



Changes to the TNI 2016 Standard

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Topics

- Review highlighted changes to the each of the volumes/modules.
- Questions/Answers





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 \geq PTRL—report result PTRL < LOQ
 - Shall report result without qualification
 - **NOTE** – if lab LOQ > 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 result as “ $<$ PTRL”
- ❑ Result between LOQ & PTRL
 - report result as “ $<$ PTRL”
 - or report result when $LOQ < PTRL$



V1M1 Changes

- ❑ Opening date of second study at least 7 days after the closing date of first study.
 - ❑ No longer analysis dates
- ❑ This reduces the waiting time for a laboratory to analyze a second PT to have accreditation reinstated



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 (AB):
 - The organization having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program.
- ❑ Expands the definition of AB.
- ❑ 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.
- ❑ “Acceptable” PT study scores from a PT Provider (PTP) 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,
 - provide the PTP with a release of results to the AB before the close of the study,
 - report results to the PTP on or 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.





V2M2 Changes

- ❑ The standard changed to require each AB to follow their individual regulatory processes for suspension and revocation.
- ❑ This allows each state AB to follow their own suspension and revocation process.
- ❑ Allows flexibility for ABs without requiring legislative activities.



V2M2 Changes

- Added allowance for Secondary ABs to make their own determinations with regard to PT evaluations and granting, denying, suspending, or revoking laboratory accreditations based on these evaluations, but they must do so for all secondary laboratories and must verify their decision with the Primary AB before taking action.





TNI Volume 3: General Requirements for PT Providers



Volume 3 Changes

- All PT providers are required to be accredited to ISO/IEC 17043.
- Volume 3 was rewritten to match the same format as ISO/IEC 17043.
- Redundant requirements between Volume 3 and ISO/IEC 17043 were removed from Volume 3. The remaining Volume 3 only contains TNI based requirements.



Volume 3 Changes

- Appendix A from 2009 for homogeneity, verification and stability testing removed as a guidance document.
 - Requirements for verification have been revised to remove an arbitrary 10% minimum criteria, with the $\frac{1}{3}$ acceptance limit criteria remaining, and to remove the requirement that the analytical method used for verification have a repeatability relative standard deviation of not more than $\frac{1}{6}$ the acceptance limit.



Volume 3 Changes

- Appendix A from 2009 for homogeneity, verification and stability testing removed as a guidance document.
 - Requirements for homogeneity have been revised to meet the requirements found in Annex B, Section B1 through B3, of ISO/IEC 13528:2015 (E).
 - Stability testing has been expanded to allow for a second option for difficult analytes.





Volume 3 Changes

- Quantitative microbiology assigned values set to the calculated study mean of the providers' individual studies.
- Protozoan PT requirements added with the members of the EPA and Wisconsin State Protozoan PT Program for
 - assigned values,
 - data evaluation, and
 - acceptance limit calculations.



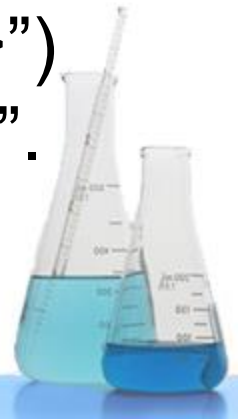
Volume 3 Changes

- Radiochemistry requirements added to Volume 3 for assigned values working with the Radiochemistry Expert Committee.
- WET requirements have been added to Volume 3 through working with the members of the Expert Committee for
 - assigned values,
 - data evaluation, and
 - acceptance limit calculations.



PT Result Evaluation

- Section with the largest amount of change.
- The evaluation criteria is being altered to match the criteria in the 2003 NELAC standard.
- Added the evaluation of greater than (“>”) values as well.
 - All values reported with a greater than (“>”) sign will be evaluated as “Not Acceptable”.



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.



Volume 3 Changes

- A section was added requiring PTPs to provide data to support the development of the TNI FoPT tables.
- The requirement was developed with the PT Program Executive Committee in conjunction with the PTPAs and the PT Providers.
- Note was developed for special circumstances where more detailed information may be requested.





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



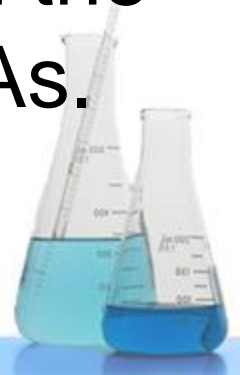
Volume 4 Changes

- Volume 4 was harmonized to the ISO/IEC 17011:2004 standard.
 - The redundant requirements were removed as appropriate for simplification.
- The accreditation time frame for the PT Provider Accreditors (PTPAs) was extended to 4 years to be more consistent with the international quality standards.



Volume 4 Changes

- Many requirements relating to the activities of the PT Program Executive Committee (PTPEC) were removed allowing for the focus of the standard to be the accreditation of the PTPAs.
- Requirements for the development of a program status report were added with the involvement of PT Providers and PTPAs.





Requirements for Accreditation of PTPs

- Added information for PTPA data monitoring:
 - 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.





Questions?





Thank you!

