ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 1: Proficiency Testing

WORKING DRAFT 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 4.2.1 a), 6.1 a), and 7.2 (deleted section) 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.

Standard Revision History

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Proficiency Testing

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VOLUME 1, MODULE 1

Proficiency Testing

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

1.1 Introduction

Volume 1, Module 1 provides the requirements for laboratory participation in the TNI Proficiency Testing (PT) program.

1.2 Scope

The purpose of the TNI PT program is to provide a means for a primary accreditation body (Primary AB) to evaluate a laboratory's performance, under specified conditions relative to a 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 1, Module 1 is applicable to any laboratory attempting to gain or maintain accreditation from a Primary AB that uses this Standard as the basis for accreditation regardless of the number of personnel working in the laboratory or the scope of testing performed by the laboratory.

1.3.2 This Standard does not apply to fields of accreditation that are not designated as fields of proficiency testing (FoPT) by the TNI Proficiency Testing (PT) Board.

~~1.3.3 Where there is an Appendix to this Volume that describes the proficiency testing requirements for a specific FoPT, the requirements of such an Appendix supersedes this module.~~

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 territorial, state or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

3.2 **Accreditation Field of Proficiency Testing:** Fields of Proficiency Testing (FoPT) for which a laboratory is required to successfully analyze a PT sample for in order to obtain or maintain accreditation. Accreditation FoPT are established by the Proficiency Testing Program Executive Committee.~~Same as "Field of Proficiency Testing".~~

~~**3.3 Analysis Date:** The calendar date of analysis associated with the analytical result reported for an accreditation or experimental field of proficiency testing.~~

~~**3.4 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**)**:** 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.
~~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, 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.

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~~ an 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 Reporting Limit (PTRL):** A statistically derived value that represents the lowest acceptable theoretical concentration for an analyte in a PT sample, if the analyte is spiked into the PT sample at the lowest concentration as specified in the TNI FoPT tables.

3.11 **Proficiency Testing Sample (PT Sample):** A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.

3.12 **Proficiency Testing Study (PT Study):** A single complete sequence of circulation of proficiency testing samples to all participants in a proficiency test program.
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3.13 **PT Study Closing Date:** The calendar date for which a laboratory must submit analytical results for a PT sample to a PT Provider.~~analytical results for a PT sample shall be received by the PT provider from the laboratory.~~

3.14 **PT Study Opening Date:** The calendar date that a PT sample is first made available to any laboratory by a PT provider.

3.15 **Revocation:** The total or partial withdrawal of a laboratory's accreditation by an accreditation body.

3.16 **Study:** This term refers to a PT Study or Supplemental PT Study.

3.17 **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.

3.18 **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.

3.19 **TNI PT Program Executive Committee**:~~**Board:**~~ An executive committee ~~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 Program Executive Committee ~~Board~~ are defined in ~~the TNI PT Board~~their Charter.

3.20 **TNI PT Expert Committee:** The PT Expert Committee is a group with balanced representation from laboratories, AB, and consultants to environmental laboratories that support the Executive Committee by developing PT standards. The standards are consensus based.

4.0 REQUIREMENTS FOR ACCREDITATION

4.1 Initial Accreditation

4.1.1 Chemical Testing, Radiochemical Testing, Asbestos and Microbiology

a) To attain initial accreditation the laboratory shall demonstrate to the primary accreditation body (Primary AB) a performance history of two (2) unique "Acceptable" performance evaluation scores for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory has applied. Unique performance evaluation scores are from two different PT samples.

b) To retain accreditation the laboratory shall maintain a performance history of at least two (2) "Acceptable" performance score evaluations out of the most recent three (3) attempts for each accreditation FoPT per technology/matrix.

Note: PT results are required by federal drinking water regulation, per test method rather than technology for potable water PTs.

c) The PT samples used to establish performance history must be obtained from a PTPA-accredited proficiency test provider (PTP) approved to provide PT samples for the FoPT. The PT samples shall be from a PT Study or a Supplemental PT Study.

d) If the PT samples used to establish performance history were analyzed prior to the date of application for accreditation, the closing date of the first PT sample used to establish history shall be no more than eighteen (18) months prior to the date of application and the closing date of the most recent PT sample analyzed shall be no more than six (6) months prior to the date of application.

4.1.2 Whole Effluent Toxicity

a) To attain initial accreditation the laboratory shall demonstrate to the primary accreditation body (Primary AB) that the laboratory has participated and received an "Acceptable" evaluation of one PT study for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory has applied.

b) The PT samples used to fulfill the participation requirement must be obtained from a PTPA-accredited proficiency test provider (PTP) approved to provide PT samples for the FoPT.

c) The closing date of the PT study used to establish participation shall be shall be no more than eighteen (18) months prior to the date of application.

~~To obtain initial accreditation, the laboratory shall successfully analyze two unique TNI compliant PT samples for each accreditation FoPT that correspond to the fields of accreditation for which it seeks accreditation.~~

~~Note 1: The requirements for successful PT performance are described in Volume 2, Module 2, and in Volume 3.~~

~~Note 2: Accreditation and experimental FoPT are established by the TNI PT Board. The official Tables of FoPT are posted to the TNI website.~~

~~4.1.2 The PT samples used for initial accreditation shall be obtained from any PTPA-accredited PTP as part of a TNI-compliant study. If a PT sample for an accreditation FoPT is not available from any accredited PTP, the laboratory shall obtain the PT sample from any non-PTPA-accredited PTP.~~

~~4.1.3 When the PT samples used for initial accreditation were analyzed by the laboratory prior to the date of application, the analysis dates of the PT samples for the same accreditation FoPT shall be no more than eighteen (18) months prior to the application date of accreditation, with the analysis date of the most recent PT sample having been no more than six (6) months prior to the application date for accreditation. Otherwise, there shall be at least fifteen (15) calendar days between the analysis dates of successive PT samples for the same accreditation FoPT.~~

4.2 Continued Accreditation

4.2.1 Chemical Testing, Radiochemical Testing, Asbestos, and Microbiology

a) To retain accreditation the laboratory shall maintain a performance history of at least two (2) "Acceptable" performance score evaluations out of the most recent three (3) attempts for each accreditation FoPT.

Note: PT results are required by federal drinking water regulation, per test method rather than technology for potable water PTs.

b) The PT samples used to establish performance history must be obtained from a PTPA-accredited proficiency test provider (PTP) approved to provide PT samples for the FoPT. The PT samples shall be from a PT Study or a Supplemental PT Study.

c) The opening dates of successive PT samples used for continued accreditation for the same accreditation FoPT shall be at least five (5) months apart and no longer than seven (7) months apart unless PT samples are not available from any PTPA approved PTP within this time frame, in which case the laboratory shall analyze the PT samples in the minimum time-frame in which the PT samples are available.

d) If results are scored 'unacceptable, see V1M1 Section 6.

4.2.2 Whole Effluent Toxicity

To maintain accreditation the laboratory shall participate in one WET PT study per calendar year for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory is accredited. If results are scored 'unacceptable, see V1M1 Section 6.~~4.2.1 To maintain accreditation the laboratory shall:~~

~~a) analyze at least two TNI-compliant PT samples per calendar year for each accreditation FoPT for which the laboratory is accredited unless TNI-compliant PT samples are not available from any PTPA approved PT provider at least twice per year, in which case the laboratory shall analyze the PT samples in the minimum time frame in which the PT samples are available . The analysis dates of successive PT samples for the same accreditation FoPT~~

~~shall be 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;~~

~~b) maintain a history of at least two (2) successful performances out of the most recent three (3) attempts; for each accreditation FoPT; and~~

~~c) obtain the PT samples from any PTPA-accredited PTP. If a PT sample for a FoPT is not available from any accredited PTP, the laboratory shall obtain the PT sample from any non-PTPA-accredited PTP.~~

~~4.2.2 When a laboratory is accredited for a field of accreditation for which the FoPT is an experimental FoPT, the laboratory shall analyze two (2) PT samples for the experimental FoPT per year within the same time frames specified for accreditation FoPT. However, successful performance of the experimental PT is not a requisite for continued accreditation.~~

5.0 REQUIREMENTS FOR PT SAMPLE HANDLING, ANALYSIS & REPORTING

5.1 Chemical Testing, Radiochemical Testing, Asbestos, and Microbiology

5.1.1 ~~PT Sample~~ Analysis Requirements

a) PT samples shall be analyzed in accordance with the laboratory's established standard operating procedures (SOP) using the same quality control and acceptance criteria as used for the analysis of routine environmental samples.

The following exception applies to Chemistry Testing:

The laboratory may, but shall not be required to, rescale the calibration used to analyze the PT sample so that the concentration of the lowest standard in the calibration correlates with the lowest spike concentration of the PT sample or to a value near the FoPT's PTRL.

b) The laboratory shall not analyze quality control (QC) standards along side the PT sample when the QC standards are designed solely to optimize the laboratory's performance for the PT sample and the QC standards are not otherwise routinely analyzed by the laboratory with environmental samples.

~~5.1.1 The laboratory shall analyze PT samples in the same manner as used for routine environmental samples using the same staff, sample tracking, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures and acceptance criteria.~~

~~Note: The laboratory is permitted to analyze the same PT sample for any accreditation or experimental FoPT by multiple methods so long as those test methods are within the same field of accreditation matrix. If the laboratory is accredited for multiple test methods that use the same technology within a field of accreditation, the laboratory is not required to analyze a PT sample for each test method, except for fields of accreditation for the drinking water accreditation matrix for which a PT sample per test method is required. The laboratory may analyze and report the PT sample by one test method and an acceptable performance score for that test method will be acceptable for all test methods that use that same technology within that field of accreditation. When the laboratory reports an analytical result for an accreditation FoPT within the same field of accreditation and accreditation matrix by more than one test method using the same technology, an unacceptable score for either test method will result in an unacceptable score for all test methods for that accreditation FoPT.~~

c) Prior to the closing date of a study, laboratory personnel, including corporate personnel, shall not:

- subcontract the analysis of any PT sample or a portion of a PT sample to another laboratory for any accreditation or experimental FoPT.
- knowingly receive and analyze any PT sample or portion of a PT sample from another laboratory for which the results of the PT sample are intended for use for initial or continued accreditation.
- communicate with any individual at another laboratory concerning the analysis of the PT sample prior to the closing date of the study.
- attempt to obtain the assigned value of any accreditation or experimental FoPT from the PTP.

5.1.2 ~~PT Sample~~ Reporting Requirements

The laboratory shall evaluate and report the ~~analytical~~ result ~~for accreditation or experimental FoPT~~ as follows:

a) If the value found is equal to or above the PTRL for the FoPT, the laboratory shall report the value found as the analytical result for the FoPT. If the PTRL is less than the laboratory's LOQ for the FoPT the laboratory shall report the analytical result without the qualification of result required in V1, M4 of this Standard.

b) If the value found is less than the PTRL for the FoPT, the laboratory shall report a result of "<" the FoPT PTRL value, a result between the LOQ (if below PTRL) and PTRL, or a result less than (<) laboratory's LOQ (if below PTRL). The PTRL value shall not be adjusted for sample amount used, percent moisture or dilution factors.

c) The laboratory shall report the analytical results for accreditation FoPT to the PTP using a reporting format offered by the PTP.

d) Prior to the closing date of the study, the laboratory shall authorize the PTP to release the laboratory's final evaluation report to the laboratory's primary accreditation body. (Primary AB).

e) The laboratory shall retain all records necessary to facilitate historical reconstruction of the preparation, processing and reporting of analytical results for PT samples for a minimum of five years. The laboratory shall make these records available for review upon request by the Primary AB.

~~a) For instrument technology that employs a multi-point calibration, the laboratory shall evaluate the analytical result to the value of the lowest calibration standard established for the test method used to analyze the PT sample. The working range of the calibration under which the PT sample is analyzed shall be the same range as used for routine environmental samples.~~

~~i. A result for any FoPT at a concentration above or equal to the lowest calibration standard shall be reported as the resultant value.~~

~~ii. A result for any FoPT at a concentration less than the lowest calibration standard shall be reported as less than the value of the lowest calibration standard.~~

~~b) For instrument technology (such as ICP-AES or ICP-MS) that employ standardization with a zero point and a single point calibration standard, the laboratory shall evaluate the analytical result to the limit of quantitation (LOQ) established for the test method used to analyze the PT sample. The LOQ for the FoPT shall be the same as used for routine environmental samples.~~

~~i. A result for any FoPT at a concentration above or equal to the LOQ shall be reported as the resultant value.~~

~~ii. A result for any FoPT at a concentration less than the LOQ shall be reported as less than the value of the LOQ.~~

~~Note: The definitions and requirements for calibration and limit of quantitation are included in Volume 1, Module 2.~~

5.2 ~~5.2.2 The laboratory shall report the analytical results for accreditation and experimental FoPTs to the PTP on or before the closing date of the study using the reporting format specified by the PTP.~~

~~5.2.3 On or before the closing date of the study, the laboratory shall authorize the PTP to release the laboratory's final evaluation report directly to the laboratory's Primary AB.~~

Whole Effluent Toxicity

a) The laboratory shall analyze PT samples in the same manner as used for routine environmental samples using the same staff, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures and acceptance criteria.

b) The requirements from V1M1 5.1.1.b and c apply to WET PTs.

~~**5.3 PT Sample Record Retention Requirements**~~

~~5.3.1 The laboratory shall retain all records necessary to facilitate historical reconstruction of the analysis and reporting of analytical results for PT samples for a minimum of five years.~~

~~5.3.2 The historical records shall include a copy of the reporting forms used by the laboratory to report the analytical results for PT samples to the PTP. If the analytical results for the PT samples were entered or uploaded electronically to a PTP website, the laboratory shall retain a copy of the on-line data entry summary or similar documentation of entry of the PT results from the PTP's website.~~

~~5.3.3 The laboratory shall make these records available for review upon request by the Primary AB.~~

6.0 REQUIREMENTS FOR CORRECTIVE ACTION

6.1 Chemistry, Radiochemical Testing, Asbestos, and Microbiology

If the laboratory receives a "not acceptable" performance score for any accreditation FoPT per the scoring criteria specified in V3 of this Standard, the laboratory shall perform corrective action. The requirements for corrective action are described in Volume 1, Module 2 of this Standard.

6.2 Whole Effluent Toxicity

For any "not acceptable" performance score for any accreditation FoPT the laboratory shall perform correction action. The requirements for corrective action are described in Volume 1, Module 2 of this Standard.

The laboratory shall perform corrective action when the laboratory receives a "not acceptable" score on a PT. Corrective action documentation shall include:
a) A copy of the raw data used for the study
b) A copy of the current Standard Reference Toxicant (SRT) control chart relevant to the PT study
c) The corrective action report shall be available upon request.
d)

7.0 REQUIREMENTS TO RE-ESTABLISH PERFORMANCE HISTORY

7.1 Chemistry, Radiochemical Testing, Asbestos, and Microbiology

The laboratory shall be allowed, but not required, to analyze a PT sample outside of the established time-frames to re-establish successful performance history. Re-establishing performance history is defined in section 4.2.1.a.

Note: This is not referring to corrective action for a single failed study.

The following requirements apply:

a) The PT sample used to re-establish performance history must be obtained from a PTPA-accredited proficiency test provider (PTP) approved to provide PT samples for the FoPT. The PT samples shall be from a PT Study or a Supplemental PT Study. If the PT sample is from a Supplemental PT Study, the laboratory shall notify the PTP that the PT sample is being used to re-establish performance history

b) The laboratory shall obtain successive PT samples for the same accreditation FoPT and report the results at least seven (7) calendar days apart. The laboratory shall analyze the two PTs in separate preparation and analytical batches.

c) All other requirements specified in this standard for the analysis and reporting of PT samples apply.

7.2 Whole Effluent Toxicity

If the laboratory receives an evaluation of not acceptable for an accreditation FoPT in any study, the laboratory may choose to re-establish successful history for the accreditation by either analysis of a PT sample from any study or supplemental study or by successful analysis of a standard reference toxicant analyzed after the not acceptable PT. Successful SRT analysis is established per V1M7 Section 4.1.2.

~~When the laboratory receives a "not acceptable" performance score from a PTP or a Primary AB, the laboratory shall perform corrective action. The requirements for corrective action are described in Volume 1, Module 2.~~

~~When the laboratory receives an evaluation of not acceptable for an accreditation FoPT in any study, the laboratory may choose to re-establish successful history for the accreditation FoPT with a PT sample from any study. The following requirements shall apply to the PT sample used to re-establish successful history:~~

~~**a) The PT sample shall be obtained 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. The laboratory shall notify the PTP that the PT sample will be used for corrective action purposes so the PTP may ensure that the PT sample supplied meets the requirements for supplemental PT as defined in Volume 3 of this standard.**~~

~~**b) The laboratory shall ensure that there are at least fifteen calendar days between the analysis dates of successive PT samples for the same accreditation FoPT.**~~

~~**c) The PT sample shall be analyzed and reported in accordance with the requirements described this Module.**~~

8.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

The laboratory shall submit questions about PT samples or performance evaluations made by the PTP to the PTP. If the PTP is not able or is unwilling to resolve the question to the satisfaction of the laboratory, the laboratory shall refer those questions to the PTP's PTPA.

9.0 REQUIREMENTS FOR REINSTATEMENT OF ACCREDITATION AFTER SUSPENSION OR REVOCATION

9.1 To reinstate accreditation for an accreditation FoPT after suspension, the laboratory shall meet the requirements for continued accreditation as described in Section 4.2 of this module.

9.2 To reinstate accreditation for an accreditation FoPT after revocation, the laboratory shall meet the requirements for initial accreditation as described in Section 4.1 of this module.