SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

JUNE 17, 2016

The Committee met by teleconference on Friday, June 17, 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)	Absent
Patrick Garrity, KYDOW (AB)	Present
Scott Hoatson, Oregon DEQ (AB)	Absent
Craig Huff, ERA (Other)	Present
Shawn Kassner, Neptune (Chair; Other)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Present
Mitzi Miller, Dade Moeller Assocs. (Other)	Present
Tim Miller, Phenova (Other)	Present
Judy Morgan, Pace (Lab)	Present
Joe Pardue P2S (Vice-Chair; Other)	Absent
Donna Ruokenen, Microbac (Lab)	Present
Ken Jackson, Program Administrator	Absent

Associate Committee Members present: Mike Blades, ERA; Chandra Thekkekalathil Chandrasekhar, FLDEP; Brian Stringer, ERA.

2 – Previous Minutes

It was moved by Mitzi and seconded by Judy to approve the minutes of June 3, 2016. All were in favor.

3 – Volume 3 and Volume 4

The Committee continued discussion of voters' comments on the Interim Standards. Shawn was waiting to discuss a couple of comments with a commenter. He had also talked to Maria Friedman, who was going to write some language for requesting study-specific data from PT providers for the FoPT tables.

V3, 5.9.3.2.1 *"This section of the TNI NELAP PT Interim Standard is in conflict with NYS Rules and Regulations, specifically, Title 10, Subpart 55-2.8. We will not be able to implement it. The use of the term 'or' at the end of clause a) is in conflict with our regulation. If an 'and' is used, then it will be meet NYS Rules and Regulations for proficiency testing."* As discussed previously, Shawn had continued his dialogue with the NY program. He had been told that New York had to follow its regulations and could not change how it runs its program. However, he was told the comment was not a show-stopper. The NY program would just continue its current scoring practice for its own laboratories. Nicole stressed the whole point in revising the standards was so NY would not have to continue evaluating PTs from the 2003 standards. She added that at least one PT Provider is producing 2 reports (according to the 2003 and 2009 standards) so NY must be accepting those.

Mitzi reminded the committee that the PT standard was being re-written because NY refused to implement the 2009 standard after all the voting had been completed. The NY program must provide something in writing to give assurance this would not happen again and thus prevent NY adopting the 2016 standard. Nicole said she would reach out to the NY program.

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."* As a follow-up to discussion of this comment on the previous call, Craig had circulated some data using 1/3C limits provided by Nicole. He wanted to check if there was an impact on failure rates. He had studied two poor-performing analytes, vinyl chloride in Potable Water and hexachlorocyclopentadiene in Non-Potable Water, to check if removal of the 10% rule would impact failure rates. The data predicted a slight increase in failure rates. Nicole felt the increase in failure rates was not significant. Shawn acknowledged these were poor-performing analytes, but would have liked to see more data to show if these are worst-case scenarios. He added that the 10% rule had been added arbitrarily when NIST ran the program with no data to support it, and having it makes TNI inconsistent with other PT programs. A protracted discussion followed, with committee members split on whether to re-insert the 10% rule. Judy would have liked to see allowable exceedances for poor-performing analytes, but Mitzi argued that would be difficult to administer and audit. Eventually, it was moved by Nicole and seconded by Fred to rule the comment Non-Persuasive. Five members voted for the motion, and three members voted against it. Hence, the motion passed.

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.* As discussed during the previous call, Shawn and Mitzi had spoken to representatives of the two PT Provider Accreditors (PTPA), who had confirmed that ISO 13528

Annex B was only guidance and not enforceable on PT Providers accredited to ISO 17043. Mitzi thought the <1 standard deviation criterion should be added back in and Nicole was ambivalent. Shawn asked if the argument being presented brought anything new that would change how the Committee Members voted last time. After further discussion it was moved by Fred and seconded by Nicole to rule the comment Non-persuasive. Five members voted in favor of the motion, with one against and two abstentions. Hence the motion passed.

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.* This comment was also discussed during the previous call. Nicole said, since Section 5.6.2 provided no specific criteria, the PT Provider would have to put it in its SOP that would require approval by the PTPA. However, Mitzi was in favor of adding some of the ISO 13528 Annex B requirements to the TNI standard, to make it specific for auditing. Craig questioned if it should specify ISO 13528 or its equivalent. Craig and Shawn volunteered to craft some language for the committee to consider next time.

4 – Adjournment

The meeting was adjourned at 12:55 pm EDT. The committee would now meet weekly until the comments had been dealt with.