Modified Voting Draft Standard

EL –V1M1

March 2015

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-V1M1-2009-Rev1.1 are shown through tracking, and the further modifications made as a result of persuasive voters' comments are highlighted

VOLUME 1, MODULE 1

Proficiency Testing

Table of Contents

1.0 INTRODUCTION, SCOPE AND APPLICABILITY 1
1.1 Introduction 1
1.2 Scope 1
1.3 Applicability 1

2.0 NORMATIVE REFERENCES 1

3.0 TERMS AND DEFINITIONS 1
3.1 Accreditation Body 1
3.2 Accreditation Field of Proficiency Testing 1
~~3.3 Analysis Date ..... 1~~
~~3.4 Experimental Field of Proficiency Testing (Experimental FoPT) ..... 1~~
3.~~5~~3 Field of Accreditation 2
3.~~6~~4 Field of Proficiency Testing (FoPT) 2
3.~~7~~5 Primary Accreditation Body (Primary AB) 2
3.~~8~~6 Proficiency Testing (PT) 2
3.~~9~~7 Proficiency Testing Program (PT Program) 2
3.~~10~~8 Proficiency Testing Provider (PTP) 2
3.~~11~~9 Proficiency Testing Provider Accreditor (PTPA) 2
3.10 Proficiency Testing Reporting Limit (PTRL) 2
3.~~12~~11 Proficiency Testing Sample (PT Sample) 2
~~3.13 Proficiency Testing Study (PT Study) ..... 2~~
3.~~14~~12 PT Study Closing Date 2
3.~~15~~13 PT Study Opening Date 2
3.~~16~~14 Revocation ..... ~~2~~3
3.~~17~~15 Study (or PT Study) ..... ~~2~~3
~~3.18 Supplemental Proficiency Testing Study (Supplemental PT Study) ..... 2~~
3.~~19~~16 Suspension ..... ~~2~~3
~~3.20 TNI PT Board ..... 2~~

4.0 REQUIREMENTS FOR ACCREDITATION 3
4.1 ~~Initial Accreditation~~General requirements ..... ~~3~~4
4.2 ~~Continued Accreditation~~Sample Handling, Preparation and Analysis Requirements ..... ~~3~~6
4.3 Reporting Requirements 7
4.4 Record retention 8

~~**5.0 REQUIREMENTS FOR PT SAMPLE HANDLING, ANALYSIS & REPORTING ..... 4**~~
5.0 PT STUDY FREQUENCY REQUIREMENTS FOR ACCREDITATION 8
5.1 ~~PT Sample Analysis Requirements~~Initial Accreditation ..... 4~~8~~
5.2 ~~PT Sample Reporting Requirements~~Continued Accreditation ..... ~~4~~9
~~5.3 PT Sample Record Retention Requirements ..... 5~~

6.0 REQUIREMENTS FOR CORRECTIVE ACTION ..... ~~5~~9

7.0 REQUIREMENTS FOR COMPLAINT RESOLUTION ..... ~~5~~10

8.0 REQUIREMENTS FOR REINSTATEMENT OF ACCREDITATION AFTER SUSPENSION OR REVOCATION ……..... ~~6~~10

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 ~~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~~applies only to fields of accreditation (FOA) that are ~~not~~ also designated as fields of proficiency testing (FoPT) by the TNI Proficiency Testing ~~(PT) Board~~Program Executive Committee (PTPEC).

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

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

~~**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.~~5~~2 **Field of Accreditation (FoA):** Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

3.3~~6~~ **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, analyte.~~ Matrix, technology/method, analyte combinations for which the composition, spike concentration ranges and acceptance criteria have been established by the PTPEC.

3.~~7~~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.~~8~~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.~~9~~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.~~10~~7 **Proficiency Testing Provider (PTP):** A person or organization accredited by ~~the~~ a TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

3.~~11~~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.~~12~~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.

~~3.13 **Proficiency Testing Study (PT Study):** A single complete sequence of circulation of proficiency testing samples to all participants in a proficiency test program.~~

.

3.~~14~~11 **PT Study Closing Date:**

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

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.~~15~~12 **PT Study Opening Date:**

a) **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.

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

3.~~16~~13 **Revocation:** The total or partial withdrawal of a laboratory's accreditation by an accreditation body.

3.~~17~~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.

~~3.18 **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.~~

3.~~19~~15 **Suspension:** The temporary removal of a laboratory's accreditation for a defined period of time.

~~3.20 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.**~~

4.0 REQUIREMENTS FOR ACCREDITATION

~~4.1 Initial Accreditation~~

~~4.1.1 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 To maintain accreditation the laboratory shall:~~

~~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.~~

~~d) 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 laboratory shall perform 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.~~

~~e) 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.~~

~~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.~~

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 in the TNI FoPT tables for which the laboratory seeks to obtain or maintain accreditation.~~

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 PT studies or supplemental studies for the individual fields of proficiency testing, from a PT Provider accredited by a TNI approved PTPA.~~

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 PTP.

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 requires more stringent requirements than the requirements of this module, the laboratory shall follow the more stringent requirements.~~

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

~~5.0 REQUIREMENTS FOR PT SAMPLE HANDLING, ANALYSIS & REPORTING~~

~~5.1 PT Sample Analysis Requirements~~

~~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.~~

~~5.1.2 Prior to the closing date of a study, laboratory personnel, including corporate personnel, shall not:~~

~~a) subcontract the analysis of any PT sample or a portion of a PT sample to another laboratory for any accreditation or experimental FoPT.~~

~~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.~~

~~c) communicate with any individual at another laboratory concerning the analysis of the PT sample prior to the closing date of the study.~~

~~d) attempt to obtain the assigned value of any accreditation or experimental FoPT from the PTP.~~

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 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 and radiochemistry PT results where the concentrations are below the calibration range established by the initial calibration curve, the following actions are acceptable:~~

4.2.4 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.

~~**5.2 PT Sample Reporting Requirements**~~

~~5.2.1 The laboratory shall evaluate and report the analytical result for accreditation or experimental FoPT as follows:~~

~~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.~~

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

~~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.~~

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

~~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.~~

~~5.2.2 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.~~

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, before the closing date of the study, direct the PT Provider to report the PT study performance results directly to the selected AB(s). 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.~~

4.3.2 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 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.~~

~~4.3.1~~ 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 and radiochemistry 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.~~

4.3.5 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.

4.3.6 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.

~~4.3.6 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 AB.~~

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.**

~~4.3.8 Upon request, and only after the issuance of final evaluation reports, the laboratory may obtain from the PT Provider the results of the provider's assigned value verification, homogeneity, and stability testing for any PT sample/analyte for which results were submitted to a laboratory AB.~~

~~4.1~~
~~4.25.3 PT Sample Record Retention Requirements~~
4.4 Record Retention

~~5.3.1~~4.4.1 The laboratory shall retain all records necessary to facilitate ~~historical~~ reconstruction of the ~~analysis~~ 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.

~~5.3.2 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.~~

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 semi-annually from that point on.~~

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 semi-annually for each accreditation FoPT for which it seeks to maintain accreditation that meets the following criteria:~~

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

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 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.~~

~~6.1 If the laboratory fails to successfully analyze a PT study for a particular field of accreditation, it shall determine the root cause for the failure and take any necessary corrective action. The laboratory shall document the investigation and corrective action. The requirements for corrective action are described in Volume 1 Module 2 of this standard. The laboratory shall provide these records to the primary AB within thirty (30) calendar days upon receipt of a request by the AB. Failure to submit a corrective action within thirty (30) calendar days of a documented request from the primary AB may result in suspension.~~

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 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.

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

8.0 REQUIREMENTS FOR REINSTATEMENT OF ACCREDITATION AFTER SUSPENSION OR REVOCATION

~~8.1 To reinstate accreditation for an accreditation FoPT after suspension, the laboratory shall meet the requirements for continued accreditation as described in Section 5.2 of this module.~~

8.1 A laboratory seeking to have their 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 To reinstate accreditation for an accreditation FoPT after revocation, the laboratory shall meet the requirements for initial accreditation as described in Section 5.1 of this module.~~

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