SUMMARY OF THE

TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING FEBRUARY 4, 2015

The Committee met at the Forum on Laboratory Accreditation, Crystal City, VA, on Wednesday, February 4, 2015, at 8:00 am EDT. Chair Shawn Kassner led the meeting.

1 - Roll call

Present
Absent
Absent
Present
Present
Present
Absent
Present
Present
Absent
Absent
Present
Absent
Absent
Present

2 – Introduction

Shawn welcomed the attendees and the Committee Members introduced themselves. Shawn presented the following agenda:

Membership status
Volume 3 Comments
Volume 4 Comments
Vote Draft Standards schedule
Break
Volume 1 Module 1 Comments
Volume 2 Module 2 Comments
Prepare for public comment review

It was explained that all Volume 3 and 4 editorial corrections had been made, but there were a few remaining substantive comments that would require review by the committee. On Volume 1 Module 1 and Volume 2 Module 2, the committee needed to finish those comments assigned to the members, to plan on scheduling the Voting Draft Standard comment review, and then to move those modules to the interim standard stage.

3 – Committee Membership Status

The current membership was shown, and the attendees were invited to nominate themselves to be Committee Members.

4 – Volume 3 Comments

Comments submitted by Jeff Lowry on the Working Draft Standard were discussed.

- **3.9** The definition for Proficiency test reporting Limit (PTRL) needed to be changed for consistency with the FoPT Tables; i.e., "The lowest acceptable results that could be obtained from the lowest spike level for each analyte."
- **5.4.3.1** Jeff suggested 5.4.3.1 (a) is not needed, but the note is very informative. Perhaps make the note section 5.4.3.1 (a). It was moved by Mitzi and seconded by Scott to implement the suggested change. All were in favor.
- **5.4.3.2**; **5.4.3.3**; **5.4.3.4** It was moved by Mitzi and seconded by Fred to add language suggested by Jeff, and to add to the definition section Supplemental PT and Analyte Group Supplemental PT. All were in favor.
- **5.6.1.2**; **5.6.1.3**; **5.6.1.4** Jeff provide language to refer to ISO Guide 34 and Certified Reference Material (CRM). Joe Konschnik suggested checking there was no conflict with ISO definitions. Matt Sica mentioned ISO 17034 is being updated, so the definition may change. It was discussed whether a second source standard is necessary if a CRM is available, and Jeff thought it would be acceptable to put second source in under verification (5.6.1.4). In 5.6.1.3 Mitzi was worried about PT Providers making their own CRMs, leading to verification against their own material. Shawn suggested adding "independent" in 5.6.1.4, but Steve Arpie argued against alleged inconsistencies in CRMs between providers. There was some concern about clarifying the difference between CRM and RM. It was suggested in 5.6.1.4 to add "second" before "calibration verification", but Mitzi said that would need a definition of what "second" means. Jeff suggested using "a different lot number" instead of "second source". Joe Konschnik said a "lot" needed to be defined, and Matt Sica pointed out there is a definition in ISO Guide 30. The definition chosen was "A definite amount of a material produced during a single manufacturing cycle and intended to have uniform character and quality". It was suggested to add to 5.6.1.4: "The assigned value verification analytical event shall also include the analysis of a different lot of CRM/RM from the PT sample being verified". Section 5.6.1.4.1 would become 5.6.1.5.

The 30 minute mid-morning break followed, during which a new 5.6.1.4 was drafted. Its acceptance, after the break, was moved by Scott and seconded by Mitzi. All were in favor.

5.5.1 This states that the committee can require the PT Provider to demonstrate that their PT sample design is consistent with historical norms, but "historical norms" are not defined. It was questioned if this refers to the PT providers own historical norms, or the national ones. Maria Friedman said the Proficiency Test Program executive Committee (PTPEC) was working on getting the national failure rate, but was not there yet. Kelly Black said it must be decided what this means, as it is not auditable otherwise. Jeff said his company could not calculate national norms in the absence of the data. Kelly Black said ISO 17043 just talks about "fit for use", leading Mitzi to question if the section is even needed when it is covered in ISO 17043. Mitzi moved, and Fred seconded to go back to the

- 2009 language, modify (a), leave in (b), and delete (c). All were in favor. Maria added that PT Providers should be required to upload their files to the PTPEC.
- **5.6.2.2** Jeff had suggested clarifying language, but Mitzi moved and Stacie seconded that the language could be removed because it was redundant with ISO 17043, clause 4.4.3.2. All were in favor.
- **5.6.4.1** and **5.6.4.2** contain the same thing, with one clause for ABs and the other for participating laboratories. Jeff suggested combining them. Shawn said the committee would work on the language.
- **5.7.2** It was pointed out that assigned values for pH and other aqueous analytes are determined through measurement and cannot be based on gravimetric and volumetric measurements of the starting material. The committee agreed to develop language to address this. Jeff added this also needed to be done for 5.7.4 (Solid and Chemical Materials matrix).
- **5.8.1** This clause described undue assistance that PT providers must not provide to the participant laboratories, and Jeff had suggested instead to list the requirements of the instructions accompanying the samples. In the meeting, however, he suggested none of it was needed because it is a laboratory auditing issue. After some discussion, it was agreed the clause was mostly redundant, because ISO 17043 has an ethics requirement that covers it. It was moved by Mitzi and seconded by Stacie to remove (a), (b), and (d), but to retain a reworded version of (c), with the rewording to be developed. All were in favor.
- **5.9.2** Jeff pointed out the acceptance limit determination was missing the determination of acceptance limits and assigned values for Whole Effluent Toxicity Testing (WET). The committee agreed to add this.
- **5.9.2.8.1** and **5.9.2.8** were removed.
- **5.9.2.9** Jeff said the calculation of WET acceptance limits must use all the data with < and > signs for the median. He suggested noting this and adding a section on the calculation of WET parameters. The committee agreed to add alphanumeric characters and include a section on WET acceptance limits.
- **5.9.3.1.1** (a) On Jeff's suggestion, "within the established acceptance limits" was changed to "within or equal to".
- **5.10.1.1** referred incorrectly to 5.10.3 and 5.10.4. It was agreed to change it to 5.10.1.3 and 5.10.1.4.

5 – Volume 4 Comments

Comments submitted by Jeff Lowry on the Working Draft Standard were discussed. Several were editorial corrections, which the committee agreed to fix.

5.1.2 It was questioned why TNI does not require the Proficiency Test Provider Accreditor to be accredited to ISO 17011. It was decided to drop 5.1.2 (a) by putting it into 5.1.2.

- **5.1.2** (b) Matt Sica offered to provide language. The committee agreed with Jeff's recommendation to add ISO Guide 34 to 5.1.2 (c) as it had been added to Volume 3 for PT Providers.
- **5.2.1** The committee agreed to drop "Section 6 of", and would clarify its reference to clauses in other volumes.
- **5.4.3** As suggested, this new clause would require PTPAs to verify that PTPs have the means to provide (or upload) data to the TNI server, upon PTPEC's request.

It was agreed to drop the requirement for the PTPEC to be collecting data from the PTPs directly.

- **6.3.1 a)** Jeff said the random number generator requirement in Volume 3 will not conform to this requirement of distribution of assigned values. If Volume 3 is changed to allow a distribution instead of a random number for the assigned value, than this could be a requirement. Presently the PT Providers are spending time proving their random number generator doesn't produce a consistent distribution during their audit. He suggested the committee rewrite this section.
- **6.3.2** Jeff said if section 5.4.3 is added, then this requirement can be added. If there is no way to get the data (failure rate) to the PTPEC then there cannot be a requirement to monitor the data for compliance. Scott had suggested language that would be forwarded to the PTPEC for their help in defining this procedure.

6 - Volume 1 Module 1 and Volume 2 Module 2 Voting Draft Standard Comments

The committee continued to discuss the remaining comments that had not yet been resolved. At this point the quorum was lost so no votes could be taken.

Included were two comments remaining from Rachel's assignment, and the comments assigned to Shawn, Bob O'Brien, Jim Todaro, Mitzi Miller, and Scott Hoatson.

Adjournment

The meeting was adjourned at 4:30 pm EST.