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 1, MODULE 1

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 an accreditation body 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 applies only to fields of accreditation (FOA) that are also 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 **Accreditation Body (AB):** The organization having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program.

3.2 **Field of Accreditation (FoA):** 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 PTPEC.

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

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.

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3.11 **PT Study Closing Date:**

a) **Scheduled PT Study:** The calendar date by which all participating laboratories must submit analytical results for a PT sample to a PT Provider.

b) **Supplemental PT Study:** The calendar date a laboratory submits the results for a PT sample to the PT Provider.

3.12 **PT Study Opening Date:**

a) **Scheduled PT Study:** The calendar date that a PT sample is first made available to all participants of the study by a PT provider.

b) **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 **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. The study must have 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 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 longer, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the standard.

4.0 REQUIREMENTS FOR ACCREDITATION

4.1 General Requirements

4.1.1 TNI publishes lists of FoPTs on the TNI website for which PT studies are required, called TNI FoPT Tables. These FoPT tables may be updated, as needed, by publishing revised FoPT tables on the TNI website.

4.1.2 The laboratory shall participate in PT studies for each field of accreditation where corresponding FoPTs exist in the TNI FoPT tables and for which the laboratory seeks to obtain or maintain accreditation.

4.1.3 The laboratory shall obtain scheduled PT studies or supplemental studies for the individual fields of proficiency testing from a PT Provider accredited to Volume 3 of this Standard by a TNI approved PTPA.

4.1.4 The laboratory shall analyze unique, single blind, single concentration PT samples, when required as stated in the TNI FoPT tables described in section 4.1.1, to determine compliance for each field of accreditation for which the laboratory seeks to obtain or maintain accreditation.

Note: PT results are required by Federal Regulations, 40 CFR 141, per test method rather than technology for potable water PTs.

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

a) send a PT study, or a portion of a PT study, in which it is participating, to another laboratory for the analysis of a field of accreditation for which it seeks accreditation or is accredited;

b) 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 of that laboratory;

c) communicate with any individual at another laboratory, including other laboratories under common ownership, concerning the analysis of the PT sample;

d) attempt to obtain the assigned value of any portion of the PT study from the PT Provider.

4.1.6 Participation in any of the above activities listed in 4.1.5 is cause for revocation of accreditation.

4.1.7 When a regulatory program has additional PT requirements for FoPT's not covered by this standard, then the laboratory shall follow those requirements.

4.2 Sample Handling, Preparation and Analysis Requirements

4.2.1 The laboratory shall handle and prepare the PT study samples in accordance with the instructions provided by the PT Provider.

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

4.2.3 ~~4.2.3~~ The laboratory shall evaluate the analytical result for each chemistry and radiochemistry field of accreditation to the PTRL as established by the TNI FoPT Tables~~. If the laboratory's Limit of Quantitation (LOQ) is below the PTRL, they may evaluate results to their normal LOQ.~~

4.2.4 For chemistry analyses, if the laboratory's Limit of Quantitation (LOQ) is below the PTRL, they may evaluate results to their normal LOQ.

4.2.~~4~~ 5 For chemistry PT results where the concentrations are below the calibration range established by the initial calibration curve, the following actions are acceptable:

a) the laboratory may re-scale its initial calibration curve to bracket the concentration of the PT sample result; or

b) the laboratory may report the results, as measured with the initial calibration curve, without qualification to the PT Provider, provided the laboratory adheres to the requirements of section 4.3.7.

4.3 Reporting Requirements

4.3.1 The laboratory shall report PT study results to the PT Provider on or before the closing date of the study using the reporting format offered by the PT Provider.

4.3.2 The laboratory shall, on or before the closing date of the study, direct the PT Provider to report the PT study performance results directly to the AB(s) designated by the laboratory. For initial accreditation(s) the laboratory shall direct the PT Provider to provide all relevant PT study results to the AB to support their accreditation application.

4.3.3 The laboratory shall report results in such a way that there is a specific match between the analytical result for the FoPT and the corresponding Field of Accreditation for which the PT sample was analyzed.

4.3.4 Except for drinking water analytes referenced in 40 CFR 141, a laboratory may choose to analyze and report a single method to represent a technology in a single PT study for a particular analyte. If the laboratory analyzes and reports PT studies by "technology," the score obtained for the reported method will be applied to all methods in that technology for which the laboratory seeks to obtain or maintain accreditation in that matrix.

4.3.5 The laboratory shall report chemistry PT study results to the PTRL as established by the TNI FoPT Tables, or if the laboratory LOQ is below the PTRL, the laboratory may report results down to their normal LOQ, and as specified in section 4.2.~~3~~4.

4.3.6 ~~The laboratory shall report radiochemistry PT study results, including negative numbers whether above or below the MDA. Each result shall be reported with its Combined Standard Uncertainty (CSU). At no time shall radiochemistry results be reported as "<" the MDA.~~ Radiochemistry results shall be reported as measured, including zero, negative, and positive results, and shall not be censored or reported as "less than" values. All radiochemistry PT study results shall be reported in association with the measurement uncertainty, as appropriate to the program.

~~4.3.7 The laboratory shall evaluate and report each FoPT result as follows:~~

~~a) If the value found by the laboratory is equal to or above the PTRL, the laboratory shall report the value found as the analytical result. If the PTRL is less than the laboratory's Limit of Quantitation (LOQ), the laboratory shall report the result without the qualification of result required in Volume 1, Module 4 of this Standard.~~

~~b) If the value is < LOQ and the LOQ is less than the PTRL, the laboratory may choose to evaluate results to the LOQ rather than the PTRL. If the value found is equal to or above the laboratory LOQ, the laboratory shall report the value found as the result.**~~

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

~~**** Note: In the case where the laboratory LOQ is greater than the PTRL: If the laboratory chooses to report a value of < LOQ and the analyte is present above the PTRL, the result will be scored as "Not Acceptable" by the PT provider.~~

4.3.7 The laboratory shall evaluate and report each chemistry FoPT result to the PT Provider as follows:

a) If the analytical result is a numeric value above or equal to the PTRL, the laboratory shall report the value. If the PTRL is less than the laboratory's Limit of Quantitation (LOQ), the laboratory shall report the result without the qualification of result required in Volume 1, Module 4 of this standard.

b) If the analytical result is a numeric value below the PTRL, the laboratory shall report one of the following:

i. <PTRL or,

ii. the obtained analytical result, if the result is between the LOQ and the PTRL or,

iii. <LOQ, if the analytical result is below the LOQ and the PTRL.

c) If the analytical result is a non-detect the laboratory shall report one of the following:

i. <PTRL or

ii <LOQ**

Note: In the case where the laboratory LOQ is greater than the PTRL: If the laboratory chooses to report a value of <LOQ and the analyte is present above the PTRL, the result will be scored as "Not Acceptable: by the PT Provider.

4.3.8 The PTRL value shall not be adjusted for sample amount used or percent moisture

4.4 Record Retention

4.4.1 The laboratory shall retain all records necessary to facilitate 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.

5.0 PT STUDY FREQUENCY REQUIREMENTS FOR ACCREDITATION

5.1 Initial Accreditation

5.1.1 Chemical Testing, Radiochemical Testing, Asbestos and Microbiology

a) The laboratory shall achieve a history of two (2) successful (acceptable scores) PT studies out of the most recent three (3) attempts for each field of accreditation specified in section 4.1.1 for which the laboratory seeks accreditation.

Note: if the laboratory has two consecutive acceptable PT scores, a third study is not needed.

b) The two PT studies identified in section 5.1.1 a) must be performed no more than 18 months prior to obtaining initial accreditation from an AB.

c) The opening date of the second study must be at least seven (7) calendar days after the closing date of the first study.

d) The closing date of the most recent successful PT study for an FoPT must be no more than six (6) months prior to the application for initial accreditation and the laboratory shall continue to participate in PT studies at least semi-annually (no more than 7 months apart between consecutive attempts) from that point on.

5.1.2 For Whole Effluent Toxicity (WET) testing, the laboratory shall demonstrate to the primary AB that it has received an acceptable evaluation for at least one (1) PT study to obtain initial accreditation. The study closing date of the most recent successful PT study shall be no more than 12 months prior to obtaining initial accreditation from an AB and the laboratory shall continue to participate in PT studies annually from that point on.

5.2 Continued Accreditation

5.2.1 Chemical Testing, Radiochemical Testing, Asbestos and Microbiology

5.2.1.1 The laboratory shall maintain a history of two (2) successful (acceptable scores) PT studies out of the most recent three (3) attempts for each field of accreditation specified in Section 4.1.1 for which the laboratory holds accreditation. Failure to do so may result in suspension of the affected field of accreditation. The laboratory's accreditation for a field of accreditation may be revoked for failure of three (3) consecutive PT studies, either by failure to participate in the required PT study or due to failure to obtain acceptable results.

5.2.1.2 The laboratory shall analyze and report a PT study at least twice per year for each accreditation FoPT for which it seeks to maintain accreditation in accordance with the following criteria:

a) The closing dates of subsequent PT study samples for a particular accreditation FoPT shall be no more than seven (7) months apart.

b) The opening date of PT study samples for a particular field of accreditation must be at least seven (7) calendar days after the closing date of a PT study for the same field of accreditation.

c) A laboratory that analyzes and reports PT study results with an opening date of subsequent PT studies for the same field of accreditation that are closer than seven (7) days from the closing date of the previous PT study are invalid for the purposes of compliance with this standard and are not counted toward the laboratory's PT history of the most recent three (3) attempts.

5.2.2 For Whole Effluent Toxicity Testing: 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.

a) This requirement can be met by annual participation in the EPA DMRQA studies for WET, or

b) If the laboratory is not participating in an EPA DMRQA study for WET, the closing dates of subsequent PT study samples for WET testing PT studies must be no more than 14 months apart.

5.2.3 A laboratory that fails to analyze and report PT studies for a particular field of accreditation with the frequency specified in Sections 5.2.1 or 5.2.2 for which it seeks to maintain accreditation is charged with a failed PT study.

Note: A laboratory may withdraw from a PT study, but withdrawal from a PT study does not exempt the laboratory from analyzing and reporting a PT study as specified in Sections 5.2.1 and 5.2.2.

6.0 REQUIREMENTS FOR CORRECTIVE ACTION

6.1 A laboratory that fails to successfully analyze a PT study for a particular FOA shall determine the root cause of the failure and take corrective action.

6.2 The laboratory shall document the root cause investigation and subsequent corrective action.

Note: The requirements for corrective action are described in V1M2 of this standard.

6.3 The laboratory shall provide the root cause investigation and corrective action documentation to the Primary AB within 30 calendar days of a request from the AB.

6.4 Failure to submit documentation of the root cause investigation or corrective action records, or both, to the AB within 30 calendar days of the request from the primary AB is due cause for suspension of accreditation for a particular FOA.

6.5 Documentation for WET corrective actions 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.

7.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

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

7.2 ~~Laboratories~~ The laboratory shall ~~have~~ submit questions to ~~their~~ its AB in regards to the AB's PT evaluation, if necessary.

8.0 REQUIREMENTS FOR REINSTATEMENT OF ACCREDITATION AFTER SUSPENSION OR REVOCATION

8.1 A laboratory seeking to have its accreditation reinstated for an FoPT after suspension shall meet the requirements for continued accreditation as described in Section 5.2 of this module.

8.2 A laboratory seeking to have its accreditation reinstated for an FoPT after revocation shall meet the requirements for initial accreditation as described in Section 5.1 of this module.

8.3 A laboratory seeking to have its accreditation reinstated for an FoPT after suspension due to not supplying a requested corrective action report shall meet the requirements for continued accreditation as described in Section ~~6.0~~5.2 of this module.