Virginia Division of Consolidated Laboratory Services
Virginia Environmental Laboratory Accreditation Program

TECHNICAL ASSISTANCE DOCUMENT

KEY CHANGES FROM 2009 TNI STANDARD TO 2016 TNI STANDARD AND THE REVISION of 1VAC30-46

March 25, 2022

This document highlights regulatory information expected to be most significant to laboratories transitioning from the 2009 TNI Standard to the 2016 TNI Standard and the update of 1VAC30-46. All laboratories accredited under 1VAC30-46 are responsible for review and implementation of the 2016 TNI Standard in full, with continual adherence to its requirements, when the regulatory update is implemented.

- ***Effective date of revised 1VAC30-46: April 1, 2022.***
- ***Date when VELAP will begin to assess to the 2016 TNI Standard: November 1, 2022.***
- ***Between April 1, 2022 and November 1, 2022 VELAP will accept compliance with either the 2009 TNI Standard or the 2016 TNI Standard.***

Volume 1 Module 1: Proficiency Testing (PT)

Volume 1 Module 1 (V1M1) was completely revised. Laboratories must review the module, in full, very carefully to ensure full compliance. Significant changes are described below.

Definitions of PT Study Opening Date and PT Study Closing Date [2016 TNI V1M1 3.10, 3.11]

These definitions will be important for application of compliance rules for consecutive studies:

PT Study Opening Date:

- Scheduled PT Study: The calendar date that a PT sample is first made available to all participants of the study by a PT Provider.
- Supplemental PT Study: The calendar date the PT Provider ships the sample to a laboratory.

PT Study Closing Date:

- Scheduled PT Study: The calendar date by which all participating laboratories must submit analytical results for a PT sample to a PT Provider.
- Supplemental PT Study: The calendar date a laboratory submits the results for a PT sample to the PT Provider.

Consecutive PT Studies: Minimum amount of time [2016 TNI V1M1 5.1.1 c, 5.2.1.2.b,c]

When reviewing the validity of consecutive studies, the opening date of the second study must be at least seven calendar days after the closing date of the first study. This change from 15 days to 7 days between studies will be helpful to laboratories needing to perform make-up PT studies. Note the change in the way the study times are evaluated: formerly, the 15-day rule was evaluated based on analysis dates. The new 7-day rule is evaluated based on closing dates and opening dates.

Example of a compliant timeline: Study A Closes on Tuesday May 1; Study B Opens on Tuesday May 8, using the definitions of “closing date” and “opening date” provided in sections 3.10 and 3.11.

Consecutive PT Studies: Continual Proficiency Test Participation [2016 TNI V1M1 5.1.1.d, 5.2.1.2.a]

Changes to language for PT requirements for initial accreditation provide clarity that PT participation on a semi-annual schedule, not to exceed 7 months between closing dates of subsequent semi-annual studies, is evaluated continually starting with the date of the most recent PT study when a laboratory applies for accreditation or applies for a change in scope. Laboratories will need to be mindful of this rule when adding tests and when consolidating new testing into the laboratory's current semi-annual testing schedule to ensure the semi-annual schedule (or "7-month rule") is continuously met, even if the change-in-scope is in progress or incomplete. The continuous monitoring will begin at the time of the submission of the new application or the application for change in scope and will be based on the most recent study at the time the application is made. Laboratories must plan PTs carefully to avoid assignment of a non-participation failure in accordance with the language in the Standard.

Reporting Limits: Reporting to the PTRL [2016 TNI V1M1 3.8, 4.2.3, 4.2.4, 4.2.5, 4.2.7, 4.3.5, 4.3.7]

PTs for all programs are scored by PT Providers in accordance with the reporting rules described in 2016 TNI Volume 1 Module 1. Laboratories are required to report PT results down to the TNI FoPT analyte+matrix reporting limit designated on the TNI FoPT tables. This PT reporting limit or PTRL is available in the tables located at http://www.nelac-institute.org/content/NEPTP/fopt.php.

- **The laboratory needs to review all reporting limits against PTRL limits to become aware of which PTs (if any) might possibly have a study result that is lower than the laboratory's typical reporting limits (RL).**
- If a PTRL is equal to or higher than the laboratory's RL:
  - The laboratory does not need to make any special accommodations in the testing or reporting of the proficiency sample.
- If a PTRL is lower than the laboratory's RL:
  - The laboratory must modify its normal RL to the PTRL value for the analysis of the PT sample. For this situation the following options are available to the laboratory:
    - The laboratory may report the PT, if needed, as a value lower than the lowest calibration standard. In this situation a qualifier on the reported PT sample is not required. OR,
    - The laboratory may change its typical calibration range when the PT sample is analyzed and use a lower standard that accommodates the PTRL.
- TNI has provided a guidance document on reporting PTs to the PTRL in accordance with the 2016 TNI Standard. The document includes numeric examples to illustrate various reporting scenarios and may be helpful for further review of this topic. https://nelac-institute.org/docs/guidance/21728507.pdf Training is also available from TNI on this topic.

Cause for Revocation of Accreditation [V1M1 4.1.6]

The activities described in V1M1 4.1.5 are cause for revocation of accreditation. This is not a new cause for revocation, but it was previously stated only in Volume 2. Having this statement in Volume 1 provides more awareness for laboratories. The Virginia regulation at 1VAC30-46-100 B has been updated to include this reason for the withdrawal of accreditation.

Recordkeeping Specification for PTs [V1M1 4.4.1]

Records for the reconstruction of the preparation of PT samples are specified in V1M1.4.4.1. This would be applicable for reconstitution, dilution, etc. of a PT sample as instructed by the PT provider.

Continued Accreditation for WET Testing Laboratories [V1M1 5.2.2]

Refer to V1M1 5.2.2 for specific information and changes regarding PT studies for WET testing laboratories.

Volume 1 Module 2: Quality Systems

Volume 1 Module 2 (V1M2) was edited only in the support equipment section as described below.

Calibration Requirements: Support Equipment [2016 TNI V1M2 5.5.13.1]

- V1M2 5.5.13.1.d.i allows temperature measuring devices, when used over a range of temperatures spanning 10°C or less, to be verified with a single point (rather than bracketing the range of use).
- V1M2 5.5.13.1.e describes verification practices for volumetric measuring devices "if quantitative results are dependent on their accuracy." Laboratories should carefully review the use of all volumetric measuring devices to determine when this verification practice applies. Typically, laboratories will need to implement these procedures for all of its devices which measure volume:
    - For glass microliter syringes and Class A glassware: no verification is required beyond what is stated in Section 4.6.2;
    - Once-per-lot verification of disposable or single use items;
    - Prior to first use and quarterly verification of mechanical devices; and
    - Prior to first use verification of all other volumetric support equipment.

Volume 1 Module 4: Chemical Testing

Volume 1 Module 4 (V1M4) was revised significantly in the sections described below. Laboratories must review the revised sections, in full, very carefully, to ensure full compliance. Significant changes are described below. Sections not mentioned below were not revised.

Limit of Detection (LOD) and Limit of Quantitation (LOQ) [2016 TNI V1M4 1.5.2.1, 1.5.2.2]

- Limit of Detection (LOD) has been renamed Detection Limit (DL). This is an administrative edit by TNI. Laboratories may still use the LOD or MDL terms; VELAP considers these terms interchangeable.
- The former TNI language has been removed which stated that if a laboratory is not reporting a value below the Limit of Quantitation (LOQ), a Limit of Detection study is not required. Initial LOD studies are now required for all testing that falls under Module 4, unless otherwise specified by the module or by the method.
- The Standard does not contain any language that exempts a laboratory from doing the initial DL study for methods already in use or for methods with a DL study done by another procedure. VELAP will assess all laboratories to the requirements of section 1.5.2.1.1 for all testing done under Module 4, unless otherwise exempted by the module or by the method.
- Refer to 2016 TNI V1M4 sections 1.5.2.1 (Detection Limit) and section 1.5.2.2 (Limit of Quantitation) in their entirety to review all requirements for DL and LOQ.
- The initial DL procedure in the TNI Standard may be met by the EPA 821-R-16-006 Definition and Procedure for the Determination of the Method Detection Limit,

Revision 2 as published in 40CFR136 Appendix B, hereafter referenced as the EPA MDL procedure.
    - The EPA MDL procedure uses results from low level spikes and blanks collected across multiple analysis dates, along with laboratory blanks, to determine an initial DL. The procedure then uses results from same-level spikes and blanks collected quarterly to re-evaluate the determined MDL on an annual basis.
- In addition to the DL procedure, the Standard describes a required process for initial verification of the LOQ and ongoing verification of the LOQ**. With careful planning, the laboratory can implement one procedure that meets the initial and ongoing DL requirements and simultaneously meets the initial and ongoing LOQ requirements.**
    - For example, when the spiking level is slightly below the expected LOQ, use of the EPA MDL procedure will meet the requirements of V1M4 1.5.2.1 (DL determination and verification) and 1.5.2.2 (LOQ initial and ongoing verification).
    - Resources for using the EPA MDL procedure are available on VELAP's Accreditation and Certification toolbox page (www.dgs.virginia.gov/dcls) under the heading MUR/MDL.
    - Laboratories are strongly encouraged to use VELAP's checklist, based strictly on the EPA MDL procedure, to self-audit adherence to all requirements.
- **Remember that the EPA MDL procedure is required for testing done in support of the Clean Water Act. Most laboratories will find it most suitable to implement the EPA MDL procedure throughout the laboratory to address the DL and LOQ requirements of the 2016 TNI Standard.**
    - ** One point needing special consideration is that the EPA MDL procedure allows data to be collected from multiple instruments if a laboratory uses multiple instruments for one test, so that only one MDL for the test is determined. However, drinking water testing, if done on multiple instruments, requires instrument-specific MDL determinations.**
    - The EPA MDL procedure includes specific information about the number of samples to be collected per instrument and the number of different analysis dates required for the initial and quarterly determinations. Laboratories should review these requirements carefully to ensure attention to all details of the procedure.
- Laboratories using the EPA MDL procedure to meet the LOD requirements of the 2016 TNI Standard do not need to have their own written procedure for LOD if the laboratory's quality system documentation refers to the EPA MDL procedure as published (EPA 821-R-16-006 Definition and Procedure for the Determination of the Method Detection Limit, Revision 2 as published in 40CFR136 Appendix B).
- Laboratories should carefully review the data collection requirements found at 2016 TNI V1M4 1.5.2.4 before starting the initial and ongoing testing and data collection, to ensure plans are made at the outset for complete recordkeeping for initial and required quarterly testing.
- Drinking Water note: MDLs are calculated per instrument for Safe Drinking Water Act testing.
- While the process is new to the laboratory, frequent self-audits to the requirements of the EPA MDL procedure (if used) and the requirements of the Standard will be important tools for ensuring adherence with the details specified in the EPA and TNI requirements.

- TIP: Organizing all fields of accreditation into a chart(s) capturing MDL, LOQ, spiking amounts, and dates when quarterly checks were done may be helpful, along with notes for where to find associated/supporting data.
- TNI has provided a guidance document on the determination and validation of detection and quantitation limits as required by the 2016 TNI Standard. The document includes detailed explanations and examples, and may be helpful for further review of this topic. https://nelac-institute.org/docs/guidance/22639211.pdf
- ***To summarize: using the EPA MDL procedure with a spiking level at or below the laboratory's LOQ, throughout the laboratory, for each quality system matrix, will concurrently satisfy the requirements of the Clean Water Act and the 2016 TNI Standard's LOD and LOQ requirements. When the procedure is done per instrument, the MDL requirements of the Safe Drinking Water Act will additionally be satisfied.***

Demonstration of Capability [2016 TNI V1M4 1.6]

- The 2016 Standard specifically states that an individual who performs any activity involved with the preparation and/or analysis of samples must have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC (per Section 1.6.2) is completed [V1M4 1.6.1.a]. This language provides additional flexibility to laboratories in designing their training procedures.

Initial Calibration and Continuing Calibration [2016 TNI V1M4 1.7.1.1, 1.7.1.2]

- The Initial Calibration section has been fully revised. Laboratories must review the section, in full, very carefully, to ensure full compliance.
- TNI has provided a guidance document on the instrument calibration requirements of the 2016 Standard. The document includes detailed explanations and examples, and may be helpful for further review of this topic. https://nelac-institute.org/docs/guidance/21666708.pdf. Training is also available from TNI on this topic.
- Highlights of the revised Initial Calibration section:
    - Addition of allowance for removal and replacement of initial calibration standards when specified requirements are in the laboratory's written procedure and are met [V1M4 1.7.1.1.e]
    - Addition of minimum number of non-zero calibration standards specified for regression or average response/calibration factor calibrations [V1M4 1.7.1.1.f]
    - Introduction of requirement to use and document a measure of relative error in the calibration [V1M4 1.7.1.1.k]
        - For calibrations evaluated using average response factor: Relative Standard Deviation (RSD)
        - For calibrations evaluated using correlation coefficient or coefficient of determination: Relative Error (%RE) or Relative Standard Error (%RSE)
    - Addition of specific information related to the analysis of Aroclors [V1M4 1.7.1.1.m]
- Highlights of the revised Continuing Calibration section:
    - Fully revised section [V1M4 1.7.1.2], but reflects practices already in place by most laboratories. Laboratories should review to ensure full compliance throughout the quality system and to review new options.
    - Addition of a requirement for the calibration check standard to be equal to or less than one half the highest level [V1M4 1.7.1.2.c]

Volume 1 Module 5: Microbiological Testing

Volume 1 Module 5 (V1M5) was revised throughout with minor revisions for clarity and to address all previous Standard Interpretation Requests. In doing so, the revision also now has become clearer about when a laboratory must perform a certain task. Laboratories should review the module in full to ensure compliance. Some changes are highlighted below.

Demonstration of Capability [2016 TNI V1M5 1.6]

- The 2016 Standard specifically states that an individual who performs any activity involved with the preparation and/or analysis of samples must have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC (per Section 1.6.2) is completed [V1M5 1.6.1.1]. This language provides additional flexibility to laboratories in designing their training procedures.

Quality of Dilution Water [2016 TNI V1M5 1.7.3.1.e]

- The revised standard specifies that dilution water shall be monitored for sterility, pH, and volume once per lot or batch whether purchased or lab-prepared. Many laboratories are already performing these checks under method-specific QC requirements; under the 2016 Standard these checks are required for all microbiology laboratories using dilution water.

Test Variability/Reproducibility [2016 TNI V1M5 1.7.3.3]

- Formerly, reproducibility between analysts was measured on tests that required colony counts. The revised standard expands the reproducibility requirement to all quantitative methods: "…methods that specify counts (i.e., cfu/100mL or MPN/100mL), such as membrane filter, plated media or other methods which specify a quantitative result".

Equipment: Labware (Glassware and Plasticware) [2016 TNI V1M5 1.7.3.7.b.vi.c]

- The Inhibitory Residue Test is no longer required annually; the revised standard requires this verification "initially and each time the laboratory changes the detergent formulation or washing procedures".

Sample Handling: Checks for absence of Chlorine Residual [2016 TNI V1M5 1.7.5.2]

- The section describing checks of samples for disinfectant residual has been revised. The revised section should be fully reviewed to ensure compliance with the requirements and exceptions provided.

Volume 1 Module 3: Asbestos Testing

Volume 1 Module 3 (V1M3) was re-organized with minimal change to content. Laboratories performing asbestos testing should review the module in full to ensure compliance.

Volume 1 Module 6: Radiochemical Testing

Volume 1 Module 6 (V1M6) was substantially revised. While the substance of the 2009 Standard was retained overall, the text underwent substantial reorganization with some revision to add clarity and better address some concepts previously not well-developed. Laboratories performing radiochemical testing should review the module in full to ensure compliance.

Volume 1 Module 7: Whole Effluent Toxicity Testing

Volume 1 Module 7 (V1M7) was not revised.

1VAC30-46, Effective April 1, 2022: TNI 2016 Standard Access

The Certification of Compliance statement signed annually by the laboratory's key staff members is based on requirements of 1VAC30-46-70 F 3. The revised 1VAC30-46-70 F 3 includes a statement of access to the TNI Standards.

- The 2016 TNI Standard Volume 1 is available on the TNI webpage. Purchase information is available at https://nelac-institute.org/content/CSDP/standards.php.
- Refer to TNI 2016 V1M2 4.3.1 and 4.3.2.2.a regarding a laboratory's responsibility to manage authorized editions of appropriate documents and to control documents, including standards, which are part of the laboratory's management system.
- The laboratory's authorized copy of the 2016 TNI Standard Volume 1 should be available for inspection at a future laboratory assessment. Laboratories do not need to purchase Volume 2 of the TNI Standard.

Additional Resources

This summary is intended to highlight the most impactful changes to laboratories. THIS IS NOT A SUMMARY OF ALL CHANGES. For a more detailed summary of changes, refer to a summary available on the TNI website.

All accredited laboratories should thoroughly review the 2016 Standard Volume 1 in its entirety and perform internal audits to ensure full compliance. A checklist for the 2016 Standard is available on the TNI website, once a copy of the standard has been purchased.

TNI offers numerous webinars relevant to compliance with the 2016 TNI Standard. Information on available training from TNI is available here.