
Modified Voting Draft Standard

EL-V2M2

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Description

The Voting Draft Standard was published for voting through October 15, 2014. It has now been modified in response to persuasive comments from voters. This modified version is presented to allow any Member to change his/her vote after reviewing the changes.

The changes from EL-V2M2-2009-Rev1.1 are shown through tracking, and the further modifications made as a result of persuasive voters' comments are highlighted.

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 ~~that shall be used by an accreditation body for a Primary Accreditation Body~~ (AB) to ~~assess aensure an accredited~~ laboratory ~~or a laboratory seeking accreditation~~ to ~~meets~~ the proficiency testing requirements set forth in this Standard.

1.2 Scope

The ~~purpose of the~~ TNI Proficiency Testing program (PT Program) is ~~established~~ to provide ~~a means~~ for a primary ~~accreditation body (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, yielding PT data that are technically defensible on the basis of the type and quality of the PT samples provided.~~

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 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).~~

~~This Standard does not apply to fields of accreditation that are not designated as fields of proficiency testing (FoPT) 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 ~~**Analysis Date:** The calendar date of analysis associated with the analytical result reported for an accreditation or experimental field of proficiency testing.~~

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

~~The territorial, state or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program.~~

- [sch1]

~~3.2 **Experimental Field of Proficiency Testing (Experimental FoPT):** Analytes for which a laboratory is required to analyze a PT sample if they seek or maintain accreditation for the field of accreditation, but for which successful analysis is not required in order to obtain or maintain accreditation.~~

~~**Accreditation Field of Proficiency Testing:** 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, and analyte.~~

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

3.4 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, and analyte.~~ 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.

3.5 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.

3.6 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.

3.7 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.

3.8 Proficiency Testing Provider (PTP): A person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

3.9 Proficiency Testing Provider Accreditor (PTPA): An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.

3.10 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.

~~3.11 **Proficiency Testing Study (PT Study):** A single complete sequence of circulation of proficiency testing samples to all participants in a proficiency test program.~~

3.1211 PT Study Closing Date:

- ~~**Scheduled PT Study:** The calendar date by which all participating laboratories must submit analytical results for a PT sample to a PT Provider. The calendar date for which analytical results for a PT sample shall be received by the PT provider from the laboratory.~~ all participating 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.~~

3.1312 PT Study Opening Date:

- **Scheduled PT Study:** The calendar date that a PT sample is first made available to ~~any~~ laboratory ~~all participants of the study~~ by a PT provider.
- **Supplemental PT Study:** The calendar date the PT Provider ships the sample to a laboratory.

3.13 Revocation: The total or partial withdrawal of a laboratory's accreditation by an Accreditation Body.

3.14 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.

3.15 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 must have~~ has the same pre-defined opening and closing dates for all participants.
- **3.16 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.

~~3.17 Supplemental PT Study Closing Date:~~ The calendar date for which analytical results for a PT sample shall be received by the PT provider from the laboratory.

~~3.18 Supplemental PT Study Opening Date:~~ The calendar date that a PT sample is shipped from the PT provider to a laboratory.

~~3.16 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 ~~longer~~ shorter, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.

~~3.19 TNI 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.

~~3.20 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 longer, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.

~~3.21 Revocation:~~ The total or partial withdraw of a laboratory's accreditation by an accreditation body.

4.0 ACCREDITATION BODY REQUIREMENTS

4.1 Primary Accreditation Body (Primary AB)

- 4.1.1 The Primary AB shall ~~ensure the laboratory meets~~ require laboratories to meet the proficiency testing requirements as specified in Volume 1 Module 1 of this Standard. ~~for initial and continued accreditation as specified in this Standard. In this capacity the Primary AB shall have procedures in place to:~~
- 4.1.2 ~~The Primary AB shall review the evaluation report issued by a PTP 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 PTP.~~
- 4.1.3 ~~The Primary AB shall only accept PT Study reports that come directly from the PTP 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 PTP 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. 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 release the 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 the AB.

- d) deny, suspend or revoke a laboratory's accreditation when the laboratory has not met the requirements of the ~~proficiency testing~~ PT program as specified in this Standard;
 - e) ~~evaluate that the laboratory performed and implemented corrective action for failed PT Studies and;~~
 - ef) maintain the current accreditation status of laboratories in their program in the National Database, also known as the Laboratory Accreditation Management System (LAMS), maintain the current accreditation status of laboratories in their program in the National Database, when the database is established;
 - fg) notify all Secondary ABs of revocation of accreditation of any laboratory in their program. ~~notify all Secondary ABs of revocation of accreditation of any laboratory in their program.~~
- 4.1.2 ~~The Primary AB shall allow a laboratory to withdraw from a study for any FoPT on or before the close date of the study. Withdrawing from a study shall not exempt the laboratory from meeting the semi-annual analysis requirement necessary for continued accreditation.~~

~~4.1.3 — The Primary AB shall accept evaluation reports from any PTPA-accredited PT Provider.~~

~~4.1.4 — The Primary AB shall accept results from non-PTPA-accredited PTPs when the FoPT is not available from any accredited PTP.~~

4.2 Secondary Accreditation Body (Secondary AB)

~~4.2.1 — The Secondary AB shall accept the assessment decisions made by the Primary AB regarding a laboratory's performance and compliance with the proficiency testing requirements set forth in this Standard.~~

~~4.2.1 — The Secondary AB shall have procedures in place to evaluate and 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 contact the Primary AB to confirm and verify their evaluation prior to taking action on a laboratory.~~

~~4.2.2.3 — 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. The Secondary AB shall not impose additional requirements for proficiency testing that are not included in this Standard as a requisite for initial or continuing accreditation.~~

5.0 REQUIREMENTS FOR ACCREDITATION

5.1 Initial Accreditation

~~The Primary AB shall require that a laboratory seeking initial accreditation for a field of accreditation successfully analyze two (2) PT samples for the corresponding FoPT for which the laboratory seeks accreditation.~~

~~5.1.2 — The Primary AB shall require that the PT samples for initial accreditation be obtained from any PTPA-accredited PT provider as part of a TNI-compliant PT study, unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.~~

~~5.1.3 — The analysis date of the PT samples for an accreditation FoPT shall be no more than eighteen (18) months prior to the application date for accreditation, with the analysis date of the most recent PT sample for an accreditation FoPT having been no more than six (6) months prior to the application date for accreditation.~~

~~5.1.4 — There shall be at least fifteen (15) calendar days between the analysis dates of successive PT samples for the accreditation FoPT.~~

~~NOTE 1: The requirements for successful performance are described in Section 6.0.~~

~~NOTE 2: The requirements for supplemental PT samples are specified in Volume 3 of this Standard.~~

~~NOTE 3: The TNI PT Board maintains the official listing of FoPT and experimental FoPT on the TNI website.~~

5.2 Continued Accreditation

~~5.2.1 In order to maintain accreditation, the Primary AB shall have procedures in place that track the following requirements:~~

- ~~a) The laboratories analyze at least two (2) TNI-compliant PT samples per year for each accreditation FoPT for which the laboratory holds accreditation with the Primary AB.~~
- ~~b) The laboratories maintain a history of at least two (2) successful performances out of the most recent three (3) PT samples analyzed for the same accreditation FoPT.~~
- ~~c) The laboratories obtain PT samples from any PTPA accredited PTP unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.~~
- ~~d) Ensure that the analysis dates of successive PT samples for the same accreditation FoPT are at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive PT samples for the same accreditation FoPT shall be at least fifteen (15) days apart.~~
- ~~e) Whole Effluent Toxicity testing laboratories shall analyze at least one (1) TNI-compliant PT sample per calendar year for each accredited FoPT for which the laboratory holds accreditation with the primary AB. The primary AB shall require corrective action when a PT study has been failed. Corrective action shall include:~~

~~i. A written corrective action report;~~

~~ii. A copy of the raw data used for the study;~~

~~iii. A copy of the current Standard Reference Toxicant (SRT) control chart relevant to the PT study, and~~

~~iv. Other documentation the laboratory deems necessary to support the conclusions of the report.~~

~~f) For Whole Effluent Toxicity Testing fields of proficiency testing, the study closing date for non-DMR-QA Studies shall be no more than ninety (90) calendar days after the opening date of the study. For DMR-QA Studies, the laboratory must meet the time frames as stated in the Announcement letter.~~

~~5.2.2 When PT samples are not available for the FoPT from any PTPA recognized PT provider at least twice per year, the Primary AB shall require the laboratory to analyze the PT samples in the minimum time frame in which the PT samples are available from any PTPA recognized PT provider.~~

~~5.2.3 If the laboratory holds accreditation that is designated an experimental FoPT, the primary AB shall require the laboratory to analyze two (2) PT samples for the experimental FoPT per year using the same time frames specified for accreditation FoPT. However, successful performance of the experimental PT is not a requisite for initial or continued accreditation.~~

~~NOTE: A Primary AB may specify the month(s) in which laboratories within its accreditation authority shall participate in PT studies and if the Primary AB chooses to specify such, then the Primary AB shall adhere to the semi-annual schedule.~~

~~6.0 REQUIREMENTS FOR ASSESSMENT OF PT SAMPLE ANALYSIS~~

~~6.1 The Primary AB shall assess the laboratory to ensure that PT samples are tracked, prepared, and analyzed in the same manner as routine samples.~~

~~The Primary AB shall require the laboratory demonstrate through their records that:~~

- ~~a) PT samples are tracked through the laboratory in the same manner as routine samples;~~
- ~~b) PT samples are prepared according to the PT provider's instructions and subsequently handled as a routine sample;~~
- ~~c) PT samples are analyzed under the same analytical conditions and instrument calibrations as used for routine samples;~~
- ~~d) the type, composition, concentration, and frequency of quality control samples analyzed with the PT samples are the same as with routine samples;~~
- ~~e) PT samples are not analyzed multiple times unless routine samples are analyzed multiple times and results from multiple analyses are calculated in the same manner as routine samples;~~
- ~~f) the laboratory has procedures in place for the analysis of environmental and PT samples when the concentration range of the samples is outside of its normal range of measurement;~~
- ~~g) the laboratory has performed corrective action for any unacceptable evaluation received from the PT provider for any FoPT.~~

~~6.2 If a Primary AB discovers that a PTP has suggested or directed a laboratory to purchase QC standards that are specifically designed for a given PT sample or that the PT provider has given the laboratory analysis instructions beyond those specified in this Standard, the Primary AB shall report the results of their findings to the PTP's PTPA.~~

~~6.3 The Primary AB shall allow the laboratory to analyze the same PT sample using different technologies and/or multiple test methods for any FoPT. If a laboratory reports more than one test method per technology per FoPT, an unacceptable score for either test method shall result in an unacceptable score for both test methods for that FoPT.~~

~~7.0 REQUIREMENTS FOR ASSESSMENT OF FINAL EVALUATION REPORTS~~

~~The Primary AB shall complete the assessment of the final evaluation report within sixty (60) days of receipt of each study report and determine the accreditation status for any field of accreditation for which Not-acceptable evaluations were assigned for the corresponding FoPT.~~

~~7.2 The Primary AB shall consider the analytical result for a FoPT acceptable when the result reported by the laboratory for a FoPT is evaluated acceptable by the PT provider.~~

~~7.3 The Primary AB shall consider the analytical result for a FoPT not acceptable when:~~

- ~~a) the result reported by the laboratory does not meet the criteria for "acceptable" as specified in V3, Section 10.3 and associated subsections of this Standard. If the criteria in V3, Section 10.3 are met, and the result for the FoPT was scored "not acceptable" by the PTP, the AB shall overturn the performance evaluation and score the analytical result "acceptable";~~
- ~~b) the laboratory does not report results for an accredited FoPT within the timeframes specified in this Standard;~~
- ~~c) the laboratory makes any reporting error or omission that results in a non-specific match between the analytical result for the FoPT and any criterion that identifies the laboratory or the field of accreditation for which the PT sample was analyzed for the purpose of initial or continued accreditation; or~~

~~d) the laboratory submits analytical results for a FoPT from a PT provider that is not accredited by the PTPA unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.~~

REQUIREMENTS FOR ASSESSMENT OF CORRECTIVE ACTION

~~8.1 The Primary AB shall assess the laboratory to ensure that the laboratory has performed corrective action for each FoPT for which the laboratory receives an evaluation of not acceptable from the PT provider.~~

~~8.2 The Primary AB shall accept the results of a proficiency testing (PT) sample used for corrective action when the laboratory follows these requirements:~~

~~a) The PT sample used for corrective action shall be obtained from any PTPA recognized PT provider. A scheduled or a supplemental proficiency testing sample may be used for corrective action.~~

~~b) The laboratory shall notify the PT provider that the PT sample is for corrective action to ensure that the PTP provides a PT sample that meets the requirements for supplemental PT samples as specified in Volume 3 of this Standard.~~

~~c) There shall be at least fifteen (15) calendar days between the closing date of a previous study and the analysis date of any subsequent study for the same FoPT.~~

~~d) The subsequent PT sample shall be analyzed and reported in accordance with the requirements described in this Standard.~~

9.05.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

5.1 Complaints relating to PT Providers

~~9.15.1.1 The Primary AB shall submit questions about PT samples or performance evaluations made by the PTP to the PTP. If the PTP is unable or unwilling to resolve the questions, the Primary AB shall refer those questions to the PTP'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.~~

~~9.25.1.4 The Primary AB shall have procedures to resolve a laboratory's questions about related to the validity of a not acceptable evaluation made by the Primary AB for a FoPT in any PT sample or when the validity of an entire study from a PTP may be questionable based on complaints, failure rates or data provided by the PTP.~~

5.2 Complaints Relating to Laboratories

~~5.2.1 The AB shall have procedures to respond to a laboratory's question about the validity of the AB's evaluation of the laboratory's performance on a PT Study.~~

10.06.0 SUSPENSION OR REVOCATION OF ACCREDITATION

6.1 Suspension

~~10.16.1.1~~ The Primary AB ~~shall may~~ suspend ~~the a laboratory's~~ accreditation ~~of a laboratory~~ for a ~~FoPT field of accreditation~~ when:

- a) ~~the The~~ laboratory ~~receives an unacceptable score for the FoPT infails~~ two (2) out of the ~~most recent three (3) most recent~~ PT studies attempted for ~~the FoPT, or a particular field of accreditation, when participation is required for a particular FoPT as established by Volume 1 Module 1 of this Standard.~~
- b) ~~the The~~ laboratory ~~does not fails to~~ provide a corrective action report to the ~~Primary~~ AB within thirty (30) calendar days of ~~a request of such report from the AB.~~

~~10.2~~ To ~~reinstate accreditation for a FoPT after suspension, the primary AB shall ensure that the laboratory meets the requirements for continued accreditation as described in this Standard.~~

~~10.3~~ The Primary AB shall ~~revoke the accreditation of a laboratory for a FoPT when:~~

- ~~a) the laboratory does not participate in the PT program as required by this Standard, or~~
- ~~b) the laboratory submits results for PT samples that were generated by another laboratory.~~

~~10.4~~ To ~~reinstate accreditation after revocation, the primary AB shall require the laboratory to meet the requirements for initial accreditation as described in this Standard.~~

NOTE: ~~The Primary AB may have regulatory processes for revocation and/or suspension that supersede the conditions under which suspension or revocation of accreditation is taken by this Standard.~~

6.2 Revocation

~~6.2.1~~ The AB may ~~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 – 4.1.87 of this Standard.~~

~~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 reinstates~~ accreditation of a laboratory whose accreditation is suspended, as specified in section 6.1.1a 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 reinstates accreditation of an environmental laboratory whose accreditation was suspended as specified in section 6.1.1b 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 reinstates 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.