

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

NOVEMBER 20, 2015

The Committee met by teleconference on Friday, November 20, 2015, at 11:00 am EST. Chair Shawn Kassner led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (Other)	Present
Kareen Baker, Independent (Other)	Present
Nicole Cairns, NYSDOH (Other)	Present
Rachel Ellis, NJ DEP (AB)	Absent
Patrick Garrity, KYDOW (AB)	Present
Scott Hoatson, Oregon DEQ (AB)	Absent
Craig Huff, ERA (Other)	Present
Shawn Kassner, Phenova (Chair; Other)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Absent
Mitzi Miller, Dade Moeller Assocs. (Other)	Present
Tim Miller, Phenova (Other)	Absent
Judy Morgan, Pace (Lab)	Present
Joe Pardue, P2S (Vice-Chair; Other)	Absent
Donna Ruokenen, Microbac (Lab)	Absent
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Present
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Mike Blades, ERA; Amanda Bruggeman, Phenova; Audrey Cornell, ERA; Brian Stringer, ERA.

2 – Previous Minutes

It was moved by Kareen and seconded by Judy to approve the minutes of November 13, 2015, after correcting two typographical errors: the misspelling of “flexibility” 4 lines from the bottom of the section labeled 5.6.1; and the removal of a superfluous “there” 4 lines from the bottom of the section labeled 5.6.1.1, 5.6.1.8 and 5.7.3. All were in favor.

3 – Comments on V4 Voting Draft Standard

The comments assigned to Nicole were considered.

A general comment concerned the use of “PTPA(s)” in the standard. It was pointed out in some instances the standard should refer to just one PTPA at a time. It was agreed this was a Persuasive comment and the text would be modified editorially.

5.0 *“Remove clause. The PTPEC reference is not applicable to the PTPA. Without the PTPEC reference, this statement provides no further information from that of the heading REQUIREMENTS FOR A PROFICIENCY TESTING PROVIDER ACCREDITOR. Possible Resolution: Applicable criteria can be place in a requirements document.”* Nicole suggested just

removing the sentence, and this was so moved, as a Persuasive comment, by Fred and Seconded by Kareen. All were in favor.

5.3.1 *“This seems to be in conflict with V3 section 5.1.3, which states, “If the PT provider holds specific accreditations related to any of the requirements in Sections 5.1.1 through 5.1.2, this shall not limit the PTPA’s ability to assess and make determinations related to the PT Provider’s conformance to these requirements.” V3 sections 5.1.1 and 5.1.2 refer to the requirements of ISO Guide 34 and ISO 17025, respectively. Nicole suggested the comment was Persuasive, but she recommended updating V3 so that it addresses MRAs as stated in V4; i.e., V3 Clause 5.1.3 would state: “If the PT Provider holds specific accreditations related to any of the requirements in Sections 5.1.1 through 5.1.2, this shall not limit the PTPA’s ability to assess and make determinations related to the PT Provider’s conformance to these requirements, unless the PT Provider’s specific accreditation was issued by an organization that has a mutual recognition agreement with the PTPA for that accredited activity, product, or characteristic”. It was moved by Craig and seconded by Fred to rule the comment Persuasive and to incorporate Nicole’s suggested V3 language. All were in favor.*

5.4.3 and 5.4.4 A commenter recommended changing the acronym “PTP” to “PT Provider”. The committee agreed this was Persuasive and would be an editorial change.

5.4.4 *“This is not about the PTPA PT data management system. There is no equivalent requirement on the PTP in EL V3. Either remove the requirement from this volume or add it to EL V3. The “data” is not defined. Remove language or add similar language to EL V3.” It was agreed to table this comment until V3 language was in place.*

5.5 *“Redundant language of ISO/IEC 17011 requirement. 8.2.1 The accreditation body shall make publicly available information about the current status of the accreditations that it has granted to CABs. This information shall be updated regularly. The information shall include the following: a) name and address of each accredited CAB; b) dates of granting accreditation and expiry dates, as applicable; c) scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes. Possible Resolution: Remove Clause.” On discussion, the committee considered it includes language specific to the TNI FoPTs, so that part is not redundant. Nicole volunteered to re-word the section, recognizing ISO 17011, but adding the scope (FoPTs). A further comment on this section recommended adding “its” between “of” and “accredited”. Nicole said she would incorporate that editorial change into her language.*

4 – Comments on V3 Voting Draft Standard

The minutes of October 9, 2015, describe a comment made on Clause **5.10.4**, concerning PT Providers uploading data to TNI per PTPEC request. This had raised a confidentiality issue. The comment had been tabled until the PTPEC had met with the PTPAs. Nicole was to attend that meeting and report back to this committee. Nicole said the meeting was constructive and they had agreed on language that would address specific information the PT Provider would upload to TNI. The PTPEC would then be able to get the data from the TNI webmaster. Maria Friedman would provide the suggested standard language that might include a confidentiality statement and the intended use of the data. This would then be considered during the next conference call of this committee.

The comments assigned to Joe were considered next.

5.4.3.1(a), 5.4.3.2, 5.4.3.3, 5.4.3.4 5.4.3.1(a) *“Since it uses “may,” this should be deleted as a standard and added as a Note. 5.4.3.2, 5.4.3.3, 5.4.3.4: These paragraphs contain laboratory requirements, which should be reworded to be PT Provider requirements (e.g., “If the laboratory informs the PT Provider...”)* and restated in VIM1, if needed. *EL-VIM1-2009 section 6.1(a) is sufficient for the latter: “The laboratory shall notify the PTP that the PT sample will be used for corrective action purposes so the PTP may ensure that the PT sample supplied meets the requirements for supplemental PT as defined in Volume 3 of this standard.” The current wording seems to imply this was the intent; otherwise the sentence structure is incorrect.*” Shawn said, in the case of Clause 5.4.3.1 (a), “may” referred to a choice (either/or), so it should be retained, but it was agreed to re-write the sentence to remove that word. Nicole suggested: “provide samples from either lots that have been previously used in a PT study or new lots that have been shown to meet all the requirements of Sections 5.5, 5.6, and 5.7 of this Volume.” It was moved by Mitzi and seconded by Craig to rule the comment Persuasive, to accept Nicole’s language, and the commenter’s suggested language “If the laboratory informs the PT Provider...”. All were in favor. Shawn said he would make the change and the committee could then vote on the specific language.

This covered four more similar voters’ comments.

5.4.3.5 and 5.4.3.6 *“The clause 5.4.3.5 is redundant to the definition at 3.12.b which states: 3.12 PT Study Closing Date: Supplemental PT Study: The calendar date a laboratory submits the results for a PT sample to the PT Provider. Also, the clause at 5.4.3.6 could be added to the definition at 3.12.b so that it would read as: 3.12 PT Study Closing Date: Supplemental PT Study: The calendar date a laboratory submits the results for a PT sample to the PT Provider and not to exceed 45 days from the opening date of the study. With this, you can delete 5.4.3.5 and 5.4.3.6 since they are covered earlier in the definition at 3.12.b.* Mitzi said Clause 5.4.3.6 could be removed but not 5.4.3.5, which needed to stay in the standard for enforcement. It was moved by Fred and seconded by Kareen to rule the comment Non-Persuasive.

This concluded Joe’s assigned comments.

As agreed at the previous meeting, Shawn provided a narrative responding to a voter’s comment on **5.5.2**. It was moved by Nicole and seconded by Craig to accept the language. All were in favor.

Judy’s assigned comments were discussed.

5.4.3.1 There were 4 separate comments similar to those already dealt with above in Joe’s section.

5.6.1.4 *“What are “ISO Guide 34 materials”?* Recommended language to the last sentence of the clause after changes are made: *The calibration and calibration verification standards shall consist of CRM; and/or RM; ~~and/or ISO Guide 34 materials~~, as applicable, from different lots.* Shawn said he would write a definition to be considered on the next call.

5.6.1.5 *“There should be verification of criteria used. Possible Resolution: Add similar language as that in the last paragraph of sections 5.6.1.7 and 5.6.1.8 that the PT Provider shall establish criteria approved by their PTPA.”* On discussion, it was agreed the standard had not really changed

and did not require further change. It was moved by Mitzi and seconded by Nicole to rule the comment Non-Persuasive.

This completed consideration of Judy's comments.

Adjournment

The meeting was adjourned at 12:25 pm EST.