SUMMARY OF THE
TNI PROFICIENCY TESTING EXPERT COMMITTEE MEETING

SEPTEMBER 21, 2012

The Committee met by teleconference on Friday, September 21, 2012, at 11:00 am EDT.

1 – Minutes from September 7

In the absence of a quorum the minutes were not discussed.

2 – Vote on Motion of Sept. 7

During the September 7 call it had been moved to create a separate interest category for PT Providers, and the Committee members voted electronically. Ken reported that 8 affirmative votes had been received and no negatives. One more positive vote would be required for the motion to pass. Mitzi said she would contact the five Committee members who did not yet vote (Steve, Stacie, Lisa, Joe, and Kareen), asking them to vote electronically.

Scott suggested delaying the vote on the second motion (to appoint another PT provider as a Committee Member) until the first motion was passed and the charter was amended. There was general agreement on this.

3 - Discussion of Comments received on the Working Draft Standard

Comments Alger1, Cairns14, Cairns15, Cairns 16, and Cairns19.

These comments, all concerned with referencing the requirements of V1 in V2, had been assigned to Scott. He recommended they are persuasive, but said he had not yet re-drafted the specific sections of the standard that were identified in each comment. Mitzi said at this stage he should indicate the changes on the forms and if he wished he could also change the wording in the standard.

Aaron Alger had submitted a re-write of V1M1, and Scott presented his edits of this (see Attachment 1). He had re-worded Sections 4.1.2 and 4.1.4 for clarity. He merged 4.1.6 and 4.1.7 into a new 4.1.5. In response to a question on the note in 4.1.6, Shawn verified that ABs are authorized to specify the month(s) in which laboratories must participate in specific PT studies. It was asked if it also applies to DMR samples, and Shawn said the DMR requirements have changed so that, before the end of the study, all laboratories' results only go to the AB. In 4.2.2, Nicole recommended removing (f). Kirstin said this section had been left vague to be consistent with ISO 17025, but Nicole said it should still state that PTs are analyzed using the same staff as routine samples because that is not in ISO. However, Mitzi said it is now ISO policy that PTs have to be rotated among the staff. Judy said in her laboratory this would be very difficult because they have multiple shifts. After a protracted discussion, there was general agreement to remove (a) through

(f), but add the requirement of the same staff that analyzes routine samples. In referencing 4.2 3, Kirstin said it was not a requirement in the WDS for the laboratory to report to the PTRL. It states in V3 that if you do not detect an analyte you can report < LOQ, but then you are taking a risk if the analyte is present in the sample at a concentration > PTRL. However, it was pointed out that some ABs may score the result as not acceptable if the laboratory does not report to the PTRL. It was suggested that perhaps 4.2.3 should be removed from Section 4.2, because it is a reporting requirement. Another suggestion was to wait for the V3 reporting requirements and then come back to this. Kirstin questioned whether the Committee should be working from Aaron's draft, because it is very different from the WDS; e.g., Aaron's 4.3.5 has a different intent from the WDS. At this point Mitzi asked the Committee if they should be working from Aaron's version or from the WDS. There was general agreement to go back to working from the WDS and Scott said he would do that.

Comments Wyatt2, Wyatt6, Alger4, and Alger8

These comments had been assigned to Kirstin.

Wyatt2 said the standard should be written in "active voice", and there was agreement on this.

Wyatt6 concerned the wording of a Tentative Interim Amendment that was now incorporated into the WDS. It was agreed to refer this matter back to the Consensus Standards Development Executive Committee (CSD-EC).

Alger 8 concerned definitions and this triggered a discussion on whether the current practice of each module having its own list of terms and definitions is the best way to go, or if there should be a central glossary. The current practice is consistent with ISO 17025 and Ken said there had been a lot of discussion on this topic when the TNI standard was first written. At one time there was a glossary committee. Since this issue concerns the entire standards development process, Mitzi said she would take it to the CSD-EC.

Alger4 concerned stating requirements in the affirmative. On the first comment ("This standard does not apply to fields of accreditation…."), Scott said it is persuasive and Susan agreed that is consistent with the way regulations are written; i.e., you do not say what not to do. On the second comment, referring to 5.1.1 a, Aaron had provided alternate language, but this is an AB requirement in the standard. The third comment, referring to 7.1, was agreed persuasive if it is truly a requirement and for ABs rather than laboratories. It was decided to either change the language or remove the requirement from this section.

Comment Westerman5

This concerned the "5 month rule" for laboratories to analyze PT samples. It was generally agreed that ABs prefer just requiring laboratories to analyze PT samples no more than 7 months apart, and that is what the standard should state.

4 – Next Steps

Scott will make his suggested changes to the WDS, rather than Aaron's version. Others will complete the boxes on the comment forms, and when this is complete Ken will transpose the new language into the WDS.

6 – Adjournment

The meeting was adjourned at 12:50 pm EDT. The next meeting will be October 5, 2012

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ATTACHMENT 1

4.0 PT STUDY REQUIREMENTS

4.1 General PT Study Requirements

4.1.1 TNI publishes lists of FoPTs on the TNI website for which PT studies are required, called TNI FoPT Tables. These FoPT Tables may be updated, as needed, by publishing revised FoPT Tables on the TNI website.

4.1.2 The laboratory shall participate in PT studies, when required as stated in the TNI FoPT tables described ~~as specified~~ in section 4.1.1, for each field of accreditation for which the laboratory seeks to obtain or maintain accreditation.

4.1.3 The laboratory shall obtain PT studies for the individual fields of proficiency testing, from a PT Provider accredited by a TNI approved PTPA.

4.1.4 The laboratory shall analyze unique, single blind, single concentration PT samples, when required as stated in the TNI FoPT tables described in ~~required by~~ section 4.1.1, to determine compliance for each field of accreditation for which the laboratory seeks to obtain or maintain accreditation.

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

- send a PT study, or a portion of a PT study, in which it is participating, to another laboratory for the analysis of a field of accreditation for which it seeks accreditation or is accredited.
- knowingly receive and analyze any PT sample or portion of a PT sample from another laboratory for which the results of the PT sample are intended for use for initial or continued accreditation of that laboratory.
- communicate with any individual at another laboratory, including other laboratories under common ownership, concerning the analysis of the PT sample prior to the closing date of the study.
- attempt to obtain the assigned value of any portion of the PT study from the PTP.

~~4.1.5 The laboratory shall not send a PT study, or a portion of a PT study, in which it is participating, to another laboratory for the analysis of a field of accreditation for which it seeks accreditation or is accredited, prior to the release of the study results by the PT Provider. .~~

~~4.1.6 The laboratory shall not knowingly analyze a PT study, or portion of a PT study, for another laboratory for which the sending laboratory seeks accreditation or is accredited, prior to the release of the study results by the PT Provider.~~

~~4.1.7 The laboratory shall not communicate with another laboratory, including other laboratories under common ownership, concerning the PT study prior to the release of the study results by the PT Provider.~~

~~4.1.8 The laboratory may not attempt to obtain the assigned value of the PT study from the PT Provider prior to the release of the study results by the PT Provider.~~

~~4.1.9~~4.1.6 When a regulatory program requires more stringent requirements than the requirements of this module, the laboratory shall follow the more stringent requirements.

NOTE: An AB may specify the month(s) in which laboratories must participate in specific PT studies.

4.2 Sample Handling, Preparation and Analysis Requirements

4.2.1 The laboratory shall handle the PT study samples in accordance with the instructions provided by the PT Provider.

4.2.2 The laboratory shall manage and analyze the PT study samples in the same manner as real environmental samples used during routine analysis for the particular field of accreditation, including using the same:

a) Staff for sample preparation and analysis,

b) Standard Operating Procedures,

c) Laboratory instrumentation, equipment and facilities,

d) Number of replicates,

e) Quality control, and

f) Methods

4.2.3 The laboratory shall evaluate the analytical result for each chemistry and radiochemistry field of accreditation to the PTRL as established by the TNI FoPT Tables, or if the laboratory's LOQ is below the PTRL, they may evaluate results to their normal LOQ ~~as established by the TNI FoPT Tables~~.

4.2.4 For chemistry and radiochemistry PT results that are below the calibration range established by the initial calibration curve:

a) The laboratory may choose to re-scale its initial calibration curve to bracket the concentration of the PT study sample result, analyze the PT study using the re-scaled initial calibration curve, and report the measured result to the PT Provider, or

b) The laboratory may report the results, as measured with the original calibration curve, without qualification to the PT Provider, provided the laboratory adheres to the requirements of section 4.3.5.

4.3 Reporting Requirements

4.3.1 The laboratory shall report PT study results to the PT Provider on or before the closing date of the study using the reporting format offered by the PT Provider.

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

4.3.3 Except for drinking water, a laboratory may choose to analyze and report a single method to represent a technology in a single PT study for a particular analyte. If the laboratory analyzes and reports PT studies by "technology," the score obtained for the reported method will be applied to all methods in that technology for which the laboratory seeks to obtain or maintain accreditation in that matrix.

NOTE: The USEPA requires successful analysis and reporting of drinking water PT studies per method once per year.

4.3.4 A laboratory may choose to analyze and report multiple methods for the same technology in a single PT study for the same analyte. When a laboratory analyzes and reports more than one method for the same technology the following provisions apply:

a) The PT study score obtained for the reported method applies to ~~only that~~ all methods with the sample technology/matrix.

b) The laboratory must ensure that it analyzes and reports PT study results for each method for which it seeks to obtain or maintain accreditation within the particular technology.

Comment [sch1]: This was definitely shot down by the AC during the meeting. If labs want to do PTs by method/sample preps then they just don't submit the additional results to the AB.

4.3.5 The laboratory shall report chemistry and radiochemistry PT study results to the PTRL as established by the TNI FoPT Tables, or if the laboratory LOQ is below the PTRL, the laboratory may report results down to their normal LOQ, and as specified in section 4.2.3. A laboratory that chooses to report results below the lowest calibration standard of the initial calibration curve, as allowed by section 4.2.4.b, shall ensure that its internal recordkeeping system includes documentation that the laboratory reported the PT study sample results differently than real environmental samples based on the allowances of this PT standard.

NOTE: The laboratory's internal recordkeeping system may include:

- documentation in the LIMS system that the sample was reported according to V1M1: 4.3.5,
- a test report that includes the appropriate qualification of the analytical result as if it were a real environmental sample reported to a client, or
- some other system as established by the laboratory's quality system documentation and reporting procedures.

4.3.6 The laboratory shall retain all records necessary to facilitate reconstruction of the preparation, processing and reporting of analytical results for PT samples for a minimum of five years. The laboratory shall make these records available for review upon request by the AB.

5.0 PT STUDY FREQUENCY REQUIREMENTS FOR ACCREDITATION

5.1 Initial Accreditation

5.1.1 The laboratory shall successfully analyze and report at least two (2) PT studies prior to obtaining initial accreditation from an Accreditation Body (AB), when required as specified in section 4.1.1, for each field of accreditation for which it seeks to obtain accreditation, except Whole Effluent Toxicity.

a) The two PT studies identified in section 5.1.1 must be performed no more than 18 months prior to obtaining initial accreditation from an AB.

a) The opening date of the second study must be at least seven (7) calendar days after the closing date of the first study.

b) The closing date of the most recent successful PT study must be less than six (6) months prior to obtaining initial accreditation from an AB.

NOTE: The USEPA requires analysis and reporting of drinking water PT studies per method.

5.1.2 A laboratory seeking to obtain accreditation for Whole Effluent Toxicity (WET) testing shall successfully analyze and report at least one (1) PT study, when required as specified in section 4.1.1, for each field of accreditation, no more than 18 months prior to obtaining initial accreditation from an AB.

5.2 Continued Accreditation

5.2.1 The laboratory shall maintain a history of two (2) successful PT studies out of the most recent three (3) attempts for each field of accreditation, as required as specified by section 4.1.1, for which the laboratory seeks to maintain accreditation.

Comment [sch2]: Do we want this for WET as well?

5.2.2 The laboratory shall analyze and report a PT study for each field of accreditation for which it seeks to maintain accreditation that meets the following criteria:

a) Except for WET testing, as described in section 5.2.3, t~~T~~he closing dates of subsequent PT study samples for a particular field of accreditation ~~must~~ shall be no more than seven (7) months apart, ~~except for WET testing as described in section 5.2.2.c~~.

b) The opening date of subsequent PT study samples for a particular field of accreditation must be at least seven (7) calendar days after the closing date of a PT study for the same field of accreditation.

5.2.3 For WET Testing: To maintain accreditation the laboratory shall participate in one WET PT study per calendar year for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory is accredited

a) This requirement can be met by annual participation in the EPA DMRQA study's for WET or

b) If the laboratory is not participating in an EPA-DMRQA study for WET, t~~T~~he closing dates of subsequent PT study samples for WET testing PT studies must be no more than ~~15~~ 14 months apart.

Comment [sch3]: Since we allow 1 month leeway when defining 6 months, we should use a 2 month leeway when defining a year.

~~5.2.3~~5.2.4 A laboratory that analyzes and reports PT study results with an opening date of subsequent PT studies for the same field of accreditation that are closer than seven (7) days from the closing date of the previous PT study are invalid for the purposes of compliance with this standard and are not counted toward the laboratory's PT history of the most recent three (3) attempts.

~~5.2.4~~5.2.5 A laboratory that fails to analyze and report PT studies for a particular field of accreditation with the frequency specified in sections 5.2.2 or 5.2.3 for which it seeks to maintain accreditation is charged with a failed PT study.

NOTE: A laboratory may withdraw from a PT study, but withdrawal from a PT study does not exempt the laboratory from analyzing and reporting a PT study as specified in section 5.2.2.a.

Comment [sch4]: We discuss withdrwaing from a study, however it simply means that a lab does not submit the PT results. They don't actively withdraw.

6.0 CORRECTIVE ACTION

If the laboratory fails to successfully analyze a PT study for a particular field of accreditation, it shall determine the cause for the failure and take any necessary corrective action. The laboratory shall document the investigation and corrective action. The laboratory shall provide these records to the Primary AB within thirty (30) calendar days upon receipt of a request by the AB.

Documentation for WET corrective actions shall include:

a) A copy of the raw data used for the study
b) A copy of the current Standard Reference Toxicant (SRT) control chart relevant to the PT study

7.0 COMPLAINT RESOLUTION

The laboratory shall submit questions about PT study samples or the resulting scores directly to the PT Provider. If the PT Provider is not able or is unwilling to resolve the question to the satisfaction of the laboratory, the laboratory shall refer those questions to the PT Provider's PTPA.

8.0 SUSPENSION, REVOCATION, AND REINSTATEMENT OF ACCREDITATION

8.1 Suspension

8.1.1 A laboratory's accreditation will be suspended for a particular field of accreditation for failure to maintain a history of two (2) successful PT studies out of the most recent three (3) attempts, as specified in section 5.2

8.1.2 A laboratory's accreditation will be suspended for a particular field of accreditation for failure to provide a Primary AB with a corrective action report investigation as required by section 6.

8.2 Revocation

8.2.1 A laboratory's accreditation for a particular field of accreditation will be revoked if the laboratory fails three consecutive PT studies, either by failure to participate in a required PT studies or due to failure to obtain acceptable results for PT studies as specified in section 5.2.

8.2.2 A laboratory's accreditation for a particular field of accreditation will be revoked for violation of the provisions outlined in sections 4.1.4 - 4.1.8.

8.3 Reinstatement of Accreditation

8.3.1 A laboratory whose accreditation is suspended, as specified in section 8.1, shall establish 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 section 5.2, in order to regain accreditation.

8.3.2 A laboratory whose accreditation is suspended, as specified in section 8.1 for a particular method because the laboratory chose to analyze and report PT studies as described in section 5.2.1.d must establish a history of two (2) successful PT study results out of the most recent three (3) attempts for the particular field of accreditation per method as described in section 5.2, in order to regain accreditation.

8.3.2 A laboratory whose accreditation is revoked as specified in section 8.2, shall meet the requirements for initial accreditation, as specified in section 5.1 and the 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.

9.0 NOTIFICATION REQUIREMENTS

The laboratory shall notify ~~its~~ any Secondary ABs of suspension or revocation of accreditation in writing within 72 hours of receiving notice of a suspension or revocation of accreditation from the Primary AB for a particular field of accreditation.