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

**JUNE 24, 2016**

The Committee met by teleconference on Friday, June 24, 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) | Present |
| Scott Hoatson, Oregon DEQ (AB) | Present |
| Craig Huff, ERA (Other) | Present |
| Shawn Kassner, Neptune (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 |
| Ken Jackson, Program Administrator | Present |

Associate Committee Members present: Mike Blades, ERA; Amy Blum, NYCDEP; Amanda Grande, Phenova; Rob Knake, A2LA.

**2 – Previous Minutes**

It was moved by Scott and seconded by Craig to approve the minutes of June 17, 2016. All were in favor.

**3 – Volume 3 Comments**

**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."* Nicole gave an update on discussions with the NY AB program. They confirmed, as a PT Provider, their regulations will be compliant with the standard. However, as an AB they will be unable to score a small number of reports in accordance with the standard. Therefore, for their own laboratories, they will provide a NY-compliant report, and a TNI-compliant report for the rest. The NY program agreed to provide something in writing to this effect and to confirm it would not prevent them from adopting the 2016 standard. In any case, the standard could not be changed at this point, because it would be inconsistent with Volume 2, Module 2, and the problem was not raised during the voting of that standard. It was moved by Nicole and seconded by Donna that the comment was Non-Persuasive. All were in favor.

**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.* As discussed during the previous call, a new Clause 5.6.2.3 was proposed as follows: "Homogeneity testing shall be compliant to ISO 13528:2015 (E), Annex B, Section B1 through B3." It was moved by Craig and seconded by Mitzi to rule the comment Persuasive and to insert the clause in the standard. All were in favor.

**V3 5.9.3.2.1 and 5.9.3.2.2** *"So, if the Assigned Value for a PT is <0.5 ug/L and the laboratory reports <5%, the result is scored acceptable? To correct for this possible problem, I would word clause 5.9.3.2.2(a) as follows: "the numeric value reported is greater than or equal to the PTRL, whether or not a less than (<) sign is included; or"."* Shawn was seeking clarification from the commenter and he would report on this at the next call.

**V3 5.10.4.3** *"This section does not cover cases where more specific information may be required by a subcommittee's charter. Example; request of necessary additional subdivision of NELAC codes on an FoPT to aid in assessing potential method bias. For a FoPT (or other) subcommittee to evaluate this bias, data would need to be evaluated based on specific methods reported and associated results. It's likely this information would only be needed under specific circumstances, so it should not be part of the "normal request"."* Maria Friedman had provided the following note to be added at the end of the section:

"NOTE: The information delineated in Section 5.10.4.3 is considered sufficient for the PTPEC's routine or normal course of proceedings to update FoPT Tables. However, in certain cases that affect the further continual improvement of FoPTs and the TNI PT Program as a whole, the PTPEC may request additional information, not specified in section 5.10.4.3, to be included in a summary report. When this situation occurs, the PTPEC shall convene with the PT Providers to explain or clarify the additional request."

Mitzi questioned adding this note, because it did not provide any auditable requirement. Craig said this would meet his concerns. It was suggested making it a requirement, but Ken believed it was too late to add a requirement that could be controversial at this stage. Scott pointed out the last sentence would need "shall" being replaced by "may". He favored adding the note, because it would provide a segue to make it a requirement in the next version of the standard. It was then moved by Scott and seconded by Fred to insert the note with the last sentence deleted. All were in favor.

**4 – Volume 4 Comments**

**V4 General "***There is inconsistent naming for ISO 17011. Examples: a. In Section 4.1 (b): "ISO/IEC 17011"; b. In Section 5.0: "ISO 17011"; c. In Section 5.1.2: "ISO/IEC 17011:2004"; d. In Section 6.0, "ISO 17011"; e. V3, Section 2.6: "ISO 17011:2004. Suggest normalizing references throughout both volumes."* The committee agreed an editorial change should be made for

consistency. Ken also said he would assure this was done throughout the TNI standard. All the "1700s" will be in the format "ISO/IEC 17011: 2004. Others will be "ISO 17043:2010" and "ISO Guide 34: 2009".

**V4 4.1 "***Would this "undue delay" pertain to a PTPA processing a request for accreditation from PT Providers, or does it pertain to TNI processing a request for accreditation from a PTPA? Does it apply to both situations? Please clarify."* It was moved by Mitzi and seconded by Craig to rule the comment Non-Persuasive and to provide the following response prepared by Shawn: "The clause is referring to the actions that shall be taken by the PTPEC approving the PTPA. The accreditations of PT Providers are not involved in this clause." All were in favor.

**V4 5.3.1** *""To the extent feasible, the PTPA shall not assess those activities that are so recognized." I think that this statement should be better worded or explained in more detail. While I think that the intent is to minimize the need to review the "ILAC" elements of the program, if taken literally, the assessment wouldn't need to include a review of quality documentation, organizational structure and other fundamental aspects that need to be included for any meaningful assessment. Does this mean that the required elements listed in section 6.2 may be overlooked if they were assessed by another organization?"* This clause received an unrelated comment at the Voting Draft Standard stage, but was not changed for the Interim Standard. Therefore, the present comment could not be addressed by the committee.

**V4 5.6 a) i** *"Does the "list of PT Providers" for the PTPA's presentation pertain to just the accredited providers? Or, does it include any applicants for accreditation? My recommendation is to clarify subclause 5.6(a)(i) to read: "list of applicant and accredited PT Providers – additions, withdrawals, renewal status;"".* It was agreed that PTPAs can only list the accredited providers. It was moved by Mitzi and seconded by Donna to rule the comment Non-Persuasive with the following response that had been drafted by Shawn: "PTPAs have to adhere to the confidentiality of the applicants as to whether they can publically provide the information.". All were in favor.

**V4 6.0** *"Again, would this "undue delay" pertain to a PTPA processing a request for accreditation from PT Providers, or does it pertain to TNI processing a request for accreditation from a PTPA? Does it apply to both situations? Please clarify."* It was moved by Mitzi and seconded by Donna to rule the comment Non-Persuasive and to provide the following response: "The title of the section is "PTPA REQUIREMENTS FOR ASSESSMENT AND ACCREDITATION OF PT PROVIDERS", therefore the undue delay would be in the review PT provider applications." All were in favor.

**V4 General** This was the same comment made on V3, that the standard should state that the most recent version of an ISO standard is applicable, rather than cite specific dated ISO standards. It was moved by Mitzi and seconded by Nicole to rule the comment Non-Persuasive and to provide the same response that was provided for the V3 comment. All were in favor.

**V4 General** *"Please note that issues for the evaluation of radiochemistry samples should be added to issues to be addressed in the next revision.".* It was moved by Fred and seconded by Mitzi to rule the comment Non-Persuasive, because it would not be relevant to V4 (it was previously noted this would be done for the next modification of V3). All were in favor.

**5 – Next Steps**

The committee having completed the V4 responses, Shawn said he would edit the response-to-comments spreadsheet. He would also put together V3 with the agreed changes and would circulate the spreadsheet for review.

**6 – Adjournment**

The meeting was adjourned at 12:00 pm EDT.