SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

JANUARY 15, 2016

The Committee met by teleconference on Friday, January 15, 2016, at 11:00 am EST. Chair Shawn Kassner led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (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)r	Present
Tim Miller, Phenova (Other)	Present
Judy Morgan, Pace (Lab)	Present
Joe Pardue, P2S (Vice-Chair; Other)	Present
Donna Ruokenen, Microbac (Lab)	Present
Ken Jackson, Program Administrator	Present

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 18, 2015. All were in favor.

3 – Volume 3 Comments

The sub-committee had met the previous week and had submitted its recommendations on 5 voters' comments on V3.

5.6.1.8 *"Regarding "Dropped. 'The standard deviation of the verification analyses shall be less than one standard deviation as calculated for the participant laboratories.'": Dropping this requirement disconnects the required precision of the verification method selected by PT providers for the products final intended use. Additional Comment: PT providers have been meeting this standard for years. Removing it serves no purpose other than to give more "wiggle" room to the verification process performed by the PT providers. It can introduce additional variability across providers and adds no value to the accrediting athorities or participants. Possible Resolution: Add statement back to standard"* The subcommittee recommended the comment was Persuasive and the requirement should be added back into the standard.

5.6.2.2 *"Regarding "Dropped. Section on homogeneity as described in Appendix A": Dropping specificity of homogeneity criteria described in Appendix A and allowing PT providers to follow general requirements under ISO guide 17043 which will likely result in different schemes of homogeneity evaluations and differing levels of homogeneity. This does not meet the defined scope of this standard, 1.2c, The preparation of PT samples which pose equivalent difficulty and challenge regardless of the manner in which the PT samples are designed and manufactured by the PT providers. Additional Comment: PT providers have been meeting this standard for years. Removing it serves no purpose other than to give more "wiggle" room to the verification process performed by the PT providers. It can introduce additional variability across providers and adds no value to the accrediting athorities or participants. Possible Resolution: Add statement back to standard"* The subcommittee recommended the comment was Non-Persuasive.

5.6.3.1 *"Regarding "Dropped. Section on stability testing, 'after the closing date of the PT study but prior to the issuance of final reports,'": Section must specify timing of stability event. If testing is not performed within this window of defined time, validity of sample stability cannot be confirmed and any unacceptable results by participants should be questioned. Additional Comment: PT providers have been meeting this standard for years. Removing it serves no purpose other than to give more "wiggle" room to the verification process performed by the PT providers. It can introduce additional variability across providers and adds no value to the accrediting authorities or participants. Possible Resolution: Add statement back to standard"* The subcommittee recommended the comment was Non-Persuasive.

5.6.3.3 *"Regarding "Dropped. 'The difference between the two means cannot be shown to affect an evaluation, then the analyte can be considered stable for the study period.'": Without this statement the intent of stability testing is lost and the requirement of the PT provider to prove that the sample was appropriately stable is questionable. Additional Comment: PT providers have been meeting this standard for years. Removing it serves no purpose other than to give more "wiggle" room to the verification process performed by the PT providers. It can introduce additional variability across providers and adds no value to the accrediting athorities or participants. Possible Resolution: Add statement back to standard"* The subcommittee recommended the comment was Non-Persuasive, but recommended incorporating the statement into Section 5.6.3.4 and renumbering the requirements for the section.

5.6.3.4 *"Regarding "5.6.3.4 The stability of an analyte is verified if either: a) the difference between the mean of the providers verification analyses and the mean of the providers stability analyses is within one-fifth of the laboratory acceptance limits as calculated per Section 5.9.2 or b) the mean of the providers stability analyses meet the requirements for verification as defined in Section 5.6.1.7 or 5.6.1.8 depending on the study matrix ": Section a) is trying to duplicate the 0.2C criteria in the previous standard without using Appendix A, since they have decided to drop it. The previous standard was more precise on the requirement. b) is completely inappropriate. For example: PCBs in Oil is considered a Solid Matrix and requires extraction prior to verification...thus per section 5.6.1.8, needs to be within one-half of the laboratory acceptance limits, this would mean that the AR1254 in Oil at 16.2 mg/kg would have a final study acceptance interval of 1.62-26.8, per current FoPT's. The one-half interval for PT verification acceptance would be 8.10-24.3. Per b) the provider could get an initial verification result of 24.3 and the product would meet verification criteria. The stability analysis could generate a result of 8.10 (3 fold difference) and would still be considered "stable" per this standard. Additional Comment: PT providers have been meeting this standard for years. Removing it serves no purpose other than to give more "wiggle" room to the*

verification process performed by the PT providers. It can introduce additional variability and adds no value to the accrediting athorities or participants. Possible Resolution: Drop entire section and add previous statements back to the standard and add back the appendix A. The subcommittee recommended the comment was persuasive and suggested incorporating proposed language into the standard: "5.6.3.3 Stability testing shall be conducted after the study close date. The stability of an analyte is verified if either:

a) the difference between the mean of the provider's verification analyses and the mean of the provider's stability analyses is within one-fifth of the laboratory acceptance limits as calculated per Section 5.9.2; or

b) it can be demonstrated that the difference between the provider's verification mean and the mean of the provider's stability analyses does not affect laboratory evaluations.

The PT Expert Committee discussed the above sub-committee recommendations. Mitzi asked, regarding 5.6.3.1, 5.6.3.3, and 5.6.3.4, if the standard could not just go with ISO 17034; i.e., with no specificity. Shawn said some PT Providers do things differently from Appendix A of the 2009 standard. It was moved by Scott and seconded by Craig to accept the subcommittee recommendations, except 5.6.2.3 should be ruled persuasive, and to change V3 accordingly. All were in favor.

Scott was concerned with the wording of Section 5.6.2.3, because most TNI requirements had been removed to refer to ISO 17043. It was moved by Scott and seconded by Craig to change 5.6.2.3 to read "PT samples which fail to meet the ISO 17043 requirements for homogeneity shall not be used in a PT study. All were in favor.

This completed the sections considered by the sub-committee.

Shawn had met with the PT Executive Committee. There had been concern of confidentiality over release of PT Providers names. It was suggested the SOP needs to remove the identifier and Shawn said there was current language to take care of that. It was moved by Scott and seconded by Fred to accept language for section 5.1.2 incorporating the number of laboratories participating and the technology when available. All were in favor.

This completed consideration of comments on V3, that could now be moved to Interim Standard.

4 – Volume 4 Comments

Two outstanding Comments considered by Rachel were discussed.

6.0 *"Clarify minimum content for the presentation. Possible Resolution: Add as second sentence or as clause a): "The presentation, at a minimum, shall include:*
1) Changes related to PT Providers - additions, withdrawals, revised scope
2) Number of complaints received - status (still open, closed, in progress), complaint type or category (e.g., deliverables, TAT, responsiveness, etc.)
3) Summary of pass/fail rates for PT studies - A list of PTs that have historical (past 2-3 years) pass rates of <90%". Rachel agreed, saying this language can be added once the section is moved to 5.0. It was added that the committee needed to determine the DQOs prior to examining passing or

failure rates, as opposed to examining passing rates as an indication of lax DQOs. It needed more discussion at the committee level with the stakeholder community. Failure rates are more important such as failure rates of < 20% or higher on average.

6.0 *"Add statement to state the presentations shall be submitted to PTPEC upon request. Possible Resolution: Add as clause b) "Also upon request (by PTPEC) such presentation shall be submitted to PTPEC."* Rachel agreed, and suggested this could be added to the existing language or a clause could be added. There were issues with the PTPA's providing the presentation due to historical issues with PT Providers, and there was a need to consult the PTPAs willingness to provide their presentations.

Shawn suggested he should go back to the PT Executive Committee on both of these comments. He wanted to look at failure rates rather than pass rates <90%. It was suggested the presentation did not belong in a standard, and should be a TNI policy. Scott recommended saying they should provide the information on request. Shawn said the PT Executive Committee had not discussed what kind of data they wanted, and what they would do with the information when they got the data. The PT Executive Committee needed to sort this out with the PTPAs before it was put in the standard. Shawn added he thought both comments were Non-Persuasive.

It was moved by Scott and seconded by Fred to rule both comments Non-persuasive and to go back to the PT Executive Committee for further consideration. All were in favor.

Scott wanted the presentation requirement removed (Section 5.0), but that was not possible as no voter's comment had been received on that section.

Subsequent to this conference call, the PT Executive Committee was contacted, but declined to comment at this stage of standard development.

The comments assigned to Mitzi were discussed.

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.* Mitzi suggested this was Persuasive and the recommended language should be adopted.

6.1 and 6.2 *"These sections confuse activities that occur during document review and assessment to an application review. As defined in ISO/IEC 17011 3.7, assessment is the process undertaken by an accreditation body to assess the competence of a CAB, based on particular standard(s) and/or other normative documents and for a defined scope of accreditation.* ***NOTE Assessing the competence of a CAB involves assessing the competence of the entire operations of the CAB, including the competence of the personnel, the validity of the conformity assessment methodology and the validity of the conformity assessment results.*** *Furthermore, each AB has an understanding of the principles of conformity assessment as outlined in ISO/IEC 17000:2004 Conformity assessment — Vocabulary and general principles. In this case, TNI EL V3 standard is the set of requirements. There is no need to reiterate in this standard what an AB needs to assess, as ABs understand that their organization must assess the competence of the entire operations of the CAB. ABs have*

procedures to review the system during the document review and the assessment. Possible Resolution: Remove Clause. (The third comment was similar to this one.) Mitzi had suggested this would be Persuasive, saying there was a need to either split the section or say this is either done in application review or during document review or onsite. It was moved by Nicole and seconded by Judy to accept Mitzi's recommendation. All were in favor.

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."* On discussion it was moved by Nicole and seconded by Donna, that the comment was Non-Persuasive. The section had been re-written and should not be removed. All were in favor.

5 – V1M1 and V2M2

The comments on the Interim Standards would be reviewed at the Tulsa meeting.

6 – Adjournment

The meeting was adjourned at 12:35 pm

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.