

**SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING**

JANUARY 28, 2014

The Committee met at the Forum on Laboratory Accreditation, Louisville, KY, on Tuesday, January 28, 2014, at 8:00 am EST. Chair Shawn Kassner led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (Other)	Present
Stephen Arpie, Absolute Standards (Other)	Present
Kareen Baker, Independent (Other)	Absent
Yumi Creason, PA DEP (AB)	Present (on phone)
Rachel Ellis, NJ DEP (AB)	Absent
Scott Hoatson, Oregon DEQ (AB)	Present
Shawn Kassner, Phenova (Chair; Other)	Present
Roger Kenton, Eastman Chemical Co. (Lab)	Absent
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Present
Mitzi Miller, Dade Moeller Assocs. (Other)	Present
Judy Morgan, Env. Science Corp. (Lab)	Present
Virgene Mulligan, Amrad (Lab)	Absent
Joe Pardue, P2S (Other)	Present (on phone)
Jim Todaro, Alpha Analytical (Lab)	Present
Lisa Touet, MA DEP (AB)	Present (on phone)
Ken Jackson, Program Administrator	Present

2 – Introductions

Shawn welcomed the attendees, and the Committee members present and on the phone introduced themselves. Several active Associate Committee Members in the audience were recognized. Shawn outlined the agenda for the session.

3 – Status of Standards Development

It was announced that more than 90 comments received on the Modified Working Draft Standard of Volume 1, Module 1 (V1M1), and Volume 2, Module 2 (V2M2) had been dealt with, and the Voting Draft Standard was almost ready for posting. A Working Draft Standard for Volume 3 (V3) was complete and would be posted on the website within 2-3 weeks. Shawn explained it would require PT Providers to be accredited to ISO 17043 (as they all are), and hence V3 would contain only the additional TNI requirements. The committee had also started working on Volume 4 (V4), and would require Proficiency Test Provider Accreditors (PTPA) to be accredited to ISO 17011, thus allowing V4 to contain only the additional TNI requirements. Comments on the first draft of V4 had already been received from the PTPAs and others, and they would be considered during this morning's session.

4 – New Charter

Shawn went through the updated committee charter that had been arranged in the new format. He said the term expiration dates of the Committee members would be added. The charter included the subcommittees which were outlined.

5 – Standard Interpretation Requests (SIR)

Four SIRs had been received. They were each shown on the screen and the committee went through them.

SIR 168. There were no comments on the committee’s response. It was moved by Jim and seconded by Judy to approve the response, and all Committee Members voted in favor.

SIR 176. It was moved by Mitzi and seconded by Stacie to send this back to the Laboratory Accreditation System Executive Committee (LASEC) for action, because this was an accreditation question. All were in favor. It was added that LASEC would then decide if it should be dealt with by the NELAP Accreditation Council or the Proficiency Test Program Executive Committee (PTPEC).

SIR 184. This SIR had been answered by the committee, but was returned for clarification. On Nicole Cairns suggestion, the words “within the PT time-frames” were added to make the response “If a laboratory fails to report a single proficiency testing result within the PT time-frames it is evaluated as “not acceptable” per V2M2 7.3 part b. If the laboratory fails to report results for 2 out of 3 proficiency testing study time frames, then the laboratory’s accreditation shall be suspended per V2M2 10.1 for failing to participate in the timeframes specified in the standard.” It had also been questioned if the penalty was revocation or suspension. Ken Jackson reminded the committee that the intent of the standard was to apply revocation only if a laboratory refused to participate at all in the PT program. It was moved by Mitzi and seconded by Stacie to accept the modified response. All were in favor.

SIR 185. This SIR had been answered by the committee, but was returned for revision. It was believed the revised response would be acceptable. It was moved by Mitzi and seconded by Judy to accept the response. All were in favor.

6 – V1M1, V2M2, and V3

Shawn said a few comments remained to be addressed. Aaron Alger had withdrawn an outstanding comment on V2M2, and one other from Susan Wyatt still needed to be addressed. He said the committee had imposed a deadline of the end of February to complete V1M1 and V2M2 VDS. Then comments would be taken during a public meeting (probably the August meeting) on the V3 WDS.

7 – V4

Mitzi said a version of V4 had been generated that removed ISO 17011 requirements, since the PTPAs would be separately accredited to ISO 17011. This draft had been sent to the two PTPAs for

comment and their comments had been received. There were 2 major comments. The first was whether the term “database” or “data management system” would be used. It would be necessary to write V4 so the 2 PTPAs could continue to use their separate databases in the absence of a central database. Stacie added the 2009 standard was written when there was only one PTPA and the “central database” was actually that PTPA’s database.

Rob Knake commented that the draft V4 had a lot of requirements for which TNI is responsible as well as the PTPA. He asked if there should be a Volume 5 for the TNI responsibilities. This generated a lot of discussion. Matt Sica suggested PTPAs should have a charter from TNI to allow the TNI requirements to be kept out of the standard. However, Bob Wyeth cautioned putting this issue into a parking lot if its consideration would delay the standard. Marlene Moore described the arrangement within the National Environmental Field Activities Program (NEFAP) where a contract describes the roles. She suggested, in the case of NELAP, an SOP might be used for TNI responsibilities. Nicole Cairns added that the PTPEC has been considering forming a subcommittee for this for a long time. Bob Wyeth said perhaps a joint PT Expert Committee/PTPEC subcommittee should be formed to work on V4. There was general agreement to form a subcommittee, and Shawn added that the two PTPAs should be included on that subcommittee. Shawn said he would raise the issue of simultaneously developing V4 and an SOP during the NELAP Accreditation Council and LASEC meetings during the week to check if anyone would have a problem with this idea. Mitzi said the next draft version of V4 would therefore remove the responsibilities of the PTPEC.

Mitzi worked through the appended draft V4, soliciting comments from the Committee members and the audience.

1.4. This new clause explained that ISO 17011 requirements had been removed. Mitzi said Jerry Parr would be asked to get licensed copies of ISO 17011 for committee use in developing the standard.

3.0 Terms and Definitions. In the opening statement Randy Querry had suggested adding ISO 17043 Section 3, that describes requirements for stability homogeneity and verification. It was agreed to add this in.

4.1 Fields of Proficiency Testing. Matt Sica’s comment referred to the earlier discussion on removing TNI requirements from the standard. Stacie suggested removing Section 4, because from its title it discusses PTPEC requirements. However, Matt cautioned that some of section 4 which had PTPA requirements embedded needed to be retained. Mitzi said perhaps that should be merged into Section 5 (that would then be the new Section 4).

4.3 Determining Criteria for Oversight. Referring to Matt’s comment, Mitzi suggested this should also go into the SOP; i.e., the PTPEC has to make sure the PTPA has a system for oversight of providers. However, 4.3.2 will need to stay in so the PTPA will know what to ask for. Mitzi said it would need to remain in the standard that the PTPEC is the arbiter, but agreed with a suggestion by Matt that discussion of complaints in 4.3.3 should be moved to Section 6.4.

Stacie suggested having just one reference to the SOP rather than repeating it throughout the standard.

5.0 Requirements for Approval of a Proficiency Testing Provider Accreditor. In response to Matt's question if a TNI state could become a PTPA, the answer given was "yes". Stacie said the title of 5.0 should be shortened to "Requirements for a Proficiency Testing Provider Accreditor". Matt, referring to the statement that the organization should be recognized by a national or international cooperation, said an international organization may be more rigorous than a national one. It was agreed to strike "national". On Matt's suggestion "environmental" was struck from 5.1.2. The committee agreed with Randy's suggestion that a) through e) should remain. In b) reference to compliance with ISO 17043 would be added.

5.2 Responsibilities Regarding Assessment of PT Providers. Section 5.2.1 refers to V3, and Mitzi said she would check V3 to make sure the requirements remain the same.

5.3 Development of Standard Operating Procedures and Forms. Sections 5.3.1, 5.3.2 and 5.3.4 would be deleted since they are covered in ISO 17011. In 5.3.4 the note would be removed, but Rob Knake suggested keeping the language, but not as a note (add to 5.3.3).

5.4 Development and Maintenance of a Comprehensive PT Database. Mitzi suggested changing "database" to "data management system". This would be more descriptive of the requirements that need to be more than just data storage in a database. Matt pointed out that PTP should be PTPA in 5.4.1. It was decided to restore the deleted text in 4.3.2 and move it into 5.4.1, and it was agreed 5.4.1 then required word-smithing.

5.5 List of Accredited PT Providers. It was agreed to word-smith the first sentence of 5.5.1 for clarity.

5.6 PTPA Ethics. Randy and Matt had both commented that this is addressed in ISO 17011. It was agreed to remove this section.

5.7 Confidentiality. This section was also removed because it is covered in ISO 17011.

6.0 Requirements for Accreditation of PT Providers. On Matt's suggestion a sentence would be added to state "in addition to or clarification of ISO 17011 the following are requirements of the PTPA." The note would be removed, because the requirement is met I ISO 17011.

6.1 Initial Application Review. This is not covered in ISO 17011 and would remain.

6.2 On-Site Assessment. It was agreed to remove 6.2.1 a), 6.2.1 f), 6.2.2, 6.2.3, and 6.2.4, which are all covered in ISO 17011.

6.3 Responsibilities for Ongoing Monitoring of PT Providers. Section 6.3.2 refers to a national average, but this can no longer be evaluated in the absence of a single national database. Kelly Black suggested listing the national average as an extra column in the FoPT tables, and having an SOP requiring the PTPAs to provide the data. There followed a protracted discussion on the feasibility of obtaining a national average and whether it is a meaningful metric. Mitzi asked if the section should just be deleted, since it is not being done now anyway. It was suggested it might be sufficient to just say investigate a situation where the pass/fail rate is disproportionately high or low (as it states in 5.9.1.3 of the V3 WDS). It was suggested V3 would then need to be re-worded to make the requirement less arbitrary. Shawn suggested the standard could just state the PTPA must investigate any situation where a PT provider's pass/fail rate does not comply with the requirements

set by the PTPEC. Then the PTPEC could write the SOP. After some discussion it was agreed the language should be “The PTPA shall monitor pass/fail rates per the PTPEC. The PTPA shall investigate pass/fail rates that deviate from criteria established by the PTPEC. The PTPA shall notify the PT Provider of pass/fail rate deviations and monitor associated corrective actions taken by the PT Provider.”

6.4 Complaints and Corrective Actions. This is covered in ISO 17011, so the section was deleted. However, the discussion of complaints in 4.3.3 should be moved to this section.

6.5 Suspension or Revocation of PT Provider Accreditation. Mitzi said ISO 17011 clause 7.1.3 covers this, and the only additional requirement is in 6.5.4. It was questioned what this point would serve if the PTPEC cannot change the accreditation status. The PT providers have an ANSI appeal process. After further discussion it was agreed to delete 6.5.4.

This completed V4.

Adjournment

The meeting was adjourned at 11:55 pm EDT.

VOLUME 4

GENERAL REQUIREMENTS FOR AN ACCREDITOR OF ENVIRONMENTAL PROFICIENCY TEST PROVIDERS

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VOLUME 4

GENERAL REQUIREMENTS FOR AN ACCREDITOR OF ENVIRONMENTAL PROFICIENCY TEST PROVIDERS

1.0 INTRODUCTION, SCOPE, AND APPLICABILITY

1.1 Introduction

This Volume provides the requirements for an organization to function as a TNI-approved Proficiency Testing Provider Accreditor (PTPA).

1.2 Scope

The Proficiency Testing (PT) program includes the following elements:

- a) the production and supply of PT samples that challenge the critical components of each analytical procedure, from initial sample preparation to final data analysis;
- b) the production and supply of PT samples that are as similar to real-world samples as are reasonably possible and representative of materials analyzed for environmental regulatory programs, agencies and communities;
- c) the yielding of PT data that are technically defensible on the basis of the type and quality of the PT samples provided; and
- d) the preparation of PT samples which pose equivalent difficulty and challenge regardless of the manner in which the PT samples are designed and manufactured by the PT providers.

1.3 Applicability

1.3.1 This Volume is applicable to any organization seeking to function as a TNI-approved PTPA.

1.3.2 Included in this Volume are some of the responsibilities of the TNI PT-[Program Executive Committee \(PTPEC\)](#) ~~Board~~ ~~PEC~~ regarding the determination of fields of proficiency testing (FoPT), PT program content, evaluation criteria, and ~~oversight~~ ~~[71]~~.

1.3.3 This is not intended as a complete set of requirements or procedures for the ~~PT Board~~ ~~PTPEC~~; rather, it is intended to assure (1) that these functions are controlled by the TNI consensus process, and (2) that there is an impartial selection process for the PTPA.

1.3.4 These requirements also apply to the responsibilities of the TNI-approved [PTPA \(s\) Accreditation Body \(or bodies\)](#). These requirements assume that monitoring is an essential part of accreditation, and so the accreditation and monitoring functions are seen as part of the same process. It is also recognized that the PTPA [\(s\)](#) may have other requirements and mutual recognition agreements that may need to be included in the TNI accreditation process. These requirements are outside the TNI consensus process, except that the ~~PT Board~~ ~~PTPEC~~ must approve them as applicable to TNI accreditations. In addition, these recognitions allow TNI PT providers to offer their services in regions where TNI accreditation may not be recognized.

1.4 ISO/IEC 17011

This volume is based on ISO/IEC 17011 Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies. This volume uses the language from ISO/IEC 17011 as written and provides additional requirements unique to TNI PT Program. The reader must have a valid copy/license of ISO/IEC 17011 to see the entire text.

2.0 NORMATIVE REFERENCES

Not Applicable.

3.0 TERMS AND DEFINITIONS

For the purpose of this Standard, the relevant terms conform with *ISO/IEC 17011:2004(E)*, *Clause 3* and *ISO/IEC 17025:2005(E)*, *Clause 3*. Additional relevant terms are defined below^[72].

Add Conformity Assessment Body-ISO term for organization being accredited; in this case the PT providers.

- 3.1 Field of Proficiency Testing (FoPT):** Analytes for which a laboratory is required to successfully analyze a PT sample in order to obtain or maintain accreditation, collectively defined as: matrix, technology/method, and analyte.
- 3.2 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.
- 3.3 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.
- 3.4 Proficiency Testing Provider (PT Provider):** A person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.
- 3.5 Proficiency Testing Provider Accreditor (PTPA):** An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.
- 3.6 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.
- 3.7 Proficiency Testing Study (PT Study):** A single complete sequence of circulation of proficiency testing samples to all participants in a proficiency test program.
- 3.8 TNI ~~PT Program Executive Committee~~PT BoardPTPEC (~~PT Board~~PTPEC):** A ~~board-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 Board~~PTPEC are defined in the TNI ~~PT Board~~PTPEC Charter.

4.0 REQUIREMENTS FOR PROFICIENCY TESTING BOARD OVERSIGHT OF PT PROGRAMS

4.1 Fields of Proficiency Testing

The ~~PT Board~~PTPEC shall^[73] determine the content of approved PT programs and performance expectations for laboratories. These determinations shall be based on sound technical, professional, and statistical judgment. Content of PT programs, concentration ranges, expected values, and evaluation criteria shall, where appropriate, be consistent with public health needs and best international practices.

To this end, the ~~PT Board~~PTPEC shall:

- 4.1.1 Determine the areas to be covered by PT studies, and define all requirements for content, including:
- a) the appropriate matrix;
 - b) measurement technologies;

- c) analytes or classes of analytes;
- d) required concentration range;
- e) proficiency testing reporting limit (PTRL) for each analyte.

4.1.2 Determine acceptance limit criterias for each analyte. The tables containing all analyte acceptance limit criterias established by the PT Board/PTPEC shall be publicly available.

4.1.3 Review PT data and the acceptance limit crierias at least biennially to revise existing evaluation criteria and establish new criteria, as needed.

4.2 Selection of a PTPA

The PT Board/PTPEC shall select an organization or organizations to serve as a PTPA. To accomplish this, the PT Board/PTPEC shall:

4.2.1 Assure that the prospective PTPA meets all requirements in Section 5 of this Volume.

4.2.2 Approve all policies and procedures used by the PTPA for the purposes of accreditation and oversight of PT Providers. This shall include approval of any additional (non-TNI) requirements from the PTPA that are related to their policies for compliance with ISO/IEC 17011 and international agreements.

4.2.3 Conduct appropriate biennial on-site assessments of any organization seeking to be a PTPA.

4.3 Determining Criteria for Oversight

4.3.1 The PT Board/PTPEC shall ^[74] determine criteria for ongoing oversight of PT Provider activities, including activities and objectives for the PTPA review consistent with this Standard.

4.3.2 The PTPA shall have arrangements to develop and maintain systems for ~~oversigh~~oversight of PT ~~Proviors~~Providers to ~~te~~ include:

- a) data on verification, homogeneity and stability testing;
- b) summary information about each study, including
 - i. assigned value
 - ii. means and standard deviations
 - iii. number of results
 - iv. information about unsuccessful rates
 - v. any other information requested by the PTPA for evaluation of the PT Program

[05]

4.3.2 The PT Board shall have arrangements to develop and maintain a database for oversight of PT ^[76] Providers. The database shall include the following:

- a) data on verification, homogeneity and stability testing;
- b) summary information about each study, including
 - i. assigned values
 - ii. means and standard deviations
 - iii. number of results
 - iv. information about unsuccessful rates
 - v. any other information requested by the PTPA to meet the requirements of Section 6.3.

4.3.3 The PT Board/PTPEC shall serve as final arbiter ^{for} ^[77]:

- a) complaints about the PTPA that come from Accreditation Bodies or from PT Providers;
- b) disputes between PTPAs.

5.0 REQUIREMENTS FOR APPROVAL OF A PROFICIENCY TESTING PROVIDER ACCREDITOR

These requirements apply to the approval of ~~the accreditation and oversight body~~PTPA (s). The requirements in this Section can serve as guidance for ~~PT Board~~PTPEC procedures for those functions, or as requirements that the PTPA shall meet in order to be approved.

5.1 Technical and Administrative Qualifications

5.1.1 An organization shall demonstrate to the ~~PTPEC Board~~ that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider accreditation and oversight.

5.1.2 The organization shall be recognized by a national or international ~~cooperation~~^[78] of accrediting bodies for the ~~accreditation of environmental laboratories,~~^[79] and shall demonstrate the following:

~~a) _____ a) _____~~ compliance with ISO/IEC 17011: *General requirements for accreditation bodies accrediting conformity assessment bodies*;

~~b) _____~~ Compliance with the requirements set forth in this standard above those in ISO/IEC 17011

~~_____ b) _____~~ have, or have access to, technical expertise that conforms with ISO Guide 34 and/or ISO ~~17025~~^[710] as appropriate, for the preparation and/or analysis of the types of reference materials being prepared by the PT Providers;

~~_____ c) _____~~ expertise in statistical applications used for interlaboratory comparison programs;

~~_____ d) _____~~ the capability to conduct on-site audits of PT Providers that are consistent with this Standard;

~~_____ e) _____~~ the capability to conduct technical reviews of initial applications.

5.2 Responsibilities Regarding Assessment of PT Providers

5.2.1 The assessment and oversight activities of the PTPA shall be designed to ensure that any accredited PT Provider meets the requirements specified in Volume 3 of this Standard, and in Section 6 of this Volume.

5.2.2 Any variations from these requirements or additions to these requirements shall be approved by the ~~PT Board~~PTPEC prior to use by a PTPA.

5.3 Development of Standard Operating Procedures and ~~Forms~~^[711]

~~The PTPA shall develop procedures to conduct the PT Provider evaluation. These documents shall be based upon the requirements of this Standard.~~

~~5.3.1 _____~~ The PTPA shall develop and implement procedures including, but not limited to:

~~_____ a) _____~~ the initial application submittal and review process;

~~_____ b) _____~~ on-site assessment;

~~_____ c) _____~~ accreditation process;

~~_____ d) _____~~ submittal of oversight information to the PTPA;

~~_____ e) _____~~ revoking a PT Provider's accreditation;

~~_____ f) _____~~ appealing accreditation determinations.

~~5.3.2 _____~~ The PTPA shall develop procedures for the initial application process to be followed by PT Providers applying for accreditation. The application shall include information about the qualifications of the organization seeking accreditation.

5.3.3 The PTPA's procedures shall require acceptance of other accreditations, recognitions, calibrations,

etc., if they are current and are issued by organizations that have a mutual recognition agreement with the PTPA for that activity, product or characteristic. To the extent feasible, the PTPA shall not assess those activities that are so recognized.

NOTE: By mutual recognition agreement, the PTPA is allowed to find non-conformances in activities that have recognized accreditation.

5.3.4 ~~The PTPA shall develop procedures for conducting consistent and effective on-site assessments of PT Providers. The procedures shall include a description of the circumstances for conducting any additional assessments or unannounced assessments.~~

5.3.5 A PTPA shall develop standard, concise and unambiguous checklist(s) to be used during all assessments of PT Providers.

5.4 Development and Maintenance of a Comprehensive PT Database-Data Management System^[712]

5.4.1 The PTPA shall maintain a comprehensive PT ~~database-data management system~~ that contains summaries of participant results and results of all verification, homogeneity, and stability determinations^[713].

5.4.2 The PTPA shall instruct PT Providers on procedures for submitting data to the ~~database~~PTPEC for oversight monitoring.

5.5 List of Accredited PT Providers

5.5.1 The PTPA shall maintain a list of accredited PT Providers and the FoPTs they are accredited to provide. The list shall be maintained on a continuing basis, on an electronic bulletin board or similar means, and shall be readily available to laboratories seeking accreditation, Accreditation Bodies, and other interested parties.

5.5.2 The PTPA shall ensure that all accredited PT Providers abide by the provisions of the ~~PT Board~~PTPEC and PTPA regarding the advertising and marketing of their accreditation approval status.

5.6 PTPA^[714] **Ethics**^[715]

5.6.1 A PTPA shall serve as an impartial body designed to objectively evaluate information about PT Providers and use this information to make sound determinations regarding a provider's accreditation status.

5.6.2 A PTPA shall be able to demonstrate to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of this Standard.

5.6.3 A PTPA shall remain unbiased in evaluating information gathered and received including assessment reports, referee sample results, complaints, and any other information obtained regarding a PT Provider.

5.6.4 The PTPA shall evaluate all information about a PT Provider related to providing PT programs, determine which information is relevant to the PT Provider's accreditation status, and provide that information to the appropriate parties, consistent with all confidentiality agreements.

5.7 Confidentiality^[716]

~~5.7.1 A portion of the information provided to a PTPA by the PT Provider in the course of its assessment and oversight activities shall be proprietary in nature. A PTPA shall agree to maintain the confidentiality of proprietary information provided to it by the PT Providers.~~

~~5.7.2 The PTPA shall treat all study data, sample formulation process information, analysis techniques, and other proprietary information as confidential and not accessible to any other entity; except as described in this Standard. This information shall not be released without prior written permission from the PT Provider.~~

6.0 REQUIREMENTS FOR ACCREDITATION OF PT PROVIDERS^[717]

The accreditation process shall be repeated every two years, and shall include all stages of initial review, on-site assessment and oversight.

Timelines for application review, conducting assessments, and follow-up activities shall not cause undue delay in processing a request for accreditation.

NOTE: These timelines will be consistent with the PTPA's internal policies, as approved by its mutual recognition partners. ^[718]

6.1 Initial Application Review^[719]

The PTPA shall conduct the reviews described in this Section for the applications from any candidate or renewal PT Provider. This review shall include:

- a) the initial application documents for compliance with the PT Provider qualifications described in this Standard;
- b) the sample designs used by the PT Provider for compliance with this Standard;
- c) the PT analyte and sample scoring procedures used by the PT Provider for compliance with this Standard;
- d) procedures used to validate that new PT sample formulations are fit for their intended purpose, prior to use of such material in a PT scheme. This review shall ensure, at a minimum, that samples have assigned values within the specified ranges for every technology used to report results;
- e) the adequacy of data processing and analysis techniques, including statistical procedures used on sample sets with fewer than 20 laboratories;
- f) confirmation of the absence of conflicting interests with subscribing laboratories, including:
 - i any financial interest in a laboratory seeking or having accreditation to this Standard;
 - ii the sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, accreditation to this Standard.
- g) providing PT Providers with checklist(s) to be used during the assessment as part of the initial application process. The checklist shall include all requirements that may be necessary for the PTPA to comply with their own policies and external agreements.

6.2 On-Site Assessment

6.2.1 An on-site assessment of the PT Provider shall follow the initial review and shall include, at a minimum:

- a) ~~a review of the quality management system for adherence to the requirements of this Standard~~^[720];
- b) a review of staff qualifications and technical expertise necessary to produce acceptable PT samples;

- c) a review of the sample manufacturing and analytical verification procedures, along with the study data, to ensure the requirements of this Standard are met;
- d) a review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for PT Providers and confidentiality of assigned values and participant results;
- e) a review of data reporting systems to ensure that the requirements of this Standard are met within the defined time periods; and
- f) ~~an exit meeting, which shall include delivery of the final report from the assessment and a discussion of all assessment findings~~^[721].

6.2.2 ~~The PTPA shall provide a written final report to the PT Provider during the exit briefing. The final report may only contain findings identified during the on-site assessment and discussed during the exit briefing, as defined in the PTPA's procedures~~^[722].

6.2.3 ~~The PTPA shall allow the PT Provider to submit its response to the report. In order for the PT Provider's response to be considered acceptable, it shall include a description of any corrective actions necessary to meet the criteria of this Standard, and, as appropriate, objective evidence of successful implementation of any corrective action.~~^[723]

6.2.4 ~~A PTPA shall follow its procedure for determining accreditation. This procedure shall include use of the appropriate final assessment report and associated documents submitted by the PT Provider~~^[724].

6.3 Responsibilities for Ongoing Monitoring of PT Providers

6.3.1 A PTPA shall conduct ongoing monitoring of all accredited PT Providers^[725]. This shall include a review of sample verification and PT study data to assure that every PT sample meets criteria defined in this Standard. The review shall also include:

- a) assurance that concentrations are distributed throughout the specified analyte ranges;
- b) confirmation of the required minimum number of analytes included in groups such as volatiles, semi-volatiles, herbicides, etc;
- c) approval of documentation for any change in the initial assigned value during a study;
- d) confirmation of the correct calculation of assigned values and acceptance limits as appropriate per analyte;
- e) verification of the prepared or assigned value;
- f) appropriate homogeneity testing prior to the study;
- g) appropriate stability testing.

6.3.2 The PTPA shall investigate any situation where a PT Provider's pass/fail rate for any analyte or overall is statistically different from the national average at a 95% level, as determined by appropriate statistical techniques^[726].

6.3.3 The PTPA may use an accredited referee laboratory to verify the assigned values of the concentrations when monitoring indicates that the PT Provider's sample is of unacceptable quality.

a) The determination of unacceptable quality shall use the same acceptance criteria that were used in the manufacture of the PT sample (for example, 1 standard deviation for verification or the approved criteria for homogeneity and stability).

b) The PTPA shall provide each PT Provider with a report describing the results for any required referee analyses.

6.3.4 The monitoring shall provide verification of the PT Provider's adherence to the appropriate standards for the following:

a) correct and complete analyte lists as per PT provider accreditation;

b) a process for handling complaints;

c) compliance with defined nomenclature (codes) for methods, analytes and technologies;

d) appropriate study lengths, including announced start and stop dates;

e) timeliness of reports to customers, Accreditation Bodies and the PTPA.

6.3.5 PTPA monitoring shall include review of critical operational parameters of the PT Provider, such as changes in ownership or senior management, and the evidence of internal audits and management review.

6.3.6 Unscheduled on-site assessments of the PT Provider may be conducted for exceptional circumstances, such as persistent complaints from participants or Accreditation Bodies, failure to adequately respond to inquiries from the PTPA, or other evidence of persistent non-conforming activity. The causes and resolution of exceptional visits shall be fully documented.

6.3.7 Any possible problems indicated by the monitoring shall be discussed first with the PT Provider. Complete records shall be maintained of all contacts and responses from the PT Provider.

6.3.8 Based upon the results of its ongoing monitoring and its internal appeals process, the PTPA may determine that a PT Provider's accreditation status should be suspended or withdrawn.

6.4 Complaints and Corrective Action^[727]

~~6.4.1 The PTPA shall evaluate all complaints that it receives regarding accredited or candidate PT Providers. If the PTPA determines that a complaint warrants investigation, it shall notify the PT Provider of the complaint. The PT Provider is required to resolve the complaint to the satisfaction of the PTPA.~~

~~6.4.2 The PTPA shall provide to the PT Board a summary of all PT Provider complaints received the previous year.~~

~~6.4.3 Complaints made to PT Providers and the resultant corrective actions shall be reviewed by the PTPA in the following manner:~~

~~a) review of a written summary of all complaints regarding the technical aspects of the studies and the resulting corrective actions; and~~

~~b) review of all complaints that are unresolved after ninety (90) days.~~

~~6.4.4 The PTPA shall review any complaints about PT Providers received from Accreditation Bodies, and work with the PT Provider, the Accreditation Body, and the PT Board to resolve the complaints.~~

6.5 Suspension or Revocation of PT Provider Accreditation

- 6.5.1 ~~Based on their review of study data, onsite assessments and corrective actions associated with complaints or other non-conformances, the PTPA may determine that a PT Provider fails to meet the requirements of this Standard on a continuing basis.~~
- 6.5.2 ~~The PTPA shall provide formal written notice to a PT Provider of any action to revoke or suspend the PT Provider's accreditation for any reason.~~
- 6.5.3 ~~The PTPA shall inform the PT Provider of the reasons for proposed revocation or suspension and the procedures for appeal of such a decision[728].~~
- 6.5.4 The PTPA shall respect the due process rights of the PT Provider during any revocation or suspension proceedings, including the PT Provider's right to appeal the decision to the PT ~~Board~~PEC after completion of the PTPA's appeals process.