PT Expert

Minutes May 3, 2012

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TNI Proficiency Testing Committee			
Committee Members 2012			
Member	**Affiliation**	**Email**	5/3/2012
Stephen Arpie	Absolute Standards, Inc.	stephenarpie@absolutestandards.com	x
Stacie Metzler	Hampton Roads Sanitation District	smetzler@hrsd.com	x
Shawn Kassner	ERA-A Waters Company	skassner@era.qc.com	x
Scott Hoatson	Oregon DEQ	hoatson.scott@deq.state.or.us	x
Roger Kenton	Eastman Chemical Company	rogerk@eastman.com	x
Mitzi Miller (Chair	Dade Moeller & Associates	mitzi.miller@moellerinc.com	x
Lisa Touet	Massachusetts DEP	lisa.touet@state.ma.us	x
Kirstin McCracken (Past Chair)	TestAmerica, Inc.	KirstinL.McCracken@testamericainc.com	x
Judy Morgan	Environmental Science Corp	Jmorgan@esclabsciences.com	x
James Webber, Ph.D.	New York State DOH	webber@wadsworth.org	x
Jim Todaro	Alpha	j.todaro@comcast.net	x
Rachel Ellis	New Jersey DEP	rachel.ellis@dep.state.nj.us	x
Joe Pardue	P2S - DOE Subcontractor	parduegjjr@oro.doe.gov	x
Kareen Baker	Veolia Environnement (NYSE: VE)	kareen.baker@veoliawaterna.com	x
Associate non-voting members			
Bob O'Brien	Sigma-Aldrich	Bob.OBrien@sial.com	x
Carol Smith	SC DHEC	smithcf@dhec.sc.gov	x
Susan Butts	SC DHEC	buttsse@dhec.sc.gov	x
Nicole Cairns	NY	nlc02@health.state.ny.us	x
Jeff Lowry	Wibby	Jeff Lowry <jlowry@wibby.com>	x
Keith Ward	Wibby	kward@wibby.com	
Aaron Alger	PA DEP	aaalger@pa.gov	

Approval of 4-26-12

With the addition of some organizations and emails, Scott recommended approval of the 4-26-12 minutes; seconded by Shawn. All voted in favor, 0 negatives, 0 abstain.

Section 3-Definitions

Assigned value and acceptance limits changed to be consistent with the other 3 volumes.
FoPT was edited after much discussion. The other two volumes will need update with FoPT.
This definition was sent to the PT Executive Committee.
PTRL was edited after discussion.

The AB definition is left TBD until all of the AC, LASC and other committees agree on a definition. This is per Mitzi's agreement with Jerry Parr.
It was agreed that if we find other terms needing definition, we collect them and reevaluate at the end of editing other sections. One example for addition is 'study mean'.

Judy moved that with the current edits, section 3 be accepted with the edits; Shawn seconded, all voted in favor, 0 negatives, 0 abstain.

Section 5-Quality System Requirements

A discussion of using ISO 17043 as the only requirement for the QS was presented by Steve without added information such as FoPT. The group agreed that this would not be accepted politically and that states have written regulations around the knowledge of using FoPT and that laboratories are not going to specify the use of FoPT to generate PTs for environmental. The reference to ISO 17043 was added to replace ISO 9001 because the ISO 17043 has QS section and has more appropriate information for PT provider's QS.

Steve moved that with the current edits, section 5.1.1 be accepted with the edits; Roger seconded, all voted in favor, 0 negatives, 0 abstain.

Section 5.1.2 was discussed. The suggestion was made not to put the ISO verion date, because then we have to update each time ISO changes. It was noted that when updates occur from ISO all parties are given 2 yr to meet the new requirements and TNI can reopen the standard if there are objections to the ISO update.

Steve moved that with the current edits, section 5.1.2 be accepted with the edits; Scott seconded, all voted in favor, 0 negatives, 0 abstain.

Action Item: all should look at the remainder of section 5 and section 6 submitted give comments to author to shorten the meeting times.

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The group is beginning to work on editing volume 3. The following writing assignments were made:

Section	Person	Date Due
Entire section 3	Mitzi	Done
4	Kirsten	Done
5	Jim	5/3—in progress
6	Shawn	draft
7	Judy & Jeff	draft
8	Rachel	5/10
9	Kirsten	done
10	Shawn	5/10
11	Scott	done

The group discussed removing appendix A and inserting words to the effect that ISO 17043 homogeneity/stability, and verification will be used. No vote was taken on this issue.

3.0 TERMS AND DEFINITIONS

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

~~Need to ensure all terms and definitions are consistent between modules.~~

3.1 **Assigned Value:** Value attributed to a particular quantity and accepted, ~~sometimes by convention~~, as having an uncertainty appropriate for a given purpose. See Section 6.4 for further discussion of assigned values.

3.2 **Acceptance Limits:** The range of values that constitute acceptable performance for a laboratory participating in PT study.

3.3 **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, method/technology, and analyte~~ Proficiency testing for which a laboratory is required to successfully analyze PT samples to obtain or maintain accreditation. Accreditation FoPT are established by the Proficiency Testing Executive Committee.

~~Add accreditation FoPT come up with new definition for FoPT.~~

3.4 **Primary Accreditation Body (Primary AB):** ~~The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.~~TBD based on ABs and LASC.

3.5 **Proficiency Testing (PT):** A means to evaluate a laboratory's performance, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.

3.6 **Proficiency Testing Program (PT Program):** The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of results and the collective demographics and results summary of all participating laboratories.

3.7 **Proficiency Testing Provider (PT Provider):** A person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate ~~a~~ the TNI-compliant PT program.

3.8 **Proficiency Testing Provider Accreditor (PTPA):** An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.

3.9 **Proficiency Testing Reporting Limit (PTRL):** A statistically derived value that represents the lowest acceptable theoretical concentration for an analyte in a PT sample, if the analyte is spiked into the PT sample at the lowest concentration as specified in the TNI FoPT tables. ~~The value that corresponds to the lowest acceptable result that could be obtained from the lowest spike level for each analyte in a PT sample. PTRLs are established and published by the TNI PT Board.~~

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

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Comment [71]: Edit in other volumes

3.12 **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.

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

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

3.15 **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 this Volume, but that does not have a pre-determined opening date and closing date.

3.16 **Supplemental PT Study Closing Date:** The calendar date for which analytical results of a PT sample are received by the PT provider.

3.17 **Supplemental PT Study Opening Date:** The calendar date that a PT sample is shipped from the PT provider to a laboratory.

3.18 **TNI PT** 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 Executive Committee are defined in their Charter.

Collect terms and add at end:
Study mean-??--

5.0 MANAGEMENT REQUIREMENTS

5.1 Quality System Requirements

5.1.1 The PT provider's quality management system shall ~~meet the requirements~~be accredited ~~of~~to ISO ~~9001~~ 17043 for the design, production, testing, and distribution of PT samples and the evaluation of PT results.

5.1.2 The PT provider's manufacturing system shall be accredited to ISO 17043. ~~shall meet the requirements of ISO Guide 34:2009 (General requirements for the competence of reference material producers~~
~~Quality System Guidelines for the Production of Reference Materials~~).

5.1.3 The design and operation of the PT provider's proficiency testing program shall meet the requirements of ILAC G-13 (Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes).

5.1.4 The testing facilities used to support the verification, homogeneity and stability testing required in this Standard shall meet the requirements of ISO 17025 (General Requirements for the Competency of Testing and Calibration Laboratories).

5.1.5 If the PT provider holds specific accreditations related to any of the requirements in Sections 5.1.1 through 5.1.4, this shall not limit the PTPA's ability to assess and make determinations related to the PT Provider's conformance to these requirements.

5.1.6 Providers shall maintain all records related to each PT study for a minimum of five (5) years after the close of the PT study.

5.2 Provider Conflict of Interest and Confidentiality

PT providers seeking to obtain or maintain accreditation shall:

a) document and certify to the satisfaction of the PTPA that they do not have any conflict of interest with any laboratory that may participate in their PT programs;

NOTE: Such a conflict of interest could take the form of a financial interest or sharing of personnel, facilities or equipment with any laboratory that may participate in the provider's PT studies.

b) inform all internal and contract personnel who perform work on PT studies of the PT provider's obligation to report personal and organizational conflicts of interest to the PTPA;

c) have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of PT ~~Programs~~programs;

d) immediately make a full disclosure to the PTPA of any identified actual or potential organizational conflict of interest. The disclosure shall include a description of any action that the provider has taken or proposes to take after consultation with the PTPA to avoid, mitigate or neutralize the actual or potential conflict of interest;

e) have written procedures to ensure that the confidentiality of data associated with PT samples and programs is not compromised;

f) not release the assigned values or acceptance limits of any PT sample prior to the conclusion of the study, except to the PTPA;

g) only release participant laboratories' PT study results and/or evaluations to a designated contact at ~~the~~ each laboratory and to its laboratory accreditation body(ies) and/or other entities as specifically designated by ~~the~~ each laboratory.

NOTE: PT providers may release, at the conclusion of a PT study, without permission of participant laboratories, summaries of participant laboratory results that do not identify individual laboratories.

5.3 Provider Facilities and Personnel

5.3.1 PT providers shall have appropriate facilities, equipment and analytical instrumentation in place to produce, analytically verify, distribute, and provide data evaluation and reporting functions for every PT sample for which they wish to obtain or maintain accreditation.

5.3.2 PT providers shall employ sufficient technical and support staff to design, produce, analyze, distribute, and provide data evaluation and reporting functions for every PT sample for which they wish to achieve or maintain accreditation.

5.3.3 No portion of the design, production, testing, distribution, data collection, data evaluation, or data reporting functions may be outside the direct control of the PT provider for any particular study. For the purposes of this Standard, "direct control" means that these functions are performed in the PT provider's facilities by the PT provider's staff or are sub-contracted by means

of a written agreement with defined PT provider supervision to ensure that all requirements of this Standard are met.

5.3.4 Any subcontracted function related to design, production, testing, distribution, data collection, data evaluation, or data reporting shall be assessed by the PTPA and shall meet the applicable requirements of this Standard.

5.4 Complaints Handling

5.4.1 PT providers shall have written procedures for handling both written and verbal complaints from PT study participants and from laboratory accreditation bodies who receive PT study reports.

5.4.2 PT providers shall record all complaints received concerning their PT studies including ~~any~~all remedial and~~or~~ corrective actions taken. This record shall be provided to the PTPA upon request.

5.4.3 Any complaint received by a PT provider that remains unresolved after ninety (90) days shall be submitted to the PTPA by the PT provider.

5.5 Notification of Sample Integrity

If any sample or analyte used in a PT study is found to not meet any of the requirements of this Standard, the PT provider shall notify all affected laboratories and their designated accreditation bodies and the provider's PTPA within seven (7) calendar days of the discovery of the noncompliance.