



Proficiency Testing Expert Committee

- Expert committees develop standards consistent with TNI's mission, using a consensus process
 - Working Draft Standard (WDS) under development.
 - Tentative Interim Amendments (TIAs) SOP2-100 section 5.5
 - Standards Interpretations





AGENDA & TASKS SINCE JANUARY

- WDS Development
 - Volume 1 – Out for comment --Mitzi Miller
 - Volume 2 – Out for comment --Scott Hoatson
 - Volume 3- Expect to be out of committee by Sept 2012,-- Mitzi Miller & Kelly Black
 - Volume 4 – Under development- Expect to be out of committee by Oct 2012
- SIR completed - 2
- Whole Effluent Toxicity (WET) TIA – Mitzi Miller





TIA SOP 2-100

- Tentative Interim Amendment — an amendment to a standard resulting from an emergency need, and remaining in effect for a maximum of two (2) years from the date of its adoption.





General Comments V1M1 & V2M2

- Inconsistencies—suggested placing all lab requirements in V1M1 and in V2M2 reference back to the V1M1 in V2 add — suggested statement---”The primary AB shall require applicant laboratories to meet the PT requirement as specified in V1M1”





General Comments V1M1 & V2M2

- Within a volume, state all the common requirements first, followed by analysis /technology requirements next.
- Currently statements say what not to do; suggestion state what is required





Volume 1 Module 1

Management and Technical Requirements for Laboratories Performing Environmental Analysis

□ Definitions

- Removed Analysis Date
- Field of Proficiency Testing (FoPT): Matrix, technology/method, analyte /analyte group combinations for which the composition, spike concentration ranges and acceptance criteria have been established by the Proficiency Testing Executive Committee.
- Add TNI PT Expert and Executive Committees





Comments- Definitions

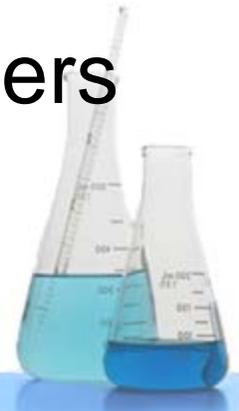
- 3.2—Accreditation **How differentiate** FoPT, why include the term “accreditation” when experimental FoPTs do not exist anymore?
- 3.3—Field of Accreditation, why define the term based on the accreditation offerings of an AB?
- 3.4—Field of Proficiency Testing, what is the rationale for changing the definition of FoPT?
- 3.7—PT Program, this term is not used in the standard.
- 3.16—Study, it probably isn’t necessary to define this term, it’s obvious and not used without “PT” before it anyway.
- 3.17—Supplemental PT Study, if you change the timeframes for acceptable study windows from “five to seven months” to “no more than 7 months” you don’t need to define supplemental PT.





Comments Definitions

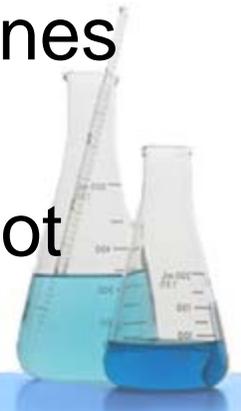
- ❑ Must use same definitions in all Volumes as related to PTs.
- ❑ Refer back in V2 to V1.
- ❑ ABs and PT Providers-what do you think?
- ❑ Advantage—much easier to maintain consistency
- ❑ So far feedback from ABs & PT Providers is they have all volumes so no added problem





Comments- Definitions

- V2M2: 3.18—Supplemental PT study closing date, not used in the standard.
- V2M2: 3.19—Supplemental PT Study Opening Date, again, not used in the standard.
- V1M1:3.19, V2M2: 3.20—TNI PT Program Executive Committee is only used in section V2M2: 1.3.2 and really doesn't need to be here anyway because the required PTs are the ones posted to the TNI website
- V1M1: 3.20—TNI PT Expert Committee is not used in the standard.



V1M1

- Initial Accreditation:
 - 4.1.1 Chemical Testing, Radiochemical Testing, Asbestos and Microbiology
 - Separate sub-section for WET
 - Kept same performance history
 - Altered the note on drinking water
 - ✦ “PT results are required by federal drinking water regulation, per test method rather than technology for potable water PTs”
 - ✦ Removed example of technology





V1M1 Comment

- If accreditation is by technology, and lab runs two or more methods with the same technology and the lab runs one PT, then if the PT fails all methods using that technology fail.
- If accreditation is by method (determinative vs preparation vs both), and fails then only that method fails.





V1M1 - Initial Accreditation – WET

- a) To attain initial accreditation the laboratory shall demonstrate to the primary accreditation body (Primary AB) that the laboratory has participated and received an “Acceptable” evaluation of one PT study for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory has applied.





V1M1 - Initial Accreditation – WET

- b) The PT samples used to fulfill the participation requirement must be obtained from a PTPA-accredited proficiency test provider (PTP) approved to provide PT samples for the FoPT.





V1M1 - Initial Accreditation – WET

- c) The closing date of the PT study used to establish participation shall be no more than eighteen (18) months prior to the date of application.





V1M1

- Continued Accreditation
 - Same requirements as in 2009 TNI
 - Updated same note on Drinking Water as in Initial Accreditation





V1M1- WET

- Continued Accreditation
 - To maintain accreditation the laboratory shall participate in one WET PT study per calendar year for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory is accredited. If results are scored 'Not Acceptable', see V1M1 Section 6.





V1M1 –PT Analysis

- The following exception applies to Chemistry Testing:
- 5.1.1.a The laboratory may, but shall not be required to, rescale the calibration used to analyze the PT sample so that the concentration of the lowest standard in the calibration correlates with the lowest spike concentration of the PT sample or to a value near the FoPT's PTRL.





V1M1 –PT Reporting

- Returned to PTRL—5.1.2
- a) If the value found is equal to or above the PTRL for the FoPT, the laboratory shall report the value found as the analytical result for the FoPT.
- If the PTRL is less than the laboratory's LOQ for the FoPT the laboratory shall report the analytical result without the qualification of result required in V1, M4 of this Standard.





V1M1 –PT Reporting

- b) If the value found is less than the PTRL for the FoPT, the laboratory shall report a result of “<” the FoPT PTRL value, a result between the LOQ (if below PTRL) and PTRL, or a result less than (<) laboratory’s LOQ (if below PTRL). The PTRL value shall not be adjusted for sample amount used, percent moisture or dilution factors.





V1M1-PT Reporting – WET-5.2

- a) The laboratory shall analyze PT samples in the same manner as used for routine environmental samples using the same staff, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures and acceptance criteria.
- b) The requirements from V1M1 5.1.1.b and c apply to WET PTs.





V1M1 Corrective Action

- 6.1 Chemistry, Radiochemical Testing, Asbestos, and Microbiology
- If the laboratory receives a “Not Acceptable” performance score for any accreditation FoPT per the scoring criteria specified in V3 of this Standard, the laboratory shall perform corrective action. The requirements for corrective action are described in Volume 1, Module 2 of this Standard.





V1M1 Corrective Action

- WET
- Perform corrective action for “Not Acceptable” per V1M2





V1M1 Corrective Action

- WET -- Corrective action documentation shall include:
 - a) A copy of the raw data used for the study
 - b) A copy of the current Standard Reference Toxicant (SRT) control chart relevant to the PT study
 - c) The corrective action report shall be available upon request.





V1M1-REQUIREMENTS TO RE-ESTABLISH PERFORMANCE HISTORY

- This is ***NOT*** normal corrective action
- This is when failed >2 of 3 PTs
- Must meet 2 of 3
- Use PTPA-accredited provider
- May analyze outside timeframes
- Allowed to use PT Study or Supplemental PT provided notify PT Provider





V1M1-REQUIREMENTS TO RE-ESTABLISH PERFORMANCE HISTORY

- This section confused the readers and needs work or removal





V1M1-REQUIREMENTS TO RE-ESTABLISH PERFORMANCE HISTORY

- **NEW:** The laboratory shall obtain successive PT samples for the same accreditation FoPT and report the results at least seven (7) calendar days apart. The laboratory shall analyze the two PTs in separate preparation and analytical batches.
- Other analysis & reporting requirements apply





V1M1-REQUIREMENTS TO RE-ESTABLISH PERFORMANCE HISTORY

- **WET**
- either analysis of a PT sample from any study or supplemental study or
- by successful analysis of a standard reference toxicant analyzed after the “Not Acceptable” PT evaluation



V1M1

- No changes were proposed to:
- Complaint resolution
- Reinstatement after revocation
- Comment that several items mentioned in V2M2 for suspension and revocation need to be both in the lab and AB volumes





Summary

- Next Steps
- Final Committee vote after your feedback
- Finish Volume 3
- TNI Vote

- NEXT—Volume 2





V2M2

- Changes made to correlate to changes in V1M1.
- Where possible, used the same verbiage as V1M1



V2M2

- Added 1.3.2 (Applicability) already in V1M1
- This Standard does not apply to fields of accreditation that are not designated as fields of proficiency testing (FoPT) by the TNI Proficiency Testing (PT) Executive Committee.





V2M2 3.0 Definitions

- Made them the same as V1M1
 - Accreditation Body
 - Accreditation Field of Proficiency Testing
 - Field of Proficiency Testing (FoPT)
 - TNI PT Executive Committee
 - TNI PT Expert Committee





V2M2 4.0 AB Requirements

- Added
- 4.1.2 The Primary AB shall not require calibration ranges that are not typically employed by the laboratory for the sole purpose of analyzing PTs.





V2M2 4.0 AB Requirements

- ❑ Removed:
- ❑ 4.1.2 The Primary AB shall allow a laboratory to withdraw from a study for any FoPT on or before the close date of the study. Withdrawing from a study shall not exempt the laboratory from meeting the semi-annual analysis requirement necessary for continued accreditation.
- ❑ 4.1.3 The Primary AB shall accept evaluation reports from any PTPA-accredited PT Provider.
- ❑ 4.1.4 The Primary AB shall accept results from non-PTPA-accredited PTPs when the FoPT is not available from any accredited PTP.





V2M2 5.0 Requirements for Accreditation

- 5.1 Requirements for Initial Accreditation
 - 5.1.1 Added Note : Accreditation FoPT are established by the TNI PT Executive Committee.
 - Made consistent to V1M1
- 5.2 Separated WET from other requirements as in V1M1
 - Made requirements the same as V1M1





V2M2 5.0 Requirements for Accreditation

- 5.3 Continuing Accreditation – Chem, Rad, micro, etc.
 - Updated to reflect V1M1 changes

- 5.4 Continuing Accreditation – WET
 - Updated to reflect V1M1 changes **There is an error in the WDS. It states that the lab has to have one “acceptable” PE score each year. This was not the intent.**





V2M2 6.0 Onsite Review

- Consolidated to remove redundancy
- During the on-site assessment the Primary AB shall review laboratory records to verify the following:





V2M2 6.0 Onsite Review

- PT samples for accreditation FoPT were prepared in accordance with the instructions provided by the PTP and subsequently prepared and analyzed by the laboratory **in accordance with the laboratory's standard operating procedures.**





V2M2 6.0 Onsite Review

- The laboratory performed root cause analysis for accreditation FoPT results that were scored “Not Acceptable”.
- Note:
 - Note: If during record review a Primary AB discovers that the laboratory analyzed QC standards that a PTP has suggested or directed a laboratory to purchase QC standards with the PT samples that are specifically designed for **the sole purpose** of improving the laboratory’s performance for a given PT sample or that the PT provider has given the laboratory analysis instructions beyond those specified in this Standard, the Primary AB **shall** report the results of their findings to the PTP’s PTPA.





V2M2 7.0 Review of PT Reports

- Important changes are the added notes:
 - Cut to WDS





V2M2 8.0 Re-establish Performance History

- Consistent with language in V1M1
- Note: This is not referring to corrective action for a single failed study.
- Rolled in old Section 8 on Requirements for Assessment of Corrective Action





V2M2 8.0 Re-establish Performance History

- Added 8.2 for WET
 - Cut to WDS





V2M2 9.0 and 10.0

- 9.0 Requirements for Complaint Resolution
- 10.0 Suspension of Revocation of Laboratory Accreditation
 - **No Substantiative Changes**





V2M2 Summary

- Changes to reflect Changes in V1M1
- Separation of WET (also in V1M1)

