

Volume 4

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 4 Negative Vote with Comments

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

Section 3.7 As noted in comments on two other modules this is not a definition but a set of requirements which cannot be met by either the labs or the PT providers. Each group has only limited knowledge of what has been provided to a lab. If sample were provided by a third party neither the lab nor the PT provider would have that knowledge. Therefore, this section should be a definition, see other comments, and the requirements should be rewritten as sections in the appropriate module.

Suggested resolution: see Volume 1 Module 1 definition submitted. Add appropriate requirements to the lab and provider modules.

*Response: Persuasive. Definitions should be consistent. This definition could be reworded to have same meaning.*

Section 3.8 This section clearly defines the duties of the PT Board as being contained in its charter which is not a consensus document. It is inappropriate for the PT Committee to define or expand upon the PT Board charter.

*Response: Non-Persuasive. This issue has been discussed at length at the last 3 TNI meetings, especially at the 2007 Boston meeting, and there is general acceptance of the need to retain this section. The main reason expressed by many TNI members,*

*PT Board members, and PT Expert Committee members is that these requirements should be part of the consensus process, not dictated by an external body.*

Section 3.9 (to be added) This section should contain a clear unambiguous definition of the PTRL. There is a definition in the other PT Volumes and Modules and while the definition is consistent with NELAC history it is not consistent with the way PTRL's were calculated for some FOT's tables.

Suggested resolution: add definition from other modules after correction or correct FOT tables.

*Response: Persuasive. The definitions will be harmonized as appropriate across volumes.*

Section 4.0 and 4.1 As noted several times and recorded in previous comments on previous drafts to the PT Committee, it is totally inappropriate for the PT Committee to be assigning rights, duties, or responsibilities to the PT Board. Furthermore, the section is vague and general in nature and could be interpreted to give the PT Board unlimited power and authority in direct conflict with the consensus Standard which will be voted on by the membership. PT Board decisions are not subject to review by the membership and the Board is not a consensus body.

Suggested Resolution: Delete the section since the PT Board establishes its own policies and procedures.

*Response: Non-Persuasive. See above for section 3.8. There is general agreement with this comment (but not the suggested resolution) - that the PT Board policies and procedures should be subject to review by the TNI membership and in a forum with a balanced representation of stakeholders, which is why this section should remain in the TNI standards.*

Section 4.1.1 This section appears to define the "content" of PT programs referred to in Section 4.1. As a Standard, this list is a definition, however, the details of each element are vague which would essentially allow the PT Board to do anything it wishes in establishing "content" for the TNI program. If this section is to remain and I strongly caution against it then there needs to be careful definitions of each of the items in the list. For example: How must the PT Board establish concentrations ranges or acceptance limits for each analyte. Must all of these items be determined based upon technically valid criteria? What are appropriate measurement technologies and why is the PT Board technically competent to perform any of these task.

Suggested resolution: Delete the entire section as vague, ambiguous, and giving uncontrolled power to the PT Board.

*Response: Non-Persuasive. See above response for retaining the section. PT Board policies and procedures will provide details on establishing concentrations and acceptance limits. The PT Board is composed of TNI members that represent all stakeholder interests, per TNI bylaws, and so does not give unlimited powers to the PT Board.*

Section 4.1.2 This is the only mention in any of the PT Volumes or Modules to data quality objectives. What are these in relation to the PT program? Are these related to PT providers or to the labs? There are no guidelines or requirements in the Standard for how the PT Board is to set DQO's which in theory they will use to set acceptance limits. This makes no sense. The PT Board could simply say that every third lab must fail and under this standard could write acceptance limits to cause this to happen without review by the membership.

Suggested resolution: Delete it section as vague, unclear and unnecessary.

*Response: Persuasive. Requirement deleted (sections renumbered); also "data quality objectives" changed to "acceptance limits" in (previous) section 4.1.4).*

Section 4.1.3 This section give the PT Board the right to set PT acceptance limits but places no requirements upon them as to how this must be done. This give the PT Board unlimited and uncontrolled power to establish limits that are inappropriate, arbitrary, or even technically invalid within out review or acceptance of the membership. This is totally inappropriate.

Suggested resolution: Delete this section or provide detailed requirements for how acceptance limits must be determined. If detailed requirements are provided they must meet the requirements noted in the Scope section 1.2

*Response: Non-Persuasive. The current language allows flexibility in setting limits, which will vary by analyte and possibly by matrix. The PT Board has representation that balances all stakeholder groups, and has accepted procedures for determining limits. The vast majority of comments at recent TNI (INELA) meetings have supported retention of these requirements in this Volume, to assure that the requirements for the PT Board are governed by the TNI consensus process.*

Section 4.2.1 This section does not say how the PT Board must "assure" that requirement of section 5 are met. It is suggested that language be added to require that a PTPA meet all requirement of ISO 17011 and that the PT Board audit the PTPA against these requirements on a biennial basis.

Suggested resolution: Provide language around "assure" to explain how this is to be done. Add the auditing requirement to ISO 17011.

*Response: Non-Persuasive. the requirement that the PTPA must be international recognized as being in compliance with ISO/IEC 17011 provides the suggested assurance.*

*Response: Persuasive. “biennial on-site” added to Section 4.2.3.*

Section 4.2.2 Neither TNI nor particularly the PT Board has any right to review or assess procedures and policies outside the scope of this Standard and should be limited to the PTPA polices and procedures related to the accreditation of PT providers. Apparently the TNI PT Board wants to have absolute control other any entity even remotely associated with the TNI process and is requiring the PT Committee to provide that control.

Suggested resolution: Limit the right of the TNI PT Board to review only policies and procedures related to the TNI PT provider accreditation program operated by the PTPA which makes more sense.

*Response: Non-Persuasive. The requirements in Volume 4 apply only to approval for TNI Proficiency Testing. However the PTPA may be obliged to assess to other requirements because of the need to be recognized as compliant with ISO/IEC 17011 and other internal policies that are necessary for international recognition.. The TNI PT Board needs to be aware of and approve those requirements as appropriate for TNI PT providers, but they do not need to assess the PTPA for compliance with those requirements.*

Section 4.2.3 This section is vague and contains no useful requirement.

Suggested resolution: Delete this section as unnecessary.

*Response: Non-Persuasive. As requested above, “biennial on-site” was added as detail to the assessment requirements.*

Section 4.3.1 This is another section which gives the PTB unlimited power in establishing, or possibly ignoring, its responsibilities in relationship to the PTPA and most importantly the members of TNI.

Suggested resolution: Delete this section or actually provide detailed requirements that the PTB must meet in fulfilling its obligation to TNI to operate a technically adequate PTPA assessment scheme.

*Response: Persuasive. The phrase “consistent with this Standard”, was added to provide the requested detail. The TNI PT Board has policies and procedures that will provide other details. The PT Board is ruled by TNI bylaws requiring openness and balanced representation, so they do not have unlimited power.*

Section 4.3.2 This section requires some sort of arrangement between the PTB and the PTPA to collect information about PT programs from the PT providers. First of all, TNI is a Standard Development organization and has no contractual relationship with any PT provider and therefore has no right to collect the proprietary information of PT providers without payment of fees to acquire that information. Secondly, the establishment of an “arrangement” presumably a contract between a PTPA and the PTB would be an apparent conflict of interest between the PTB and the PTPA since both would have a vested interest in maintaining the contract. Finally, any PTPA that would participate in such a contract would be in direct violation of ISO 17011 and compliance with ISO 17011 is requirement of this standard.

**The collection of proprietary PT provider data by any part of TNI is absolutely inappropriate since TNI has no contractual relationship with the PT providers. It is a recognized fact that PT summary data and internal testing data of the PT providers is the proprietary property of the provider. The Standard cannot set up a system where the proprietary rights of private firms are violated without risking legal challenge.**

However, PT results and summary PT data as required by this Standard are released to the AB’s as a regulatory requirement of the States. TNI is free to assemble available information from the States if this information is not protected by the CBI laws of the States. However, a fee based contract between a PTPA and TNI is highly inappropriate and would probably be challenged.

The section does not specify who owns the rights to such a database. Ownership by the PTPA would be in conflict with ISO 17011 while ownership by TNI would raise further legal complications.

Finally, item b) iv is an open door for the collection of any and all proprietary information about either the PT providers or their participating laboratories.

Suggested resolution: This entire section must be deleted.

*Response: Non-Persuasive. There must be a database for oversight of PT programs and the TNI PT Board must take responsibility to assure it is developed and remains operational. These requirements place severe limits on the extent of the data that is collected and the use of the results, as do subsequent requirements. No confidential laboratory information will be requested for oversight purposes. Only summary data will be collected, and will remain confidential to the PTPA, regarding the provider or other identifying information. The database will be controlled by the PTPA, under current ISO/IEC 17011 confidentiality requirements. Requirements for the ownership of the database and operations of oversight analysis are controlled by PTB policies and PTPA procedures.*

*Response: Persuasive. Item iv was changed from “to meet these requirements” to “the requirements of section 6.3”.*

Section 5.1.2 b) This is unclear and not standards language. What does “have access to” or “expertise that conforms with” mean?

Refer to the Note in this section. What does “accredited subcontractors” mean? What must subcontractors be accredited to do? I am not aware of any accreditation that covers technical auditors.

Suggested resolution: Clarify the exact requirements. Delete the note as being unnecessary.

*Response: Non-Persuasive. No change to the 5.1.2 b) is necessary and this language is conventional for standards. The clause states that the PTPA must have access to competent experts regarding both the relevant standards and materials. This is included in the requirements for ISO/IEC 17011 and international recognition.*

*Response: Persuasive. Note to 5.1.2 b) deleted. This was confusing because it referred to the PT provider, not the PTPA.*

Section 5.2 The TNI Standard is the TNI Standard and the requirements for the PT providers are detailed in Volume 3. Therefore, the text in () is confusing. If other requirements exist then they must be part of the Standard or they do not apply. Note: Standards do not include () text.

*Response: Persuasive. Deleted the following text within the parentheses “(which could include other standards, as appropriate)”.*

The language “All activities described herein shall be conducted by a PTPA.” Is unnecessary and vague. If “herein” refers to Volume 4 it is clearly incorrect since PTB duties are included in Volume 4. If “herein” refers to section 5.2, the section already says that oversight to requirements in Volume 3 is required.

*Response: Persuasive. The phrase “All activities described herein shall be conducted by a PTPA.” was deleted as unnecessary.*

The note is very poor standards language. The Standard does not allow variation from requirement in Volume 3 so that part of the note is incorrect. The final part of the note refers to “additions to these requirements”. Since the Standard must contain all requirements of TNI and TNI has not right to audit requirements outside the Standard, this part of the note is incorrect.

Suggested resolution: Delete text in (). Delete last sentence of paragraph 1. Delete the note.

*Response: Persuasive. Deleted the language in the parentheses () only.*

*Response: Non-Persuasive. Keep the last sentence of the paragraph. The PTPA may have other requirements, and it is possible that other standards will reference the TNI standard. The Note was upgraded to a requirement to assure that the PT Board is aware of and approves the additional requirements.*

Section 5.3 The Note appears to authorize the PTPA to include requirements outside of the Standard. This is inappropriate because the Standard must include all requirements of the TNI system and TNI has no right to interfere with the operation of programs outside of the Standard. Furthermore, notes are not requirements of the Standard so the note has no standing.

Suggested resolution: Delete the note.

*Response: Persuasive. The note is deleted (however other parts of this Volume retain the need to consider other requirements, as explained above).*

Section 5.3.1 This section requires the PTPA to have procedures for several very vague items. However, it places no detailed requirement on any of the items in the list. Therefore, all of these requirements are not auditable since any procedure, correct or incorrect, would meet section 5.3.1

It is unclear what item d) in the list refers to. It says that the PTPA must have a procedure for submittal of final reports to the PTB. Whose reports, the PTPA's or the PTP's, or the labs? What must be included in this report? There is no specification in this section.

A similar problem exists with items e) and f). There is no requirement that explains under what circumstances revocation of accreditation is appropriate or required. There is no requirement around what constitutes a legitimate appeals process under the Standard.

Suggested resolution: Either delete the section as unnecessary or provide a true set of detailed requirements around the items in the list and make the section auditable.

*Response: Non-Persuasive. The requirements only state that procedures must be developed, not what they must contain. Other requirements state that the PTB assess against the requirements and the details of what the procedures must include. They need not be included here. The requirements are meant to allow for flexible procedures that meet the other requirements of the standard.*

*Response: Persuasive. Item d) changed to "submittal of oversight information to the PTPA."*

Section 5.3.2 This section requires the PTPA application process to include “information about the qualifications of ..” PTP’s. There is no specification of what information is to be collected and what constitutes sufficient “qualifications”.

Suggested resolution: Delete section or clarify qualifications and information to be selected.

*Response: Non-Persuasive. Standards need not be specific on procedures, and compliance can be determined by the TNI PT Board audit.*

Section 5.3.3 This is yet another case where a note, not a requirement of the Standard, references information outside the bounds of the TNI Standards. What is this mutual recognition agreement? Is it between TNI and its PTPA? Why hasn’t this agreement been submitted to the membership for review since this is a consensus Standard? If this agreement is between the PTPA and another third party it should not be referenced in the Standard.

Suggested resolution: If an agreement exists between TNI and a PTPA the terms of that agreement should be included in the Standard for review by the membership. If this references a third party agreement, delete the note.

*Response: Non-Persuasive. Mutual recognition agreements may exist as part of international recognition of compliance with ISO/IEC 17011, so this requirement minimizes potentially overlapping accreditations or recognitions for the PTPA and thereby could reduce the cost of the PTPA assessment.*

*Response: Persuasive. Note is deleted.*

Section 5.3.4 This language is vague and is not auditable.

Suggested resolution: Detail how this must be done so that the PTB can effectively audit the performance of the PTPA.

*Response: Non-Persuasive. The language is sufficiently clear and conventional – the TNI PT Board can audit the PTPA with competent assessment against the requirements of the standard. Procedures need not be included in the standard.*

Section 5.3.5 Add “that are consistent with the requirements of Volume 3 of this Standard” to the end of the section to clarify what the checklist must cover.

Suggested resolution: Add text as above.

*Response: Non Persuasive. Adding this section would make the standard internally inconsistent with the PTPA’s obligation to assess against their requirements, which may be in addition to the requirements of Volumes 3 and 4.*

Section 5.4.1 This is again the database issue. If the PTPA has an “arrangement” with TNI to maintain a database of proprietary information, there is a clear conflict of interest between the PTPA and the TNI PT Board. Furthermore, the Standard cannot require the release of proprietary information that are the valuable assets of private firms. Finally, a PTPA that meets the requirements of ISO 17011, as required by this Standard, cannot participate in the collection and distribution of proprietary information collected from its accredited PTP’s. This is in direct conflict with the requirements of ISO 17011 which requires that an accrediting authority protect without exception the proprietary information of its accredited laboratories.

Suggested resolution: This section must be deleted.

*Response: Non-Persuasive. An arrangement does not imply conflict of interest, and the claimed conflict with ISO17011 is incorrect. In fact the requirements of ISO/IEC 17011 will assure the requested confidentiality. However, since the previous draft of this Volume, the need for an arrangement with TNI no longer exists, so the phrase “have an arrangement with the PTB to access and”..was deleted.*

Section 5.5.2 I have no idea where this section came from since there are no requirements in Volume 3 which reference advertising and marketing of accreditation approval status.

Suggested resolution: Delete this section since there is no requirement in Volume 3.

*Response: Non-Persuasive. There is no need to put this in Volume 3. It refers to “other requirements” that a PTPA may have, and protects TNI also.*

Section 5.6.2 This section would clearly prohibit the PTPA from having a contractual relationship with TNI regarding the database.

*Response: Not Applicable. This is an observation only, so no response is necessary.*

Section 5.6.4 This section is extremely vague and would appear to authorize the PTPA to release proprietary information collect by the PTPA from PTP’s to any and all “appropriate parties”. This is in direct conflict with ISO 17011 and it is not within the legal authority of TNI to authorize such a release. ISO 17011 suggests that a PTPA should only release the accreditation status of a PTP not “all information.. related to providing PT samples, etc”.

Suggested resolution: Revise language to assure that the PTPA can only release the accreditation status of a PTP and that all other information must be protected under confidentiality agreements.

*Response: Non Persuasive. The language is specific and clear that information will be released only according to all confidentiality agreements, which could vary in different situations, and includes those of ISO/IEC 17011.*

*Changed “samples” to “programs” for clarity.*

Section 5.7.2 This section again requires the PTPA to release proprietary information obtained from a PTP “as described in this Standard”. TNI cannot require the PTPA to release information of PTP’s that is covered by confidentiality agreements between the PTPA and the PTP’s. This is again in conflict with the requirements of ISO 17011. TNI has no authority to acquire or access the proprietary information of any private firm.

Suggested resolution: Delete “except as described in this Standard” from the section.

*Response: Non-Persuasive. Changed “participant data” to “study data” to provide clarity, but the phrase “except as described in this Standard” is retained, per other comments on earlier drafts.*

Section 6.1 d) There is no technically valid method of insuring that PT samples are “fit for use” which is a legal term. Therefore, this requirement cannot be met. Furthermore, if a PTPA agrees to make this assessment they would be liable for PT samples of PTP’s that were later determined to be unfit for use. Finally having assigned values within the specified ranges is no guarantee of fitness for use so this is an improper requirement.

Suggested resolution: Delete an impossible requirement.

*Response: Not Applicable. Standard says “fit for their intended purpose”, which is sufficient for competent assessors. This sentence was added by general TNI consensus in 2004, and has received no other negative comments.*

Section 6.1 g) TNI has no right to require that PTP’s meet any requirement outside of those of its own Standard. In fact, for the purposes of TNI there are no requirements outside of Volume 3. What the PTPA does outside of TNI requirements is no business of TNI.

Similarly, the note is not required and certainly TNI has no right to review requirements outside of Volume 3 requirements.

Suggested resolution: Add at the end of sentence one “consistent with the requirements of Volume 3.” Delete the second sentence and the note.

*Response: Non-Persuasive. Adding this section would make the standard internally inconsistent, as discussed previously concerning requirements that the PTPA may have that are not in Volumes 3 or 4. This assures that the PT provider and PT Board are aware of all accreditation requirements*

*Response: Persuasive. The note was deleted.*

Section 6.2.4 The PTPA should only make an accreditation decision based upon the demonstrated ability of the PTP to meet the requirements of Volume 3. There is no specification in this Standard for what information is required to make either a positive or negative accreditation decision. The internal procedures of a PTPA are not subject to review by TNI members in the consensus process and therefore should not be used to judge the suitability of a PTP.

Suggested resolution: Delete section and replace with; “the PTPA shall determine accreditation based solely upon the ability of the PTP to meet the requirements of Volume 3 of this Standard”

*Response: Non-Persuasive. The PTPA needs to follow its own (ISO 17011-compliant) accreditation decision rules, which could include requirements beyond the TNI standard. TNI Board may not wish to approve those other requirements, and would deal with that at the approval process. TNI needs to recognize that these requirements will be used in collaboration with other requirements, and this standard does not seek to limit those requirements.*

6.3.1 This is again another attempt by the PT Committee and the PTB to write a blank check to the PTPA. This section is an inappropriate vague authorization by the PT Committee for the PTPA to collect unspecified information from the PTP’s.

For example: What criteria should the PTPA use to assess the distribution of concentrations? How can the PTPA confirm correct calculation of assigned values without every formula for every lot of material produced by every PTP? What does verification of the assigned value mean in relation to the PTPA? What are appropriate testing procedures for homogeneity/stability since Volume 3 does not require the use of internationally recognized procedures and suggests the use of an unverified alternative which would clearly lead to inconsistent treatment of PTP’s.

Furthermore, d) requires the PTPA to confirm all calculations prior to the study. This would be an impossible task for any PTPA and totally unnecessary if PTP’s are accredited to ISO G13 and Guide 43.

Suggested resolution: This section needs a detailed review of each item and an appropriate technically valid development of the actual requirements for on-going monitoring with a set of specifications or criteria that the PTPA must use to make their evaluation. All of this information must be developed in the public form of the consensus standard development process.

*Response: Non-Persuasive. The requirements need to state what the review shall do and shall include, not how to do it. Specific procedures will be reviewed by the PT Board, and will be explained fully to the TNI community, as required elsewhere. The parenthetical phrase “(prior to study)” in item d), was deleted, for clarity.*

Section 6.3.2 This is another vague requirement. What does “investigate” mean and what action must a PTPA take based upon what criteria after the investigation? There, of course, is no national average for pass/fail rate that can be used to develop a 95% level and what is an appropriate statistical technique? Pass/fail rates in PT studies are dependent upon several factors including sample design, sample homogeneity, sample stability, and most importantly the distribution of labs in each program which vary from PTP to PTP and from time to time. Therefore, a national average is probably meaningless.

Suggested resolution: Delete this section as being inappropriate and incomplete or establish clear unambiguous requirements and specifications.

*Response: Non-Persuasive. The requirements was reworded for clarity, but not deleted. The procedures are left to the discretion of the PTPA and will be approved by the PT Board.*

Section 6.3.3 b) there should be a timeframe in which the PTPA must provide the report. Ten days is suggested. Secondly, the PTPA must provide all information from the contract lab to the PTP including the method used, dilutions made, calibration information, and contract laboratory quality control information as part of the report to the PTP. The PTPA must have an appeals process that covers such a contract lab review process.

Suggested resolution: See comment and add appropriate language.

*Response: Persuasive. Added a sentence: “The report should be provided within 10 days of receipt, and contain sufficient technical detail so the PT provider can assess the appropriateness of the reference test or measurement.”*

Section 6.3.8 under what circumstances is suspension required? Under what circumstances is revocation required? This is a vague incomplete specification.

Suggested resolution: Add language to clarify under what exact circumstances either suspension or revocation will be enforced. See Volume 1 Module 1 for an example of clear language.

*Response: Non-Persuasive. No change to the standard. This requirement allows suspension, it does not require it. The reasons are provided throughout the volume.*

Section 6.4.2 It is possible that resolution of a complaint may require the PTP to disclose proprietary information to the PTPA. Such information could not be released to the PTB because of the make-up of the PTB. Additionally, release of proprietary information to the PTB is in conflict with confidentiality agreements between the PTPA and the PTB.

Suggested resolution: Add language that specifically excludes all proprietary information for complaint summaries provided to the PTB. This would make the PTPA appropriately liable for unauthorized release of information.

*Response: Non-Persuasive. Release of proprietary information is covered elsewhere. This requirement is for a summary of complaints, not details of all complaints.*

6.5.4 the note in this section seems appropriate however where are the policies, procedures, and criteria that the PTB will use to disapprove a PTP. Since the PTB is not a consensus organization revocation by the PTB is inappropriate unless these policies, procedures, and criteria are included in the Standard.

Suggested resolution: Delete the note.

*Response: Persuasive. The note is deleted.*

Tom Coyner

July 24, 2007