SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

DECEMBER 18, 2015

The Committee met by teleconference on Friday, December 18, 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)	Present
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)	Present
Judy Morgan, Pace (Lab)	Absent
Joe Pardue, P2S (Vice-Chair; Other)	Present
Donna Ruokenen, Microbac (Lab)	Present
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Present
Ken Jackson, Program Administrator	Absent

Associate Committee Members present: Mike Blades, ERA; Chandra Thekkekalathil Chandrasekhar, FLDEP; Audrey Cornell, ERA; Bob O'Brien, Sigma-Aldrich; Lauren Smith, A2LA; Brian Stringer, ERA.

2 – Previous Minutes

It was moved by Fred and seconded by Mitzi to approve the minutes of December 4, 2015. All were in favor except Kareen who abstained.

3 – Committee Charter Update

The first terms of Rachel, Fred and Jim was expiring the end of December, and Shawn asked them to consider by the next meeting if they wished to continue to a second term. Shawn's membership was also expiring on December 31. He said he would remain until the new standard was complete and then leave the committee, probably in July 2016. Lisa and Kareen were both leaving the committee, and Shawn thanked them for the great work they had done. Shawn suggested adding two ABs, with one of them being non-TNI or non-governmental. Other committee members favored this.

3 – Sub-Committee Update

It was anticipated the sub-committee would have its comments in before the next call, so that the Volume 3 comment responses could then be completed.

4 – Comments on the V4 Voting Draft Standard

The comments assigned to Mitzi were discussed.

4.1 (b) *"While this should be removed as stated above, it is worthy to note the PTPEC does not approve all policies and procedures used by the PTPA for the purposes of accreditation and monitoring of PT Providers. The PTPEC evaluates conformance of the documented procedures of the PTPA to the requirements set forth in this Volume and the relevant requirements of ISO/IEC 17011. The PTPEC then approves the PTPA based on conformity to the specified requirements. Possible Resolution: A requirements document should state: "The PTPEC evaluates conformance of the documented procedures of the PTPA to the requirements set forth in this Volume and the relevant requirements of ISO/IEC 17011.""* It was moved by Mitzi and seconded by Fred to rule the comment persuasive and to use the wording suggested by the commenter. All were in favor.

5.1.2 (c) *"Redundant language. Under ISO/IEC 17011 ABs are evaluated to the personnel requirements of ISO/IEC 17011 including: 6.1.1 which states "The accreditation body shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time) having the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed." The current wording of the requirement implies technical knowledge."* Mitzi argued this was a case where the standard should have requirements beyond ISO 17011, saying she had observed situations where there was not sufficient statistical expertise. The PT providers on the call were divided on the issue, and the ABs (Pat and Lisa) agreed with Mitzi that it should be stronger. After further discussion, most people on the call agreed with Mitzi. It was moved by Mitzi and seconded by Joe that the comment should be ruled Non-Persuasive. All were in favor.

5.1.2 (f) *"There is no technical review of an initial application. There is a completeness review and resource review. The technical review occurs during document review and during the assessment."* It was moved by Mitzi and seconded by Nicole to rule the comment Persuasive and to remove the clause from the standard. All were in favor.

6.1 (d) *"Regarding "…This review shall include: d) shall have procedures used to validate that new PT sample formulations are fit for their intended purpose within the specified ranges per the approved TNI FoPT tables for the relevant technologies, prior to use of such material in a PT scheme": Wording doesn't make sense, need to reword. Possible Resolution: remove "shall have" and replace with "that the PTP has" or something similar."* There was general agreement this was persuasive, and the following new language was proposed: "Procedures used to validate that new PT sample formulations are fit for their intended purpose and are manufactured within the specified ranges for the approved TNI FoPT table prior to use in a PT scheme." It was moved by Mitzi and seconded by Craig that the comment was Persuasive and to substitute the above new language. All were in favor.

6.1 and **6.2** *"As the onsite assessment is performed in conjunction with the requirements of ISO/IEC 17043, there is no minimum to an assessment. As the PTPAs are required to be recognized by an international cooperation of accreditation bodies for conformance with ISO/IEC 17011:2004(E), the PTPAs are bound to review of the standard being reviewed. Is there a misunderstanding on this committee as what is meant by sampling during an assessment? This is not related to the number of requirements reviewed. As required in ISO/IEC 17011 7.5.6 The accreditation body shall establish*

procedures for sampling (if applicable) where the scope of the CAB covers a variety of specific conformity assessment services. The procedures shall ensure that the assessment team witness a representative number of examples to ensure proper evaluation of the competence of the CAB. In other words, if assessing a laboratory which performs several methods by the same technology, the AB must review at least few of those methods, but not necessarily all methods of the same technology. Redundant per ISO/IEC 17011 3.7." Mitzi explained there are three comments, but once one of them is resolved, that should fix all three. Clauses 6.1 and 6.2 confuse the activities that occur in document review and assessment and application review. So this standard is not set up the way ISO 17011 is set up or the way providers do it. The committee needed to remove some items from initial application to a new section for document review and then have a section 6.3 of on-site that is consistent with ISO 17011 and get rid of a lot of things that are already in ISO 17011. On discussion, it was moved by Nicole and seconded by Fred to task Mitzi with re-writing the section as she had recommended. All were in favor. Mitzi said she would run her draft past Rob Knake and Lauren before submitting it to the committee.

The comments assigned to Rachel were discussed. All comments were on Section **6.0**.

"Regarding "PTPAs shall upon request (by PTPEC) conduct a presentation at the PTPEC meeting during one of TNI's semiannual forums.": This requirement seems to be misplaced. What does it have to do with REQUIREMENTS FOR ACCREDITATION OF PT PROVIDERS, the header?" Rachel agreed with the commenter that it was Persuasive, and she suggested moving this requirement to a new Clause 5.6 (for "Additional Requirements). This was so moved by Nicole and seconded by Fred. All were in favor.

"Title and the verbiage are confusing. These are really requirements for the PTPA's assessment and accreditation of the PTPs. The title makes it sound like they are PTP requirements. Also, is the requirement for the accreditation process to be repeated at a minimum of every 4 years meant to be the assessment of the PTPA or the PTP (see also EL V4 Section 4.1 c)? EL V3 requires biennial onsite assessments in section 4.4. I think requirements for the PTP and PTPA are being blended/confused in this section. In the current version the requirements are directed to the assessment of the PTP, in the revised version it appears the revisions are meant to be directed to the PTPA. It is very confusing. Possible Resolution: Clarify the title and the wording to relate only to requirements for the PTPA." There was discussion on the best place in Section 5 for this clause. Shawn suggested, since it states earlier that the Volume is based on ISO 17011 Conformity Assessment General Requirements, that statement may not be required. Nicole thought the requirement for the PTPA to assess PT Providers every 2 years should be included here. Shawn volunteered to work on language for the committee to discuss on the next call.

The rest of Rachel's assigned comments were deferred until the next call.

Adjournment

The meeting was adjourned at 12:30 pm EST.