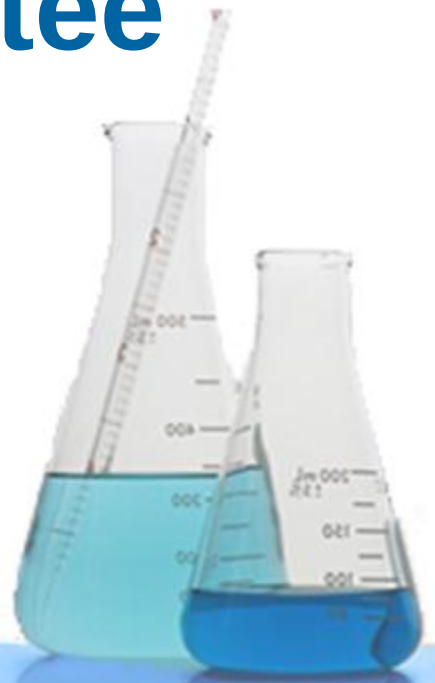
THE NELAC INSTITUTE

Welcome
PT Expert Committee

August 12, 2010
9:00-12:00 PM



Agenda

- Meet the Committee
- Tentative Interim Amendment Review
  - Microbiology
  - Radiochemistry
  - Whole Effluent Toxicity
  - Working Draft Standard
- Partnership with the PT Executive Committee
- Coffee Break 10:00 – 10:30 AM
- Accreditation Body Survey Results
- Open Forum

Who are We?

- Kirstin McCracken, Chair – TestAmerica
- Amy Doupe – Lancaster Laboratories, Inc.
- Roger Kenton – Eastman Chemical Company
- Stacie Metzler – Hampton Roads Sanitation District
- Judy Morgan – Environmental Science Corporation
- Scott Hoatson – Oregon DEQ
- Lisa Touet – Massachusetts DEP
- Matt Sica – Maine Center for Disease Control & Prevention
- James Webber, Ph.D. – New York DOH
- Stephen Arpie – Absolute Standards, Inc.
- Shawn Kassner – Environmental Resource Associates
- Mitzi Miller – Moeller
- Dan Tholen – A2LA

Associate Members

- Rachel Ellis – NJDEP OQA
- Chuck Wibby – Wibby Environmental
- Mike Miller – Member-at-Large

Interest Category Breakdown

- 5 Laboratories
- 4 Accreditation Bodies
- 4 Other
  - 2 Proficiency Test Providers
  - 1 Consultant
  - 1 PTPA / PTOB

What do we do?

Mission Statement:

Develop and maintain consensus standards for proficiency testing to support TNI programs including but not limited to:

- Roles and Responsibilities of Participants
- Production Validation and Verification of PT Samples
- Accreditation and Oversight of PT Providers
- Management & Evaluation of PT Data by PTOB/PTPA
- How PT Samples are used within the context of the program

We also….

- Review and respond to requests for standards interpretation requests (SIR)
- Monitor the TNI Discussion Board
- Whatever may be asked of us….

What do we not do?

The PT Expert Committee Does Not:

- Develop and Approve FoPT
- Evaluate and Approve PTOB/PTPA

Primary Objectives

- **Flexible**: Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel approaches. The standards specify the *What* and avoid where possible the *How To*.
- **Auditable:** Sufficient detail is included so that the assessors can evaluate laboratories consistently.
- **Practical and Essential:** The standards are necessary policies and procedures that should not place an unreasonable burden upon laboratories.
- **Widely Applicable:** Represent policies that are applicable to laboratories regardless of size and complexity.
- **Appropriate for the Use of the Data:** Ensure that associated data is of known quality and that the quality is adequate for the intended use of the data.

What is a TIA?

Tentative Interim Amendment:

An amendment to the standard resulting in an emergency need and remaining in effect for 2 years from its date of adoption

Why are TIA needed?

To account for:

- Errors or omissions in the standard that were overlooked during standards development
- Conflicts with other standard language
- Response to New Federal Regulation or Development
- Correct in a circumstance that has resulted in an adverse negative impact (unintended)

PT Module TIA Status

2009: 5 TIA issued by PT Expert Committee

Released for public comment, reviewed, approved and are included in currently included in TNI Standards as TIA

- ***TIA need to be incorporated into standard through consensus process***

2010: 5 TIA are under development by committee

Microbiology

1 TIA Proposed to PTP Volume (V3 8.2)

Problem: Standard does not include specifications for reporting of PT results for microbiology. The absence of reporting requirements has an adverse negative impact for laboratories that report PT results for the 10 sample WS FoPT set for presence / absence.

TIA: Adds a requirement to the standard for PTP to include specific reporting instructions for this FoPT.

Result: Each TNI PTP will provide the same set of reporting instructions to laboratories, since laboratories are required to report PT results per instructions, each laboratory will follow the same set of reporting instructions.

Why add language to the PTP volume instead of the laboratory module?

Radiochemistry

2 TIA Proposed to PTP Volume (V3 8.0 & V3 10.3.6)

Problem: Standard does not include requirements for radiochemistry

TIA: Adds a requirement to ensure PTP are licensed to posess, transfer and use radioactive materials & provides instructions for how to review and evaluate uncertainties.

Result: Ensures PTP comply with federal regulation for possession and handling of radioactive materials and ensures uncertainties will not affect the scoring of the PT result reported by the laboratory.

Whole Effluent Toxicity (WET)

2 TIA Proposed (V2, 5.2.1 & V3 8.1)

Problem: PTEC has approved FoPT for WET but the TNI standard does not include any requirements for WET for laboratories, ABs or PTP.

TIA: Adds requirements for required participation, open/close dates of WET PT studies and requirements for corrective action.

Result: Immediately responds to a new development (new FoPT) in the PT program.

TIA Next Steps

- Submit 2010 TIA to CSDEC (August)
- Release 2010 TIA for Comment (September)
- Review Public Comment
- Revise TIA based on Comment as Needed
- Approve TIA or Start Over
- Add TIA to Working Draft Standard (WDS)
- Initiate consensus WDS review process

PTEC and PTEC

PTEC = PT Executive Committee

PTEC = PT Expert Committee

PT Executive Committee can act quickly to respond to immediate needs or to expand the program.

PT Expert Committee is bound to consensus standards development and adoption of standard by NELAP Board and maybe even state rule change. This takes time….

As TNI PT programs evolve it will be imperative for the activities of the 2 committees to be in sync, especially when FoPT are developed for the purpose of laboratory accreditation of scientific disciplines not included in TNI Standard.