

Volume 1 Module 1

The NELAC Institute Proficiency Testing Committee's Responses (in italics) to Comments

Date: 20 December 2007

# Memo

To: TNI  
From: Thomas Coyner  
CC: File  
Date: July 24, 2007  
Re: Volume 1 Module 1 Negative Vote with Comments

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This is a continuation of comments submitted online. These comments are in the TNI format.

## Section 3.9

This definition is correct but is inconsistent with the PTRL as presented in the FOT tables for solids and chemicals which were established based upon the "best guess" of a sub-committee without review or consensus vote.

Suggested resolution: correct FOT table to remove PTRL where inappropriately calculated.

*Response: Non-Persuasive. The FoPT tables are published by the TNI PT Board. That said, the definition from PTRL was removed from this module because the term is no longer used in this module.*

Section 4.1.5 Note: line 2. "requested" This should be changed to "required"

An Accrediting Body (AB) may require a PT sample for an FOT that is not covered under TNI FOT tables either experimental or accreditation. However, this accreditation would be AB specific and not covered under the TNI system. Therefore, the lab could be required to meet any AB specific criteria for this accreditation.

Suggested resolution: see above.

*Response: Persuasive. The “note” in 4.1.15 was removed.*

#### Section 5.1.2:

PT results for multiple methods are evaluated separately by the PT providers. However, AB's make the final decision on acceptability of PT results. Currently, AB's are inconsistent in their application of this section. What is the penalty for an AB who does not perform according to the Standard.

Suggested resolution: Place requirements on the AB's to execute this policy if that is truly what is needed or evaluate PT's according to FOT which is matrix/METHOD/analyte and allow pass/fail for different methods and same analyte.

*Response: Non-Persuasive. Inconsistency in implementation or application of the standard between AB's is program issue that should be resolved above the committee level. That said the committee agrees that there needs to be specific language in the AB volume to address this issue. The change from “technology” to “method” is a substantial change to the PT program for which consideration will be held until the next revision.*

Section 5.1.3 typo add P to end of sentence should be “PTP”

*Response: Persuasive. A “P” has been added to the end of the sentence.*

#### Section 5.2.2

It has been traditional in NELAC that labs are to treat PT's as samples and report PT's as less than their reporting limit or the PTRL. Many labs run calibrations to zero but their lowest standard might be well above zero or above the PTRL. How should a PT result reported as less than something greater than the PTRL be evaluated. For example: Assigned Value=0, PTRL 5, reported result <20 (lowest calibration). Is this acceptable?

Suggested resolution: Non-detect or analytical values less than the PTRL should be reported as less than the PTRL.

*Response: Non-Persuasive. The elimination of reporting to the PTRL was a deliberate change made by the committee. The purpose of the change was to eliminate the reporting of estimated values without qualification and eliminate the need for laboratories that do not normally operate in the range of the PTRL to modify their method solely to run the PT sample. The reporting change (to the low calibration standard) ensures that laboratory performance within the range of quantitation is evaluated. Similar changes were made to the AB and PTP volumes to specify how to evaluate and assign performance scores to accommodate this reporting change so that there is not a negative impact to laboratories.*

## Section 6.2

This requirement places the burden of a PT provider error on the laboratory which is inappropriate. The burden should be placed upon the PT provider who should be required to correct the problem.

Suggested resolution: Remove section referring to an error by the PT provider.

*Response: Non-Persuasive. Item d in this section is for when the laboratory chooses to use a non-accredited PTP, not when there is an error made by the PTP. Please note that this section was removed in its entirety from the laboratory module because it describes requirements applicable to Accrediting Bodies.*

Section 7.2 b. and d. These appear to be redundant delete one.

*Response: Persuasive. 7.2.b has been deleted.*

## Section 8.1 line 1

“PT samples or performance evaluations” These are not the same thing.

Suggested resolution: delete “performance evaluation”

*Response: Non-Persuasive. The committee did not intend for PT sample or performance evaluations to mean the same thing. The PTP provides PT samples and the PTP provides a performance evaluation of “acceptable” or “not acceptable”, both or either of which a laboratory may have a question or concern and these shall be referred to the PTP.*

Tom Coyner

July 24, 2007