



Changes to the TNI 2015 Standard

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Topics

- Provide a status update for each of the volumes/modules.
- Review highlighted changes to the each of the volumes/modules.
- Questions, if there is time....





TNI Volume 1 Module 1

Laboratory Proficiency Testing





V1M1 Changes

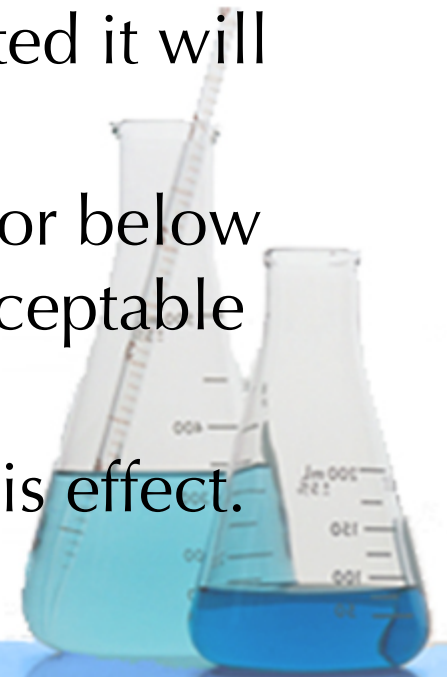
- Reporting requirements changing back to Proficiency Testing Reporting Limits (PTRLs)
- This was a major stumbling block for the implementation of the 2009 TNI standard.
- PTEC received direction during the 2011 Seattle conference from the TNI membership for the change.





V1M1 Changes

- Result = to or $>$ PTRL—report result
- $\text{PTRL} < \text{LOQ}$
 - Shall report result without qualification
 - **NOTE** – if lab $\text{LOQ} > \text{PTRL}$ and is reported it will be scored “Not Acceptable”
 - Translation, the lab’s LOQ should be at or below PTRL or they risk being scored as not acceptable (similar to 2003 NELAC Standard)
 - The standard does include a NOTE to this effect.





V1M1 Changes

- Result <PTRL
 - report a result of “<” PTRL
- Result between LOQ & PTRL
 - report result of “<” PTRL
 - or report result when LOQ < PTRL
- This was a major stumbling block for the implementation of the 2009 TNI standard.
- PTEC received direction during the Seattle conference from the TNI membership for the change.





V1M1Changes

- Opening date of second study at least 7 days after the closing date of first study.
- This reduces the time waiting time for a laboratory to analyze a second PT to regain their accreditation.





V1M1 Changes

- There are new sections for Radiochemistry and WET
 - New requirements for specific reporting requirements for both Radiochemistry and WET.
 - New PT requirements have been added for WET
 - ✦ Allow the use of DMR-QA to meet PT requirements.
 - ✦ Sets the frequency for WET to one time per year.
 - ✦ Defines what the corrective action is to be submitted.
- These were added to the standard per the requests of each expert committee.





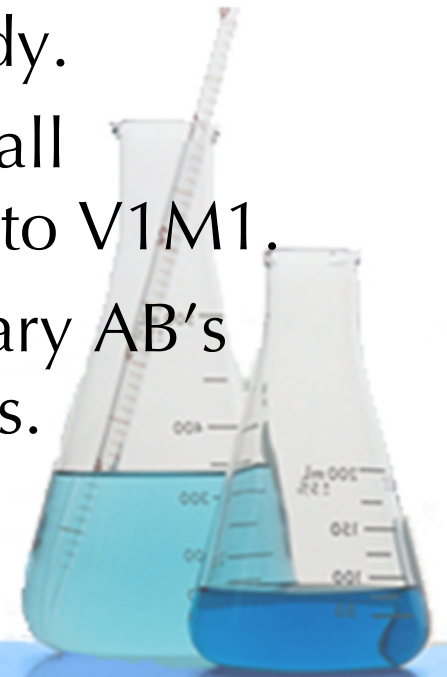
TNI Volume 2 Module 2 Accrediting Body Proficiency Testing





V2M2 Changes

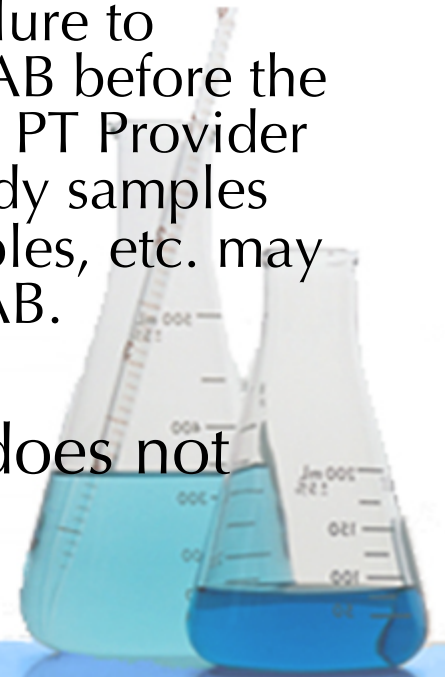
- Change definition of Accreditation Body:
 - The organization having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program.
- Expands the definition of Accreditation Body.
- Assess laboratory compliance with V1M1, all laboratory requirements have been moved to V1M1.
- Reviewed the roles of Primary and Secondary AB's specifically to ensure their appropriate roles.





V2M2 Changes

- Clarified NOTE concerning the PT results review by AB's.
 - NOTE: “Acceptable” PT study scores from a PT Provider do not automatically result in a successful evaluation of a PT study by an AB. For example, failure to report an analytical method or reporting of an incorrect method, failure to provide the PTP with a release of results to the AB before the close of the study, failure to report results to the PT Provider before the closing date, failure to handle PT study samples in the same manner as real environmental samples, etc. may be cause for an unsuccessful evaluation by an AB.
- Reminds the laboratory that “Acceptable” does not mean accreditation.





V2M2 Changes

- Edited “may” into the standard for suspension and revocation, but this weakened the standard.
- The section was changed to allow the ABs to use their established procedures for suspending or revoking a lab’s accreditation.
- And maintain criteria for all ABs for suspending or revoking a lab’s accreditation.





TNI Volume 3: General Requirements for PT Providers





Goals

- Review the requirements for PTP's with an eye to requiring the PTP's to be accredited to ISO 17043.
- Vol 3 should contain only the TNI requirements for PTP's.
- This approach will make the audits for the PTP's more efficient, consistent, and simpler.





Approach

- The entire committee was provided with ISO/IEC 17043 and Guide 34.
- Vol 3 was edited and reviewed to these guides.
- To simplify the review to the ISO standards, Vol 3 was re-organized to a similar order as ISO/IEC 17043.
- We will review each section and where the relevant sections of ISO/IEC 17043 were removed.





Volume 3 Changes

- Quality System Requirements
 - Most incorporated into ISO 17043 and Guide 34.
 - ISO 9001 mentioned *BUT NOT* related to PTP studies. Reference removed.
 - ILAC G-13 reference removed.
 - Retained
 - ✦ VHS testing by 17025 accredited laboratory
 - ✦ Specifics to PTPA
 - ✦ Documents Retention





Volume 3 Changes

- Provider Conflict of Interest and Confidentiality
 - Retained sections are references for reporting requirements to the PTPA for full disclosure and actions in the presence of a conflict of interest.





PT Sample VHS Testing

- Appendix A was removed from the standard as it was a guidance document.
- Subcommittee was formed and incorporated the requirements of Appendix A into Section 5
- The subcommittee consisted of a balanced representation of stake holders.
- Criteria were reviewed and added to the body of the standard.





PT Sample VHS Testing

- Homogeneity
 - Allows the PTP to demonstrate homogeneity to the approval of the PTPA.
 - More freedom for both PTP's and PTPA's to demonstrate and approach homogeneity.
 - More consistent with ISO.





PT Sample Assigned Values

- Assigned values for microbiology FoPT's be set to the mean of the PTP's study data.
- Previously was to be the mean of the PTP's verification analysis.
- The study mean is used to calculate acceptance limits for laboratory evaluations.





PT Study Data Analysis

- Only change made to this section.
- Does not allow the use of “<” and “>” values to be used in statistical calculations.
- Some concern that these values were being used for the calculation of microbiology results.





PT Result Evaluation

- Section with the largest amount of change.
- The evaluation criteria is being altered to match the criteria are found in 2003 NELAC standard.
- Added the evaluation of greater than (" $>$ ") values as well.





PT Result Evaluation

- Assigned Value greater than the PTRL.
 - “Acceptable” if result is within limits established acceptance limits.
 - “Not Acceptable” if the following:
 - ✦ if the result is outside limits of the established acceptance limits,
 - ✦ if the result is reported with a “>” or “<” sign.
 - Removed “<” evaluation criteria from 2009 TNI standard.





TNI Volume 4: General Requirements for Accreditors of Environmental PT Providers





Goals

- Review the requirements for Proficiency Testing Provider Accreditors (PTPAs) based on ISO 17011.
- Volume will contain only sections that contain TNI specific requirements for accrediting PTPAs.
- This approach will allow assessments of PTPAs to be more efficient and consistent.





Approach

- Vol 4 was reviewed against the ISO 17011: *General requirements for accrediting bodies accrediting conformity assessment bodies*.
- Both PTPAs, A2LA and ACLASS, submitted comments to Volume 4 changes as part of the update process.
- PTPEC/PTEC cross over membership was also important in the development of the standard.
- The sections covered in ISO 17011 were removed from the Vol 4. TNI specific requirements remain in the standard.
- SOPs will be developed to document PTPEC and PTPA responsibilities for the PT Program.





The Intro

1.3 Applicability

1.3.3 These requirements also of this standard apply to the responsibilities of the TNI-approved Accreditation Body (or bodies). These requirements assume that monitoring is an essential part of accreditation, and so the accreditation and monitoring functions are seen as part of the same process. **It is also recognized that PTPA(s) to accredit and monitor their respective PT providers to ensure the requirements listed in Volume 3 are consistently met.** The PTPA(s) may have other requirements and mutual recognition agreements that may need to be included in the TNI PT Provider accreditation process. These requirements are outside the TNI consensus process, except that the PTPEC must approve them as applicable to TNI Provider accreditations. In addition, these recognitions allow TNI PT providers to offer their services in regions where TNI accreditation may not be recognized.





Requirements for the PTPEC

Section 4 : The purpose of this section is to assure the PTPA(s) understand the PTPEC roles and written procedures maintained by the PTPEC, describe the requirements of the PTPEC review and approval of the PTPA(s).

4.1.c Conduct appropriate evaluations of any organization seeking to be a PTPA at a minimum of every four (4) years.

Important change to bring TNI in alignment with other ISO organizations.





Requirements for the PTPA

- The organization shall be recognized by an international cooperation of accreditation bodies for the accreditation of laboratories, and shall demonstrate the following:
 - a) compliance with ISO/IEC 17011: *General requirements for accreditation bodies accrediting conformity assessment bodies*;
 - *b) compliance with the requirements set forth in this standard above those in ISO/IEC 17011;*
 - c) have, or have access to, technical expertise that conforms with ISO17043 and/or ISO 17025 as appropriate, for the preparation and/or analysis of the types of proficiency testing materials being prepared by the PT Providers;





Requirements for the PTPA

- Section 5.4 Changes
 - 5.4.1 The PTPA shall maintain a comprehensive PT **data management system** that contains PT Study summary data and results of all verification, homogeneity, and stability determinations. The system shall allow for collection, storage, analysis and reporting of the PT Study summary data.





Requirements for Accreditation of PTPs

- Section
 - The PTPA shall monitor pass/fail rates per the PTPEC. The PTPA shall investigate pass/fail rates that deviate from criteria established by the PTPEC. The PTPA shall notify the PT Provider of pass/fail rate deviations and monitor associated corrective actions taken by the PT provider.
- Removed national historical failure rate.





Status Update

- Committee reviewing comments from:
 - Interim Voting Draft posting for Vol 1 and 2
 - Voting Draft posting for Vol 3 and 4
- Goal to have Vol 3 and 4 to Interim Voting Draft Standards posted by September.





Questions?





Thank you!

