

TNI V1M1 2016 Standard Update Guidance on Proficiency Testing Reporting Limit (PTRL)

GUID-3-114-Rev0 October 15, 2018

This material represents the opinion of its authors. It is intended solely as guidance and does not include any mandatory requirements except where such requirements are referenced. This guidance does not establish expectations of being implemented universally, exclusively, in whole, or in part.

This guidance does not establish or affect legal rights or obligations and is not finally determinative of the issues it addresses. It does not create any rights enforceable by any party in litigation with TNI, its accreditation bodies, or affiliated institutions. Any decisions made by TNI regarding requirements addressed in this guidance will be made by applying the applicable standards, policies or procedures to the relevant facts.

Individuals that have questions about the applicability, scope, and use of this guidance may contact TNI at www.nelac-institute.org

This document was prepared to provide guidance on the evaluation and reporting of proficiency test (PT) sample results to the PTRL for conformance with Module 1 of the 2016 TNI Standard Volume 1, i.e., V1M1. This document does not discuss all sections of V1M1, only those pertinent to PTRL. This document is not intended to be an official interpretation of the Standard, nor is it to be used in place of the Standard. This document is only intended to help users of the Standard understand the changes and implement them in their laboratory. If there are questions regarding the use and implementation of the Standard, contact the appropriate accreditation body. Standard Interpretation Requests may be made through the TNI website.

1.0 The Basics

- 1.1. A Proficiency Testing Reporting Limit (PTRL) is a statistically derived value that represents the lowest possible acceptable concentration for an analyte in a proficiency testing (PT) sample, if the analyte is spiked into the PT sample.
- 1.2. Proficiency Testing Reporting Limits (PTRLs) are specified in the TNI Fields of Proficiency Testing (FoPT) tables.
- 1.3. The TNI Fields of Proficiency Testing (FoPT) tables provide a central location for analyte specific information relating to PT manufacture, composition, and scoring to be used by all applicable stakeholders in support of the Proficiency Testing Program.
- 1.4. TNI FoPT tables are posted on the TNI website at http://www.nelac-institute.org/content/NEPTP/fopt.php

2.0 Evaluating and Reporting PT Sample Results to the PTRL

- 2.1. Laboratories must evaluate and report PT sample results for chemistry analytes to the Proficiency Testing Reporting Limit (PTRL).
- 2.2. How to evaluate your PT sample results
 - 2.2.1. Locate the PTRL on the applicable FoPT table (see link above).
 - Compare the obtained PT sample result to the PTRL (the PTRL cannot be changed for sample preparation amount or percent moisture).

Any result at or above the PTRL must be considered as reportable.

- 2.2.3. Compare the PTRL to the laboratory Limit of Quantitation (LOQ).
 - 2.2.3.1. If the laboratory LOQ is at or below the PTRL, the laboratory may evaluate and report the PT sample result to their LOQ per normal laboratory procedure, instead of to the PTRL.
 - 2.2.3.2 If the laboratory LOQ is above the PTRL, the laboratory must still evaluate and report the PT sample result down to the PTRL. If the PT sample result is below the laboratory calibration range, these options are available to the laboratory:
 - 2.2.3.2.1 re-analyze the PT sample under a new calibration that has been re-scaled to bracket the concentration of the PT sample result: or
 - 2.2.3.2.2 report the original PT sample result without qualification to the PT Provider (e.g. no "J" qualifier).
- 2.3. How to report your PT sample results to the PT Provider
 - 2.3.1. When the PT sample result is a numeric value at or above the PTRL, report the numeric value obtained (remember, if the result is below the laboratory's LOQ, qualification is not required nor accepted by PT Providers).
 - 2.3.2. When the PT sample result is a numeric value below the PTRL.
 - 2.3.2.1. report < PTRL, or

- 2.3.2.2. report the numeric value, if it is at or above the laboratory's LOQ, or
- 2.3.2.3. report < LOQ, if the numeric value is below the laboratory's LOQ.
- 2.3.3. When the PT sample result is a non-detect*,
 - 2.3.3.1. report < PTRL, or
 - 2.3.3.2. report < LOQ.

*CAUTION: If the laboratory's methodology is not capable of detecting a PT analyte down to the PTRL, the laboratory runs the risk of reporting a false negative when the analyte may be spiked into the PT sample. If an analyte is spiked into a PT sample, a reported result of < PTRL, < LOQ, non-detect, or a zero value will be scored as not acceptable.

- 2.4. Examples of PT Evaluating and Reporting to PT Providers:
 - 2.4.1. PT sample result is a numeric value above the PTRL

Example 2.4.1.1: Benzene in Nonpotable Water – Spiked PT Concentration of 12.5 µg/L

- Lab obtained PT sample result = 11.2 μg/L
- ightharpoonup PTRL = 7.0 µg/L
- \triangleright Lab LOQ = 10.0 µg/L
- PT sample result is greater than the PTRL and greater than the lab's LOQ

Report the numeric value of 11.2 µg/L

Example 2.4.1.2. Benzene in Nonpotable Water – Spiked PT Concentration of 12.5 µg/L

- Lab obtained PT sample result = 9.75 μg/L*
- ightharpoonup PTRL = 7.0 µg/L
- \triangleright Lab LOQ = 10.0 μ g/L
- PT sample result is greater than the PTRL, but less than the lab's LOQ
- Because you must evaluate down to the PTRL, report using one of two options

Option #1:

Report the numeric value of 9.75 µg/L

Note: Laboratories may report PT results below their Lab LOQ, but qualification is not required nor allowed. A PT result qualified with an alpha character (e.g. "J" qualifier) will be scored as "No Evaluation" per Volume 3 of the 2016 TNI Standard.

OR

Option #2:

If the result obtained (9.75 μ g/L) is below your lowest calibration standard, reanalyze the PT sample under a new calibration that has been re-scaled to bracket the concentration of the PT sample

Report the **newly obtained** numeric value

*CAUTION: If the laboratory's methodology is not capable of detecting a PT analyte down to the PTRL, the laboratory runs the risk of reporting a false negative in this scenario when the analyte is spiked into the PT sample. If an analyte is spiked into a PT sample, any result reported with a less than "<", as a non-detect, or a zero value is scored not acceptable.

2.4.2. PT sample result is a numeric value below the PTRL

Example 2.4.2.1. Benzene in Nonpotable Water – Not Spiked - 0 μg/L

- Lab obtained PT sample result = 5.2 μg/L
- \rightarrow PTRL = 7.0 μ g/L
- \triangleright Lab LOQ = 10.0 μ g/L
- PT sample result is less than the PTRL and less than the lab's LOQ

Report < 7.0 μg/L or < 10.0 μg/L

Example 2.4.2.2. Benzene in Nonpotable Water - Not Spiked - 0 μg/L

- Lab obtained PT sample result = 5.2 μg/L
- ightharpoonup PTRL = 7.0 μ g/L
- \triangleright Lab LOQ = 5.0 μ g/L
- PT sample result is less than the PTRL, but above the lab's LOQ

Report < 7.0 μg/L or the numeric value of 5.2 μg/L

3.0 PT Provider Scoring

- 3.1. TNI PT Providers must score PTs according to the TNI FoPT tables and Volume 3 of the TNI Standard. This ensures scoring consistency amongst these PT Providers.
- 3.2. Examples of PT Scoring as it relates to the PTRL and LOQ:

Example 3.2.1. Benzene in Nonpotable Water - Spiked PT Concentration is 12.5 µg/L

- Laboratory obtained PT sample result = 9.35 μg/L
- \triangleright PTRL = 7.0 µg/L
- Lab LOQ = 10.0 μg/L
- Acceptance Limits = 8.75 16.3 μg/L

<u>Lab reports < $10.0 \mu g/L$ </u> <u>Lab reports $9.35 \mu g/L$ </u>

Not Acceptable Acceptable

Example 3.2.2. Benzene in Nonpotable Water - Not Spiked - 0 µg/L

- Laboratory obtained PT sample result = 5.2 μg/L
- PTRL = 7.0 μg/L
- \triangleright Lab LOQ = 5.0 µg/L
- ➤ Acceptance Limits n/a

<u>Lab reports 5.2 μ g/L</u> <u>Lab reports < 7.0 μ g/L</u>

Acceptable Acceptable

3.3. Note: As defined, the PTRL is the lowest possible acceptable concentration for an analyte when that analyte is spiked into a PT sample. Therefore, if an analyte is spiked into a PT, any numerical result, including zero, that is reported below the PTRL will be evaluated as not acceptable, as that numerical result will be below the acceptance limits.

4.0 The Derivation of PTRLs

- 4.1. A PTRL for a specific analyte is derived by calculating the lower acceptance limit for that analyte when it is spiked into a PT at the lowest concentration.
- 4.2. Some examples below:

Example 4.2.1 - Arsenic in Drinking Water (Fixed Limits)

Matrix	Analyte	Conc. Range	Acceptance Criteria	PTRL
Drinking Water	Arsenic	5 to 50 μg/L	±30% fixed acceptance limit	3.5 µg/L

- Lowest Spike Concentration = 5 μg/L
- \triangleright Lower Acceptance Limit: 5 μg/L (0.30*5 μg/L) = 3.5 μg/L
- \triangleright PTRL = 3.5 μ g/L

Example 4.2.2 – Benzo(a)pyrene in Nonpotable Water (Regressed Limits)

Matrix	Analyte	Conc. Range	Acceptance Criteria	PTRL
Nonpotable Water	Benzo(a)pyrene	10 to 200 μg/L	a = 0.8207 $b = -0.0550c = 0.1484$ $d = 0.4349$	2.4 μg/L
Tromportable trater	Σ σιι Σ σ(α) ρ γισιισ		c = 0.1484 $d = 0.4349$	

- Lowest Spike Concentration = 10 μg/L
- ightharpoonup Predicted Mean = (10 μg/L * a) + b = (10 μg/L * 0.8207) 0.0550 = 8.152 μg/L
- Arr Predicted Standard Deviation (SD) = (10 μg/L * c) + d = (10 μg/L * 0.1484) + 0.4349 = 1.9189 μg/L
- ► Lower Acceptance Limit = predicted mean (3 * predicted SD) = 8.152 μg/L (3 * 1.9189 μg/L) = 8.152 μg/L 5.7567 μg/L = 2.3953 μg/L = 2.4 μg/L
- \rightarrow PTRL = 2.4 µg/L
- 4.3. Contact your PT Provider if you have additional questions regarding the derivation of acceptance limits and/or PTRLs.