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

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

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.
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

Committee Overview and Membership

PTEC

- Charter
  - Revised charter approved in 2017

- Mission
  - Develop and maintain consensus standards for proficiency testing that support TNI programs

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

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

- Labs
- ABs

August 8, 2017
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

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)

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

Status of 2016 TNI Standard
PT Volumes, Modules
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.

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.

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.

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.

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.

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 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

- **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 ≤ 1/6 acceptance limits
    - Aqueous chemistry analytes:
      - Removed arbitrary 10% maximum acceptance limit around verification mean
  - August 8, 2017

- **Homogeneity**
  - August 8, 2017

- **Stability**
  - Added second option
    - Difference between verification and stability means does not affect laboratory evaluations
  - August 8, 2017

- **Acceptance Limit Determinations**
  - Added Protozoan and WETT requirements
  - Results associated with greater than (>) are “not acceptable” – AV greater than PTRL
  - ALL results reported with less than (<) are “not acceptable” – LOQ → PTRL reporting in V1M1
  - 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.

- 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.

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!

Contact Information

- Chair – Nicole Cairns
  - Email: nicole.cairns@health.ny.us
  - Phone: 518-473-0323

- Administrator – Ken Jackson
  - Email: ken.jackson@nelac-institute.org

Thank you!

Questions/Comments