Minutes of the TNI Proficiency Testing Expert Committee
January 30, 2007

The Proficiency Testing (PT) Committee of The NELAC Institute (TNI) met on Tuesday, January 30, 2007. This meeting was part of the Forum on Environmental Laboratory Accreditation in Denver, CO. The meeting was led by Chairperson Dr. Anand Mudambi of the U.S. Environmental Protection Agency.

The purpose of the meeting was to receive comments on the modules and volumes for Proficiency Testing within the TNI Environmental Laboratory Sector Working Draft Standards (dated January 14, 2007). The TNI Environmental Laboratory Sector Working Draft Standards for Proficiency Testing consists of four (4) volumes with a module or volume for each one of the stakeholders – Laboratories, Proficiency Testing Providers, Accreditation Bodies, and Proficiency Testing Oversight Bodies. The Proficiency Testing (PT) modules and volumes are as follows:

1. Volume 1, Module 1: Proficiency Testing (Requirements for Laboratories).
2. Volume 2, Module 2: Accreditation Body Requirements: Proficiency Testing.
3. Volume 3: Proficiency Testing (PT) Provider Requirements.
4. Volume 4: Proficiency Testing (PT) Oversight.

Welcome and Introductions

Dr. Mudambi introduced himself as chairperson of the committee and welcomed the participants. The committee members then introduced themselves. Dr. Mudambi thanked the committee members as well as associate member Dr. Michael Miller (New Jersey Department of Environmental Protection) for their hard work in getting all Working Draft Standards ready for posting on the TNI website. He also thanked all attendees for taking the time to attend this meeting and discuss the Working Draft Standards.

General

Dr. Mudambi stated that Institute for National Environmental Laboratory Accreditation (INELA) received a large number (over 166) and detailed comments Draft Interim Standard on Proficiency Testing (dated June 2006). Based on the recommendation of the INELA PT Committee, the INELA Board decided to withdraw this Draft Interim Standard and asked the INELA PT committee to address the comments received and resubmit the PT volumes and modules again as a Working Draft Standard. In November 2006, INELA merged with the National Environmental Laboratory Accreditation Conference to the form The NELAC Institute (TNI). The PT committee under INELA continued as the PT committee under TNI. The TNI PT Committee continued to incorporate comments received on the INELA Draft Interim Standard and posted the revised standard as a TNI Working Draft Standard on the TNI website.

Process Regarding the TNI PT Working Draft Standards

Dr. Mudambi said that TNI is now soliciting comments on these Working Draft Standards (WDS) which must be submitted in writing to the PT Committee chair (Anand Mudambi) by February 19, 2007. The TNI PT Committee will then incorporate all relevant comments into the WDS which will then presented as a Draft Interim Standard (DIS) for vote and comment by the entire TNI membership this summer. The PT Committee would then address the comments received on the DIS at the TNI meeting in Boston (August 2007). Once all comments on the DIS have been resolved, the PT Committee anticipates posting

an Interim Standard (IS) for a vote by the TNI membership. A positive outcome will make the IS a TNI Final Standard.

Dr. Mudambi stated that the PT Committee would address one Volume in each of the four scheduled PT sessions starting with Volumes 3 and 4 in the morning sessions followed by Volumes 1and 2 in the afternoon. The PT Committee reviewed the substantive changes in each module since the August 2006 meeting and asked for comments.

Dan Tholen of the TNI PT Committee started the first session by providing an overview of activity on International Laboratory Accreditation Conference (ILAC) G13 document and International Standards Organization (ISO) Guide 43(since these are referenced in Volumes 3 and 4). ILAC G13 will be going to ILAC membership for 60 day comment period in the near future. There are no new requirements and ISO 17025 management requirements have been blended in. When it is finalized, ILAC will retire G13. Field sampling, inspection body and technician requirements are expected to be included. ISO is revising ISO Guide 43 (to become ISO 17043).

Volume 3: Proficiency Testing (PT) Provider Requirements.

Curtis Wood of the PT Committee presented this volume. The main comments received are summarized below:

- Section 1.2 regarding responsibilities of the "Standard Setting Authority (SSA)" – there were questions regarding how specific to be with respect to the responsible TNI committees. In this case the SSA would be the TNI PT Board. Comments on this question were that referencing the TNI PT Board extends their control into the standards process. The TNI PT Board must first have policies defining its responsibilities. Lack of direction and policy at the PT Board (under NELAC) has been a long-standing problem.

- Section 2 Normative references – may add ILAC G13.

- Section 4 – more comments on clarifying SSA role. Current language mixes requirements of the PT Providers and SSA, need to review for use of active voice.

- Section 5.1.5 - it was noted that NELAC doesn't have mutual recognition policy for the Proficiency Testing Provider Accreditor (PTPA) to follow if the PTPA itself does not have a mutual recognition mechanism with other recognized bodies for oversight of PT Providers for conformance with ISO requirements.

- Section 6.3 – what is the purpose of PT samples that do not contain all analytical targets? These are deemed to be more representative of real samples. It was also asked who is setting the requirements – the standard or the SSA? Clarification was requested whether the FoPT tables could supersede the requirements for number of analytes including whether the total number of analtyes includes all regulated or experimental analytes. Also some of the details of the NELAC standard were lost which should be put back into the standard.

- Section 7.1.11 – Laboratories recommend that PT Providers should ensure that no analytes are present at half the Proficiency Testing Reporting Limits (PTRL) as laboratories may report hits

and fail the PT samples. It was noted that some PTRLs can't be reached with approved methods – in the future may have multiple levels of analysis. This is currently the purview of the NELAC PT board.

- Section 7.2 and 7.3 – it was suggested that international standards should be referenced for verification, homogeneity and stability (VHS) testing, as opposed to "those approved by the PTPA".

- Sections 8.2.4 and 8.2.5 – seem to be requirements for labs, not PT Providers. However there is a need to emphasize that to the extent possible, PT samples are treated like all other samples by the laboratory.

- Section 8.2.6 – Requirement against providing "excessive volume" of PT sample is not enforceable.

- Section 8.2.7 – this defined a requirement for SSA/PTPAs, not PT Providers. Recommend removing this section. SSA/PTPA is redundant. Recommend using either PTPA or SSA.

- Section 8.4.1.2 – need to define the specific data needed to demonstrate stability. Need to reference the earlier section.

- Section 8.4.1.4 – the PT Provider may not be aware of all routes a lab may have for access to assigned values in the case of supplemental PT studies (which may sold for one PT Provider to another).

- Section 8.4.1.8 – does not state who is subject to this requirement regarding days between closing and opening dates for PT studies for a given laboratory. May be requirement for laboratories.

- Sections 10.1.1, 10.1.2 and 10.1.3 – these sections do not state any requirement for action by the PT Provider other than review of data sets. Recommend making these sections more specific or removing them.

- Section 10.2.5 – requirements here need to be reversed as it is stated backwards from the original document (use biweight mean for 7-20 sample values).

- Section 10.2.6 – clarify if this is guidance or a requirement. If it is a requirement, put in statements with "shall".

- Section 10.3.1.1 – keep this section as is.

- Section 11.2.4 – should standard define report content to this level of specificity?

- Section 11.2.5 – clarify which mean and SD to report –from the interlaboratory study or the regression equations.

- Annex A – it was noted this was drafted as a cost effective means of determining homogeneity. Could use/reference international methods. This method is less rigorous than ISO 35. Consult TNI Consensus Standards Development (CSD) Board as to whether this should be part of the standard or maintained by the PT board.

Volume 4: Proficiency Testing (PT) Oversight

Dan Tholen of the PT Committee presented this volume. The main comments received are summarized below:

- General - Should Vol. 4 be a standard or a guidance document? Recommend keeping it as a standard so that all active participants in the accreditation process are addressed. Consult CSD Board. Also recommended to separate into PTPA and SSA requirements (separate modules). Sections 1 and 2 will need to be changed if this volume is NOT a standard.

- Section 2 – Normative references should be consistent with Volume 3.

- Section 3 – Definitions should be consistent with Volume 3.

- Section 4 – this section would be moved to proposed SSA volume. Not yet sure how this will work in the new TNI organization.

- Section 4.4 – Database requirement needs to be worked out. Review for consistency with standards language.

- Section 5.3 – need to state actions for PTPAs, and need to provide for consistency among providers of there is more than one PTPA.

- Section 5.4 – needs to be consistent with 4.4. The database issue is confusing and has confidentiality issues (including CBI) to be addressed. There would be two types of databases – one internal to the PTPA and one external under the SSA where it would be a place for multiple PTPAs to house information, give status of all laboratories with accreditation, and provide information to the FoPT subcommittee. External database should be a SSA responsibility.

- Section 6.0 – need circumstances under which a PTPA can remove a PT Provider's approved status. Suggestion to add a section 5.9 to address PTPA disapproval (like Section 6.4).

- Section 6.3 – numbering error in the sub-sections.

- Annex – this is SSA guidance.

Volume 1, Module 1: Proficiency Testing (Requirements for Laboratories).

Kirstin McCracken of the PT Committee presented this volume. The main comments received are summarized below:

- General – definitions need to be harmonized between Volumes 1 and 2.
- Section 4 – This section was split into initial and continued accreditation sections.
- Sections 4.1.2 and 4.2.3 – change to "any PTPA recognized PT provider".
- Section 4.1.3 – recommend removal of this section on experimental FoPT.
- Section 5 – Need to add information on how PT tables and PTRLs are to be used. Need to add guidance for laboratories on handling low-level PT samples, or those not appropriate for their laboratory. State that laboratory can dilute sample to bring into laboratory analytical range.
- Section 6 – Review this section to see if it specifies Accrediting Body requirements. Section 6.1 would be a note or in the annex and Sections 6.2 and 6.3 need to be reworded using "standard" language.
- Section 6.2.c) is a new requirement added to the standard. Should it be in guidance document?
- Section 6.3 – was added to address experimental PT samples. There was a suggestion to write in terms of a laboratory requirement.
- Section 8 – define timeframes for appeals from laboratories, responses from PT provider, etc.
- +Section 8.2 – change "unacceptable" to "not acceptable".
- Section 9 – need to put in as note as this is for informational purposes only.
- Section 9.1 – need to correct reference to section 6.1.2.
- Section 9.2 – need to add "or" to list some items are not inclusive of whole list.

Volume 2, Module 2: Accreditation Body Requirements: Proficiency Testing.

RaeAnn Haynes of the PT Committee presented this volume. The main comments received are summarized below:

- Section 1.2 – need to rewrite the scope.
- Section 4.1.2 – change to require laboratory to notify Accrediting Body (AB) about withdrawal from PT study. Withdrawal is important to laboratory so it is not counted as failure. Labs still have to meet PT every 6 months. Need to reword this section.

- Section 5 – revised to show initial and continuing accreditation requirements.

- Sections 5.1.2 and 5.2.3 - change to "any PTPA recognized PT provider".

- Parking Lot issue: AB can grant extension when there is an issue with a particular PT analyte when needed for 6 month PT sample. Lab should be able to analyze replacement samples.

- Section 6.1 – parallel requirements in Volume 1 Section 6.1 f) allows for analysis of samples outside of normal range of measurement.

- Section 9 – add timeframes consistent with other modules.

- Section 10 – States of New York and New Jersey agree that this section should clearly delineate between conditions for suspension and revocation (can be stated in the standard) and the process used by ABs for suspension and revocation (differ due to each state statutes and laws).

- Section 10.1 – needs to recognize the discretion of the AB in applying suspension or revocation of lab. Make clear the relation to Section 7.1.

- Section 10.2 – need to add "or" to list of items. Should reinstatement be a separate item?

- Section 10.3 – new statement. Not phrased as a requirement – should it be a note? Clarification regarding conditions of accreditation versus process may be needed.

Other General Comments:

- Consistency in formatting of introductory sections needs review.

- Consistency in definitions between the volumes.

- Add back in old appendices from NELAC as needed.

- Split Volume 4 into PTPA and SSA requirements – two modules. Previous decision not to have standards for PT oversight should be revisited by the TNI Consensus Standards Development (CSD) Board.

Adjournment

Dr. Mudambi closed the discussion by thanking the audience for their lively participation and asking them to provide written comments. All written comments must be received by February 19, 2007 and can be sent by e-mail to the Committee chair (e-mail: mudambi.anand@epa.gov).

ACTION ITEMS
PROFICIENCY TESTING COMMITTEE MEETING
JANUARY 30, 2007

Item No.	Date Proposed	Action	Date to be Completed
1.	01/30/07	Revise all volumes based on comments received by February 19, 2007.	May 20007
2.	01/30/07	Consult Consensus Standards Development (CSD) Board regarding status of Volume 4.	March 2007

LIST OF PARTICIPANTS
PROFICIENCY TESTING COMMITTEE MEETING
JANUARY 30, 2007

Name	Affiliation	Address
Anand Mudambi, Chair	US EPA/OSWER	T: (703) 603-8796 F: (703) 603-9116 E: mudambi.anand@epa.gov
RaeAnn Haynes	Oregon Department of Environmental Quality	T: (503) 229-5983 ext 227 F: (503) 229-6924 E: HAYNES.Raeann@deq.state.or.us
Thomas McAninch	Laboratory Consulting Services	T: (903) 757-4269 F: (903) 234-9781 E: mcaninch@cableynx.com
Kirstin McCracken	Severn Trent Laboratories	T: (802) 655-1203 x216 F: (802) 655-1248 E: kmccracken@stl-inc.com
James Pletl	Hampton Roads Sanitation District (HRSD)	T: (757) 460-4246 F: (757) 460-2372 E: jpletl@hrsd.dst.va.us
Matthew Sica	Maine Laboratory Certification Program	T: (207) 287-1929 F: (207) 287-4172 E: matthew.sica@maine.gov
Dan Tholen	A2LA	T: (231) 929-1721 F: (610) 374-7234 E: tholen@traverse.com
Curtis Wood	Environmental Resource Associates	T: (303) 431-8454 F: (303) 421-0159 E: cwood@eraqc.com