

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

August 8, 2017

The Committee met face-to-face in Washington, DC on Monday, August 8, 2017, at 1:00 pm EST. Chair Nicole Cairns led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (PT Provider)	Present
Nicole Cairns, NYSDOH (Chair; Laboratory)	Present
Rachel Ellis, NJ DEP (AB)	Absent
Patrick Garrity, KYDOW (AB)	Present
Craig Huff, ERA (PT Provider)	Present
Susan Jackson, SC DHEC (AB)	Present
Stacie Crandall, Hampton Roads San. Distr. (Lab)	Present
Tim Miller, Phenova (PT Provider)	Present
Donna Ruokenen, Microbac (Lab)	Present
Ken Jackson, Program Administrator (Ilona Taunton, Program Administrator stepped in to help with meeting.)	Absent

2 – Previous Minutes

Minutes were not reviewed or approved.

3 – Presentation

Nicole had committee members introduce themselves. She reviewed the 2017 Accomplishments and 2017/2018 Goals – see Attachment A.

Nicole emphasized that it is assumed that the PT Providers are accredited to ISO 17043. The Standard only includes items in addition to the ISO requirements.

The committee would like to see PT Providers start collecting prep method information.

The committee would like to update requirements to accommodate the reporting needs of radiochemistry, microbiology and WET.

Nicole proceeded to review the 2016 Standard and highlighted changes made to the PT Volumes and Modules of the TNI Standard.

Volume 2 Module 2

The PTRL requirement was put back into the Standard. This was one issue the NELAP AC had it is why some ABs are still using the 2003 Standard instead of the 2009.

Volume 3

PT Providers must be accredited to ISO 17043.

PT data is provided to TNI by PT Providers for FoPT table updates using a database where they upload information.

Nicole noted that PT Providers don't necessarily perform the prep. In many cases the PT is just injected. The testing done in the laboratory is different than what the PT Providers do.

A lab would never get the same PT twice. This is relevant to quick response PTs. The PT Providers do ongoing stability testing. This is an ISO requirement.

Volume 4

The requirements for the PTPEC were removed. The PTPEC will develop SOPs.

4 – Standard Implementation

Nicole asked that people give feedback as the new modules begin being used.

Nilda commented that DW is method driven and the TNI Standard is technology driven. This creates issues for labs.

5 – Adjournment


The meeting was adjourned at 1:30 pm EDT.




Laboratory Proficiency Testing Expert Committee (PTEC)

2017 Summer Meeting

Nicole Cairns - Chair




August 8, 2017




TOPICS

- Committee Overview and Membership
- 2017 Accomplishments and Goals
- Status of Proficiency Testing Volumes/
Modules of 2016 TNI Standard
- Highlight of Major Changes in 2016
Standard




August 8, 2017




Committee Overview and Membership

PTEC




August 8, 2017




PTEC

- Charter
 - Revised charter approved in 2017
- Mission
 - Develop and maintain consensus standards for
proficiency testing that support TNI programs

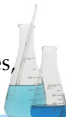


August 8, 2017




PTEC

- Elements of PT program addressed:
 - Program participant roles and responsibilities
 - PT sample manufacture, validation, and
verification
 - PT Provider accreditation and oversight
 - PT sample data management and evaluation
by PT Providers (PTP), PT Provider
Accreditors (PTPA), and the PT Program
Executive Committee (PTPEC)
 - PT sample use by labs, accreditation bodies
and regulatory programs supported by TNI




August 8, 2017




PTEC

- Membership – 9 committee members
 - Nicole Cairns (Chair), NY-DOH (Lab)
 - Donna Ruokonen (Vice Chair), Microbac Laboratories (Lab)
 - Fred Anderson, Advanced Analytical Solutions (PT Provider)
 - Rachel Ellis, NJ-DEP OQA (AB)
 - Patrick Garrity, State of Kentucky (AB)
 - Craig Huff, ERA (PT Provider)
 - Susan Jackson, SC-DHEC (AB)
 - Stacie Metzler, HRSD (Lab)
 - Tim Miller, Phenova (PT Provider)
 - Ken Jackson (Administrator), TNI

Stakeholders
3 - Labs
3 - ABs
3 - PTPs





August 8, 2017



PTEC

- 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



August 8, 2017



PTEC

- Decision-Making
 - Majority vote in presence of a quorum
- Meetings
 - Monthly conference calls– 1st Friday, 11:00AM-12:30PM EST
 - TNI Winter / Summer Conferences



August 8, 2017



2017 Accomplishments and Goals

PTEC



August 8, 2017



2017 Accomplishments

- Updated Charter using newly revised format
- 2016 Standards for all PT Volumes/Modules Final
 - + Volume 1, Module 1 – PT for Labs
 - + Volume 2, Module 2 – PT for ABs
 - + Volume 3 – PT Providers
 - + Volume 4 – PT Provider Accreditors
- Completed updates to the PT Section of the Small Lab Handbook (V1M1)
- Updated Laboratory Checklist for PT (V1M1)



August 8, 2017



2017/2018 Goals

- Gather feedback on 2016 Standards once implemented
- Look towards the next round of Standard updates
 - + Incorporate new/revised ISO standards – 17011, 17025, 17034, and 17043
 - + Continue to gather new topics for discussion
 - Prep methods
 - Additional radiochemistry requirements
 - Standardization of WETT PTs
 - Standardization of criteria and calculations used by PTPs for verification, homogeneity and stability testing


August 8, 2017




Status of 2016 TNI Standard

PT Volumes, Modules

August 8, 2017

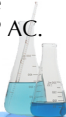





Volume 1, Module 1 PT for Labs

- Final Standard approved by TNI membership.
- Additional editorial changes made/approved by PTEC based on feedback from Laboratory Accreditation Standard Executive Committee (LASEC) and NELAP Accreditation Council (AC).
- Revised Final Standard reviewed by LASEC and Consensus Standards Development Executive Committee (CSDEC) and approved by NELAP AC.



August 8, 2017

Volume 2, Module 2 PT for ABs

- Final Standard approved by TNI membership.
- Additional editorial changes made/approved by PTEC similar to those made in V1M1.
- Revised Final Standard reviewed by LASEC and CSDEC and approved by NELAP AC.



August 8, 2017

Volume 3 - PTPs

- Final Standard approved by TNI membership.
- Editorial changes made/approved by PTEC based on feedback from PTPEC.
- Revised Final Standard reviewed by CSDEC and approved by PTPEC.



August 8, 2017

Volume 4 - PTPAs

- Final Standard approved by TNI membership.
- Editorial changes made/approved by PTEC based on feedback from PTPEC.
- Revised Final Standard reviewed by CSDEC and approved by PTPEC.



August 8, 2017

Standard Implementation

- Stalled due to Volume 1, Module 4 (Chemistry)
 - NELAP AC requested changes that could not be made editorially; a new revision required.
 - Volume 1 in its entirety was not approved by NELAP AC.
- All PT Modules must be implemented together.
 - V1M1 lab reporting requirements interconnected with V3 PT scoring requirements; one cannot be implemented without the other.
- Once 2017 Module 4 finalized it will be substituted into a Revised 2016 TNI Standard
 - All Volumes implemented together.


August 8, 2017





Highlights of Changes

PT Volumes, Modules

August 8, 2017







Volume 1, Module 1 PT for Labs

- General
 - Reorganized Sections 4 and 5
 - + Requirements for Accreditation
 - + PT Study Frequency Requirements for Accreditation
 - Added Whole Effluent Toxicity Testing (WETT) PT requirements
 - Added Note to clarify “acceptable” PT study score from PTP vs. “successful” PT evaluation by AB



August 8, 2017



Volume 1, Module 1 PT for Labs

- PT Reporting
 - Proficiency Testing Reporting Limit (PTRL)
 - Radiochemistry requirements
- PT Analysis
 - If PT result is below calibration curve, the lab may:
 - + rescale calibration curve to bracket result, or
 - + report the result without qualification



August 8, 2017



Volume 1, Module 1 PT for Labs

- PT Frequency
 - Tracking by closing date of study
 - Maximum of 7 months between PTs – twice/year
 - + Exception: WETT – maximum of 14 months between PTs – once/year.
 - Minimum of 7 calendar days between closing and opening dates of consecutive studies



August 8, 2017



Volume 1, Module 1 PT for Labs

- Corrective Action
 - Removed supplemental PT language; not required.
 - Added requirements for root case investigation and corrective action documentation for PT failures.



August 8, 2017



Volume 2, Module 2 PT for ABs

- General
 - Removed laboratory requirements
 - ABs assess to V1M1
- Roles of ABs
 - Primary vs secondary AB roles clarified
 - + Secondary ABs may make own PT evaluations
 - Revocation and suspension via AB processes


August 8, 2017




Volume 2, Module 2 PT for ABs

- PT Evaluations by AB
 - Added Note to clarify “acceptable” PT study score from PTP vs. “successful” PT evaluation by AB
 - + AB evaluations may also include proper method reporting, treatment of PTs as routine samples, data reported by closing date, authorization of data submittal to AB by closing date.
 - Removed “corrective action” PT language
 - + PTs are not required for corrective action.

August 8, 2017







Volume 3 - PTPs

- General
 - Formatted to match ISO/IEC 17043:2010
 - PTPs accredited to ISO/IEC 17043:2010
 - Clauses redundant with 17043 removed
 - ✦ Now only TNI specific requirements in Volume 3
 - Appendix A guidance document removed
 - ✦ Relevant requirements incorporated into Volume 3
 - Protozoan and Whole Effluent Toxicity Testing (WETT) requirements added



August 8, 2017

Volume 3 - PTPs

- Assigned Value (AV)
 - Quantitative Microbiology & Protozoan
 - ✦ set to calculated study mean
- Verification of Assigned Value
 - Removed requirement that analytical method have repeatability relative standard deviation $\leq 1/6$ acceptance limits
 - Aqueous chemistry analytes:
 - ✦ Removed arbitrary 10% maximum acceptance limit around verification mean



August 8, 2017

Volume 3 - PTPs

- Homogeneity
 - Testing compliant with ISO/IEC 13528:2015, Annex B, Sections B1 through B3.
- Stability
 - Added second option
 - ✦ difference between verification and stability means does not affect laboratory evaluations



August 8, 2017

Volume 3 - PTPs

- Acceptance Limit Determinations
 - Added Protozoan and WETT requirements
 - Results associated with greater than (>), less than (<) and alpha characters shall not be used in statistical calculations.



August 8, 2017

Volume 3 - PTPs

- PT Evaluations
 - All results reported with greater than (>) are "not acceptable"
 - AV greater than PTRL
 - ✦ ALL results reported with less than (<) are "not acceptable" – LOQ → PTRL reporting in V1M1
- PT Study Summary Report
 - Added requirement for PTPs to provide specific information to PTPEC via TNI for FoPT table maintenance


August 8, 2017





Volume 4 - PTPAs

- General
 - Removed PTPEC requirements/activities except where provided for clarity to PTPAs
 - Removed clauses redundant with ISO/IEC 17011:2004 removed
 - ✦ Now only TNI specific requirements in Volume 4
 - Extended recognition cycle to a minimum of every four (4) years to be more consistent with international standards.

August 8, 2017







Volume 4 - PTPAs

- PTPA Presentations at TNI Forums
 - Added requirement to conduct presentations at TNI forums at request of PTPEC
 - Defined minimum information to be included in presentations
 - Added requirement that presentations be submitted to PTPEC at their request.



August 8, 2017



Volume 4 - PTPAs

- Ongoing Monitoring of PT Provider Data
 - Added requirement to monitor pass/fail rates
 - ✦ Pass/fail rates that deviate from PTPEC defined criteria shall be investigated.
 - ✦ PTPA must notify PT Provider of deviation and monitor associated corrective action taken by the PT provider.
- Removed reference to a national historical failure rate.


August 8, 2017



Feedback

How can you help?

August 8, 2017



Feedback

- Feedback from stakeholders is imperative!
- Tell us what you think – the good, the bad, and the ugly
- Join us for a call – we're always looking for new associate members!

August 8, 2017



Contact Information

- Chair – Nicole Cairns
 - Email: nicole.cairns@health.ny.us
 - Phone: 518-473-0323
- Administrator – Ken Jackson
 - Email: ken.jackson@nelac-institute.org

August 8, 2017



Thank you!

Questions/Comments

August 8, 2017

