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MODIFIED WORKING DRAFT STANDARD

VOLUME 2: General Requirements for
Accreditation Bodies Accrediting
Environmental Laboratories

Module 2: Proficiency Testing

July 2013

Description

A Working Draft Standard (WDS) was presented and discussed during the Environmental Measurement Symposium, Washington DC, on August 7, 2012. This Modified Working Draft Standard (MWDS) was prepared as a result of input received during and after that meeting.

Note. The tracking shows only the proposed changes that have been made to the WDS to create this MWDS. The TNI Proficiency Testing Committee will limit discussion and further input to those marked changes.

VOLUME 2, MODULE 2**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 | Analysis Date | 1 |
| 3.2 | Experimental Field of Proficiency Testing (Experimental FoPT) | 1 |
| 3.3 | Field of Accreditation..... | 1 |
| 3.4 | Field of Proficiency Testing (FoPT)..... | 1 |
| 3.5 | Primary Accreditation Body (Primary AB) | 1 |
| 3.6 | Proficiency Testing (PT)..... | 2 |
| 3.7 | Proficiency Testing Program (PT Program)..... | 2 |
| 3.8 | Proficiency Testing Provider (PTP)..... | 2 |
| 3.9 | Proficiency Testing Provider Accreditor (PTPA) | 2 |
| 3.10 | Proficiency Testing Sample (PT Sample) | 2 |
| 3.11 | Proficiency Testing Study (PT Study) | 2 |
| 3.12 | PT Study Closing Date..... | 2 |
| 3.123 | PT Study Opening Date | 2 |
| 3.134 | Revocation..... | 2 |
| 3.14 | Secondary Accreditation Body (Secondary AB) | 2 |
| 3.15 | Study (or PT Study) | 2 |
| 3.16 | Suspension Supplemental Proficiency Testing Study (Supplemental PT Study) | 2 |
| 3.17 | Supplemental PT Study Closing Date..... | 2 |
| 3.18 | Supplemental PT Study Opening Date..... | 2 |
| 3.179 | TNI PT Program Executive Committee TNI PT Board..... | 2 |
| 3.18 | TNI PT Expert Committee..... | 3 |
| 3.20 | Suspension..... | 2 |
| 3.21 | Revocation..... | 2 |
| 4.0 | ACCREDITATION BODY REQUIREMENTS..... | 3 |
| 4.1 | Primary Accreditation Body (Primary AB) | 3 |
| 4.2 | Secondary Accreditation Body (Secondary AB) | 3 |
| 5.0 | REQUIREMENTS FOR ACCREDITATION..... | 3 |
| 5.1 | Initial Accreditation | 3 |
| 5.2 | Continuing Accreditation | 4 |
| 6.0 | REQUIREMENTS FOR ASSESSMENT OF PT SAMPLE ANALYSIS | 5 |
| 7.0 | REQUIREMENTS FOR ASSESSMENT OF FINAL EVALUATION REPORTS..... | 5 |
| 8.0 | REQUIREMENTS FOR ASSESSMENT OF CORRECTIVE ACTION..... | 6 |
| 9.0 | REQUIREMENTS FOR COMPLAINT RESOLUTION | 6 |
| 10.0 | SUSPENSION OR REVOCATION OF ACCREDITATION..... | 6 |

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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 for an [Primary Accreditation Body's \(AB\) evaluation of and response to to ensure an accredited laboratory's participation in the TNI Proficiency Testing \(PT\) program as set forth in a laboratory seeking accreditation meets set forth in this Standard Volume 1, Module 1.](#)

1.2 Scope

The purpose of the TNI PT program is to provide a means for an [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 2, Module 2 is applicable to any accreditation body (AB) that uses this Standard as the basis for [laboratory accreditation of laboratories regardless of the number of personnel size of the laboratory or scope or the extent of testing performed by that laboratory.](#)

[1.3.2 This Standard applies only to fields of accreditation \(FOA\) that are also designated fields of proficiency testing \(FoPT\) by the TNI Proficiency Testing Executive Committee.](#)

~~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) Program Executive Committee.~~

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

3.2 Accreditation Field of Proficiency Testing: [Analytes Field of Proficiency Testing \(FoPT\)](#) 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.~~ [Accreditation FoPT are established by the Proficiency Testing Program Executive Committee.](#)

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.
- 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 a 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 PT Study Closing Date:**
- a) Scheduled PT Study: The calendar date for which all 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.
 - ~~c) The calendar date for which a laboratory must submit analytical results for a PT sample to a 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.
- ~~The calendar date that a PT sample is first made available to any laboratory by a PT provider.~~
- 3.13 Revocation:** The total or partial withdrawal of a laboratory's accreditation by an accreditation body.
- ~~3.14 **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.~~
- 3.145 Secondary Accreditation Body (Secondary AB):** An accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of the accreditation from a Primary Accreditation Body for the same field of accreditation.
- 3.156 Study (or PT Study):** This term refers to a Scheduled PT Study ~~or 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.

- ~~3.17—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.~~
- ~~3.16—Suspension: The temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six (6) months or the period of accreditation, whichever is longer, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.~~
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- ~~3.18—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.~~
- ~~3.19—Supplemental PT Study Opening Date: The calendar date that a PT sample is shipped from the PT provider to a laboratory.~~
- ~~3.20—TNI PT Program Executive Committee: An Executive Committee 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 are defined in their Charter.~~

4.0 ACCREDITATION BODY REQUIREMENTS

4.1 Primary Accreditation Body (Primary AB)

4.1.1 The Primary AB shall require laboratories to meet the proficiency testing requirements as specified in Volume 1 Module 1 of this Standard.

4.1.14.1.2 The Primary AB shall review the evaluation report issued by a PTP to verify the laboratory has met the proficiency testing requirements set forth in this standard within sixty (60) days of receipt of the report from the PTP.

4.1.3 The Primary AB shall accept only those PT study results that meet the requirements of V1M1 and V3.

4.1.4 The Primary AB shall have procedures in place to:

~~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 Volume 1 Module 1 of this Standard;
- c) evaluate final evaluation reports as specified in this Standard;

NOTE: "Acceptable" PT study scores from a PT Provider do not automatically result in a successful evaluation of a PT study by an AB. For example, failure to report an analytical method or reporting of an incorrect method, failure to authorize the PT provider release the results to the AB before the close of the study, failure to report results to the PT Provider before the closing date, failure to handle PT study samples in the same manner as real environmental samples, etc.

- 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 Volume 1 Module 1 of this Standard;
- e) evaluate that the laboratory performed and implemented corrective action for failed PT studies
- f) 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 not require calibration ranges that are not typically employed by the laboratory for the sole purpose of analyzing PTs.

4.2 Secondary Accreditation Body (Secondary AB)

4.2.1 The Secondary AB shall have procedures in place to evaluate and update a laboratory's accreditation status based on the accreditation granted by a Primary AB.

4.2.14.2.2 The Secondary AB may choose to evaluate secondary accredited and applicant laboratories' PT study results and grant, deny, suspend, or revoke a laboratory's accreditation as if it were the Primary AB. A Secondary AB that chooses to evaluate a secondary applicant's PT studies and make accreditation changes based on this evaluation must evaluate all secondary applicants' PT studies in accordance with the requirements established by V1M1 and V2M2 and must contact the primary AB

~~to confirm their evaluation prior to taking action on a laboratory. The Secondary AB shall accept assessment decisions made by the laboratory's 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.

~~4.2.3~~

~~5.0~~ **REQUIREMENTS FOR ACCREDITATION**

~~5.1~~ **Initial Accreditation – Chemical Testing, Radiochemical Testing, Asbestos and Microbiology**

~~5.1.1~~—The Primary AB shall require that a laboratory seeking initial accreditation for a field of accreditation successfully analyze two (2) unique PT samples for for any fields of accreditation that are also designated accreditation FoPT. The primary AB shall not require analysis of a PT sample as a condition of initial accreditation for any field of accreditation that is not also an accreditation FoPT. Unique performance evaluation scores are from two different PT samples.

~~Note:~~—Accreditation FoPT are established by the TNI PT Program Executive Committee.

~~5.1.2~~—The Primary AB shall require that the PT samples for initial accreditation are obtained from a PTPA-accredited PT provider that is accredited to manufacture and distribute PT samples for the accreditation FoPT. .

~~5.1.3 When the PT samples used for initial accreditation are analyzed by the laboratory prior to the date of application, the Primary AB shall ensure the closing date of the earliest PT sample analyzed is no more than eighteen (18) months prior to the application date for accreditation and the closing date of the most recent PT sample no more than six (6) months prior to the application date for accreditation.~~

~~5.2 Initial Accreditation – Whole Effluent Toxicity~~

- ~~a) To attain initial accreditation the primary AB shall assure that the laboratory has participated in one successful 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.~~

~~5.3 Continued Accreditation – Chemical Testing, Radiochemical Testing, Asbestos, and Microbiology~~

~~The Primary AB shall have procedures in place to verify that laboratories meet the following requirements for continued accreditation::~~

- ~~a) The laboratories has analyzed at least two (2) TNI-compliant PT of the most recent three (3) for each accreditation FoPT for which the laboratory holds accreditation~~

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

- ~~b) The PT samples analyzed by the laboratory were obtained from a PTPA accredited proficiency test provider PTP that is accredited to manufacturer and distribute PT samples for the accreditation FoPT.~~
- ~~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.~~

~~NOTE: A Primary AB may specify the month(s) in which laboratories within its accreditation authority obtain PT samples and if the Primary AB chooses to specify such, then the Primary AB shall adhere to the time-frames specified in this section.~~

~~5.4 Continued Accreditation – Whole Effluent Toxicity~~

~~To maintain accreditation the laboratory shall demonstrate to the primary accreditation body (Primary AB) a performance history of one “Acceptable” performance evaluation score per calendar year for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory is accredited.~~

6.0 — REQUIREMENTS FOR REVIEW OF PT SAMPLE ANALYSIS RECORDS DURING ON-SITE ASSESSMENTS

During the on-site assessment the Primary AB shall review laboratory records to verify the following:

- a) The time frame between successive PT studies for an accreditation FoPT is in compliance with the time frames specified in this Standard.
- b) The PT sample for the accreditation FoPT was obtained from a PTP that is accredited to manufacture or distribute PT samples for the accreditation FoPT.
- c) The laboratory maintains a successful performance history of 2 out of 3 for each accreditation FoPT.

PT samples for accreditation FoPT were prepared in accordance with the instructions provided by the PTP and subsequently prepared and analyzed by the laboratory in accordance with the laboratory's standard operating procedures.

The laboratory performed root cause analysis for accreditation FoPT results that were scored "not acceptable".

Note: If during record review a Primary AB discovers that the laboratory analyzed QC standards that a PTP has suggested or directed a laboratory to purchase with the PT samples for the sole purpose of improving the laboratory's performance for a given PT sample or that the PT provider has given the laboratory analysis instructions beyond those specified in this Standard, the 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 PT EVALUATION REPORTS

The Primary AB shall review the evaluation report issued by the PTP to verify the laboratory has met the proficiency testing requirements set forth in this standard within sixty (60) days of receipt of the report from the PTP.

This evaluation shall include verification of the following:

The time frame between successive PT studies for an accreditation FoPT is in compliance with the time frames specified in this Standard.

- a) The PT sample for the accreditation FoPT was obtained from a PTP that is accredited to manufacture or distribute PT samples for the accreditation FoPT.
- b) The laboratory maintains a successful performance history of 2 out of 3 for each accreditation FoPT.

Note: The PT scoring criteria for PTPA recognized PT providers is specified in Volume 3 of this standard. If the Primary AB discovers or is otherwise notified that the PTP did not follow the scoring criteria specified in this standard, the Primary AB must report their finding to the PTOB-PTPA that issued the accreditation to the PTP. If the score issued by the PTP for the accreditation FoPT was erroneously scored "not acceptable" or "acceptable" by the PTP the Primary AB shall overturn the performance evaluation issued by the PTP and score the analytical result per the requirements specified in V3 of this standard.

~~Note: If the laboratory is accredited for multiple test methods by the same technology within the same field of accreditation matrix the laboratory is not required to analyze a PT sample for each test method except for the matrix drinking water where the laboratory must report a PT result per test method for each accreditation FoPT.~~

~~Note: Except as noted for drinking water, the laboratory may report one result for an accreditation FoPT per technology and an acceptable performance score for the test method reported is considered acceptable performance for all test methods by the same technology within the same field of accreditation matrix. Alternatively, the laboratory may report a result for each test method. If the laboratory reports an analytical result for an accreditation FoPT by more than one test method; an unacceptable score for an accreditation FoPT will be applied only to the test method for which the unacceptable result was reported.~~

~~8.0 REQUIREMENTS FOR RE-ESTABLISHING PERFORMANCE HISTORY~~

~~8.1 Chemistry, Radiochemical Testing, Asbestos, and Microbiology~~

~~The laboratory shall be allowed, 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 5.3.1.a.~~

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

~~The Primary AB shall review the evaluation report issued by the PTP to verify the laboratory has met the proficiency testing requirements set forth in this standard within 15 days of receipt of the report from the PTP for the following:~~

~~NOTE: A PT sample used for corrective action may be a supplemental PT or it may be a sample from a regularly scheduled PT study.~~

- ~~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.~~
- ~~b) Successive PT samples for the same accreditation FoPT are reported at least seven (7) calendar days apart, and~~
- ~~c) Two PTs in are reported from separate preparation and analytical batches.~~
- ~~d) All other requirements specified in this standard for the analysis and reporting of PT samples apply.~~

~~8.2 Whole Effluent Toxicity~~

~~The Primary AB shall evaluate PTs from WET. If the laboratory receives an evaluation of not acceptable for an accreditation FoPT in any study, the Primary AB shall allow the laboratory to 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.~~

59.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

5.1 Complaints Relating to PT Providers

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

5.1.2 If the AB discovers or is otherwise notified that the PT Provider did not follow the scoring criteria specified in V3, the AB shall report their findings to the PT Provider (see 5.1.1).

5.1.3 If the AB discovers that the laboratory analyzed QC standards that a PT Provider suggested or directed a laboratory to purchase with the PT study samples for the purpose of improving the laboratory's performance for a given PT sample or that the PT provider has given the laboratory analysis instructions beyond those specified in this Standard, the AB shall report the results of their findings to the PT Provider's PTPA.

59.1.42 ~~The Primary AB shall have procedures on actions to be taken when the validity of an FoPT or study from a PTP may be questionable based on complaints, failure rates or data provided by the PTP. 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.~~

5.2 **Complaints Relating to Laboratories**

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

10.06.0 **SUSPENSION OR REVOCATION OF ACCREDITATION**

160.1 **Suspension**

6.1.1 The AB suspends a laboratory's accreditation for a field of accreditation when:

- a) The laboratory fails two (2) out of the most recent three (3) PT studies attempted for a particular field of accreditation, when participation is required for a particular FoPT as established by V1M1.
- b) The laboratory fails to provide a corrective action report to the AB within thirty (30) calendar days of a request from the AB.

6.2 **Revocation**

6.2.1 The AB revokes a laboratory's accreditation for a field of accreditation when:

- a) The laboratory fails three consecutive PT studies, either by failure to participate in the required PT study or due to failure to obtain acceptable results, for the same field of accreditation.
- b) A laboratory violates any of the provisions outlined in V1M1: Sections 4.1.5 a) – d) .

6.3 **Reinstatement of Accreditation**

6.3.1 The AB reinstates accreditation of a laboratory whose accreditation is suspended, as specified in section 6.1.1, when the laboratory establishes a history of two (2) successful PT study results out of the most recent three (3) attempts for the particular field of accreditation, as specified in V1M1.

6.3.2 The AB reinstates accreditation of an environmental laboratory whose accreditation was suspended as specified in section 6.1.2, when the laboratory provides the corrective action report for the failed PT study and the Primary AB determines that corrective action acceptable, provided the laboratory meets the requirements for continued accreditation.

6.3.2 The AB reinstates the accreditation of an environmental laboratory whose accreditation is revoked as specified in section 6.2, when the laboratory meets the requirements for initial accreditation, as specified in V1M1 and the Primary AB's requirements for re-accreditation.

NOTE: The AB may have regulatory processes for revocation, suspension, and reinstatement of accreditation that supersede the conditions of this Standard.

~~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 documented receipt of a request from the primary AB to submit the report to the Primary AB..~~

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

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

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

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

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