

SUMMARY OF THE TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

FORUM ON LABORATORY ACCREDITATION MILWAUKEE, WI, JANUARY 28, 2019

The Committee met at conference on Monday, January 28, 2019, at 10:30 CST. Chair Nicole Cairns led the meeting.

1 – Roll call

Rachel Bailey, Advanced Analytical Solutions (PT Provider)	Present
Jim Brownfield, ESC (Laboratory)	Absent
Nicole Cairns, NYSDOH (Chair; Laboratory)	Present
Thekkekalathil Chandrasekhar (Chandra), FLDEP (Laboratory)	Present
Matthew Sica, ANAB (AB)	Present
Patrick Garrity, KYDOW (AB)	Absent
Craig Huff, ERA (PT Provider)	Present
Susan Jackson, SC DHEC (Laboratory)	Absent
Tim Miller, Phenova (PT Provider)	Present
Reggie Morgan, Hampton Roads San. Distr. (Lab)	Present
Lynn Bradley, NELAP Program Administrator, recording	Present

Associate Committee Members present: none identified

2 – Presentation to Meeting Participants

Nicole provided basic information about the committee and its accomplishments using a PowerPoint presentation that is presented in outline form in Attachment 1, below.

The SIR applicability review consisted of a listing of all Standard Interpretation Requests (SIRs) pertaining to Proficiency Testing, from all current and prior NELAP standards, where each SIR was examined to determine whether it has been addressed in a later standard, whether it is still applicable but not addressed in a standard, or whether it is now obsolete.

Nicole asked if there were any questions from labs or Accreditation Bodies beginning to implement the 2016 TNI Standard. The only question was whether there is a summary of Volume 3 and 4 requirements, and the response is that no such summary has been prepared.

3 – Additional Discussion of 2019 Goals

Nicole's presentation identifies some possible goals for the coming year, and these were discussed in more detail.

Beginning the next revision of the standard is a possibility, particularly since both ISO/IEC 17011 (Module 4, PT Provider Accreditors, PTPAs) and ISO/IEC 17025 (Module 3, PT Providers) were revised in 2017. Nicole asked committee members to look at these updated documents to see what changes might be needed to conform with the updates.

- Consider whether to include “prep methods” in Volume 1, prompted by development of more efficient extraction methods that are now causing PT failures because PT acceptance criteria were based on older and less efficient extractions. While all NELAP ABs assess prep methods, they do not all grant separate accreditations for these methods, and more information is needed before making a firm decision.
- Look at the DOD PT program, since DOD decided not to use the TNI PT module V1M1.

- Consider how to address the NELAP Accreditation Council's concerns about PCB PTs, where a lab can fail PTs repeatedly yet never lose accreditation for the 7-congener PCB group. This issue may be satisfactorily addressed with modifications to the FoPT tables, but if not, the standard will need to address it, probably in the form of supplemental PT requirements (qualitative vs. quantitative).
- Determine whether a requirement for supplemental PTs needs to exist. If so, it should be addressed in both V1M1 and V3:
 - revise the section in V3 about what a PTP must provide to a lab with respect to a failed PT and
 - address labs' ability to request a supplemental PT in V1M1.
- Develop training as another viable prospect. Nicole asked if any additional training in PT Reporting Limits is needed.
- Create a checklist for Volume 3 of the 2016 Standard, for use by PTPAs. ANAB stated that they already have such a checklist; A2LA was not present.
- Clarify what defines the matrix for FoPTs, especially tissue and SCM tables (per SIR 176, 6/27/11 – "A laboratory in our program has requested accreditation to measure analytes in biological tissue. The question is "If biological tissues are not listed as a matrix for the current NELAC Fields of Proficiency Testing, are proficiency tests of solid and chemical materials acceptable to demonstrate proficiency for testing biological testing?"")
- Address a few minor points that have arrived as feedback on the 2016 Standard:
 - V1M1 §3.0 -- Add definition of secondary AB and clarify definition of FoPT (per SIR 266) or else put these items in the TNI Glossary and incorporate the Glossary by reference into the Standard.
 - V1M1 §4.2 – revisit whether a second column confirmation is needed for the PT to be truly treated as an "unknown".
 - V1M1 §4.3 – address breakdown products and allow for variations in methods' ability to detect them. This could be either in the standard or in the FoPT.
 - V1M1 §6.0 – address qualitative versus quantitative supplemental PTs.
 - V2M2 §4.1.5.g – from SIR 275, about revocation notifications – review AB notification responsibilities for revocations.
 - V2M2 – who determines what FoA corresponds to which FoPT? Is that appropriately an Accreditation Council or a PT Expert Committee role?
 - V3 §4.3 – Microbiology questions the 2016 Standard's elimination of "greater than or >" reporting and also clarify that "zero" values should never be acceptable.
 - V3 §3.0 – define PTPEC, improve PTRL definition
 - V3 §4.6 – is more detail on reference lab needed?
 - V3 §5.4.3 – supplemental PTs and qualitative/quantitative usage needs clarification
 - V3 §5.6 – improve homogeneity in standards per ISO/IEC 13528.
 - V3 §5.9 – revisit scoring with breakdown products.
 - V3 §5.9.3 – dilution schemes in micro PTs are problematic
- Address PCBs as a collective FoPT; update from Guide 34 to ISO/IEC 17034; add legionella as a new PT?

A participant asked about adding PFOAs and PTFEs as PTs, since several states are regulating them. These would need to be submitted to PTPEC as an Analyte Request Application, with at least one AB as a sponsor, rather than initiated by PTEC.

Another participant asked about distinguishing between tubes and wells for microorganism analyses in the FoPT tables, since there seems to be an apparent bias between the two, while acknowledging that fewer tubes are used and the difference could be a small data set issue. This issue was not settled during the session.

At that point, the time for the session had expired, and Nicole dismissed participants for the lunch break.

4 – Adjournment

The meeting was adjourned at 12 noon CST.

Attachment 1 – Outline of Chair’s Presentation during the Session

- Laboratory Proficiency Testing Expert Committee (PTEC)
2019 Winter Meeting
Nicole Cairns - Chair
- TOPICS
 - Committee Membership and Overview
 - 2018 Accomplishments
 - 2016 TNI Standards – Questions?
 - 2019 Goals
- Committee Membership and Overview
PTEC
- PTEC
- Membership – committee members
 - Nicole Cairns (Chair), NY-DOH (Lab)
 - Craig Huff (Vice Chair), ERA (PT Provider)
 - Rachel Bailey, Advanced Analytical Solutions (PT Provider)
 - Jim Brownfield, Pace Analytical (Lab)
 - Thekkekalathil Chandrasekhar, FL-DEP (Lab)
 - Patrick Garrity, KY-DEP (AB)
 - Susan Jackson, SC-DHEC (Lab)
 - Tim Miller, Phenova (PT Provider)
 - Reggie Morgan, HRSD (Lab)
 - Matthew Sica, ANAB (AB)
- Mission
 - Develop and maintain consensus standards for proficiency testing that support TNI programs
 - ✦ Volume 1, Module 1 – Laboratories
 - ✦ Volume 2, Module 2 – Accreditation Bodies (AB)
 - ✦ Volume 3 – Proficiency Testing Providers (PTP)
 - ✦ Volume 4 – Proficiency Testing Provider Accreditors (PTPA)
- Elements of PT program addressed
 - Program participant roles and responsibilities
 - PT sample manufacture, validation, and verification
 - PTP accreditation and oversight
 - PT sample data management and evaluation by PTPs, PTPAs, and the PT Program Executive Committee (PTPEC)
 - PT sample use by labs, ABs, and regulatory programs supported by TNI
- Objectives
 - Develop and maintain consensus standards:
 - ✦ that are practical, implementable, and meet the needs of the environmental community;
 - ✦ that ensure PT samples provide equal challenge to participants regardless of manufacturer;
 - ✦ that support PT sample design and scoring criteria appropriate to evaluate a participant’s competency.
 - Support PTPEC in implementation of standards
 - Serve as technical resource to TNI membership
- Decision-Making
 - Majority vote in presence of a quorum

- Meetings
 - Monthly conference calls – 1st Friday, 11:00AM-12:30PM EST
 - TNI Winter / Summer Conferences
 - Open to all TNI Members and public
 - ✦ contact Committee Chair or Administrator to be included on call invitations
- Contact Information
- Chair – Nicole Cairns
 - Email: nicole.cairns@health.ny.gov
- 2018 Accomplishments
 - Completed 2016 V1M1 Summary of Changes Document
 - Reviewed 2009 vs 2016 Comparison Table
 - Completed PTRL Guidance Document (in final stages)
 - Hosted a training webinar on 2016 V1M1
 - Re-visited PT Frequency; concluded no change needed
 - Completed SIR Applicability Review
- 2016 TNI Standard Questions?
- 2019 Goals
- Possible Options Open for Discussion
 - Additional Training on 2016 PT Standards
 - Checklist for PTPAs for Volume 3 Requirements
 - Opening of 2016 Standards for revisions
 - ✦ Updates for ISO/IEC 17011:2017, ISO/IEC 17025:2017, and ISO 17034:2016
 - ✦ Additional/alternate Radiochem/WET requirements
 - ✦ SIRs not addressed
 - ✦ Prep methods
 - ✦ Updates based on stakeholder feedback (see compiled comments)
 - DOD vs TNI PT Requirements