, failure to handle PT study samples in the same manner as real environmental samples, etc. may be cause for an unsuccessful evaluation by an AB.

- d) deny, suspend or revoke a laboratory's accreditation when the laboratory has not met the requirements of the PT program as specified in this Standard;
- e) evaluate that the laboratory performed and implemented corrective action for failed PT Studies;
- f) maintain the current accreditation status of laboratories in their program in the National Database, also known as the Laboratory Accreditation Management System (LAMS); and
- g) notify all Secondary ABs of revocation of accreditation of any laboratory in their program.

4.2 Secondary Accreditation Body (Secondary AB)

4.2.1 ~~The Secondary AB shall have procedures in place to communicate with the Primary AB and update a laboratory's accreditation status based on the accreditation granted by a Primary AB.~~

~~4.2.2~~ The Secondary AB may choose to evaluate secondary accredited and applicant laboratories' PT study results and grant, deny, suspend, or revoke a laboratory's accreditation as if it were the Primary AB. A Secondary AB that chooses to evaluate a secondary applicant's PT studies and make accreditation changes based on this evaluation must evaluate all secondary applicants' PT Studies in accordance with the requirements established in Volume 1 Module 1 and Volume 2 Module 2 of this Standard, and must have procedures in place to contact the Primary AB to verify their evaluation prior to taking action on a laboratory.

~~4.2.3~~4.2.2 The Secondary AB shall not impose additional proficiency testing requirements for FOPT's covered by the Standard as a requisite for initial or continued NELAP accreditation.

5.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

5.1 Complaints relating to PT Providers

5.1.1 The AB shall submit questions about PT samples or performance evaluations made by the PT Provider to the PT Provider. If the PT Provider is unable or unwilling to resolve the questions, the Primary AB shall refer those questions to the PT Provider's PTPA.

5.1.2 If the AB discovers or is otherwise notified that the PT Provider did not follow the scoring criteria specified in Volume 3 of this Standard, the AB shall report their findings to the PT Provider (see 5.1.1).

5.1.3 If the AB discovers that the laboratory analyzed QC standards that a PT Provider suggested or directed a laboratory to purchase with the PT study samples for the purpose of improving the laboratory's performance for a given PT sample or that the PT Provider has given the laboratory analysis instructions beyond those specified in this Standard, the AB shall report the results of their findings to the PT Provider's PTPA.

5.1.4 The ~~Primary~~ AB shall have procedures to resolve a laboratory's questions related to the validity of a not acceptable evaluation for a FoPT in any PT sample or when the validity of an entire study from a PT Provider may be questionable based on complaints, failure rates or data provided by the PT Provider.

6.0 SUSPENSION OR REVOCATION OF ACCREDITATION

6.1 Suspension

6.1.1 The AB ~~may~~shall follow its established procedures to suspend a laboratory's accreditation for a field of accreditation when:

- a) the laboratory fails two (2) out of the most recent three (3) PT studies attempted for a particular field of accreditation, when participation is required for a particular FoPT as established by Volume 1 Module 1 of this Standard; or
- b) the laboratory fails to provide a corrective action report to the AB within thirty (30) calendar days of a request from the AB.

6.2 Revocation

~~6.2.1~~ The AB ~~may~~ shall follow its established procedures to revoke a laboratory's accreditation for a field of accreditation when:

- a) the laboratory fails three (3) consecutive PT Studies, either by failure to participate in the required PT Study or due to failure to obtain acceptable results, for the same field of accreditation;
- b) a laboratory violates the provisions outlined in Volume 1 Module 1 Sections 4.1.4 – 4.1.7 of this Standard; or
- c) The laboratory has not satisfied the accreditation requirements causing the suspension, during the period of suspension.

6.3 Reinstatement of Accreditation

6.3.1 The AB shall re-instate the accreditation of a laboratory whose accreditation is suspended, as specified in section 6.1.~~4~~a when the laboratory establishes a history of two (2) successful PT study results out of the most recent three (3) attempts for the particular field of accreditation, as specified in Volume 1 Module 1 of this Standard.

6.3.2 The AB shall re-instate the accreditation of an environmental laboratory whose accreditation was suspended as specified in section 6.1.~~4~~b when the laboratory provides the corrective action report for the failed PT study and the Primary AB determines that corrective action acceptable, provided the laboratory meets the requirements for continued accreditation.

6.3.3 The AB shall re-instate the accreditation of an environmental laboratory whose accreditation is revoked as specified in section 6.2, when the laboratory meets the requirements for initial accreditation, as specified in Volume 1 Module 1 of this Standard and the Primary AB's requirements for re-accreditation.

Note: The AB may have regulatory processes for revocation, suspension, and reinstatement of accreditation that supersede the conditions of this Standard.