

Comment Number 74

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section Section 3.4

Comment w/Rationale for Change Section 3.4: The definition of proficiency testing provider uses an acronym (PTPA â€“ proficiency testing provider accreditor) that had not been used in the standard to that point. This full term rather than the acronym should be used in this definition.

Proposed Change Section 3.4: The definition of proficiency testing provider uses an acronym (PTPA â€“ proficiency testing provider accreditor) that had not been used in the standard to that point. This full term rather than the acronym should be used in this definition.

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vote Yes + Comments

email carl_kircher@doh.state.fl.us

Phone Number 904-791-1574

Date 7/3/2007

[Details](#)

Response: Persuasive. Accepted and change made.

Comment Number 75

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section Section 3.6

Comment w/Rationale for Change Section 3.6: The definition of proficiency testing sample does not include a concluding acronym such as “PT Sample.” The other definitions include an acronym such as PT study after the term is stated (e.g., Proficiency Testing Study (PT study)). This is not done for this definition, but the acronym PT sample is used later in the standard. The acronym should be added at the end of the term at the beginning of the definition.

Proposed Change Section 3.6: The definition of proficiency testing sample does not include a concluding acronym such as “PT Sample.” The other definitions include an acronym such as PT study after the term is stated (e.g., Proficiency Testing Study (PT study)). This is not done for this definition, but the acronym PT sample is used later in the standard. The acronym should be added at the end of the term at the beginning of the definition.

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vote Yes + Comments

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Response: Persuasive. Accepted and change made.

Comment Number 76

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section Section 3.8

Comment w/Rationale for Change Section 3.8: The Committee recommends deletion of the definition for “PT Study Opening Date” since no references or wordings to this term could be found throughout this volume.

(Uniformity of Standards Committee)

Proposed Change Section 3.8: The Committee recommends deletion of the definition for “PT Study Opening Date” since no references or wordings to this term could be found throughout this volume.

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vote Yes + Comments

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Date 7/3/2007

[Details](#)

Response: Persuasive. Accepted and change made.

Comment Number 77

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section Section 3.9

Comment w/Rationale for Change Section 3.9: The Committee recommends deletion of the definition for “PT Study Closing Date” since no references or wordings to this term could be found throughout this volume.

(Uniformity of Standards Committee)

Proposed Change Section 3.9: The Committee recommends deletion of the definition for “PT Study Closing Date” since no references or wordings to this term could be found throughout this volume.

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vote Yes + Comments

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[Details](#)

Response: Persuasive. Accepted and change made.

Comment Number 78

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section Section 4.1

Comment w/Rationale for Change Section 4.1: The opening of the sentence should be revised to read as follows: "The TNI PT Board (PTB) shall determine the content . . ."

Proposed Change Section 4.1: The opening of the sentence should be revised to read as follows: "The TNI PT Board (PTB) shall determine the content . . ."

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vote Yes + Comments

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Phone Number 904-791-1574

Date 7/3/2007

[Details](#)

Response: Persuasive. Accepted and change made.

Comment Number 79

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section Section 6.3.3(a)

Comment w/Rationale for Change Section 6.3.3(a): The acronym "SD" appears and it is not defined. (Standard Deviation)

Proposed Change Section 6.3.3(a): The acronym "SD" appears and it is not defined. (Standard Deviation)

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vote Yes + Comments

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Date 7/3/2007

[Details](#)

Response: Persuasive. Accepted and change made.

Comment Number 80

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section Section 6.5.4 NOTE

Comment w/Rationale for Change Section 6.5.4 NOTE: The Committee recommends revision to the sentence so that the sentence opens as follows: "Suspension or revocation of TNI approval as a TNI-approved PT Provider . . ."

(Uniformity of Standards Committee)

Proposed Change Section 6.5.4 NOTE: The Committee recommends revision to the sentence so that the sentence opens as follows: "Suspension or revocation of TNI approval as a TNI-approved PT Provider . . ."

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vote Yes + Comments

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Date 7/3/2007

[Details](#)

Response: Persuasive. Accepted and change made.

Comment Number 81

First Name Carl Last Name Kircher

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section the whole Volume

Comment w/Rationale for Change General Comment: The Committee notes that international organizations are adopting the new international standard ISO 17043 for proficiency testing. This Committee thus strongly recommends that the PT Committee consider the impact of ISO 17043 on Volume 4 to determine any impacts on copyright infringement and consistency of its Draft Interim Standard with proposed ISO 17043 language.

(Uniformity of Standards Committee)

Proposed Change General Comment: The Committee notes that international organizations are adopting the new international standard ISO 17043 for proficiency testing. This Committee thus strongly recommends that the PT Committee consider the impact of ISO 17043 on Volume 4 to determine any impacts on copyright infringement and consistency of its Draft Interim Standard with proposed ISO 17043 language.

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vote Yes + Comments

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Date 7/3/2007

[Details](#)

Response: Persuasive. Accepted and change made.

Comment Number 177

First Name Thomas Last Name Coyner
Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT
Section 1.3 all sub-sections

Comment w/Rationale for Change I have several comments on this Standard. This comment is supplemented by written comments to TNI and the PT Committee.

Section 1.3.2, 1.3.3 and 1.3.4 are absolutely inappropriate in this Volume as was commented on the previous drafts. These sections refer to the TNI Board which is not a Consensus body and does not operate under the consensus procedure approved by ANSI.

Section 1.3.2 contains very vague language which is designed to justify the operations of the PT Board within the consensus Standard while Section 3.8 in definitions clearly explains that the duties of the PT Board are defined in its charter.

Section 1.3.3 is an attempt by the PT Committee to legalize the operates of the TNI PT Board as based upon consensus. The polices, procedures and decisions of the TBNI PT Board are not subject to review by the membership of TNI and are therefore not part of the Consensus Standard.

Section 1.3.4 is an attempt to set requirements for the AB's which is equally inappropriate in the Volume on Oversight of Proficiency Testing.

Proposed Change Delete all of Section 1.3 except the first sentence (1.3.1)

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Phone Number 740-423-4200

Date 7/24/2007

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Response: Non-Persuasive: There are 3 comments concerning the authority of the TNI PT Board and one comment on the PTPA. These comments are in conflict with the large majority of opinions expressed in recent TNI meetings. TNI has assured that the PT Board has balanced representation from all stakeholder groups and an adequate level of competence to assure that the TNI consensus interests are represented.

Comment Number 374

First Name Mike Last Name Haller
Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT
Section 4.2.2

Comment w/Rationale for Change Neither TNI nor particularly the PT Board has any right to review or assess procedures and policies outside the scope of this Standard and and should be limited to the PTPA polices and procedures related to the accreditation of PT providers.

Proposed Change 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.

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vote No + Comments

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Phone Number 740-423-4200

Date 7/31/2007

[Details](#)

Response: Non-Persuasive: There has been general support within the PT Committee and TNI membership for having a PT Provider Accreditor that has been internationally recognized to be in compliance with ISO/IEC 17011. This recognition carries obligations that exceed the requirements of TNI. However, because these changes are beyond the control of TNI, there has also been general acceptance that the requirements must be approved by the TNI PT Board, to ensure that the requirements are appropriate for TNI PT providers.

Comment Number 540

First Name Sharon Last Name Mertens
Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT
Section General

Comment w/Rationale for Change This Volume is not consistent with the ISO module. Following the general ISO format, requirements for program oversight is handled in mutual recognition agreements, policies and procedures, not standards.

Proposed Change No specific changes to the document. It looks good, but is should not be a standard. Suggest turning this over to the PTOB to incorporate into their documentation.

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vote No + Comments

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Date 8/3/2007

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Response: Non-Persuasive. Most of the TNI members have requested that this Volume be a standard as well.

Comment Number 576

First Name Chuck Last Name Wibby

Section Number Item 10 VOLUME 4: PROFICIENCY TESTING OVERSIGHT

Section 3.8, 4.1, 4.2 and 4.3

Comment w/Rationale for Change V4 Section 3.8, 4.1, 4.2 and 4.3

These sections of Volume 4 grant extensive rights and responsibilities to the TNI PT Board which is totally inappropriate given the lack of definition in the volume regarding how the PT Board would carry out these responsibilities.

Proposed Change The volume should be withdrawn from voting until these critical problems are corrected.

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vote No + Comments

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Date 8/3/2007

[Details](#)

Response: Non-Persuasive: This concern has been discussed at length within the TNI community and there is general acceptance that the requirements for the PT Board should be specified in this Volume, which is within the consensus process, just as the membership of the TNI PT Board should contain a balanced representation of the stakeholder groups, and operate according to policies and procedures that assure representation of all stakeholder groups.