

# 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**

#### **TNI Standard**

Chapter 2: General Requirements
 Volumes 1 & 2

Appendix A: PTP ApprovalVolume 3

Appendix B: PT Sample Design Volume 3

Appendix C: Acceptance Criteria Volume 3

Appendix D: PT Oversight Volume 4

Appendix E-H: Technology
 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



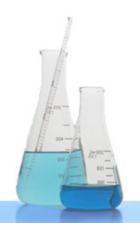
### **Example: Specific to General**

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



# Questions??

