

Volume 2 Module 2

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 2 Module 2 Negative Vote with Comments

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

Section 3.10 This is not the definition of a PT Study and neither PT providers nor the labs can meet this requirement. See comment under Volume 1 Module 1 for correction.

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

Section 4.1.1 e) There should be a timeframe in the requirement to insure that the database is up-to-date.

Suggested resolution: add "Updates to the database shall be made within 30 days of the close of any PT study."

Response: Hold Till Next Revision. This standard references a national database which needs to be implemented. Timeframes will be addressed in an SOP when the database becomes available.

Section 4.1.1 f) There should be a timeframe in the requirement to insure that Secondary AB's are aware of this important change in status.

Suggested Resolution: add "Secondary AB's shall be informed of revocation or suspension within 72 hours of such action by the Primary AB."

Response: Not Applicable. This is a Policy Issue and a resolution is currently in the policy documents with the TNI NELAP Board.

Section 5.1.6 Note: This note is inappropriate since any accreditation outside of the FOT's are the sole responsibility of the issuing AB and not part of the TNI system.

Suggested resolution: remove the note.

Response: Persuasive. Note is being removed from this standard.

Section 6.1 g) This requires root cause analysis which is a very specific term. Root cause analysis is not required in Volume 1 Module 1 under corrective action.

Suggested resolution: Make the two citations consistent in language.

Response: Persuasive. 'Corrective Action' will be used consistently throughout the standard.

Section 6.2 As has been repeated and repeated in NELAC for many years, neither NELAC nor TNI has any control over how PT providers promote materials which are not TNI specific PT samples. AB's may require labs to not run QC samples specifically with PT samples but they have no right to be involved in the sale of QC materials by the PT providers. This section is absolutely inappropriate.

Suggested resolution: Delete this section it is an embarrassment to TNI.

Response: Non-Persuasive. The AB's requested that this wording be added to the standard to reflect what they agreed upon under the current program. This wording is intended to direct AB's to the PTPA when they have concerns about the activities of a PTP.

Section 7.3 d) As noted in comment in Volume 1 Module 1, this section make the lab responsible for errors by the PT provider which is inappropriate.

Suggested resolution: Delete reference to error by PT providers.

Response: Persuasive. This wording will be changed to be similar to this proposed wording. Added wording to section 9.2 to cover this possibility.

Section 8.2 The language uses in several section refers to Corrective Action PT where everywhere else in the Standard the terminology is "supplemental PT sample"

Suggested resolution: Make language consistent in all Volumes, Modules.

Response: Persuasive. Committee will re-phrase this term since these are: 'PT samples used for corrective action purposes'. We feel that it will be less confusing and we will have fewer terms. Also some laboratories choose quick turn

supplemental PT's and others choose regular PT studies to serve there needs to demonstrate the corrective action has been successful.

Tom Coyner

July 24, 2007