

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

JULY 13, 2015

The Committee met at the Environmental Measurement Symposium, Chicago IL, on Monday July 13, 2015. Chair Shawn Kassner led the meeting.

1 – Roll call

| | |
|--|---------|
| Fred Anderson, Advanced Analytical Solutions (Other) | Present |
| Kareen Baker, Independent (Other) | Absent |
| Nicole Cairns, NYSDOH (Other) | Absent |
| Rachel Ellis, NJ DEP (AB) | Present |
| Scott Hoatson, Oregon DEQ (AB) | Present |
| Shawn Kassner, Phenova (Chair; Other) | Present |
| Stacie Metzler, Hampton Roads San. Distr. (Lab) | Absent |
| Mitzi Miller, Dade Moeller Assocs. (Other) | Present |
| Judy Morgan, Env. Science Corp. (Lab) | Present |
| Joe Pardue, P2S (Vice-Chair; Other) | Present |
| Jim Todaro, Alpha Analytical (Lab) | Absent |
| Lisa Touet, MA DEP (AB) | Absent |
| Ken Jackson, Program Administrator | Present |

2 – Introductions

Shawn opened the meeting at 9:00 am CDT, and the committee members introduced themselves. Shawn presented the agenda for the day as consideration of the Volume 1 Module 1 and Volume 2 Module 2 Interim Standards (IS) in the morning, followed by the Volumes 3 and 4 Voting Draft Standards (VDS) in the afternoon session.

3 – Discussion of Volume 1 Module 1

The IS had been posted for membership vote on July 8, with a closing date of August 21, 2015. The purpose of this session was to present for discussion the changes that had been made to the VDS to produce the IS as a result of persuasive comments.

Shawn provided an overview of the changes. Steve Arms asked when all the standards would be complete. It was explained that the committee remains on track to complete all volumes and modules before the end of 2015, but there was some discussion over whether all volumes and modules have to be ready together; e.g., the Accreditation Bodies only need Volume 1 for rule-making. Steve also asked how different the module is from the 2003 NELAC standard. Shawn suggested a cross-walk between the two standards could be done if requested.

The only comment on the standard was whether in clause 4.1.3 “approved” should be changed to “recognized”. Judy consulted the appropriate SOP and reported that it uses the term “approved”, so this should not be changed in the standard.

4 – Discussion of Volume 2 Module 2

Shawn provided an overview of the changes made from the VDS. The following includes changes to the IS as a result of discussion during the meeting. The PT Expert Committee agreed with those changes, but in conformance with SOP 2-100, they will only be made if they are presented as comments on votes made on the IS.

George Detsis expressed concern over the use of “may” in clauses 6.1.1 and 6.2.1. He argued that the standard would not be applied consistently (and on a national basis) if an Accreditation Body (AB) “may” suspend a laboratory and asked why it did not say “shall”. It was understood the intent of the language was to provide latitude since some ABs had legal authority to immediately suspend, while others did not. However, the use of “may” could unintentionally give an AB discretion on whether or not to suspend. Discussion followed, resulting in a proposed modification of the language to say “shall”, but that it must be consistent with States’ legal requirements.

Clause 3.1.6 had been modified in the IS to change the definition of Suspension to read “*The temporary removal of a laboratory’s accreditation for a defined period of time, which shall not exceed six (6) months or the period of accreditation, whichever is shorter, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.*” Previously it had read “..whichever is longer.”, and Cathy Westerman pointed out the change would be inconsistent with other parts of the standard. It was agreed this should be changed back to “longer”.

The meeting temporarily adjourned at 11:00 and re-convened at 1:30 pm

In the VDS, Clause 4.2.1 had stated “*The Secondary AB shall have procedures in place to evaluate and update a laboratory’s accreditation status based on the accreditation granted by a Primary AB.*” In the IS, “evaluate” was changed to “communicate with the Primary AB”. Cathy Westerman felt, as a Secondary AB, she should not have that responsibility. On discussion, it was agreed clause 4.2.1 is redundant, since it is covered in 4.2.2. It was agreed 4.2.1 should be removed, with its language being merged into 4.2.2.

Clause 4.1.5 (g) states that the Primary AB shall have procedures in place to notify all Secondary ABs of revocation of accreditation of any laboratory in their program. Concern was expressed that ABs may not know which are the laboratory’s Secondary ABs. After a protracted discussion it was generally agreed the only “Secondary ABs” are those in the NELAP program, and does not include laboratories accredited by non-NELAP states to the TNI or NELAC standards. Therefore, it was agreed to change the wording to change “all Secondary ABs” to read “all NELAP recognized ABs”. There had been no comment on this at the VDS stage, but the change could be made as an editorial change, since the intent would remain the same.

5 – Discussion of Volume 3

The committee opened for discussion, and considered comments from the recent vote on the VDS. Those comments that were purely editorial were not discussed.

General “*Other comments have made reference to redundancies with ISO 17011 which is a standard for Accreditation Bodies. TNI EL V3 is a standard for Proficiency Testing Providers and not accreditation bodies. While it is a legitimate comment that there are redundancies with ISO*

17011 I would not expect the PTP to be familiar with ISO 17011 and thus don't really have a problem with some things that could be considered redundant to requirements for an AB. It might actually be beneficial for EL V3 to have these "redundant" requirements as they are for the PTP and not the AB and the PTP is clear what requirements are "pushed down" on them from the AB who has to meet ISO 17011. I guess these items don't really give me heartburn unless they cause me as an AB to be in conflict with ISO 17011 and my MRA obligations. I tried to address those potential issues specifically in my comments above." Mitzi suggested adding a sentence in the scope to clarify this issue. She volunteered to work with the PTPAs and to draft language that the committee would consider as a new subsection (d) under Section 1.2.

2.0 *"References do not include ISO Guide 30:2015. This Guide is the appropriate reference for the definitions of lot, RM and CRM. Possible Resolution: Add Clause: 2.7 ISO Guide 30:2015 Reference materials - Selected terms and definitions, as a reference."* The committee agreed to add this.

3.0 *"References do not include ISO Guide 30:2015. This Guide is the appropriate reference for the definitions of lot, RM and CRM. Possible Resolution: Possible language: For the purpose of this Standard, the relevant terms and definitions are conformant with ISO Guide 30:2015, ISO/IEC 17043:2010(E), ISO/IEC 17011:2004(E), Clause 3 and ISO/IEC 17025:2005(E), Clause 3."* The committee agreed to add this.

3.0 *"Intro wording in section 3.0 is confusing, it seems that the definitions are meant to "conform" to the ISO definitions but sometimes they are the same, sometimes they are different, sometimes they are new and distinct terms from the ISO definitions. Also, some definitions are from ISO Guide 30/34 and should be referenced in the document. It just seems very confusing and an organization having to conform to all standards might be pulling their hair out with terms that mean different things in different standards. Also, it seems like the definitions are meant to be in alphabetical order but they get random (or it appears) after 3.13. There are also numbering errors where some numbers are duplicated. Possible Resolution: Use the ISO definitions when possible and appropriate and clearly reference the applicable ISO standard. Perhaps even separate the ISO definitions from the unique TNI definitions so it is really clear. If alphabetical order is intended you'll want to rearrange the definitions. Also, renumber the definitions so there are no duplications."* Shawn said there is a copyright problem in using ISO definitions, though the standard can refer to Guide 30/34 definitions. Several other comments were received on incorrect or incomplete definitions. Mitzi suggested going through all the definitions and bringing this back to the committee. Rob Knake would be asked to do this.

3.16 *"The appropriate reference for lot is ISO Guide 30:2015, not ISO/IEC 17043:2010(E)."* The committee agreed to make this change.

3.17 *"IC25 definition. Change inhibitory to inhibition. Per EPA 821-B-00-004, Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing (40 CFR Part 136), IC indicates inhibition concentration."* The committee agreed to the change.

4.1 *"I would suggest to change 4.1 to the following to insure PT Providers are accredited to the most recent version of the ISO document: 4.1 The PT providers shall be accredited to the most recent version of ISO 17043 General Requirements for Proficiency. There are other instances where ISO Standards are listed and the PT Provider is required to be accredited, it would be a good practice to use "Most recent version" as these Standards do change over time, some should be*

changing quite soon.” Randy Querry and Kelly Black said the version of the standard needs to be specified. The committee agreed the comment was Non-Persuasive, because ISO references by year and TNI should do the same.

4.3 and 4.4 It was commented there was redundancy with the requirements of ISO 17011. However, the commenter Matt Sica withdrew both comments.

4.5.2 *“This violates the requirements documents of the ILAC AB, ISO/IEC 17011 and the contractual obligations of the PTP. By standard, requirements documents and contract all relevant aspects both documents and records of the PTP are subject to review by the PTPA. This sets precedent for the PTP to cherry pick what records are reviewed, a PTP can claim, a record has a client ID on it therefore cannot be reviewed. OF the most simple examples, how would an AB review conformance to the requirements relating to a final report? The employees and contracted assessors sign confidentiality agreements to the AB and reaffirm them regularly, as well as provide a signed agreements to the customer at the time of assessment. Aspects related to confidentiality are reviewed at both the opening and closing meetings as well. Possible Resolution: Remove Clause.”* Matt Sica added that it says he cannot look at data unless authorized by the laboratory and that would prevent him doing his job as an assessor. It was agreed the standard needs to limit this to data submission. The language would be modified to add “in data submitted” after “laboratory”.

4.6 *“This is redundant to requirements of the PTPA accreditation requirements documents relating to investigation of complaints and the contractual obligations of the PTP with the PTPA, so it should be removed. Possible Resolution: Remove Clause.”* Shawn commented this requirement has always been in the standard. The commenter said he did not feel that strongly about it, so the committee ruled it Non-Persuasive.

4.7 *“If this requirement remains in the standard, the word “conflicts” does not sound appropriate here. Consider: If aggrieved by a finding or accreditation decision of the PTPA, the PT Provider shall follow the PTPA’s appeals process. Noting that this creates redundancy. If this remains, change language. Possible language: If aggrieved by a finding or accreditation decision of the PTPA, the PT Provider shall follow the PTPA’s appeals process.”* The committee accepted the proposed wording.

4.8 *“This violates the requirements documents of the ILAC AB, ISO/IEC 17011 and the contractual obligations of the PTP. By standard, requirements documents and contract all relevant aspects the ILAC AB makes the decision on appeals. These cannot be unresolved. This also violates the impartiality requirements of ISO 17011. The PTEC cannot put undue pressure on the PTPA to change a decision. Possible Resolution: Remove Clause.* Matt Sica added this was a clear violation of ISO 17011, that would cause conflict with the signatory states. Shawn responded that it has been in the standard for a long time. However, Randy Querry agreed it should be removed, because a system is already in place.

There were two more comments on Clause **4.8**, but these were now redundant as the clause would be removed.

5.1.1 *“I realize this language is present in EL-V3-2009 and you are just updating it. The minor issue I have is that the term “manufacturing system” is not used in the Guide 34 nor defined in any ISO normative document, that I am aware. My larger point is that none of the language in the*

quality systems requirements section addresses the use of ISO/IEC 17043:2010 Conformity assessment- General requirements for proficiency testing. Since this is a proficiency testing standard and not a reference material standard, a reference to 17043:2010 ought to be included and emphasized more than ISO Guide 34. After all, it is listed on our A2LA Certificate. I suggest the following language where we re-add the clause 5.1.1 from EL-V3-2009 and substitute ISO/IEC 17043:2010 where ISO 9001 appears: “The PT provider’s quality management system shall meet the requirements of ISO/IEC 17043: 2010 for the design, production, testing and distribution of PT samples and the evaluation of PT results.”” The committee agreed with the recommended change.

5.3.1 The committee agreed to delete this clause, agreeing with the commenter that it is already covered in ISO 17043.

At this point, Shawn announced the committee would defer working through the comments one at a time, but he asked the audience if anyone wanted any other specific comment addressed. Hearing none, the committee closed the discussion on Volume 3.

6 – Discussion of Volume 4

Mitzi said most comments are redundant to ISO 17011, so she suggested focusing on the remaining comments. Mitzi also suggested asking Rob Knake to also work on the V4 definitions.

6.3.1 – 6.3.4 It had been commented that much of this was redundant to clause 5.4. However, after discussion the comment was withdrawn.

1.3.1 *“A single person cannot be this function. This is due to the impartiality requirements of ISO/IEC 17011. 4.3.5 The accreditation body shall ensure that each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment. Possible Resolution: This Volume is applicable to any organization seeking to function as a TNI approved PTPA. The committee agreed to remove “person(s) or”.*

3.1 *“Consider adding PTRL to the list, such as “...composition, spike concentrations, PTRL and spike concentration ranges...”.”* The committee was unable to change the definition at this time, so the comment was ruled Non-Persuasive.

4.0 *“These are not requirements for the PTPA. This entire section 4.0, 4.1 and 4.2 should be removed. ISO/IEC 171011 does not make statements such as “APLAC shall” related to the evaluation process of ABs . These organizations maintain documents which specify requirements, for example and the TC008 and TC009 of APLAC. To maintain mutual recognition, the ABs follow the requirements. Possible Resolution: The PTPEC should create a requirements document for PTPAs citing the applicable criteria within this section. The next round of contracts between the PTPA and TNI should include that the PTPA will follow all application criteria set forth in ISO/IEC 17011, this Volume and the requirements document. This criteria includes review of documents and records related to the management system of the PTPA and technical requirements for accreditation of TNI PTPs. There is an added advantage that criteria documents can change relatively quickly compared to consensus standards development”* Matt Sica added that this should be a note, an SOP, or a requirements document. The committee agreed to remove clause 4.0. Added to Clause 1.2 (d) would be “..according to the PTPEC requirements document.”

5.0 *“The use of the auxiliary verb "can" in the sentence negates the intention for the requirements to be followed, as opposed to being permitted. Remove the word "can" from the sentence. Please note the revised meaning: "The requirements in this Section ~~can~~ serve as guidance for PTPEC procedures for those functions, or as requirements that the PTPA shall meet in order to be approved.”* This was persuasive, and the committee decided to remove the sentence.

5.1.1 *“Redundant to language of ISO/IEC 17011, noting that the requirements of ISO/IEC 17011 does not differentiate what type of accreditation occurs, be it RMP, PT, or laboratory. Remember the title of ISO/IEC 17011 is Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies. ISO/IEC 17011 6.1.1 addresses staffing. "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." Possible Resolution: Remove Clause.”* After discussion, the comment was withdrawn.

5.1.1 *“If this statement remains, remove PTPEC reference. Possible Resolution: The PTPA shall have the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider accreditation.”* This was ruled Persuasive, but the language was modified to read “The PTPA shall demonstrate to the PTPEC...”

5.1.2 (b), (c), and (f) These were three separate comments, all stating the clauses were redundant. The committee agreed and the clauses were removed.

Two comments on **5.2.2** were withdrawn by Matt Sica after discussion.

Three comments on **5.3.1** said the clause was redundant. Mitzi agreed, since this is covered by the MRA. The clause was removed. Similarly, **5.3.2** was removed.

5.3.3 *“This requirement should be reworded to indicate EL V3. ABs already use checklists for other standards. Possible Language: A PTPA shall develop a standard, concise and unambiguous checklist(s) to be used based on the requirements set forth in TNI EL V3 in addition to existing checklists during all assessments of PT Providers.* This was ruled persuasive. The proposed language was modified slightly by inserting “used by the PTPA” after “checklists”.

Two comments on **5.4.3** were withdrawn by Matt Sica.

5.4.3 *“Needs corresponding requirement in V3 for PTPs to provide data to TNI. Possible Resolution: See V3 comments.”* The committee agreed there should be a separate clause for the PTP to submit to the PTPEC for FoPT investigation and updating.

As time was running out, Shawn ended the systematic discussion of the comments, but he invited the audience to comment on any of the other comments. Hearing none, it was moved by Fred and seconded by Judy to accept all decisions made during the session on Volumes 3 and 4. All were in favor.

Adjournment

The meeting was adjourned at 5:00 pm CDT.