SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

JUNE 3, 2016

The Committee met by teleconference on Friday, June 3, 2016, at 11:00 am EDT. 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)	Present
Patrick Garrity, KYDOW (AB)	Absent
Scott Hoatson, Oregon DEQ (AB)	Absent
Craig Huff, ERA (Other)	Absent
Shawn Kassner, Neptune (Chair; Other)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Absent
Mitzi Miller, Dade Moeller Assocs. (Other)	Absent
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.

2 – Previous Minutes

It was moved by Fred and seconded by Judy to approve the minutes of May 20, 2016. All were in favor.

3 – Volume 3 and Volume 4

The Committee continued discussion of voters' comments on the Interim Standards.

V3, 5.4.3.4. *"An issue has arisen in the NELAP Accreditation Council regarding PCBs in supplemental PT samples. Currently, if the laboratory mis-identifies the Aroclor and quantitates the wrong PCB, the laboratory would pass 5 "non-detect" Aroclors and fail the other 2 Aroclors (the one that was not correctly identified and the one that was quantitated in error). As the Standards are worded now, the supplemental PT would have to contain the 2 failed PCBs in non-zero Assigned Values. While the quantitative effort is accommodated, the identification portion of the PT study effort is not imposed on the laboratory. Thus, one NELAP Accreditation Body is proposing that if a laboratory fails one of the 7 Aroclors in the PCB analyte group, the laboratory must participate in a supplemental PT for ALL SEVEN PCBs in that analyte group. The supplemental PT must contain only one randomly-selected PCB at a randomly-selected Assigned Value, and the laboratory will report and receive a PT grade for all 7 PCBs. The NELAP AB is proposing that >80% of the PCBs must be scored acceptable, for two out of three study attempts, for the laboratory to be accredited for all PCBs by the matrix and technology. The description for Analyte Group Supplemental PT in*

clause 5.4.3.3 does not seem to address this situation for the PCB analyte group. Does the PT Expert Committee have any comments on this proposal? Is this within the purview of the Consensus Standard Development process? Or is this issue better addressed by the PT Program Executive Committee with the FoPT Tables (i.e., the FoPT is based on the PCB analyte group instead of each Aroclor as an individual FoPT?)?" The Committee had considered this comment previously without reaching a resolution. The AB in question was NJ, and Rachel elaborated on their problem. She added that other ABs had reported the same problem, and there was some inconsistency in the way ABs were handling it. Mike said the re-test sample should have a randomly chosen Aroclor (other PT Providers agreed they do the same). This results in the laboratory not having two failures of the same Aroclor, and hence retaining its accreditation. Shawn asked if the standard needed something specific for PCBs, and questioned if there had been a specific comment on this that would allow it to be changed at this stage of the standard development. On further discussion it was agreed this should be dealt with through the FoPT table. It was moved by Tim and seconded by Mitzi to rule the comment Non-Persuasive, and to recommend that NJ work with the PT Executive Committee (PTPEC) to add an analyte to the FoPT table as appropriate. All were in favor.

V3, 5.10.4.3 *"Several possible corrections may be needed in this clause:*
- Make sure the section number is "5.10.4.3"
- Not make the "technology ID" optional if the PT Program Executive Committee really wants to have method-specific FoPTs.
- Add "Test method number" to the bulleted list (again, if the PT Program Executive Committee really wants to have method-specific FoPTs).
- Add "sample preparation method ID or technology, if applicable and if available" (if the PT Program Executive Committee is really serious about FoPTs based on more than matrix-analyte, then the most disparities in PT results would show up in different sample preparation techniques rather than in analytical technologies)." It was moved by Scott and seconded by Nicole to rule the comment Non-Persuasive, because the PTPEC meeting minutes showed they would not add the suggested fields. All were in favor.

V3, 5.6.1.6. *"In addressing the VDS comments , the committee concluded that the current criteria as noted in the standard of < 1 standard deviation was stringent enough to warrant removal of the requirement. One item the committee may have overlooked was that the 1/6 repeatability and the <1 SD requirements are not related in a way which supports that conclusion as stated. They are independent evaluations of separate parts of the process . The 1/6 repeatability is a demonstration that the method you have selected to use for verification is fit for intended purpose for all possible analytes that could be included. The 1sd criteria is in place to evaluate each specific analytical verification event, for only the analytes included in that event, to make sure that the method was performing adequately for the analytes included in the design. However, if the standard being verified does not contain all analytes of interest in a given event, a <1 SD requirement has no bearing on those unspiked analytes. To support sect 5.6.1.10 (1/2 PTRL)the evaluation criteria of a method's fitness for use needs to be in place and appropriate for all analytes at multiple levels across the design range including at ½ the PTRL. ISO 13528-Annex B recognizes that both method repeatability and standard deviation for proficiency assessment are separate, yet related components (under homogeneity check). And when combined, provides an internationally recognized criteria component that is consistent with the "1/6 rule". Perhaps the committee can investigate this approach?"* Shawn said all PT Providers are required to be accredited to ISO 17043, which requires valid statistics for homogeneity and stability testing. However, Mike pointed out that the ISO standard specifies use of ISO 13528, Annex B, and he thought this could only be

used as a guide. The Committee deferred a decision until Mitzi could talk to a representative of a Proficiency Test Provider Accreditor (PTPA) to affirm whether this is a requirement.

V3. 5.6.2. *"We still have concerns about what remains of the Homogeneity Testing section of this standard. To cite another previous commenter on the issue, " The whole section on homogeneity seems to be pretty empty…" We understand that not all PT providers utilize the same model (and criteria) to assess homogeneity, but with the absence of at least some specified criteria in the standard, the burden of consistent interpretation, application and enforcement falls to the PTPA's—and from a "fitness for use" perspective, what does that look like? Homogeneity testing criteria is particularly relevant in study schemas like TNI's, whereby the participant acceptance criteria are prescribed vs. consensus-based acceptance criteria. Again, ISO 13528 does an adequate job of describing homogeneity testing and defining what criteria may or may not be appropriate. Even though it is only a "guidance" document, it does contain some recognized and defensible content that we should at least assess for potential incorporation into the standard?"* Shawn said this was essentially the same question as in the previous comment; i.e., is ISO 13528 enforceable under ISO 17043? Mitzi said she would also check on this with the PTPA. Shawn volunteered to ask the other PTPA, to get an Accreditation Body perspective, and to check what the subcommittee said in their minutes.

V3. 5.6.1.7. "*Analytical verification of many of these products typically involves the back to back direct injection of solvent based analytical standards which should reasonably meet the 10% rule in the absence of significant manufacturing errors, poorly performing instrumentation or inadequate validation methodology. The limits obtained through reliance on the 1/3 criteria alone would allow for verification limits that would be questionable to applicable stakeholders. Removal of the "not to exceed a maximum of 10%"… clause (albeit a clause with no foundation in ISO Standards or statistical vetting) allows PT providers to generate and accept a verification analysis which yields a verification mean that is arguably not sufficient for intended use. Some examples demonstrating this are included on the next page."* The concern had been raised by a PT Provider, and Tim questioned their calculations showing acceptance limits too wide without the 10% rule. Nicole also had calculations suggesting the 10% rule was not needed. It was agreed that Tim and Nicole would send their calculations to Shawn, and then they would meet to discuss.

4 – Adjournment

The meeting was adjourned at 12:30 pm EDT.