TNI PT Expert Committee
Meeting Summary

August 7, 2012

1) Roll call and approval of minutes:

Chair Mitzi Miller called the TNI PT Expert Committee meeting to order on August 7, 2012 in Washington, DC at 1:30 PM EST. Attendance can be viewed in Attachment A. There were 7 committee members present.

2) Overview

See Washington DC meeting PowerPoint slides on the TNI website. Mitzi explained that the meeting today was for gaining information and there would be no voting.

The committee is planning to have Volume 3 ready for community review in the fall. The comment period for Volume 1 and Volume 2 will be for 15 days from the date of this meeting.

3) Working DRAFT Standard

The standard will now reference other parts of the standard. Mitzi Miller plans to place all lab requirements in V1M1 and in V2M2 will reference back to the V1M1. In V2 add: "The primary AB shall require applicant laboratories to meet to the PT requirement as specified in V1M1".

Cathy Westerman (VA) commented that she is in agreement with this new approach. Matt Sica (ACLASS) also supports the approach and Jeff Lowry expressed a concern as to whether this approach will be consistent with the other sections of the standard. Kirstin (Chair – LAS EC) noted that the Consensus Standards Development Program (CSDP) has agreed with this approach.

Additional Comments:

- Things should be written an affirmative manner, rather than a negative manner. Don't focus on what not to do … focus on what is required. Kirstin commented that came from a 2004 AB policy that listed "do not do this". Curtis disagreed with this approach – difficult to audit. Kelly Black noted that International Standards state what not to do. Cathy Westerman, Matt Sica, Susan Butts and Eric Smith preferred to leave as is.

- There needs to be a separate module just for definitions. There was some support expressed for this idea, but others were concerned about affect on cross-referencing and applicability to all TNI programs (NELAP, NEFAP and PTP).

- Number of labs that run by method in audience – 3 (18 people in room). Florida is adamant that it be by technology.

- Need to explore the need for including prep methods when evaluating PTs.

- Mitzi would like to see the chair of the PTP EC, PTEC and an AB meet to start working on alternatives on how PTs should be be organized and run. Talk to LAS EC and see if they can coordinate something like this. Kirstin will take this to LASEC. (ACTION)

V1M1

A copy of the working draft standard the committee presented at the meeting with the additions and deletions can be viewed if proof of ownership of the standard with the ISO language can be submitted to Ilona Taunton at ilona.taunton@nelac-institute.org.

Comments – Definitions:

3.2: Is there still a need to include the term "accreditation" when experimental FoPTs don't exist anymore? Eric Smith noted that keeping the term would help better define which PTs are for TNI accreditation programs. Matt Sica reminded everyone that the PTs are used by people outside of TNI too.

3.3: No comments

3.4: No comments

3.7: No comments

3.17: Get rid of closing date? It is still in V1M2. Confirm Volume 3 still has element of 6 months.

Comments – Other Parts of Standard:

4.1.1. a) : Does not state the PTs should be in different batches
Matt Sica: No value in different batches and could be done in the same day.
Also in section 7.1.

7.1.b) : Cathy Westerman: This is confusing using words such as obtain and report. Does not have problem with two days if it is an initial PT and you are using two different PTs.

In general – There was a lot of confusion and it was stated that we should not use "Open Date". Section 7 should be carefully reviewed by the committee. (ACTION)

4.1.1. b): Kirstin commented that this is for initial accreditation and says that 2 PTs are required as opposed to the drinking water standard.

The intended user should be clarified. Enter 40 CFR. (ACTION)

Comments – Accreditation By Technology – Remove this clause?

- If accreditation is by technology, and the lab runs two or more methods with the same technology and the lab runs one PT, then if the PT fails all methods using that technology fail.

- Kirstin – This is needed because of the way the program is set-up.

- Matt Sica: This is a dated issue. No one agrees.

- Jeff Lowry: Put prep and method together and call it by technology.

- General consensus is to leave it. This issue is very controversial and changing it could slow the acceptance.

- Mitzi Miller: Suggested there be a AB rep, Expert Committee rep and also a Consensus rep to deal with this on a higher level and that we need a long-term plan - not just PT committee. We should not be doing this in this working draft standard. (ACTION) Start conversations with multiple committees and outside groups. Look at "if that" language could work as interim.

7.0: There was lots of discussion surrounding this section. There was concern that a lab could not submit a PT outside the routine PT schedule. This needs to be revisited and the 2 out of 3 rule needs to be clarified. (ACTION)

V2M2

A copy of the working draft standard the committee presented at the meeting with the additions and deletions can be viewed if proof of ownership of the standard with the ISO language can be submitted to Ilona Taunton at ilona.taunton@nelac-institute.org.

1.3.2: Added

4.1.2: To run PTs, ABs should not require calibration ranges outside of typical range used by the lab. Mitzi noted that Treatment labs often have narrow ranges and can fail

PTs. The states should be considering multiple range PTs. This should be discussed with the PT Program Executive Committee. (ACTION)

5.1.1 Note added.

5.4 Section was updated to reflect V1M1 changes.

6.0 Cathy Westerman noted that V1M1 does not have instructions for PT samples to be prepared according to the instructions they come with. Matt Sica commented that he questions removing instructions from this section.

ACTION. Add to V1M1: "PT samples for accreditation FoPT were prepared …."

ACTION. Revise note – has "shall" statement. PTPA is incorrect and Preface with word except.

10.3 Needs to be clarified. ACTION.

V3

Kelly Black worked on this section with PT Providers and provided the following update:

7: Kelly Black explained options

- Honor the current intent
  - Use the procedures from Appendix A, or
  - Equivalent procedures approved by the PTPA.
- Accept the current verification criteria in 7.1
- Accept the criteria for homogeneity and stability currently in Appendix A.

Kelly Black: Stated that we did not bring in the procedures for "how to".

10.2.1: Use "C" to denote the acceptance interval.

7.1.6:

Kelly Black: One of the challenges is that they rely on the acceptable interval but don't necessarily know until the study is over. We added language to accept that this is an issue and not hide it and bring it forward. "For analytes that are based on the study mean and study standard deviation, the PT provider shall establish equivalent criteria approved by the PTPA that demonstrate verification of the assigned value".

7.1.8: Remove "to a maximum of 10%."

1.1.10: Remove: "The standard deviation of the verification analyses shall be less than one standard deviation as calculated for the participant laboratories". This removes

awkwardness for PT providers. When Scott Hoatson asked what happens when it fails, Stephen Arpie responded it is rerun until it passes.

7.2.2: Added criteria from Appendix A to this section.

7.3.4 b): Added: "the provider's stability analyses meet the requirements for verification as defined in section 7.1".

ISO 17043 Discussion

Mitzi Miller: Do we define the criteria or do we reference ISO 17043 'fitness for purpose' and allow the provider to propose an approach and the proficiency testing provider Accreditor (PTPA review and approve?
If we reference ISO 17043 only and remove appendix A this will allow for more creativity and various approaches on case-by-case basis. There are ISO guidelines that already exist and this is internationally accepted. All of the ABs that are PTPAs require ISO 17043 as a baseline.

Stephen Arpie: This helps the community. We are already doing this for calibration standards. It is already without definition for homogeneity, stability and validity. If we feel we have the need for the PT program why not have it for the others. Objection is to the process, constantly changing the rules but the process doesn't change. The chemistry doesn't change.

Matt Sica: Is there any added value to adding the criteria?

Kelly Black: Pros for ISO 17043:

- Internationally accepted
- Allows more creativity
- PT Provider approaches are evaluated case by case
- There are ISO guides for the statistics

Mitzi Miller: Cons for ISO 17043:

- Very different than previous approaches defined by EPA (current approaches based on EPA water PT programs from years ago)
    - Current practice does not differ from TNI criteria, but this approach would allow PTPs to begin to diverge in their approaches
- More expertise required in statistics for auditors
- More variation due to interpretation by PTPAs and providers

Action Item: Contact EPA for approval/input
Matt Sica: Would be using the technical skills of the auditor during the assessment.

Roger Kenton: Would it be equivalent if you had the 1/3 or 1/6 or something equivalent. Which would allow the PT providers to use their ingenuity?

Kirstin: Original instructions were if an ISO standard existed then we use the ISO standard.

Mitzi Miller: We could create a guidance document.

Kelly Black: ISO 13528 already provides guidance.

Mitzi Miller: Options:

1. Specify ISO 17043 approach for VHS
2. Add the criteria from the current Appendix A into section 7 & 10
3. Plan to move to ISO 17043 in future. Until then place criteria in section 7 and write Guidance so that we will better define fitness for purpose.

Mitzi Miller: If we take approach 1 we will have to do a lot of education. There is no ILAC agreement.

Stephen Arpie: We could say you have to do it the same way as CRM customers. ISO 17043 has a note - "someone who is accredited to Guide 34 meets the requirements for ISO 17043" . You pick up the program in ISO 17043.

Kelly Black: She has noticed that during audits, she sees a difference in how each provider defines 'fit for purpose'. Bottom line for TNI is whether you are willing to give PT providers the ability to define their own approach or do you want to dictate. By providing ability to define, an auditor would check whether or not it is being done.

Roger Kenton: You could have a provider that could become looser in how they approach this and overtime would be driven out of the market.

Mitzi Miller: Providers as a whole have come to a more centered approach. Don't expect quality deterioration.

Roger Kenton: It would appear we would have a cleaner standard with the same quality.

Mitzi Miller: Only other reason to consider Alternative 3 is that we have many states that use the accreditation of the PT for non-NELAC states and drinking water uses the same specific criteria. Alternate 3, at this time, is probably the best but ultimately we would like Alternate 1.

4) New Business

None

5) Next Meeting

The next meeting of the PT Expert Committee will be planned by E-mail.

The meeting was adjourned at 5pm EST.

Attachment A – Attendance

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Committee Members 2012			
Member	**Affiliation**	**Email**	8/7/2012
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