Volume 3

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 3 Negative Vote with Comments

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

Section 3.9 This definition is consistent with previous versions of the Standard but inconsistent with the way PTRL's were calculated for some FOT elements.

Suggested resolution: Revise FOT to be consistent with definition.

Response: Non-Persuasive. The PT Committee does not have the ability to modify the FoPTs – that is a function of the TNI PT Board.

Section 3.11 This is not a definition but a set of requirements that cannot be met by either the PTP or the laboratory if a third party is involved. See comment on Volume 1 Module 1 and Volume 4. A study is simply a distribution of samples with a start date and a close date. If there are other requirements these should be built into other sections of the various standards.

Suggested resolution: Correct definition and add requirements.

Response: Persuasive. A definition based on international standards will be used.

3.18 The definition clearly identifies that the duties of the PTB are defined in its charter. The "addition" duties an rights assigned to the PTB by the PT Committee in this volume are inappropriate and must be removed.

Suggested resolution: Remove sections of volume assigning rights and duties to the PTB.

Response: Persuasive. It is assumed that Mr. Coyner is referring to the "additional" responsibilities listed in the note in Section 1.1 which has been removed.

Section 4.4 This requirement is vague and is an attempt to justify the release of proprietary data to the PTPA outside the guidelines of international standards. There is no definition of what data is to be released and a "blank check" is totally inappropriate. The data generated by the labs are the proprietary information of the labs and cannot be released. Similarly, the summary data and internal testing results of the PTP's are the proprietary data of the PTP's and neither TNI nor the PTPA has any right to that data.

Note that the PTPA has the right to review PTP data only as provided by contractual agreements between the PTPA and the PTP.

Suggested resolution: Delete this requirement as being inappropriate and outside the scope of TNI to require.

Response: Non-Persuasive. This requirement is not an attempt to justify the release of proprietary data to the PTPA. This requirement is intended to allow flexibility for the PTPA to complete its oversight responsibilities understanding that the data to be collected are not currently defined and may change in the future as new programs are added to TNI and the PTPA makes changes to its database. TNI, and the PTPA, do have a right to this data to the extent that TNI has established this as a requirement for a PTP to participate in the TNI program. The committee believes that there are sufficient protections for the PTPs through the PT Board should the PTPA make inappropriate requests.

Section 4.4.1 This is another "blank check" for the PTPA to establish any format and frequency without review or agreement by the members of TNI as to the appropriateness of the imposed requirements. This is again totally inappropriate and well outside the authority of TNI to authorize. If data is to be submitted to the PTPA it must be covered under a confidentiality agreement, must be clearly define in a consensus process, and must be limited to the actual data required by the PTPA to meet clearly defined consensus develop ed requirements. This Standard does not provide these limitations and protections.

Suggested resolution: This section must be deleted until such time that the requirements for data are defined through a consensus process and the data can be properly protected by confidentiality agreements.

Response: Non-Persuasive. See response to comment to section 4.4 above.

Section 4.5.1 This section requires that a timeframe for reporting be added to the requirement. It is suggested that the report be submitted within 10 days by the PTPA to the PTP. This report should include at a minimum: the method use, dilutions used, complete calibration data, contract lab quality control results, and traceability of analysis.

Suggested Resolution: See comment for details.

Response: Persuasive. Section 4.5.1 has been removed as the committee has determined that participation in PT programs is not an appropriate requirement for PTPs.

4.5.2 The PTPA is required to have a due process appeals process in place. This process should be used prior to submittal of anything to the PTB. The PTB does not in fact have a due process appeals process and direct submittal to the PTB would undermine the rights of the PTP.

Suggested resolution: If a conflict between the PTP and the PTPA cannot be resolved by the internal appeals process of the PTPA then the matter may be submitted to the PTB for further resolution.

Response: Persuasive. See response to 4.5.1 above.

Section 4.6 The section refers to "specified" samples but there is no specification. This requirement needs better definition. The samples should be requested at least 90 days before the start of a study in writing, the number and use of the samples must be specified in the request, and finally since the PTPA is receiving compensation for the accreditation process, they should pay for the samples. Thousands of samples were submitted to NIST that were never used for any purpose at great cost to the PTP's and ultimately to the laboratories.

Suggested resolution: See comments for additional text.

Response: Persuasive (add clarfication). The committee has added additional description to clarify the requirement.

Response: Non-Persuasive (request prior to study and compensation). The intent of the requirement is for samples to only be requested by the PTPA in the case of a questionable PT study, therefore they can not be requested prior to the study opening. The requirements related to the PTPAs requesting and handling such samples are included in Volume 4.

Section 5.1.3 ILAC G13 should be added as a normative reference.

Suggested resolution: Add ILAC G13 to section 2

Response: Persuasive. ILAC G-13 has been added to Section 2.

Section 5.1.5 This section is in conflict with standard international guidelines covering mutual recognition agreements. Normally, if accreditation or certification is received and an MRA exists between two PTPA then each accepts the others accreditation without reservation similar to reciprocity in the old NELAC system. Review by a second accreditation body is totally unnecessary and a cost burden on the PTP that cannot be justified.

Suggested resolution: PTPA should accept accreditation by a MRA member as being sufficient to meet requirements in 5.1.1 through 5.1.4 and not be permitted to audit against those requirements.

Response: Non-Persuasive. It is common in this industry for various accreditors to review general quality system requirements, even though a company's quality system has already been accredited. The committee believes that there is value associated with the PTPA reviewing all aspects of the PTP's quality system and manufacturing process as it relates specifically to the TNI program.

Section 5.2 g) The note under this section is not with the power of TNI to deceide. The PT summary data is the proprietary data of the PTP and they deceide who to release it to and who they will not release it to and under what conditions. Furthermore, notes are no standard requirements.

Suggested resolution: The note must be deleted.

Response: Non-Persuasive. The committee agrees with Mr. Coyner that the summary data belongs to the PT Providers. The purpose of the note is to ensure that this information is documented somewhere even though it is not a requirement, but an allowance.

Section 6.1 a) This is an impossible requirement. Many of the TNI FOT limits were developed based upon criteria which are not technical valid as judged by technical experts in the field. Therefore, it is unknown whether laboratories or PTP's can meet those limits. Similarly, there is no generally accepted criteria which exist to define this requirement. This means that the PTPA auditors will make individual judgments and this will lead to inconsistencies in the PT samples supplied under the TNI standard.

Suggested resolution: Delete requirement or define the technical criteria that must be met.

Response: Non-Persuasive. This section is needed to ensure that PT Providers perform fitness-for-use testing prior to releasing a new PT product.

Section 6.1 b) There is no definition of "equivalent challenge" and no generally accepted technical means to verify "equivalent challenge". Therefore, this requirement cannot be met as written.

Suggested resolution: Delete section or provide technically valid criteria.

Response: Non-Persuasive. This requirement is needed to ensure that the PTP's fitness-for-use studies take into account various analytical methods that may be used by laboratories as well as other conditions that could create differences between groups of labs.

Section 6.1 c) There, of course, no "historic norms" for pass/fail and this term is no defined. As noted elsewhere in the comments, the pass/fail rate of any provider is unique and determined by sample design, homogeneity, stability, and most importantly lab population. There is no evidence that this criteria could be met.

Suggested resolution: Delete requirement or provide technically valid criteria.

Response: Non-Persuasive. The PTPA, through their oversight responsibilities, will be generating this data.

Section 6.2.1 What is "well-characterized" there is not definition. Similarly, section 6.2.1 requires that the matrix be as natural as possible. Sand is a natural matrix. What is the technical justification for the 90%? What technical evidence exists to support this apparently arbitrary requirement?

Suggested resolution: Remove requirement or sight references to appropriate matrices.

Response: Non-Persuasive. The requirement for "well characterized" has been in the standard since its inception and has not caused problems. The PTPA will have to use their expertise to make determinations relative to this point. The justification for no more than 90% sand is to ensure that a provider does not use a sample that is effectively all sand which, while "natural", has a much higher extraction efficiency for most analyses than does a soil that contains some silt and clay.

Section 6.3.1 This is another of the "blank check" requirements. The PT Committee is giving the PTB unlimited control over the criteria that the PTP's must meet without review by TNI

members or participation in the consensus development process. This is absolutely inappropriate and inconsistent with the consensus develop process.

Suggested resolution: This section must be deleted.

Response: Non-Persuasive but will provide clarification. This section refers to the requirements in the FoPT tables, so the section will be edited to state this. This requirement has always been in place and has not resulted in any reported problems. The PT Committee is not giving the PT Board this control, TNI has given the PT Board this control.

Section 6.3.2 This section of the NELAC Standard provide for a six month implementation by the PTP's. Since PTB decisions are not within the consensus process and are purely arbitrary and could be impossible to met, it is suggested that the six month implementation requirement be added to this section.

Suggested resolution: Revise language to require implementation of changes within six months of approval by the TNI Board of Directors.

Response: Non-Persuasive: There may be minor changes to the FoPTs that can and should be implemented in a time period shorter than 6 months. TNI has established the TNI PT Board to implement the PT program and it is not up to the TNI PT Committee to determine its make up or process of making decisions.

Section 6.3.3 This previous standard the language only applied to organic standards. This language would allow PTP's to omit inorganic as well as organic parameters.

Suggested resolution: Only a clarifying comment.

Response: Persuasive. While Mr. Coyner is incorrect that the previous standard (NELAC Chapter 3, 2003) only applied to organic standards, it is understood that this was the intention. Those standards that can have analytes left out are now documented in the FoPT tables. The committee will make reference to this in this section.

Section 6.3.6 What technical criteria need to be met to insure that additional analytes do not interfere? This is a poorly defined requirement.

Suggested resolution: Revise to say "do not interfere as demonstrated by…(add appropriate criteria)…"

Response: Persuasive. The committee has added that this requirement must be demonstrated to the satisfaction of the PTPA.

Section 7.1.2 Incomplete listing of reference material producers.

Suggestion resolution: Add at end of sentence "other Certified Reference Material producers."

Response: Non-Persuasive. By definition, e.g., indicates a partial list. The following section, 7.1.3, indicates what to do when a primary reference material is not available.

Section 7.1.4 This is a redundant requirement since the analysis is already traceable or verified by a third party standard.

Suggested resolution: Delete requirement as adding nothing to the quality of the analytical result.

Response: Non-Persuasive. It is common in environmental analyses to run both a calibration standard and a calibration check standard during each analysis. The committee believes that `this requirement adds to the level of assurance as to the accuracy of the assigned values.

Section 7.1.9 Many of the solid matrix analytes have acceptance limits that are based upon study data (i.e. Mean±3SD), for these analytes what is the expected mean? Also many of the solid sample methods are highly biased, how should the expected mean be calculated?

Suggested resolution: Clarify exact technical requirements or allow exception where limits cannot be calculated.

Response: Non-Persuasive. This requirement is in the current standard and providers have found ways to handle it.

Section 7.1.10 For analytes with interlaboratory limits there is no SD at the point of verification. Therefore this requirement cannot be met in some cases.

Suggested resolution: Clarify technical requirement where this section cannot be met.

Response: Non-Persuasive. This requirement is in the current standard and providers have found ways to handle it.

Section 7.2.2 As commented last year, without response, the procedure in Appendix A is an unverified, one off, procedure which has no national or international technical standing and should be deleted. Similarly, most international standards require the use of a generally accepted statistical protocol for both homogeneity and stability testing. This language must be revised to reverse the order of preference. The requirement should be: generally accepted statistical procedure or equivalent. The Appendix A procedure is not technically equivalent.

Suggested resolution: Require use of a statistically valid, generally accepted, procedure or equivalent.

Response: Non-Persuasive. Appendix A provides a method specific to the US environmental PT industry. Providers are able to use any other method that produces equivalent or greater assurance as to the homogeneity and stability of their PT samples.

Section 7.3.4 Appendix A does not include a generally accepted suitable procedure. The note should be deleted.

Suggested resolution: Require the use of a generally accepted, technically valid, procedure for stability testing. Delete the note.

Response: Non-Persuasive. Appendix A provides a method specific to the US environmental PT industry. Providers are able to use any other method that produces equivalent or greater assurance as to the homogeneity and stability of their PT samples.

Section 7.4.3 This is an attempt by the PT Committee to justify the release in an uncontrolled fashion of the proprietary data of the PTP's. TNI and the PTB have no contractual relationship with the PTP's and they similarly have no right to require the release of proprietary data. This section must be deleted.

Suggested resolution: This section must be deleted.

Response: Non-Persuasive. This requirement is not an attempt to justify the release of PTP proprietary data. This requirement is intended to allow the PT Board to conduct investigations when concerns are raised about a specific PT study. TNI does have a right to this data to the extent that TNI has established this as a requirement for a PTP to participate in the TNI program.

Section 7.4.4 The PTPA currently have access to this information on-site at the PTP's facility. In order to verify the performance of the PTP's this information need not be sent to the PTPA as required. Note that the PTPA has a contractual obligation to protect this data and is required by ISO 17011 to meet that obligation.

Suggested resolution: Delete as unnecessary.

Response: Non-Persuasive. This requirement is needed to allow the PTPA to conduct the oversight required of them. The committee aggress that the PTPA does have an obligation to protect this data.

Section 7.4.5 This is another "blank check" requirement. The format of any data released by a PTP, the specific data to be released, and the schedule of such release must be part of the consensus standards development process. It is absolutely inappropriate to require the release of anything in an unspecified format or on an unspecified schedule.

Suggested resolution: This section must be deleted.

Response: Non-Persuasive. This section allows the PTPA to establish a data format and schedule for receiving the required data. Until such time as this system is developed, it would be inappropriate for this standard to dictate that level of detail. Even after a system is established, this standard must allow for revisions that may need to be made. The committee believes that there are sufficient protections for the PTPs against any inappropriate requests made by the PTPA.

Section 8.1 NELAC studies have always been 45 days. There is no need for the final clause which says that the PTB can change the length of any study with consensus review or approval and does not even include under what circumstances this could be done. This is another "blank check" to the PTB.

Suggested resolution: Delete the final clause referring to the PTB and totally inappropriate.

Response: Non-Persuasive. As new PT programs are added to TNI (possibly DMR-QA with a three-month time frame) the committee understood that it was necessary to provide flexibility for the PT Board to establish criteria at this level of detail.

Section 8.2.2 b) We have had this discussion in NELAC a thousand times, neither TNI nor the individual States or AB's have any right to tell the PTP's how to market or handle their Quality Control samples or any materials not required by this program. It is appropriate for TNI to prohibit the labs from using additional QC samples and that exists in Volume 1 Module 1.

Suggested resolution: Delete item b.

Response: Non-Persuasive. The committee feels that TNI should have this authority, through the PTPA, in order to keep PTPs from encouraging laboratories to analyze QCs in a manner that could result in a finding from their accrediting body.

Section 8.3.1 This is an impossible requirement because of the mention of a third party entity. The PTP can insure that they have not provided the material to the lab but they cannot insure that it have not been provided by a third party through or through a non-TNI study.

Suggested resolution: Remove "by any entity" and clarify requirement.

Response: Non-Persuasive. PTPs can meet this requirement by not releasing PT study samples to any entity prior to the opening date of their PT studies. This requirement is needed to ensure that all PT studies are truly blind to all participant laboratories.

Section 8.3.2 It can be argued that since the PTPA is a private entity that the assigned values should not be released to them prior to the close of a study because the PTP loses control once the values are released to anyone and therefore has no liability for release by a PTPA.

Suggested resolution: Comment for consideration.

Response: Comment considered. Whether the PTPA should receive data prior to, or during, a PT study can be controlled by the PT Board. By leaving the section as is, it allows for this release should it be deemed necessary.

Section 8.4.4 This is a requirement for the laboratory to meet and is in Volume 1 Module 1. The PTP cannot determine if the lab participated in another PTP's program within 15 days.

Suggested resolution: Delete from this Volume covered in Volume 1.

Response: Persuasive. This is a laboratory requirement and is addressed in Volume 1. This section has been removed from Volume 3.

Section 10.1.1 What criteria are to be used for this analysis and what action is to be taken. This is an incomplete requirement.

Suggested resolution: Clarify criteria and require action or delete the section.

Response: Non-Persuasive. Providers should develop their own criteria and follow their quality system requirements for handling questionable data. Section 10.1.2 provides guidance for some instances when multi-modal distributions are found.

Section 10.1.2 This section is in direct conflict with the FOT requirements and should be deleted.

Suggested resolution: Delete the section.

Response: Non-Persuasive. This section is not in conflict with the FoPTs. It provides an option for separating out multimodal data only if the FoPT indicates that the data are to be evaluated using robust statistics.

Section 10.1.3 See previous comments of historic norms for pass/fail rate. Furthermore, there is no requirement in the section if unusual rates are found.

Suggested resolution: Delete as not being a requirement.

Response: Non-Persuasive. PTPs have their own historical norms and industry-wide norms may be available in the future. The PTPs' quality system should provide a mechanism if unusual rates are found.

Section 10.2.5 We have comment for five years that the use of the biweight for large sample sizes is inappropriate and this was a typo in the original criteria document. The biweight should be used of samples LESS THAN 20. For sample sizes greater than 20 the Actual mean and standard deviation should be used. Please make the correction. Finally, the requirement is 10.2.5 c) is new and inappropriate. The EPA criterion to use the biweight covers small samples. If there is a limit 7 cannot be justified technically. An criteria used to determine lab evaluations must be subject to consensus approval. Trusting the PTPA to make that decision will lead to inconsistent treatment of labs.

Suggested resolution: Finally get the number straight in a) and b) and delete c)

Response: Non-Persuasive. (10.2.5) Dr. Kafadar's article shows that the biweight procedure breaks down at sample sizes <20. Discussions with Dan Tholen and another statistician supported that it is not inappropriate to use biweight statistics on larger data sets.

(10.2.5 c) The purpose of having the PTPA review the procedures used for sample sizes <7 is to help provide a greater level of assurance that labs are treated consistently.

Section 10.2.7 There are no limits calculated based on Median.

Suggested resolution: Delete as useless.

Response: Non-Persuasive. There are currently no limits calculated using the Median, but this section allows TNI flexibility should it add DMR-QA Whole Effluent Toxicity, or some other FoPT that does use the study median to calculate limits.

Section 10.3.3.1.1 Requires that if a less than is reported for an unspiked analyte then the results is acceptable. Consider the case of a lab that reports less than 200 and the PTRL is 5 should this lab be acceptable.

Suggested resolution: Comment for consideration.

Response: Comment considered. The committee has discussed this issue and determined that this approach is the best option for solving the problem related to laboratories with detection or reporting limits higher than the ones currently allowed by the FoPT tables.

Section 10.3.1.2 I cannot interpret this requirement. If a lab reports less than 117 and the lower acceptance limit is 17 then the lab is acceptable even though the upper limit was 25. This makes no sense. Please correct logic.

Suggested resolution: Provide correct logic or better explanation of the issue.

Response: Non-Persuasive. The committee has determined this to be an acceptable method for dealing with those laboratories with higher detection/reporting limits. Mulitple ABs have approved of this method.

Section 10.3.5 (NEW) How should the lab be evaluated if the PT sample is invalidated by the PTP. I suggest that it be a "No evaluation". Please add for clarity.

Suggested resolution: add per comment.

Response: Persuasive. This section has been added.

Section 11.2.4 d) This information is not available to the PTP's.

Suggested resolution: Delete as not required to be reported.

Response: Non-Persuasive. This information is available to the PTPs via their scope of accreditation provided by their PTPA.

Section 11.2.4 j), k) these are unclear as written.

Suggested resolution: Change language to "mean used for evaluation" and "standard deviation used for evaluation".

Response: Persuasive. Further clarification has been added to these items.

Tom Coyner

July 24, 2007