



Review of the New TNI PT Standard

The Forum on Laboratory Accreditation
Miami Interim Meeting
January 13, 2009





Agenda

- Update on status of the TNI standards
- Review the general changes between the NELAC 2003 Standards and the TNI Standards
- Question and answer period





STATUS OF TNI STANDARDS

- All TNI standards have been approved and are being considered for adoption into the NELAP.
- TNI Standards will replace, if adopted, the 2003 NELAC standard in ~2010ish.
- TNI Standards are available on the TNI website.





Overview of Changes





Goals of TNI PT Program

- Provide equal challenge to participating laboratories
- Ensure consistent evaluation of PT sample results
- Reduce complexity and cost from different regulatory programs
- Ensure PT samples are prepared correctly with the right composition and concentrations appropriate for environmental testing
- Accepted nationally





THE NEW TNI PT STANDARD

- Everything in one place with organization specific modules.
 - Volume 1, Module 1 – Laboratory Requirements
 - Volume 2, Module 2 – AB Requirements
 - Volume 3 – PT Provider Requirements
 - Volume 4 – PT Provider Accreditation Requirements
- Increased clarity.
- Few, if any, new requirements.
- Improved technical requirements.
- Follows current ISO guidelines.





COMPARISON TO NELAC

NELAC 2003

- Chapter 2: General Requirements
- Appendix A: PTP Approval
- Appendix B: PT Sample Design
- Appendix C: Acceptance Criteria
- Appendix D: PT Oversight
- Appendix E-H: Technology

TNI Standard

Volumes 1 & 2
Volume 3
Volume 3
Volume 3
Volume 4
Volumes 1 & 3

Not all of the requirements in Appendix E-H were incorporated into the TNI standard.





COMPARISON TO NELAC

NELAC 2003

- Definitions of terms and acronyms not included in Chapter 2.
- Lacked process flow
- Sometimes confusing or unclear language

TNI STANDARD

- Each volume and each module includes terms and definitions.
- Maps process flow
- Concise language & auditable requirements





Example: Specific to General

NELAC STANDARD

- Laboratory may withdraw from a PT Study if it notifies the AB and PTP before the close date of the study.

TNI STANDARD

- Withdrawal notification requirement removed.





COMPARISON TO NELAC

NELAC 2003

- PTRL Reporting
- PT Scheduling calculated from study open/close dates
- Some program requirements not in standard-(Experimental PT)

TNI STANDARD

- LOQ Reporting
- PT Scheduling calculated from analysis date
- All program requirements included





CONSISTENT REQUIREMENTS

For every requirement for which an accredited organization (lab, PTP) must comply, there is a matching requirement for the AB or PTPA.

- *Ensures equitable evaluation and consistent interpretation of standard requirements.*





INTERNATIONAL BASIS

The TNI PT program follows international guidelines for proficiency testing schemes including: ISO17025, ISO17011, ISO43

- *Promotes national & international recognition of TNI PT program*





Implementation Guidance Document

- PT Expert Committee is developing a Implementation Guidance Document.
- This document will go into specifics for the implementation of the standard for each category of stakeholder.
 - Accrediting Bodies
 - Laboratories
 - PT Providers





Laboratory Reporting Changes





Current PTRL Analysis and Reporting Problems

- Laboratories are required to analyze PT samples as they would normal production samples.
- However the lower concentration ranges for some analytes in the FOPT's are below the working calibration ranges for some laboratories.
- This causes some laboratories to have separate SOPs, calibrations, and procedures for PT samples as well as PT data reporting issues.





TNI Solution: LOQ Reporting for Laboratories

- Under the TNI Standard (if adopted) laboratories will be reporting PT data based on their documented Limit of Quantitation (LOQ).
- This allows the laboratories to analyze the PT samples in the same manner as their normal samples.
 - Same SOP, calibration, quality control, and reporting requirements.





Changes for PT Providers

- Under the TNI standard (if adopted), PT Providers will have to alter their scoring criteria based on the laboratories' LOQ reporting.





Changes for Accrediting Bodies

- Accrediting Bodies (AB's) using the new TNI standard (if adopted) will need to review the reported PT data as part of the on-site assessment to ensure the laboratory has analyzed the PT sample according to their normal procedures.
- The PT Committee will be providing guidance as to what documentation laboratories will need to provide to AB's to ensure compliance to their SOPs.





Please remember.....





Implementation Guidance Document

- PT Expert Committee is developing a Implementation Guidance Document for the TNI PT standards.
- This document will go into specifics for the implementation of the standard for each category of stakeholder.
 - Accrediting Bodies
 - Laboratories
 - PT Providers





No program changes will occur until the standard has been formally adopted.





Questions??

