



ENVIRONMENTAL LABORATORY SECTOR

VOLUME 2

GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING ENVIRONMENTAL LABORATORIES

Module 2: Proficiency Testing

TNI Standard

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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Proficiency Testing Committee. The TNI Board of Directors wishes to thank these committee members for their efforts in preparing this Standard as well as those TNI members who offered comments during the voting process.

This Standard may be used by any organization that wishes to implement a program for the accreditation of environmental laboratories.

Sections 5.1.2, 5.2.1 c), 7.3 a), and 7.3 d) of this document have been processed in accordance with the TNI requirement for a Tentative Interim Amendment. The same or similar amendment will undergo the consensus standards development process within the time-frame specified in SOP 2-100.

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 (AB) to assess a laboratory to meet the proficiency testing requirements set forth in this Standard.

1.2 Scope

The TNI Proficiency Testing program (PT Program) is established to provide 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 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.

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* and *ISO/IEC 17025*. 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.
- 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.
- 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.
- 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.

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- 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.
- 3.12 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
- 3.13 PT Study Opening Date:** The calendar date that a PT sample is first made available to any laboratory by a PT provider.
- 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:** This term refers to a PT Study or Supplemental PT Study.
- 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.
- 3.19 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 the proficiency testing requirements for initial and continued accreditation as specified in this Standard. In this capacity 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;
 - d) deny, suspend or revoke a laboratory's accreditation when the laboratory has not met the requirements of the proficiency testing program as specified in this Standard;
 - e) maintain the current accreditation status of laboratories in their program in the National Database, when the database is established; and
 - f) 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.
- 4.2.2 The Secondary AB shall not impose additional requirements for proficiency testing that are not included in this Standard as a requisite for initial or continued accreditation.

5.0 REQUIREMENTS FOR ACCREDITATION

5.1 Initial Accreditation

- 5.1.1 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.

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

7.1 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.

8.0 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.

9.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

- 9.1 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.
- 9.2 The Primary AB shall have procedures to resolve a laboratory's question about 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.

10.0 SUSPENSION OR REVOCATION OF ACCREDITATION

- 10.1 The Primary AB shall suspend the accreditation of a laboratory for a FoPT when:
 - a) the laboratory receives an unacceptable score for the FoPT in two (2) out of the three (3) most recent studies attempted for the FoPT, or
 - b) the laboratory does not provide a corrective action report to the Primary AB within thirty (30) calendar days of request of such report.

- 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.