

TNI PT Expert Committee Meeting Summary

January 31, 2012

1) Roll call and approval of minutes:

Chair Mitzi Miller called the TNI PT Expert Committee meeting to order on January 31, 2012 in Sarasota, FL at 8:30 AM EST. Attendance: Mitzi Miller, Stacie Metzler, Shawn Kassner, Joe Purdue, Jim Webber, Rachel Ellis, Steve Arpie, and Scott Hoatson.

Mitzi also asked Mike Miller, Nicole Cairns, Susan Butts and Keith Ward to stand to thank them for all their help on the standard.

2) Tentative Interim Amendments (TIAs)

Mitzi described the process of using TIAs. (See slides in Attachment A.)

3) Working Draft Standard – Volume 1

See Attachment A for presentation slides.

Definitions need to be consistent in all the standards.

Section 3: Definitions:

- Field of Proficiency Testing – eliminate term “analyte group”.
- The definitions for TNI PT Expert Committee and TNI PT Executive Committee have been added to the standard. (Need to confirm they are consistent with other TNI documents.)

Section 4.1: Initial Accreditation:

4.1.1

- Separate sub-section for WET (4.1.2)
- 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”. Also removed example of technology.

4.1.2

- The slides (Attachment A) include the text for WET. A major change from the current standard is that there is only 1 PT study for each initial accreditation.

Section 4.2: Continued Accreditation

- Same requirements as in 2009 TNI Standard.
- Updated note on Drinking Water as in Initial Accreditation
- There has been a change in 4.2.1 (c): The opening dates of successive PT samples used for continued accreditation for the same accreditation FoPT shall be at least five (5) months apart and no longer than seven (7) months apart unless PT samples are not available from any PTPA approved PTP within this time frame, in which case the laboratory shall analyze the PT samples in the minimum time-frame in which the PT samples are available.
- There is again a separate section for WET and only one PT is required.

Section 5.1.1: Analysis Requirements

- An exception was added to 5.1.1 (a). This is a result of the issue of PTRL and LOQs. Addition: 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.
- 5.1.2 (Reporting Requirements) had one of the most controversial issues. The committee is returning to PTRL reporting. It passed by one vote of the committee. If this is passed by the membership, this will affect labs that have already moved away from this. Some labs are working with states that have not required this yet. If the lab's LOQs are below the PTRL, there shouldn't be any problem making the switch.
- Comments –
 - o Dale P. – Asked if the PT providers will include reporting instructions with the PTs. The response is that they will. It will be clear how to report using the 2009 standard, new standard update being worked on here or 2003 standard. The update will not be effective until the states adopt it.
 - o Tom M. – If my LOQ for chloroform is 50 ppb and the PT sample is spiked at 5-10 ppb, do I have to report the estimated value I measure, and be scored on it ... even though it is well below my LOQ? The response was yes. Mitzi reminded people that they are encouraging low level and higher level PTs.
 - o Jim – How long will it take for the standard to go into effect? States have to adopt it within 2 years. The difference between the 2003 and 2009 standard is that if a lab reported a result below the PTRL they can have a failure.
 - o Mike Miller – The change does not fix the problem that Waste Water and Municipal labs have until there are two PT levels. Eric Smith noted that there are already two levels for PAHs, mercury and chlorine. It will take a few years for more to be put in place.
 - o Carol S. – The LOQ must be at or above your lowest calibration standard. There are issues where you have to report to the low standard and in other instances a lab needs to report to the LOQ. Mitzi noted that the problem was

that some labs were not using a standard low enough to meet the PTRL. This is a big issue for the waste water industry and they do not pass the PT. Nicole C commented that the new standard allows 2 options:

- Calibrate lower than you normally would and report down that low, below your LOQ. This would be deemed OK by your AB as the exception for calibrating lower is allowed by the standard.
 - Calibrate as normal, but report down to the PTRL, below your curve, and consider it a qualified number (result). This exception is allowed by the standard and thus allowed by your AB.
- Dale P – Asked about two level PTs. Shawn noted that PT providers have been looking at this. There is additional research needed to find out what the real needs are. This is being added to the standard, so the PT Executive Committee needs to work on this immediately so that it is ready. Stacie expressed her concerns on whether this is going to happen the same time. Eric Smith confirmed her concern. Eric noted that the process could be expedited by dealing with a specific subset of analytes. Stephen Arpie encouraged members in the meeting to sign-up for the Chemistry FoPT subcommittee to help with this process.
- **Action Item:** Need to work with the PT Executive Committee and work with labs to find out what the priority analytes are, what levels are needed, etc. This information will help the Chemistry FoPT Subcommittee. Susan Butts suggested that states would also be a good resource – what levels are they looking for? Stephen Arpie asked for a link to South Carolina's levels. Mitzi and Eric will look at establishing a joint subcommittee on this topic.

Section 6: Corrective Action

- The lab is directed to the corrective action procedures within the standard.
- WET – Corrective action procedures are described.

Section 7: Requirements to Re-Establish Performance History

- This is not normal corrective action. The lab has a serious accreditation issue and has to handle it immediately.
- New: The laboratory shall obtain successive PT samples for the same accreditation FoPT and report the results at least 7 calendar days apart. The laboratory shall analyze the two PTs in separate preparation and analytical batches.

Scott noted that there is also corrective action that needs to be done in the lab to ensure that another PT is not failed. They should also begin work on the corrective

- action immediately – don't wait for the state to let you know there is a problem. A lab knows they have a problem when they receive their PT results.
- WET: Their corrective action is a little different. They have 2 options: If the laboratory receives an evaluation of “Not Acceptable” for an accreditation FoPT in any study, the laboratory may choose to re-establish successful history for the accreditation by 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. Successful SRT analysis is established per V1M7 Section 4.1.2.

4) Volume 2 – Working DRAFT Standard

- The committee tried to align Volume 2 to Volume 1.
- An Applicability Section was added.
- Definitions were looked at. There are different definitions for Accreditation Body. This will need to be worked on and be the same. It will be forwarded to LAS EC (**Action Item**).
- The definitions were moved from Volume 1.

Section 4: AB Requirements

- 4.1.1 Leave it the way it was. (**Action Item**)
- 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. It emphasizes what is in Volume 1. Steve noted this could be an issue for laboratories stating that their accreditation is based on 17025. They should demonstrate they can do a PT.
- Removed original 4.1.2, 4.1.3 and 4.1.4.

Section 6: Onsite Review

- “Root cause analysis” needs to be in both Volume 1 and Volume 2 or Volume 2 needs to refer to the corrective action language to be consistent. Mitzi pointed out that the Volumes should stand on their own, so referring to the Corrective Action in another volume is a problem. The language in Volume 1 needs to be the same as Volume 2. A change to the language was made: The laboratory performed *corrective action including* root cause analysis for accreditation FoPT results that were scored “Not Acceptable”.

Section 7: Review of PT Reports

- Important changes were added to notes.

Note: The PT scoring criteria for PTPA recognized PT providers are specified in Volume 3 of this standard. If the Primary AB discovers or is otherwise notified that the PTP did not follow the scoring criteria specified in this standard, the

Primary AB must report their finding to the PTOB-PTPA that issued the accreditation to the PTP. If the score issued by the PTP for the accreditation FoPT was erroneously scored “Not Acceptable” or “Acceptable” by the PTP the Primary AB shall overturn the performance evaluation issued by the PTP and score the analytical result per the requirements specified in V3 of this standard.

Note: If the laboratory is accredited for multiple test methods by the same technology within the same field of accreditation matrix the laboratory is not required to analyze a PT sample for each test method except for the matrix drinking water where the laboratory must report a PT result per test method for each accreditation FoPT.

Except as noted for drinking water, the laboratory may report one result for an accreditation FoPT per technology and an acceptable performance score for the test method reported is considered acceptable performance for all test methods by the same technology within the same field of accreditation matrix. Alternatively, the laboratory may report a result for each test method. If the laboratory reports an analytical result for an accreditation FoPT by more than one test method; an unacceptable score for an accreditation FoPT will be applied only to the test method for which the unacceptable result was reported.

- Delete PTOB. It should only be PTPA.
- Eric Smith: Is there something in the standard about multiple level PTs? Is a lab required to run multiple levels? Or just one level? Mitzi agreed that this needs to be formalized. Currently it is just an agreement with the NELAP AC that the lab needs to run only 1 level when two levels are available. They need to run the appropriate level. It was also commented that Volume 1 needs to be looked out for the need to this note too. (**Action Item**)

8.2 WET

- Added WET information.
- There is a reference to Volume 1 in this section. This language will be added to this Volume. (**Action Item**)

The Expert Committee definition needs to be looked at too. PT Executive Committee needs to be looked at too. It should probably be PT Program Executive Committee. It needs to be passed along to the LAS EC. (**Action Item**).

TNI members are asked to provide any additional suggestions to the PT Expert Committee on the standard.

5) WET TIA Update

See slides in Attachment B.

- There were only 4 comments provided during the posting process.
- Stacie reviewed the TIA process through the use of the PPT in Attachment B.
- The TIAs are posted on the TNI website. They were posted for voting that closed January 30, 2012.
- Comments:
 - o Kirstin Daigle – There is a subcommittee within the PT Executive Committee that is working on updating the WET PT limits and concentration.
- The TIA will be in place within 2 months.
- Stacie noted that the PT Executive Committee and PT Expert Committee need to be in better communication.

6) Membership

Rachel Ellis is being added to the committee.

Scott moved to add Rachel to the committee. Joe Purdue seconded the motion. It was unanimously approved.

Another laboratory person needs to be added to the committee for balance. Anyone interested should complete the application on the TNI website. Contact any committee member for information.

7) Straw Poll

The audience was polled:

Who would like to continue the LOQ reporting? 5 (After discussion – 5)

Who would like to return to PTRL reporting? 5 (After discussion – 6)

- Kirstin Daigle commented that we will be working with LOQs for some time before the standard is updated back to PTRLs. This will cause issues again.
- Stephen Arpie commented that the Chemistry FoPT SOP needs to be updated to allow the inclusion of about 125 analytes that need to be looked at for inclusion in the FoPT table.
- Shawn commented that the PT Providers are not asking for the laboratory LOQ data.

8) New Business

None

9) Next Meeting


The next meeting of the PT Expert Committee will be planned by E-mail.

The meeting was adjourned at 12 EST. (Motion: Gary Second: Carl Unanimously approved.)





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





AGENDA

- WDS Development
 - Volume 1 – discussion lead by Mitzi Miller
 - Volume 2 - discussion lead by Scott Hoatson
 - Volume 3- Under development
- Whole Effluent Toxicity (WET) TIA – Stacie Metzler





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.





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




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 - 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

- **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 to:
- Complaint resolution
- Reinstatement after revocation



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
 - Field of Proficiency Testing (FoPT)
 - TNI PT Executive Committee
 - TNI PT Expert Committee





V2M2 4.0 AB Requirements

- 4.1.1 The Primary AB shall ensure ~~the laboratory~~ **the laboratories for which the primary AB has issued primary accreditation** meet the proficiency testing requirements...




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







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".





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

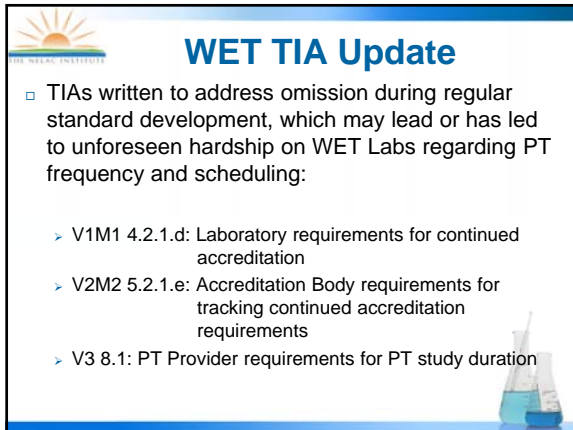
- 9.0 Requirements for Complaint Resolution
- 10.0 Suspension of Revocation of Laboratory Accreditation
- **No Changes**



V2M2 Summary

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





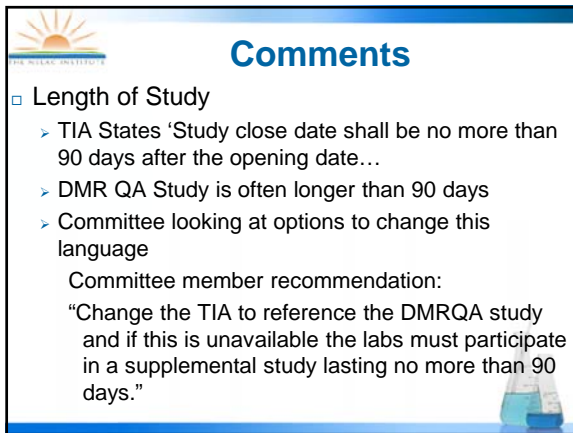
WET TIA Update

- TIAs written to address omission during regular standard development, which may lead or has led to unforeseen hardship on WET Labs regarding PT frequency and scheduling:
 - V1M1 4.2.1.d: Laboratory requirements for continued accreditation
 - V2M2 5.2.1.e: Accreditation Body requirements for tracking continued accreditation requirements
 - V3 8.1: PT Provider requirements for PT study duration



WET TIA Update

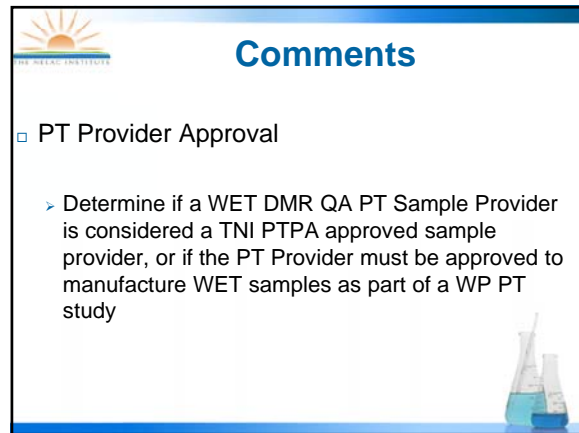
- Consensus Standard Development Committee voted to accept the TIA on January 12th
- Posted on TNI Website for Comments
 - Comment Period Closed January 30th
- Comments received cover:
 - Length of Study- Three comments
 - PT Provider Approval- One comment



Comments

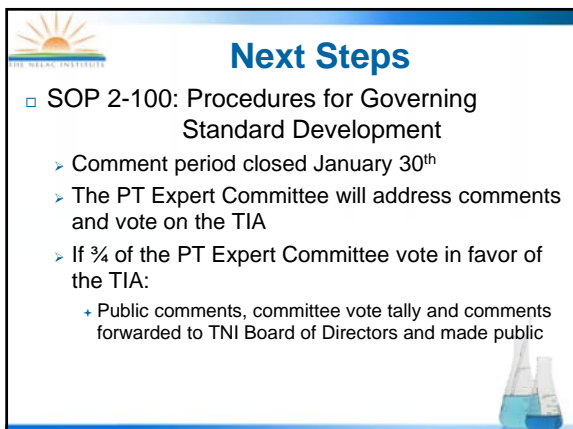
- Length of Study
 - TIA States 'Study close date shall be no more than 90 days after the opening date...
 - DMR QA Study is often longer than 90 days
 - Committee looking at options to change this language

Committee member recommendation:
"Change the TIA to reference the DMRQA study and if this is unavailable the labs must participate in a supplemental study lasting no more than 90 days."



Comments

- PT Provider Approval
 - Determine if a WET DMR QA PT Sample Provider is considered a TNI PTPA approved sample provider, or if the PT Provider must be approved to manufacture WET samples as part of a WP PT study



Next Steps

- SOP 2-100: Procedures for Governing Standard Development
 - Comment period closed January 30th
 - The PT Expert Committee will address comments and vote on the TIA
 - If $\frac{3}{4}$ of the PT Expert Committee vote in favor of the TIA:
 - ✦ Public comments, committee vote tally and comments forwarded to TNI Board of Directors and made public



Next Steps

- TIA will become effective 20 days after approval by the PT Expert Committee unless Chair of the TNI Board of Directors determines effective date shall be delayed pending consideration of an appeal
- TIA can remain in effect for maximum of two years from effective date
 - ✦ Time for language to be re-introduced as a Voting Draft Standard
 - ✦ Adopted by TNI after proceeding through normal standard development process