SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

OCTOBER 4 , 2013

The Committee met by teleconference on Friday, October 4, 2013, at 11:00 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, Veolia Water N. American (Other)	Absent
Yumi Creason, PA DEP (AB)	Absent
Rachel Ellis, NJ DEP (AB)	Present
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)	Absent
Judy Morgan, Env. Science Corp. (Lab)	Present
Virgene Mulligan, Amrad (Lab)	Present
Joe Pardue, P2S (Other)	Present
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Present
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Nicole Cairns, NYSDOH; Audrey Cornell, ERA; Mark Hammersla, NSI; Brian Stringer, ERA.

2 – Previous Minutes

It was moved by Fred and seconded by Stacie to approve the August 5, 2013 minutes. All were in favor except Lisa who abstained.

It was moved by Fred and seconded by Judy to approve the August 23, 2013 minutes. All were in favor.

It was moved by Joe and seconded by Judy to approve the September 6, 2013 minutes. All were in favor except Lisa who abstained.

3 – Preparation Method Data

Shawn had not heard back from the EPA people, but he said he would keep asking for their input.

4 – Subcommittees

Virgene said she had not yet asked David Sill of the DOE RESL laboratory to join the Radiochemistry Subcommittee, and she was waiting for the Radiochemistry Expert Committee to get back to her.

Shawn said he would send out e-mails later that day to confirm members of the Microbiology Subcommittee, and he would then get the subcommittee started.

Shawn had looked at the WET table and thought the criteria were satisfactory. He asked the committee if Volume 3 would need more on WET, and receiving no positive response he announced that no language on WET would therefore be added to V3. A discussion followed on whether the evaluation criteria from the FoPT table should be added to the standard. It was pointed out the criteria cannot be quickly changed if they are in the standard. Scott suggested leaving the criteria in the table, while others preferred moving them into the standard, as are the chemistry criteria. Lisa said she would ask the PT Executive Committee if they plan to have evaluation criteria in the standard or the tables. Stacie and Joe volunteered to also ask the subcommittee for an opinion.

Shawn said he would follow up with the SIR Subcommittee for progress. Judy said PT was caught up with its SIRS.

5 – Volume 3

Shawn had previously circulated a revised draft of V3, in which he had arranged the clauses in the same order as in ISO 17043. The following clauses were discussed to decide if they should be considered TNI-specific and hence retained in V3.

(It was noted that ISO 17043 would need adding as a reference.)

4.1 PT PROVIDER ACCREDITATION

4.1.1 The PT provider shall be accredited by a TNI-approved PTPA for every TNI FoPT which they will offer in their PT programs.

4.1.2 In order to receive and maintain accreditation for any analyte in any FoPT, the PT provider shall demonstrate compliance with all requirements of this Standard during onsite audits and ongoing oversight conducted by the PTPA per Volume 4 of this Standard.

4.1.3 PT providers shall be subject to biennial onsite audits conducted by their chosen TNI-approved PTPA. They may also be subject to unannounced audits for cause.

4.1.4 PT providers shall submit data from each of their PTPA-accredited PT studies to the PTPA for review to determine compliance with this Standard.

4.1.4.1 The information required in these submittals, including the format and frequency/timing, shall be determined by the PTPA.

4.1.4.2 The provider shall not identify any participant laboratory to the PTPA without the expressed written consent of the laboratory.

4.1.5 Upon request by the PTPA, the PT Provider shall supply, at no charge, PT samples as specified by the PTPA, which are included in the PT Provider's scope of accreditation, to the PTPA for submission to a referee laboratory.

4.1.6 In conflicts with the PTPA, PT providers shall follow the PTPA's appeals process.

4.1.7 Unresolved conflicts with the PTPA shall be submitted to the PTP Executive Committee.

It was agreed all the above clauses should be in V3. Virgene asked if, in clause 4.1.5, "referee laboratory" needed to be defined and what is expected of it. Shawn said he would add it to the definitions for discussion later. Steve said the PT Provider laboratory must be ISO 17025 compliant. The best location for criteria and definitions was discussed. It was suggested some should be in V4, while some should be retained in V3. Scott suggested removing "will" from clause 4.1.1.

4.2 MANAGEMENT REQUIREMENTS

4.2.1 Quality System Requirements

4.2.1.1 The PT provider's quality management system shall meet the requirements of ISO 9001 for the design, production, testing, and distribution of PT samples and the evaluation of PT results.

4.2.1.2 The PT provider's manufacturing system shall meet the requirements of ISO Guide 34 (Quality System Guidelines for the Production of Reference Materials).

4.2.1.3 The design and operation of the PT provider's proficiency testing program shall meet requirements of ISO 17043 (General Requirements for Proficiency Testing).

4.2.1.4 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).

4.2.1.5 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.

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

It was discussed if the ISO 9001 requirement should be retained in clause 4.2.1.1. Clause 4.2.1.2 was retained in V3. It was suggested clause 4.2.1.3 should be amended to read "shall be accredited to ISO 17043". There was general agreement to leave clauses 4.2.1.4, 4.2.1.5 and 4.2.1.6 in V3 as written. It was pointed out that some states require records to be retained longer than 5 years, but it is the laboratory that must retain the records and not the PT provider.

4.3 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;

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 upon request;

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

ISO 17043 has a big section on this, and it was agreed the highlighted text is TNI-specific and needs to be in V3. Shawn volunteered to combine the highlighted text into 1-2 sentences before the next call. Although f) is in ISO 17043, it was agreed this should also remain in volume 3 for added strength.

4.4 Provider Facilities and Personnel

4.4.1 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.

4.4.2 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.

4.4.3 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.

4.4.4 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.

All of Section 4.4 is in ISO 17043, and it was agreed to omit this from V3. However, the header will be put in V3 with a statement that it is covered in ISO 17043.

4.5 PROVISION OF PT SAMPLES

4.5.1 Study Duration

The study closing date shall be no more than forty-five (45) calendar days after the opening date of the study or as specified by the PTP Executive Committee.

4.5.2 Regularly Scheduled PT Studies

4.5.2.1 Regularly scheduled PT studies shall consist of PT sample lots (or batches) that have not been provided, in any form or by any entity, to actual or potential participant laboratories prior to the opening date of the study.

4.5.2.2 The assigned values for regularly scheduled PT samples shall not be released to any entity outside of the PT provider, other than the provider's PTPA, prior to the closing date of the PT study.

4.5.3 Supplemental PT Studies

4.5.3.1 For supplemental PT samples, the PT provider shall:

a) select a batch of PT samples that has been shown to meet all of the requirements of Sections 6 and 7 of this Volume;

NOTE: Supplemental PT samples may be from lots that have been previously used in a PT study.

b) conduct stability testing at the close of the supplemental PT study or have data showing, to the satisfaction of the PTPA, that the sample was stable during the time period of the

supplemental study;

c) have documented procedures and systems in place to track all lots and assigned values of samples received by laboratories that may be used as supplemental PT samples;

d) not supply a supplemental PT sample to a laboratory that has received that sample in a previous PT study, or in any other form, or has had access to the assigned values for that sample;

e) remove the original lot number, study number, and/or tracking ID number of each supplemental PT sample and assign a unique identifier.

4.5.3.2 If the laboratory informs the PT provider that a supplemental PT sample is being used for corrective action purposes for a specific qualitative (presence/absence) test, whether the analyte of interest is spiked into the sample shall be randomly determined by the PT provider so that the laboratory will not automatically know that it is present or not.

4.5.3.3 The closing date of a supplemental PT study shall be the date that the participant(s) has reported study data for the required analytes.

4.5.3.4 The closing date of supplemental PT studies shall be no more than forty-five (45) days after the opening date of the study.

It was agreed clauses 4.5.1 and 4.5.2.1 are TNI and should be in V3. However, clause 4.5.2.2 is redundant to a statement above on confidentiality, so it would be removed. All of 4.5.3, being TNI-specific, would be retained in V3. Mark Hammersla questioned if clause 4.5.3.1 a) could be made more flexible to allow a CRM, in case a laboratory has already received every previous lot the PT Provider has prepared. It was therefore agreed to modify this clause to read "*select a batch of samples that has been shown to meet all of the requirements;"* It was also decided to make the note no longer a note, but a clause of the standard. Steve, in reference to clause 4.5.3.2, said sometimes ABs want it to require a positive result for the analyte. On Nicole's suggestion, Shawn said he would ask the ABs what they want as a corrective action PT for qualitative analytes. It was decided to combine clauses 4.5.3.3 and 4.5.3.4.

At this point, the discussion stopped and Shawn said he would make the changes and circulate the document to the committee.

Adjournment

The meeting was adjourned at 12:30 pm EDT.