

**Virginia Division of Consolidated Laboratory Services
Virginia Environmental Laboratory Accreditation Program**

FREQUENTLY ASKED QUESTIONS

PROFICIENCY TESTING

UPDATED MARCH 30, 2017

Why is proficiency testing important?

Satisfactory and continuing proficiency testing (PT) is a **critical component** of the certification or accreditation process under the Virginia Environmental Laboratory Accreditation Program (VELAP). Proficiency testing is required by regulation to demonstrate a laboratory's ability to satisfactorily perform tests for which it is certified or accredited.

Where are PT requirements described in the regulation?

For Chapter 45 Certification: 1VAC30-45, Part II, Article 3 (1VAC30-45-500 through 1VAC30-45-520)

For Chapter 46 Accreditation: 1VAC30-46-200 A, which incorporates by reference 2009 TNI Volume 1 Module 1 (proficiency testing requirements for laboratories) and Volume 2 Module 2 (requirements for accrediting body oversight of proficiency testing)

What is the relationship between Fields of Proficiency Testing and Fields of Certification or Accreditation?

A "Field of Accreditation" (FoA) or a "Field of Certification" (FoC) is a matrix + method + analyte combination for which a laboratory is certified or accredited. The matrices offered under VELAP are non-potable water, solid and chemical materials, drinking water, biological tissue, and air and emissions.

A "Field of Proficiency Testing" (FoPT) is defined as an approach to offer proficiency testing by matrix, technology/method, and analyte/analyte group. A laboratory must ensure that the matrix + analyte of the PT study is the same as that for the Field of Certification or Accreditation for which the laboratory is requesting certification or accreditation.

For practical purposes and within this document, FoPT means the FOC/FOA held by the laboratory for which PTs are required/analyzed because the analyte has been listed on the TNI FoPT table for the matrix listed in the laboratory's FOC/FOA. Any questions about whether a PT is required for a FOC/FOA can be referred to the VELAP office (Lab_Cert@dgs.virginia.gov).

What are the PT requirements for VELAP certification or accreditation?

- VELAP certified/accredited laboratories are responsible for meeting all regulatory requirements and should refer to the regulations, in their entirety, for complete PT information.
- For **Chapter 45** (non-commercial laboratories) certification:
 - The laboratory seeks and maintains certification by participating in **one single blind, single concentration PT study, where available, per calendar year for**

each Field of Proficiency Testing. The laboratory is required to perform a PT study prior to September 30 each year.

- The PT study submitted to VELAP to satisfy the initial application requirement must have been performed within 12 months of the application date.
- For **Chapter 46** (commercial laboratories) accreditation:
 - The laboratory participates in **two single blind, single concentration PT studies, where available, per calendar year for each Field of Proficiency Testing** for which the laboratory wishes to seek or maintain accreditation. The laboratory maintains accreditation by successfully completing two PT studies for **each** requested FOA within the most recent three rounds attempted. Successive PTs are completed on an ongoing testing schedule with at least five (5) months and no longer than seven (7) months separating the analysis dates of the subsequent studies.
 - The PT Studies submitted to VELAP to satisfy the initial application requirements (including a Change in Scope request) must have been performed within 18 months of the application date and the most recent study must have been performed within 6 months of the application date.
- Both commercial and non-commercial laboratories seeking a change in scope must meet the PT requirements for initial certification/accreditation for the additional fields of certification or accreditation requested.
- PT samples are handled (i.e., managed, analyzed, reported) in the same manner as real environmental samples utilizing the same staff and methods as used for routine analysis of that analyte (procedure, equipment, and facilities).
- When analyzing a PT sample, the laboratory must use the same preparation, calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates, and other procedures as used when analyzing routine samples.
- Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document for its own records and provide for DCLS both the investigation and the action taken, upon request.
- A laboratory may not send a PT sample or any portion of a PT sample to another lab for any analysis for which it seeks certification or accreditation.
- Laboratory management or staff may not communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample.
- A laboratory may not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks certification or accreditation.
- When a laboratory has failed to meet the calendar year PT requirements, the PT studies done as “make-up” studies to address the absent (non-participation) studies are not credited toward compliance for the new year.

For example: A laboratory does not participate in PT testing in the 2017 calendar year as required by the regulation. The laboratory performs a PT study in January of 2018 in order to address the reason the laboratory’s potential certification suspension. The make-up study does not count towards meeting the PT requirements in calendar year 2018 in this example.

Where can I find a list of the available Fields of Proficiency Testing (FoPT)?

The NELAC Institute (TNI) website maintains a list of available Fields of Proficiency Testing: <http://www.nelac-institute.org/content/NEPTP/fopt.php>

The TNI website has an option for subscribing to e-mail notifications when updates are made to the FoPT tables. **All laboratories are encouraged to subscribe to this notification service and review the FoPT tables periodically for information pertinent to their certifications or accreditations.**

There are Fields of Proficiency Testing for the following matrices: drinking water, non-potable water, and solid and chemical materials.

Where can I find a list of approved proficiency test providers?

The NELAC Institute (TNI) website maintains a list of approved PT providers: <http://www.nelac-institute.org/content/NEPTP/ptproviders.php>

Do I need to perform a PT study if the FoPT corresponding to my accreditation is not on the TNI FoPT table?

No, a Field of Proficiency Testing that is not on the NELAC Institute approved list is not required to be performed for VELAP accreditation or certification. However a NELAC Provider may offer PT samples that have not been approved by NELAP. Although not required to maintain certification or accreditation, successful participation in proficiency studies provides an external validation to a laboratory's internal quality assurance program. For those Fields of Certification or Accreditation where a PT Study is not available by an approved NELAC provider and no proficiency sample was performed, the VELAP assessor will require additional on-site time with data review.

How do laboratories report PT study results to DCLS?

The laboratory communicates the request to the PT provider for results to be directly reported to DCLS / VELAP prior to the closing date of the study.

What steps must laboratories take to ensure successful reporting?

Laboratories are responsible for accurate reporting PT studies in a manner that correlates with the certifications or accreditations held. Laboratories must:

❖ **Assure a specific match between PT results and laboratory fields of certification/accreditation:**

Effective September 1, 2016, VELAP is required per 2009 TNI V2M2 and 1VAC30-45-520 B 7 to consider an analytical result for a FoPT not acceptable *“when the laboratory makes any reporting error or omission that results in a non-specific match between the analytical result for the FoPT and any criterion that identifies the laboratory or the field of accreditation for which the FoPT sample was analyzed for the purpose of initial or continued accreditation.”*

Laboratories assure a specific match between their analytical result for a PT study and their field of certification or accreditation by:

- Assuring the purchase of the correct PT study matrix to correspond with the FOC/FOA.
- Assuring accurate reporting of the analyte to correspond with the FOC/FOA.
- Assuring accurate reporting of the method to correspond with the FOC/FOA.
*Note that **method coding using TNI METHOD CODES** provides the necessary link between the PT provider's records and VELAP records. VELAP will provide the laboratory assistance regarding appropriate method codes for its PT reporting upon request.*

❖ **Submit a PT result for every applicable field of certification/accreditation:**

It is critical that laboratories assure complete PT reporting for EVERY FOA held by the laboratory for every PT study, when a PT is required.

- *Note that when a laboratory analyzes a PT sample one time to satisfy the PT requirements for more than one method of the same technology, **the laboratory must REPORT the PT sample result BY EACH ACCREDITED METHOD.***
- For example, if the laboratory performs a series of volatile compounds in non-potable water by EPA 624 and also holds accreditation for EPA 8260 B in non-potable water, the laboratory **MUST REPORT THE RESULTS BY BOTH EPA 624 AND EPA 8260 B IN ORDER FOR THE PT DATA TO BE RECORDED IN VELAP RECORDS FOR ALL APPLICABLE FIELDS OF ACCREDITATION.**
- **Failure to report the results to the PT provider for each FOC/FOA will result in the assignment of non-participation failures for the un-reported FOCs/FOAs.**
- For drinking water fields of accreditation, the PT must be analyzed by each accredited method; reporting an analysis for all methods in the same technology is not allowed for drinking water samples. (See Drinking Water PT questions, below.)

❖ **Report PT results with respect to the laboratory's lowest calibration standard or customary limit of quantitation (LOQ):**

Per revised regulations for Chapter 45 and Chapter 46 laboratories, effective September 1, 2016, laboratories are no longer required to report PT results down to the TNI FoPT analyte+matrix reporting limit designated on the TNI FoPT tables.

- 2009 TNI V1M1 5.2 directs laboratories to report PT results down to, but not below, the laboratory's lowest calibration standard, or Limit of Quantitation (LOQ) for single point calibrations. Analysis results lower than the low standard (or LOQ) are to be reported as "less than" the lowest calibration standard (or LOQ).
- As these are the current TNI scoring rules and 1VAC30-45 directs laboratories to use TNI-approved PT providers, these reporting instructions are also appropriate for laboratories certified under 1VAC30-45.
- These changes simplify the PT reporting process for all VELAP laboratories as they allow laboratories to treat PT samples in the same manner as routine environmental samples tested by the laboratory.

How do Chapter 46 laboratories satisfy the requirement for two studies per calendar year?

- To maintain certification, dates of successive proficiency rounds for a given PT Field of Testing are to be between five (5) and seven (7) months apart.
- **Failure to meet the semiannual schedule is regarded as a failed study. A failure is assigned if more than seven (7) months passes between successive studies.**
- Note that for the purposes of evaluating PT timelines, a month is defined as a period of time extending from one date to a corresponding date in the next calendar month. For example, from January 15 until July 15 is six months.

What happens if my instrument is down when it is time to do my PT study, or for some other reason I cannot perform the PT before there has been a 7 month lapse since the closing date of the previous study?

The laboratory has two options:

- Accept the PT failure for the affected Fields of Certification or Accreditation for non-participation, OR
- Voluntarily withdraw the certification or accreditation until such time that the lab is able to resume testing.
 - To re-instate certification or accreditation and resume this testing, the laboratory will meet PT requirements applicable to a change in scope.
 - This option will generally require payment of the \$150 base fee for a change in scope as described in the “Information and Fees for Adding Fields of Certification” FAQ document posted on the VELAP web page.

What happens if a laboratory cannot maintain a successful history of PT studies?

- Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document for its own records and provide for DCLS both the investigation and the action taken, upon request.
- For Chapter 46 accreditation, failure of any two out of the most recent three PT studies for a given Field of Certification or Accreditation could result in **withdrawal of accreditation** for the failed fields of testing (See 1VAC30-46 100).
- For Chapter 45 certification, failure to perform annual PT testing as required by the regulation could result in **decertification**.
- To give the laboratory an opportunity to correct this deficiency before decertification or withdrawal of Fields of Certification or Accreditation, DCLS may **suspend** the certification or accreditation for the affected fields of testing for up to six months or the period of certification, whichever is longer.
- Please note that DCLS Standard Operating Procedures regarding suspension will give the laboratories an opportunity to restore the PT history before taking final action to suspend failed fields of testing. The laboratory can perform additional PT studies during this window of time provided to the laboratory to meet the regulatory requirements and avoid suspension.
- Suspension cannot exceed six months or the period of certification, whichever is longer. If the laboratory has not successfully restored certification or accreditation during the allowed suspension period, the Field of Certification of Accreditation will be **decertified or withdrawn**.
- **Suspended Fields of Certification or Accreditation may not be analyzed/reported.**
- Certification or accreditation will be restored for FOCs that have been suspended after the laboratory successfully meets regulatory requirements for PT performance.
- Following decertification or withdrawal/revocation, the laboratory must re-apply for those fields of certification and additional fees will be charged in keeping with Change in Scope procedures.

Can a laboratory perform supplemental PT Studies?

- A laboratory may elect to participate in supplemental PT studies when the laboratory desires to add Fields of Proficiency Testing to its scope of certification or accreditation, or when a laboratory fails an initial or continuing PT study and wishes to re-establish its history of successful reporting.
- **There must be at least 15 calendar days from the analysis date of one study to the analysis date of another study for the same PT field of testing.**

Does DCLS accept revised results from the PT provider?

- DCLS does not accept modifications to analysis results submitted after the close of the study.

What are the special requirements applicable to drinking water PT studies?

A PT sample must be successfully analyzed by every accredited method at least once per year to satisfy PT requirements in 40 CFR 141 through 143 for compliance testing under the Safe Drinking Water Act. To satisfy both the EPA and the NELAC requirements, a laboratory holding drinking water fields of accreditation through 1VAC30-46 must:

- perform proficiency testing continually on a semi-annual basis, and maintain a successful PT history of 2 out of 3 of the most recent PT studies;
- analyze each PT sample by each accreditation method (Note: DCLS requires each accredited drinking water method to be subjected to proficiency testing on a semi-annual basis regardless of the technology.); and
- meet any specialized PT requirements of 40CFR141 or TNI, such as:
 - Volatile Organic Compounds (VOCs) – pass 80% per study and additionally pass vinyl chloride [40 CFR 141.24 (f)(17)(i)(B)].
 - Organic Disinfection Byproducts (Haloacetic acids or HAA5) – pass 4 of 5 HAA5s per study [40 CFR 141.131(b)(2)]
 - Total Trihalomethanes (TTHM) – pass 4 of 4 TTHMs per study [40 CFR 141.131(b)(2)]
 - Gamma emitters – pass 5 of 5 gamma emitters per study [TNI Radiochemistry FoPT Table, footnote 6].