Volume 1 Module 1 RESPONSES TO COMMENTS 20 December 2007

Comment Number 4
First Name Bob **Last Name** Di Rienzo
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 1.2 a)
Comment w/Rationale for Change The production and supply of PT samples that challenge the critical components of each analytical procedure, from initial sample preparation to final data analysis;

Can you define what "challenge the critical components" means?

Does it mean that all compounds must be spiked or is there a specific list of critical compounds? Was the list scientifically developed or was it a list just selected from the method? Isn't the absence of an analyte good PT data also?
Proposed Change Add to this standard the requirement to report all data for a PT from the laboratories analyte lists, even if it isn't present in the PT sample and use the absence of data as criteria for acceptance.
Uploaded Document
vote Yes + Comments
email dirienzo@datachem.com
Phone Number (801) 266-7700 X331
Date 6/28/2007
Details
Response: Hold until Next Revision. The proposed change is substantial change to the PT program that cannot be made at this time.

Comment Number 5
First Name Bob **Last Name** Di Rienzo
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 1.2 b)
Comment w/Rationale for Change The production and supply of PT samples that are as similar to real-world samples as reasonably possible and representative of materials analyzed for environmental regulatory
programs, agencies and communities;

There is no requirement for real world matrix in PT samples. Sample in ampules spiked in DI water and sandy solids are not representative of materials routinely analyzed.
Proposed Change Use PT spiking solutions as MS/MSD spikes in real samples. Generate limits based on real world matrices.
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vote Yes + Comments
email dirienzo@datachem.com
Phone Number (801) 266-7700 X331
Date 6/28/2007
Details
Response: Hold until Next Revision. The proposed change is substantial change to the PT program that cannot be made at this time.

Comment Number 6
First Name Bob **Last Name** Di Rienzo
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.0
Comment w/Rationale for Change REQUIREMENTS FOR ACCREDITATION

I propose we limit PT and other type of demonstration of competency to FOT by matrix/instrument and remove method from the equation. This requirement show also include the demonstrations of competency like round robins studies and Blind spiking programs similar to what AIHA does (ISO 17025 compliant).
Proposed Change See attached document from AIHA for Demonstration of Competency
Specifically see 6B.2 and 6B.3
Incorporate concepts from 6B.3.2 and 6B.3.3 into PT for Environmental testing
Uploaded Document Policy Module6B_R5_Final_2007_01_02.pdf
vote Yes + Comments
email dirienzo@datachem.com
Phone Number (801) 266-7700 X331
Date 6/28/2007
Details
Response: Hold until Next Revision. The proposed change is substantial change to the PT program that cannot be made at this time.

Comment Number 7
First Name Bob **Last Name** Di Rienzo
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 7.0
Comment w/Rationale for Change Why does this section exist? These requirement exist in Volume 1 Module 2 section 4.11
4.11 Corrective Action (ISO/IEC 17025:2005(E), Clause 4.11)

4.11.1 General

The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

NOTE: A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.

4.11.2 Cause Analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE: Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

4.11.3 Selection and Implementation of Corrective Actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

4.11.4 Monitoring of Corrective Actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

4.11.5 Additional Audits

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

NOTE: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

4.11.6 The laboratory shall have documented procedure(s) to address 4.11.1 through 4.11.5. These procedure(s) must also include:

a) which individual(s) or positions are responsible for assessing each QC data type;

b) which individual(s) or positions are responsible for initiating and/or recommending corrective actions; and

c) circumstances which would require a cause analysis investigation as described in section 4.11.2.
Proposed Change PT failures should initiate corrective action under V1, M2 section 4.11
Uploaded Document V1M2_DIS07.pdf
vote Yes + Comments
email dirienzo@datachem.com
Phone Number (801) 266-7700 X331
Date 6/28/2007
Details
Response: Persuasive. The change was made to reference Volume 1, Module 2 as proposed.

Comment Number 9
First Name Bob **Last Name** Di Rienzo
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 8
Comment w/Rationale for Change Why does this corrective action have to be evalyuated by ABs. If corrective action is requred for PT under V1M2 section 4.11 why isn't this evaluated during the onsite and not a seperate system which requires paperwork for the lab and evaluation by ABs. The onsite should assess the corrective action systems and the assessor should see evidence of PT corrective actions during the assessment of the quality system.
Proposed Change Delete this entire section or change to say that corrective actions for PT failures will be assessed at the onsite.
Uploaded Document V1M2_DIS07_1.pdf
vote No + Comments
email dirienzo@datachem.com
Phone Number (801) 266-7700 X331
Date 6/28/2007
Details
Response: Persuasive: The new Section 6.0 now refers to Volume 1, Module 2 regarding requirements for Corrective Action.

Comment Number 10
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 1.2(b)
Comment w/Rationale for Change Section 1.2(b): The language in this section should be reworded to "..that are as similar to real-world samples as reasonably possible. . ."
Proposed Change Section 1.2(b): The language in this section should be reworded to "..that are as similar to real-world samples as reasonably possible. . ."
Uploaded Document
vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The language was removed rather than revised as suggested because the language describes requirements for the composition of PT samples and is therefore not applicable to the laboratory module.

Comment Number 11
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 1.3.3
Comment w/Rationale for Change Section 1.3.3: The language in this section should be reworded to read, ". . .the requirements of such an appendix supercedes this volume. . ."
Proposed Change Section 1.3.3: The language in this section should be reworded to read, ". . .the requirements of such an appendix supercedes this volume. . ."
Uploaded Document
vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The clerical change was made to add an "s" to supersede.

Comment Number 12
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 3.7
Comment w/Rationale for Change Section 3.7: The definition of PT 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 3.7: The definition of PT 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 7/1/2007
Details

Response: Persuasive. The proposed change was already made in the draft interim standard that was published on June 15, 2007.

Comment Number 13
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 3.8
Comment w/Rationale for Change Section 3.8: The definition for PTPA should actually mean "an organization that is evaluated by the TNI PT Board and approved by the TNI NELAP Board to accredit PTPs." The Committee also recommends that the Proficiency Testing (PT) Committee also consider making a definition for the "NELAP Board."
Proposed Change Section 3.8: The definition for PTPA should actually mean "an organization that is evaluated by the TNI PT Board and approved by the TNI NELAP Board to accredit PTPs." The Committee also recommends that the Proficiency Testing (PT) Committee also consider making a definition for the "NELAP Board."
(Uniformty of Standards Committee)
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vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The definition was changed as proposed.

Comment Number 14
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 3.10
Comment w/Rationale for Change Section 3.10: The definition of proficiency testing sample does not include the subsequent acronym "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 3.10: The definition of proficiency testing sample does not include the subsequent acronym "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
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The acronym was added.

Comment Number 15
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 3.14
Comment w/Rationale for Change Section 3.14: The PT Committee should consider deleting the definition for "Secondary Accreditation Body" since no references or wordings to this term could be found elsewhere in this module.
Proposed Change Section 3.14: The PT Committee should consider deleting the definition for "Secondary Accreditation Body" since no references or wordings to this term could be found elsewhere in this module.
Uploaded Document
vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The proposed change was already made in the draft interim standard that was published on June 15, 2007.

Comment Number 16
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 4.1.1
Comment w/Rationale for Change Section 4.1.1: To incorporate the relevant definition, and to clarify the language more accurately, the concluding portion of the statement should be revised to read, ". . . two unique PT samples for each TNI FoPT corresponding to the fields of accreditation for which it is seeking accreditation."

For all examples in this report, the new text is given in the underlines. However, please note that the current text that should be removed is not provided here in strike-through format, due to time constraints in preparing this report.
Proposed Change Section 4.1.1: To incorporate the relevant definition, and to clarify the language more accurately, the concluding portion of the statement should be revised to read, ". . . two unique PT samples for each TNI FoPT corresponding to the fields of accreditation for which it is seeking accreditation."

For all examples in this report, the new text is given in the underlines. However, please note that the current text that should be removed is not provided here in strike-through format, due to time constraints in preparing this report.
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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The proposed change has been made.

Comment Number 17
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 4.1.5
Comment w/Rationale for Change Section 4.1.5: The opening of the NOTE should be clarified so that it reads, "For fields of accreditation that do not have available FoPTs, the laboratory may . . ."
Proposed Change Section 4.1.5: The opening of the NOTE should be clarified so that it reads, "For fields of accreditation that do not have available FoPTs, the laboratory may . . ."
Uploaded Document
vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The note has been removed.

Comment Number 18
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 4.2.1
Comment w/Rationale for Change Section 4.2.1: To be more accurately stated, the Committee recommends that the first sentence be reworded to read, "In order to maintain accreditation, the laboratory shall, for each field of accreditation for which it is accredited and for which a FoPT is available:" The reason for the change is that NELAP Accreditation Bodies (ABs) accredit to fields of accreditation, not to fields of proficiency testing.
Proposed Change Section 4.2.1: To be more accurately stated, the Committee recommends that the first sentence be reworded to read, "In order to maintain accreditation, the laboratory shall, for each field of accreditation for which it is accredited and for which a FoPT is available:" The reason for the change is that NELAP Accreditation Bodies (ABs) accredit to fields of accreditation, not to fields of proficiency testing.
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vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The first sentence has been reworded.

Comment Number 19
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.3(c), 5.2.3-5.2.5
Comment w/Rationale for Change Sections 5.1.3(c), 5.2.3, 5.2.4, and 5.2.5: These sections refer to a "close" date for a PT study. Section 3.13 defines it as the "closing" date. The term in these sections should be revised to "closing" to be consistent with the definition.
Proposed Change Sections 5.1.3(c), 5.2.3, 5.2.4, and 5.2.5: These sections refer to a "close" date for a PT study. Section 3.13 defines it as the "closing" date. The term in these sections should be revised to "closing" to be consistent with the definition.
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Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Non-Persuasive. After extensive discussion and consideration of all comments received for this topic, the PT committee decided that all time-frames for tracking PT samples should be calculated using analysis date. All references to “open, opening, close or closing” dates were changed to analysis date.

Comment Number 20
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 4.2.3
Comment w/Rationale for Change Section 4.2.3: To be more accurately stated, this section should be reworded as follows: “When a laboratory has been granted accreditation for a field of accreditation in which the available FoPT is an Experimental FoPT, the laboratory shall analyze two PT samples for the Experimental FoPT, per year. However, successful analysis of the Experimental PT is not a requisite for continued accreditation.”
Proposed Change Section 4.2.3: To be more accurately stated, this section should be reworded as follows: “When a laboratory has been granted accreditation for a field of accreditation in which the available FoPT is an Experimental FoPT, the laboratory shall analyze two PT samples for the Experimental FoPT, per year. However, successful analysis of the Experimental PT is not a requisite for continued accreditation.”
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vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The sentence has been revised as proposed.

Comment Number 21
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 5.2.5
Comment w/Rationale for Change Section 5.2.5: The Committee recommends that the applicable expert committee examine the language in the second sentence to be if the appropriate word should be “withdrawal”.

(Uniformity Standards Committee)
Proposed Change Section 5.2.5: The Committee recommends that the applicable expert committee examine the language in the second sentence to be if the appropriate word should be “withdrawal”.

(Uniformity of Standards Committee)
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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Not Applicable. The grammatical change to 5.2.5 was made in the standard that was published June 15, 2007. The committee has since decided to remove the requirement based on consideration from other comments received.

Comment Number 22
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Sections 7.1 & 7.2
Comment w/Rationale for Change Sections 7.1 and 7.2: These sections have the term “corrective action PT sample,” but this term is not previously defined. A corrective action PT sample is analyzed under the supplemental PT study, but the supplemental PT study may be used for purposes beyond “corrective.” Therefore, the term should be defined in Section 3.0. This Committee provides the following suggested text for the definition of a corrective action PT sample: “A PT sample analyzed under the requirements of a supplemental PT study, but is used to provide corrective action in response to a not acceptable PT sample result.”
Proposed Change Sections 7.1 and 7.2: These sections have the term “corrective action PT sample,” but this term is not previously defined. A corrective action PT sample is analyzed under the supplemental PT study, but the supplemental PT study may be used for purposes beyond “corrective.” Therefore, the term should be defined in Section 3.0. This Committee provides the following suggested text for the definition of a corrective action PT sample: “A PT sample analyzed under the requirements of a supplemental PT study, but is used to provide corrective action in response to a not acceptable PT sample result.”

(Uniformity of Standards Committee)

vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The PT sample used for corrective action can be from a supplemental PT study or a PT study, the term "study" refers to both and the language has been changed to indicate such. All references to corrective action PT have been removed.

Comment Number 23
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Sections 7.1 & 7.2
Comment w/Rationale for Change Sections 7.1 and 7.2: These sections have the term "corrective action PT sample," but this term is not previously defined. A corrective action PT sample is analyzed under the supplemental PT study, but the supplemental PT study may be used for purposes beyond "corrective." Therefore, the term should be defined in Section 3.0. This Committee provides the following suggested text for the definition of a corrective action PT sample: "A PT sample analyzed under the requirements of a supplemental PT study, but is used to provide corrective action in response to a not acceptable PT sample result."
Proposed Change Sections 7.1 and 7.2: These sections have the term "corrective action PT sample," but this term is not previously defined. A corrective action PT sample is analyzed under the supplemental PT study, but the supplemental PT study may be used for purposes beyond "corrective." Therefore, the term should be defined in Section 3.0. This Committee provides the following suggested text for the definition of a corrective action PT sample: "A PT sample analyzed under the requirements of a supplemental PT study, but is used to provide corrective action in response to a not acceptable PT sample result."

(Uniformity of Standards Committee)
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vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The PT sample used for corrective action can be from a supplemental PT study or a PT study, the term "study" refers to both and the language has been changed to indicate such. All references to corrective action PT have been removed.

Comment Number 24
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 7.2(b)
Comment w/Rationale for Change Section 7.2(b): To be consistent with Section 7.2(d) in the same Module, the Committee recommends the additional phrase to the sentence, to read as follows, ". . . for which the open date is at least 15 days after the closing date of the study . . ."
Proposed Change Section 7.2(b): To be consistent with Section 7.2(d) in the same Module, the Committee recommends the additional phrase to the sentence, to read as follows, ". . . for which the open date is at least 15 days after the closing date of the study . . ."

(Uniformity of Standards Committee)
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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Non-Persuasive. After extensive discussion and consideration of all comments received for this topic, the PT committee decided that all time-frames for tracking PT samples should be calculated using analysis date. The intent to specify a time-period for tracking PT samples is to ensure that there is sufficient time (15 calendar days) between the analysis of successive PT samples for any FoPT, thus analysis date is the date that should be used for tracking. All dates used to track time-frames between studies have been changed to analysis date.

Comment Number 25
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 7.2(e)

Comment w/Rationale for Change Section 7.2(e): In this section it may be better to replace the word "must" with the word "shall".
Proposed Change Section 7.2(e): In this section it may be better to replace the word "must" with the word "shall".
Uploaded Document
vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The proposed change was already made in the draft interim standard that was published on June 15, 2007.

Comment Number 26
First Name Carl **Last Name** Kircher
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 8.2
Comment w/Rationale for Change Section 8.2: The term "NELAP Board" appears in this clause, and this term is not defined in this module. The Committee recommends defining this term in Section 3.
Proposed Change Section 8.2: The term "NELAP Board" appears in this clause, and this term is not defined in this module. The Committee recommends defining this term in Section 3.

(Uniformity of Standards Committee)
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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/1/2007
Details
Response: Persuasive. The term NELAP board has been removed from this sentence.

Comment Number 122
First Name June Last Name Flowers
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1
Comment w/Rationale for Change This comment is regarding the number of and frequency that NELAC accredited laboratories are required to analyze PT samples for the aqueous matrices "Potable" and "Non-Potable" water. Labs that are accredited in the two aqueous categories potable and non-potable are performing 4 PT's per year for similar methodologies. Prior to the EPA 40 CFR Monday, March 12, 2007 update, we were at least reporting different methods for the DW and WW PT's, but now, they are the same method references. In order to attract more participating labs and AB's we need to harmonize the TNI PT standard with the EPA DW Manual. The 5th Edition, page IV-5, Section 7.2 states:

". . .analyze PT samples. . .at least once every 12 months for each analyte and by each method used to analyze compliance samples. . . ...A make up PT sample must be successfully analyzed."

One approach would be to change the definition of matrix to combine potable and non-potable water and call them "Aqueous". This would not be easy since Accreditation Bodies have framed their applications and fees by category, and potable rules must also follow the EPA DW Manual. This adjustment to the PT schedule would facilitate a cooperative relationship with EPA Office of Ground Water and Drinking Water concerns as stated in the Director Cynthia C. Dougherty's May 14 2007 Memorandum on Drinking Water Laboratory Program Oversight.
Proposed Change Here is very simple suggested text to change the draft V1, M1: Proficiency Testing language for Continued Accreditation:

4.2.1 a) analyze at least one TNI-compliant PT sample per year;
4.2.1 b) maintain a history of at least one successful performance, as describe in Section 6.0, out of the most recent two attempts;
4.2.1 d) analyze PT samples for the sample FoPT no fewer than 15 days apart and no more than 12 months apart.

The remaining text may be clarified to require a passing corrective action PT within the same year. With this type of schedule, labs may perform in 2 studies per year, i.e., potable then non-potable. For soil PT's, there could still be the 2 studies per year requirement if there is too much disagreement from the TNI members.

Please consider this idea for the sake of time and cost to laboratories and AB's.

Respectfully Submitted,

June S. Flowers
TNI LASC Chair
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vote No + Comments
email june@flowerslabs.com
Phone Number 407.339.5984 x212
Date 7/10/2007
Details
Response: Hold until Next Revision. The committee has taken the comment under consideration and the proposed change will be held until the next revision as this topic is currently under discussion with the TNI PT Board and ELAB. The committee determined that such a change is a substantial change to the PT program that cannot be made at this time. Since there are many interests at stake the committee believes a full discussion within the membership must be part of any proposed change.

Comment Number 141
First Name Thomas Last Name McAninch
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.5
Comment w/Rationale for Change The committee discussion on this item was that teh lab could withdraw from a study without any notifications. A lab would be scored on only what it submitted before the study close.
Proposed Change The laboratory shall be allowed to withdraw fom a study on or before teh close date of the study for any FoPT without notice to the PT Provider or the AA.
Uploaded Document
vote Yes + Comments
email mcaninch@cablelynx.com
Phone Number 903-757-4269
Date 7/20/2007
Details
Response: Persuasive. The requirement for notification of withdrawal has been removed.

Comment Number 143
First Name Thomas Last Name McAninch
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.2
Comment w/Rationale for Change This language is not as clear as we discussed i nteh committee meeting. The language must be simple and clear or it will be subject to multiple interpretations and inconsistency in assessments. I have received several calls on this already. The current complicated language creates a gap between a lab's LOQ and the PTRL relative to "detected" analystes belwo the LOQ. The language is not clear that a lab shall use its normal calibration curve for PT analyses and if the value is less than the LOQ, the lab shall report <"value of lowest calibration standard"
Proposed Change a) The lab shall use its normal calibration curve to analyze PT samples. If the measured value is above the highest calibration standard, the sample shall be diluted and re-analyzed. If the measured value is less than the lowest calibration standard, the result shall be reported as <"value of lowest calibration standard"
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vote Yes + Comments
email mcaninch@cablelynx.com
Phone Number 903-757-4269
Date 7/21/2007
Details
Response: Non-Persuasive. The elimination of reporting to the PTRL was a deliberate change made by the committee. The purpose of the change is 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 its normal range of quantitation is evaluated. Similar changes have been 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.

Comment Number 151
First Name Carol Last Name Schrenkel
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5 Note
Comment w/Rationale for Change It is not a consistant Standard if one AB can request a lab to purchase and analyze PT samples (that aren't available?) when other labs are not required to do the same.

Since PTs are not required by the Standard for some fields of accreditation, ABs do not have the authority to require a lab to analyze one.
Proposed Change Remove the clause.
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 7/23/2007
Details
Response: Persuasive. The note has been removed.

Comment Number 152
First Name Carol Last Name Schrenkel
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1
Comment w/Rationale for Change This is unclear and open to interpretation. If lab A uses a PT provider that includes numerous analytes other than those on the FoPTs, are they required to run them because they're available? If lab B uses a PT provider that only provides the FoPTs, can they still be accredited for the same analytes as lab A? Or, do they have to go to another PT provider because they're available?
Proposed Change Revise the sentence to : In order to maintain accreditation, the laboratory shall, for each accredited FoPT:
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 7/23/2007
Details
Response: Persuasive. The section has been revised to specify that the laboratory must analyze 2 PT samples per year for each accreditation FoPT for which the laboratory holds accreditation.

Comment Number 153
First Name Carol Last Name Schrenkel
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 6.2 c)
Comment w/Rationale for Change Please clarify
Proposed Change no suggestions (I don't understand the statement)
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 7/23/2007
Details
Response: Not Applicable. This section has been removed as it describes procedures for the PTP or the AB and is not applicable to laboratories.

Comment Number 154
First Name michele Last Name potter
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1.d)
Comment w/Rationale for Change section 4.2.1.d) is confusing regarding the time limit required between studies for continiuning accreditation. 4.2.1.d) states it must be no fewer than 15 days apart and no more than 7 months apart. for continuing accreditation, studies cannot be 15 days apart-that only applies to initial accreditation or for labs to come back into compliance after failing two out of the most recent three studies. also, section 5.2.5 of the module references a semi-annual frequency.
Proposed Change the new language needs to mirror what the accreditation bodies proficiency test module 2 volume 2 states in sections 5.2.1 through 5.2.3, specifically section 5.2.3.
Uploaded Document
vote Yes + Comments
email michele.potter@dep.state.nj.us
Phone Number (609) 292-3950
Date 7/23/2007
Details

Response: Persuasive. The language has been revised to specify a time-frame of analysis for successive PT samples used for continuing accreditation to 5-7 months, unless the laboratory is using a PT sample for corrective action to reestablish successful history or to reinstate accreditation after suspension, in which case the time-frame is 15 days.

Comment Number 162
First Name Thomas Last Name Coyner
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.11
Comment w/Rationale for Change I have several comments on several sections. These will be emailed in this format to TNI and to the Chair of the PT Committee.

3.11 This definition is consisten througout several modules. It is not possible for the laboratory or the PT provider to know if the same lot, or batch, was provided to the laboratory be a separate entity. That is outside of the control of either lab or PTP.

Similarly, TNI has responsibility for only TNI PT programs. A PT provide can provide TNI PT samples to non-TNI labs in a non-TNI study since TNI has no control over these samples. It is impossible for a lab to be aware of such an action.

A PT Study is a defined set of PT samples shipped at a designated time with a defined close date, nothing more.
Proposed Change The requirements of this "definition" should be built into each module as appropriate. The definition should be corrected to actually be a definition of a PT Study.
Uploaded Document
vote No + Comments
email t.coyner@apgqa.com
Phone Number 740-423-4200
Date 7/24/2007
Details
Response: Persuasive. The definition for PT study has been revised and is now based on international standards.

Comment Number 163
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.12
Comment w/Rationale for Change The definition for PT Study Opening Date may unintentionally preclude a laboratory from joining a study after it is "first made available," which becomes important when a "regular" study is being used for corrective action, and the lab needs to comply with the 15-day separation requirement. For clarity and consistency with V3, 8.4.4, "There shall be at least fifteen calendar days after the closing date of one study and the shipment date of the next study, whether supplemental or regularly scheduled, for the same field of proficiency testing for a given laboratory," additional language is needed.
Proposed Change Add to 3.12: For the purposes of calculating the required fifteen-day separation between closing date and opening date of successive studies, Opening Date shall mean the date that the PT Provider ships the study, whether supplemental or regularly scheduled, to the laboratory.
Uploaded Document
vote No + Comments
email steve-arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Not Applicable. After consideration by the PT committee, the committee decision was made to use "analysis date" as the basis for tracking the time-frames between successive PT samples. The definition for PT Opening Date was removed from the module because the term is no longer used in the module. See also response to comment #166.

Comment Number 164
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.2 Note
Comment w/Rationale for Change There needs to be a specific location of the PT listing
Proposed Change add to 4.1.2 Note: This listing is posted on The NELAC Institute website.
Uploaded Document
vote No + Comments
email steve-arms@doh.state.fl.us

Date 7/24/2007
Details
Response: Persuasive. The location of the posted FoPT tables was added.

Comment Number 165
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5 Note
Comment w/Rationale for Change The note is self-contradictory and unnecessary. If a FoPT is not available, then how can the AB request its analysis? If the meaning is to say that the AB can require a "non-required" PT, such must not be allowed. If it is not a requirement, it should be omitted from the standard.
Proposed Change Strike the note to 4.1.5 in its entirety.
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Persuasive. The note has been removed.

Comment Number 166
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.4
Comment w/Rationale for Change Analysis date cannot be readily tracked and is not included in the Final Evaluation Report, V3, 11.2.3.
Proposed Change Change "analysis" to "closing" in 4.1.4.
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Non-Persuasive. After extensive discussion and consideration of all comments received for this topic, the PT committee decided that all time-frames for tracking PT samples should be calculated using analysis date. The intent to specify a time-period for tracking PT samples is to ensure that there is sufficient time (15 calendar days) between the analysis of successive PT samples for any FoPT, thus analysis date is the date that should be used for tracking. Analysis date is provided on each test report and is readily available for review by ABs.

The opening date of a PT study is an arbitrary date assigned by a PT Provider. The closing date of a PT study is calculated as 45 days from the opening date. For supplemental PTs, the opening date is the date that the PT sample was shipped to the laboratory and the closing date is the date that the laboratory reported results for the supplemental PT to the PT provider. Using opening/closing dates as the basis for tracking PTs is restrictive because the opening date of a subsequent PT study may occur before the closing date of the previous study, thus the lab is precluded from participation in subsequent PT studies. Using the ship date for PTs is awkward because the ship date may or may not correspond with the opening date, the ship date is not provided on any PT providers evaluation report, the ship date may be different for every laboratory participating in a study and there may even be different ship dates for multiple PT samples shipped to the same laboratory for a single study. To use ship date as the basis for tracking PTs would require PT providers to include the ship date for every PT sample on the PT report. Additionally, the use of ship date requires the PT provider to track PT scheduling for a laboratory, when the scheduling of PTs is the responsibility of the laboratories.

Comment Number 167
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1
Comment w/Rationale for Change "Available" is not defined.
Proposed Change Add before the colon in 4.2.1: "and designated in the official listing referenced in 4.1.2"
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details

because PT samples for FoPT are available 2X per year. The requirement was added to anticipate a lesser frequency with toxicity and other specialty methods. After discussion from the committee, the committee agreed that specialty methods would be handled in the appendix and as noted in section 1.3.3, the appendices supersede the main text.

Comment Number 168
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1 (c)
Comment w/Rationale for Change "for" should be"from"
Proposed Change Change "for" to "from" in 4.2.1 (c).
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Persuasive. The editorial change has been made as suggested.

Comment Number 169
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1 (d)
Comment w/Rationale for Change Analysis date cannot be readily tracked; the word "sample" should be "same"; clarification is needed to explicitly define the time intervals. The suggested wording below is consistent with the 2003 NELAC standard, which has been adequate.
Proposed Change Reword 4.2.1 (d): analyze PT samples for the same FoPT obtained no fewer than 15 days apart, as measured from the closing date of one study to the opening date of any successive study, and no more than 7 months apart, as measured from the closing date of one study to the closing date of any successive study.
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Non-Persuasive. After extensive discussion and consideration of all comments received for this topic, the PT committee decided that all time-frames for tracking PT samples should be calculated using analysis date. The intent to specify a time-period for tracking PT samples is to ensure that there is sufficient time (15 calendar days) between the analysis of successive PT samples for any FoPT, thus analysis date is the date that should be used for tracking. Analysis date is provided on each test report and is readily available for review by ABs.

The opening date of a PT study is an arbitrary date assigned by a PT Provider. The closing date of a PT study is calculated as 45 days from the opening date. For supplemental PTs, the opening date is the date that the PT sample was shipped to the laboratory and the closing date is the date that the laboratory reported results for the supplemental PT to the PT provider. Using opening/closing dates as the basis for tracking PTs is restrictive because the opening date of a subsequent PT study may occur before the closing date of the previous study, thus the lab is precluded from participation in subsequent PT studies. Using the ship date for PTs is awkward because the ship date may or may not correspond with the opening date, the ship date is not provided on any PT providers evaluation report, the ship date may be different for every laboratory participating in a study and there may even be different ship dates for multiple PT samples shipped to the same laboratory for a single study. To use ship date as the basis for tracking PTs would require PT providers to include the ship date for every PT sample on the PT report. Additionally, the use of ship date requires the PT provider to track PT scheduling for a laboratory, when the scheduling of PTs is the responsibility of the laboratories.

Comment Number 170
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.2
Comment w/Rationale for Change I understand the impetus behind this clause, but think there needs to be something here to assign the responsibility for determining if PT samples are not available twice per year. Otherwise, there may be no consistency in enforcement.
Proposed Change Add to 4.2.2: The TNI PT Board shall verify such lack of availability and communicate this to the TNI NELAP Board.
Uploaded Document

email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Not Applicable. The proposed change has not been made as suggested in comment 167. The section has been deleted because PT samples for FoPT are available 2X per year. The requirement was added to anticipate a lesser frequency with toxicity and other specialty methods. After discussion from the committee, the committee agreed that specialty methods would be handled in the appendix and as noted in section 1.3.3, the appendices supersede the main text.

Comment Number 171
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.2
Comment w/Rationale for Change Inconsistent wording.
Proposed Change Change "either" to "any" and "both" to "all" in 5.1.2.
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Persuasive. The words “both and either” were changed to all.

Comment Number 173
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.3 (c)
Comment w/Rationale for Change redundant wording
Proposed Change Strike the words "prior to the closing date of the study" in 5.1.3 (c).
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Non-Persuasive. After extensive discussion and consideration of all comments received for this topic, the PT committee decided that all time-frames for tracking PT samples should be calculated using analysis date. All references to “open, opening, close or closing” dates were changed to analysis date.

Comment Number 174
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.3(d)
Comment w/Rationale for Change Omitted word.
Proposed Change Add the word "Provider" before the period in 5.1.3(d).
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Persuasive. The sentence has been corrected to specify PT Provider.

Comment Number 175
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.4
Comment w/Rationale for Change Clarification needed to allow authorization on the closing date.
Proposed Change Add “On or” at the beginning of 5.2.4.

vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Not Applicable. Based on other comments received, the committee decided to remove the requirement to notify of withdrawal from the standard.

Comment Number 176
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 7.1
Comment w/Rationale for Change Reword for consistency with V2, M2, 6.1 (g).
Proposed Change Change "investigate the cause" to "perform root cause analysis" in 7.1.
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Persuasive. After consideration of all comments received, the committee decided to use the term “corrective action” and indicate that corrective action be performed following the requirements given in the Quality Systems module of Volume 1.

Comment Number 178
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 7.2 (b), (d) and throughout
Comment w/Rationale for Change Use "opening" and "closing" date for consistency with the definitions.
Proposed Change Change “open” to “opening” and “close” to “closing” in 7.2 (b) and (d).
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Non-Persuasive. After extensive discussion and consideration of all comments received for this topic, the PT committee decided that all time-frames for tracking PT samples should be calculated using analysis date. The intent to specify a time-period for tracking PT samples is to ensure that there is sufficient time (15 calendar days) between the analyses of successive PT samples for any FoPT, thus analysis date is the date that should be used for tracking. All dates used to track time-frames between studies was changed to analysis date.

Comment Number 179
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 8.2
Comment w/Rationale for Change The second sentence imposes a responsibility on the NELAP Board that is not within its duties.
Proposed Change Strike the entire second sentence of 8.2.
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/24/2007
Details
Response: Persuasive. The reference to the NELAP Board was removed and replaced with a reference to the TNI appeals process policy which will define the appropriate authorities. It should be noted that Ken Jackson, Chair of the Consensus Standard Development Board indicated that the NELAP Board is the group with the proper authority to handle these appeals.

Comment Number 196
First Name Stephen Last Name Arms
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.1

Comment w/Rationale for Change I understand the impetus behind the last sentence in this clause but think there needs to be something here to assign the responsibility for determining if PT samples are not available twice per year. Otherwise, there may be no consistency in enforcement.
Proposed Change Add to 5.2.1: The TNI PT Board shall verify such lack of availability and communicate this to the TNI NELAP Board.
Uploaded Document
vote No + Comments
email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/25/2007
Details
Response: Non-Persuasive. The comment does not apply to Section 5.2.1, but may be applicable to section 4.2.2., in which case the comment is persuasive. After consideration, the committee removed the language in section 4.2.2 because current FoPTs are available twice per year and the requirements for specialized FoPTs such as toxicity will be included in appendices that will supersede this section.

Comment Number 203
First Name Steve **Last Name** Axelrod
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1
Comment w/Rationale for Change Where the opportunity presents itself, it seems reasonable that a PT standard should be able to be reported for more than one field of accreditation to provide a cost savings to the laboratory. NELAC certification is an extremely costly proposition and it seems that there has been little regard to consider the cost to the labs as part of the development of the standards. Perhaps a new TNI committee can be created for that purpose.
Proposed Change Allow PT standards to be used for more than one field of accreditation when possible. Promote this concept with the PT providers.
Uploaded Document
vote Abstain + Comments
email axelrods@hillsboroughcounty.org
Phone Number 813-264-3887
Date 7/26/2007
Details
Response: Not Persuasive & Hold until Next Revision. Laboratories are already permitted to analyze a single PT sample for multiple methods and multiple fields of proficiency testing when the FoPT are within the same field of accreditation matrix. To clarify the standard, the Note in section 5.1.1 was revised. If the intent of the comment was to suggest that laboratories be allowed to report a single PT across field of accreditation matrices such as non-potable and drinking water, the Committee has taken the comment under consideration and the proposed change will be held until the next revision as this topic is currently under discussion with the TNI PT Board and ELAB. The committee determined that such a change is a substantial change to the PT program that cannot be made at this time.

Comment Number 210
First Name Carol **Last Name** Schrenkel
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 7.2 b) and d)
Comment w/Rationale for Change redundant

Also, the 15 days between the open date of the study and the close date of the previous study is too long. Since the lab is required to take corrective action (and document it), why make them wait longer prior to performing another PT?

For example, a study opens Jan 15 and closes March 1. The lab finds out from the preliminary results March 2 that they failed an analyte for the second time. To get it back as quickly as possible (before the dercert letter comes out), they could perform the next study wich closes March 29. There is almost a month to do corrective action prior to the study results being due. However, this is not allowed since the second study opened Feb 12.

The study open and close dates are irrelevant. It is the between analyses that the corrective action occurs. (previous language tried to capture that, but used analysis and ship dates).
Proposed Change
The PT study for corrective action shall be a supplemental study or quick response PT standard; and must be analyzed at least 15 days after any previous PT for the same FoPT to allow time for corrective action.
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 7/26/2007
Details

corrective action process.

Response: Persuasive: PT samples used for corrective action may be from a regularly scheduled PT study or a “quick response” PT study, which is defined in the standard as a supplemental PT study. The term “study” refers to both types of PT studies. All dates used to track time-frames for PT samples has been changed to analysis date.

Comment Number 216
First Name Roger Last Name Kenton
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1
Comment w/Rationale for Change It appears that "for" was used when "from" is the more appropriate word.
Proposed Change Change "obtain their PT samples for any PTPA-accredited PT provider" to "obtain their PT samples from any PTPA-accredited PT provider".
Uploaded Document
vote No + Comments
email rogerk@eastman.com
Phone Number 903-237-6882
Date 7/26/2007
Details
Response: Persuasive. The editorial change has been as suggested.

Comment Number 217
First Name Roger Last Name Kenton
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.3
Comment w/Rationale for Change Two prepositions are not typically used in sequence.
Proposed Change Change "Until after the closing date of a PT study," to "Until the closing date of a PT study passes,".
Uploaded Document
vote No + Comments
email rogerk@eastman.com
Phone Number 903-237-6882
Date 7/26/2007
Details
Response: Persuasive. The sentence has been revised to correct grammar.

Comment Number 219
First Name Roger Last Name Kenton
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.2
Comment w/Rationale for Change Section 5.2.2 seems to indicate that J flagged analytes (detected analytes above the LOD but below the LOQ) should be reported for proficiency testing studies. By definition, J flagged results are of lower quality and should be flagged when reported.

Section 5.2.2.a) addresses non-detected analytes and analytes with results below the TNI established PTRL. Section 5.2.2.b) indicates that all other results should be reported as the resultant value of the analysis for the PT sample . . .

If the LOQ is above the PTRL, then a J flagged result is not covered by Section 5.2.2.a). The result is not non-detect and it is not necessarily below the TNI PTRL.
Proposed Change Update Section 5.2.2.a) to indicate: Non-detected analytes and analytes with results below the LOQ shall be reported as less than (<) the value equal to the laboratory's lowest calibration standard for the test method used to analyze the PT sample.
Uploaded Document
vote No + Comments
email rogerk@eastman.com
Phone Number 903-237-6882
Date 7/26/2007
Details
Response: Not Applicable. The elimination of reporting to the PTRL is a deliberate change made by the committee. The purpose of the change is 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 have been 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 no negative impact to laboratories.

Comment Number 225
First Name Jeff Last Name Flowers
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1
Comment w/Rationale for Change With this schedule, labs will be required to perform two (2) aqueous studies per year, i.e., potable then non-potable, instead of four (4).

This comment is regarding the number of and frequency that NELAC accredited laboratories are required to analyze PT samples for the aqueous matrices "Potable" and "Non-Potable" water. Labs that are accredited in the two aqueous categories potable and non-potable are performing 4 PT's per year for identical methodologies. Prior to the EPA 40 CFR Monday, March 12, 2007 update, labs were at least reporting different methods for the WS (potable) and WP (non-potable) PT's, but now, the same methods are referenced. In order to attract more participating labs and AB's, TNI should harmonize the TNI Volume 1, Module 1 PT standard with the EPA Drinking Water Manual for Laboratory Certification. The DW manual 5th Edition, page IV-5, Section 7.2 states:

". . .analyze PT samples. . .at least once every 12 months for each analyte and by each method used to analyze compliance samples. . . ...A make up PT sample must be successfully analyzed."

It would be complicated to change the definition of matrix to combine potable and non-potable water categories, since Accreditation Bodies have framed their applications and fees by category, and the PT provider products are well known as WS and WP. Adjusting the PT schedule, however, would facilitate a cooperative relationship with EPA Office of Ground Water and Drinking Water concerns as stated in the Director Cynthia C. Dougherty's May 14 2007 Memorandum on Drinking Water Laboratory Program Oversight.

This idea will cut the time and costs to both labs and AB's.
Proposed Change 4.2.1 a) analyze at least one TNI-compliant PT samples per year;
4.2.1 b) maintain a history of at least one successful performances, as described in Section 6.0, out of the most recent two attempts;
4.2.1 d) analyze PT samples for the sample FoPT no fewer than 15 days apart and no more than 12 months apart.

OR

As another option, we could define a PT matrix called "Aqueous PT", considering that the PT Providers use the same materials to prepare WS and WP aqueous PT's. So the text could stay the same, but add: of "two TNI-compliant Aqueous PT samples per year". There would still be the 2 studies per year requirement for soil PT's. Non-NELAP states and participating labs would still be demonstrating their performance on the methods two times per year, which is twice as often as EPA requires for certification.
Uploaded Document
vote No + Comments
email jeff@flowerslabs.com
Phone Number 407 339 5984
Date 7/29/2007
Details
Response: Hold until Next Revision: The committee has taken the comment under consideration and the proposed change will be held until the next revision as this topic is currently under discussion with the TNI PT Board and ELAB. The committee determined that such a change is a substantial change to the PT program that cannot be made at this time.

Comment Number 254
First Name Carol Last Name Schrenkel
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.9
Comment w/Rationale for Change The PTRL is not necessarily the lowest acceptable result. Using DOD control limits as an example of multi-lab acceptance limits, 3,3'-dichlorobenzidine has a lower limit of 20%. If it were spiked at the lowest concentration, 60 ug/L, and had a 20% recovery, the result would be 12 ug/L; but the PTRL is 10 ug/L. What control limits are being used to determine the lowest acceptable result?
Proposed Change Either raise the PTRLs that do not meet, or raise the lower concentration that can be spiked.
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 7/30/2007
Details
Response: Non-Persuasive. The definition of PTRL was taken from the FoPT tables posted by the NELAP PT Board and to remain consistent with these tables, the definition was not changed. The comment should be forwarded to the TNI Board for their consideration. However-due to other revisions made in this module, the definition for PTRL has been removed as this term is no longer used in this module.

Comment Number 256
First Name Carol Last Name Schrenkel
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 7.2 b) and d)
Comment w/Rationale for Change These are not clear. I think they are saying the same thing, in which case one needs to be deleted. If not, they need to be explained clearer.
Proposed Change as above
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 7/30/2007
Details
Response: Persuasive. Item b has been deleted.

Comment Number 257
First Name Carol Last Name Schrenkel
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 9.0
Comment w/Rationale for Change My understanding of the purpose of the volumes and modules was to have all the requirements (e.g., laboratory requirements) in one volume. Therefore, this shouldn't refer to requirements in volume 2.
Proposed Change Discuss suspension/revocation of accreditation here.
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 7/30/2007
Details
Response: Persuasive. This section has been deleted from the laboratory module. The definitions for suspension and revocation are included in Section 3.0. After committee discussion it was determined that beyond inclusion of the definitions, procedures for revocation or suspension could not be included in the standard due to differing AB regulations.

Comment Number 308
First Name Chuck Last Name Wibby
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5
Comment w/Rationale for Change The "Note" that appears at the end of this section will result in non-uniform requirements for accreditation. The “Note” will permit an Accrediting Authority to require a laboratory to purchase and analyze PT samples that are not required by other Accrediting Authorities.
Proposed Change This “Note” is unnecessary and should be removed from the document. If the expert TNI Expert Committee wishes to modify the requirements regarding which PT samples must be run to be compliant with international standards, much more extensive language needs to be incorporated into the standard.
Uploaded Document
vote No + Comments
email cwibby@wibby.com
Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Persuasive. The note has been removed.

Comment Number 309
First Name Chuck Last Name Wibby
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.2
Comment w/Rationale for Change The “Note” at the end of Section 4.1.2 (“The TNI PT Board maintains the official listing of FoPT and experimental FoPT”) is inconsistent with nomenclature used elsewhere in the PT program.
Proposed Change Modify the note to read “The TNI PT Board maintains the official listing of accreditation FoPT tables and experimental FoPT tables.”
Uploaded Document
vote No + Comments

Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Persuasive. The language has been revised as suggested and the location of the posted FoPT tables has been added.

Response: Persuasive. The note has been removed.

Comment Number 311
First Name Chuck Last Name Wibby
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.2
Comment w/Rationale for Change The language ("the laboratory shall analyze the PT samples in the minimum time frame in which the PT samples are available from any PTPA-accredited PT Provider") in Section 4.2.2 does not clearly address the issue of what a laboratory must do if PT samples are not available twice each year.
Proposed Change The language should be rewritten to clearly address what a laboratory must do in the situation described in this section or be removed entirely.
Uploaded Document
vote No + Comments
email cwibby@wibby.com
Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Not Applicable. The proposed change has not been made as suggested in comment 167. The section has been deleted because PT samples for FoPTs are available twice per year. The requirement was added to anticipate a lesser frequency with toxicity and other specialty methods. After discussion, the committee agreed that specialty methods would be handled in the appendix and, as noted in section 1.3.3, the appendices would supersede the main text.

Comment Number 312
First Name Kathleen Last Name Roach
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1 and 4.2
Comment w/Rationale for Change Our municipal lab currently pays more >$10,000 a year in PT samples. We view this as excessive especially in the light of Florida Governments having to make serious cutbacks. We question what the benefit is here, other then providing revenue to the PT providers. Consider the following:
1) The majority of the wet chemistry and metals PT samples that many
of us are required to analyzed are duplicated for WP and WS samples, resulting in the requirement to analyze 4 PTs sample a year for the same/similar method and technology!
2) The EPA DW Manual only requires one sample to be analyzed every 12 months.
3) PT samples are in a clean matrix, and if a lab is following the method, they should yield results similar to the calibration verification standards, of which an auditor should be reviewing upon inspection. So why require this extra expense? The value of analyzing PTs has its place, but we question the value of the frequency, which directly equates to cost. The cost of these samples should equal the benefit!
Proposed Change 1) For initial accreditation, only require the analysis of one PT sample.
2) For continued accreditation, require labs to analyze one PT per twelve month period, and when labs utilize the same method/technology for both drinking water and non-potable water certifications; allow labs the opportunity to report one FoPT sample for both WP and WS. If sample concentration is an issue, and labs want to kill two birds with one stone, then require labs to order the lower concentration.
Uploaded Document
vote No + Comments
email kroach@pinellascounty.org
Phone Number 727-582-2302
Date 7/31/2007
Details
Response: Hold until Next Revision. The committee has taken the comment under consideration and the proposed change will be held until the next revision as this topic is currently under discussion with the TNI PT Board and ELAB. The committee determined that such a change is a substantial change to the PT program that cannot be made at this time.

Comment Number 315
First Name Chuck Last Name Wibby
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.2
Comment w/Rationale for Change The language in this Section ("When a laboratory reports more than one test method using the same technology for a FoPT, an unacceptable score for either test method shall result in an unacceptable score for both test methods for that FoPT.") is only applicable if all Accrediting Authorities using this standard accredit laboratories by technology only and not by method.

Proposed Change Change the language in this section to read "If an Accrediting Authority using this standard only accredits laboratories by technology and if a laboratory reports more than one test method using the same technology for a FoPT, an unacceptable score for either test method shall result in an unacceptable score for both test methods for that FoPT."
Uploaded Document
vote No + Comments
email cwibby@wibby.com
Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Non-Persuasive. The definition of Field of Accreditation includes matrix, technology/method and analyte combinations and all ABs should be applying this definition consistently when offering fields of accreditation. A note has been added to clarify this requirement.

Comment Number 317
First Name Chuck Last Name Wibby
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.3 d)
Comment w/Rationale for Change The language in this Section ("attempt to obtain the assigned value of any PT sample from the PT.") needs to be corrected.
Proposed Change The language in this Section should read "attempt to obtain the assigned value of any PT sample from the PT Provider."
Uploaded Document
vote No + Comments
email cwibby@wibby.com
Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Persuasive. The sentence has been revised to correct grammar.

Comment Number 319
First Name Chuck Last Name Wibby
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.2 a)
Comment w/Rationale for Change 5.2.2 a)
The language in this Section ("Non-detected analytes and analytes with results below the TNI-established PTRL shall be reported as less than (<) the value equal to the laboratory's lowest calibration standard for the test method used to analyze the PT sample.") requires the laboratory to at a minimum treat PT samples as non-routine samples. In the worst case scenario, the requirement could be interpreted to require the laboratory to report fraudulent data. For example, the laboratory detects an analyte in a PT sample at 10 ppb, the TNI PTRL is 15 ppb and the laboratory's lowest calibration standard is 5 ppb. This Section would require the laboratory to report a result of <5 ppb for an analyte detected at 10 ppb.
Proposed Change The language in this Section should read "Non-detected analytes and analytes with results below the TNI-established PTRL shall be reported as less than (<) the TNI PTRL for the analyte."
Uploaded Document
vote No + Comments
email cwibby@wibby.com
Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Not Applicable. The elimination of reporting to the PTRL is a deliberate change made by the committee. The purpose of the change is 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 have been 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 no negative impact to laboratories.

Comment Number 331
First Name Terri Last Name Grimes
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2 & 5.2.5
Comment w/Rationale for Change What is the purpose of running a WS and a WP study, each, twice a year? Both are in nice clean matrices, therefore, one study for each per year would provide the same information without making the labs buy and perform duplicate analyses. With the ever-increasing costs of PTs, we labs have trouble understanding why more than one study per year isn't sufficient.

Proposed Change 4.2.1.a) analyze one TNI-compliant PT sample per year per FoPT;
b) maintain a history of at least one successful performance, as described in Section 6.0, out of the most recent two attempts;

4.2.2 "...at least once per year..."
4.2.3 "...shall analyze one PT sample for the experimental..."
5.2.5 "...annual analysis schedule necessary to amintina accreditation..."
Uploaded Document
vote No + Comments
email Tgrimes@co.pinellas.fl.us
Phone Number 727-582-2302
Date 7/31/2007
Details
Response: Hold until Next Revision. The committee has taken the comment under consideration and the proposed change will be held until the next revision as this topic is currently under discussion with the TNI PT Board and ELAB. The committee determined that such a change is a substantial change to the PT program that cannot be made at this time.

Comment Number 337
First Name Paul Last Name Junio
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 1.2 b)
Comment w/Rationale for Change Real world samples don't require specific methods without regard to the level of analyte present (i.e., if the level of analyte isn't appropriate to the method requested, it can be changed in the real world, but not for a PT sample). Therefore (and considering other issues regarding creation of samples and the requirement to fill out forms as opposed to reporting data in a standard reporting format), the requirement to be as similar to real-world samples as reasonable possible can't be met.
Proposed Change Strike "as similar to real-world samples as reasonably possible and"
Uploaded Document
vote Yes + Comments
email Paul.Junio@testamericainc.com
Phone Number 920-261-1660
Date 7/31/2007
Details
Response: Not Applicable. The language was removed rather than revised as suggested because the language describes requirements for the composition of PT samples and is therefore not applicable to the laboratory module.

Comment Number 338
First Name Paul Last Name Junio
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.3.c
Comment w/Rationale for Change No communication regarding PT samples should be acceptable, whether among laboratories or with a Corporate representative. This loophole should be eliminated by deleting "at another laboratory".
Proposed Change communicate with any individual concerning the analysis of the PT sample prior to the closing date of the study;
Uploaded Document
vote Yes + Comments
email Paul.Junio@testamericainc.com
Phone Number 920-261-1660
Date 7/31/2007
Details
Response: Non-Persuasive. If "at another laboratory" were removed from the sentence. The language would specify that no communication whatsoever is permitted. Laboratory personnel within the facility must communicate within one another regarding analysis of the PT sample.

Comment Number 339
First Name Paul Last Name Junio
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.3.d
Comment w/Rationale for Change The word "Provider" appears to be missing at the end of this sentence.
Proposed Change attempt to obtain the assigned value of any PT sample from the PT Provider.
Uploaded Document
vote Yes + Comments
email Paul.Junio@testamericainc.com
Phone Number 920-261-1660

Details
Response: Persuasive. The sentence has been corrected to specify PT Provider.

Comment Number 340
First Name Paul Last Name Junio
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.3.2
Comment w/Rationale for Change This section requires that the lab archive reporting forms for PT data. What if no forms are used to report data, such as with electronic upload of data to a PT Provider? I suggest replacing forms with format, scheme, or some other non-specific term.
Proposed Change These records shall include a copy of the results in the reporting format used by the laboratory to report PT results to the PT provider
Uploaded Document
vote Yes + Comments
email Paul.Junio@testamericainc.com
Phone Number 920-261-1660
Date 7/31/2007
Details
Response: Persuasive. A requirement for electronic upload has been added to the module.

Comment Number 361
First Name Elizabeth Last Name Humple
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.2a
Comment w/Rationale for Change The standard states that laboratories should report non-detected analytes and results below the TNI-established PTRL as less than the value of their lowest standard. The lowest standard is required to be between their LOD and their LOQ, not necessarily at the LOD. If laboratories are required to verify their detection limits on a quarterly basis, they should be able to use that value as a reporting level. Or, perhaps non-detected analytes and results below the TNI-established PTRL should be reported as less than the PTRL.
Proposed Change Non-detected analytes and results below the TNI-established PTRL shall be reported as less than the value equal to the laboratory's limit of detection for the test method used to analyze the PT sample.

OR

Non-detected analytes and results below the TNI-established PTRL shall be reported as less than the value equal to the TNI-established PTRL.
Uploaded Document
vote No + Comments
email ehumple@broward.org
Phone Number 954-519-1451
Date 7/31/2007
Details
Response: Not Applicable. The elimination of reporting to the PTRL is a deliberate change made by the committee. The purpose of the change is 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 have been 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 no negative impact to laboratories.

Comment Number 362
First Name Elizabeth Last Name Humple
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.3.2
Comment w/Rationale for Change Some PT providers allow for on-line data entry. Would a copy of the PT summary meet this requirement?
Proposed Change These records shall include a copy of the reporting forms used by the laboratory to report PT results to the PT provider and/or a printout of the on-line summary information from the PT providers web site.
Uploaded Document
vote No + Comments
email ehumple@broward.org
Phone Number 954-519-1451
Date 7/31/2007
Details
Response: Persuasive. A requirement for electronic upload has been added to the module.

Comment Number 363
First Name Elizabeth Last Name Humple
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 7.2b and 7.2d
Comment w/Rationale for Change These sections seem redundant.
Proposed Change Eliminate 7.2d
Uploaded Document
vote Yes + Comments
email ehumple@broward.org
Phone Number 954-519-1451
Date 7/31/2007
Details
Response: Persuasive. Item b has been deleted.

Comment Number 365
First Name Wade Last Name DeLong
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.2
Comment w/Rationale for Change 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?
Proposed Change Suggested resolution: Non-detect or analytical values less than the PTRL should be reported as less than the PTRL.
Uploaded Document
vote No + Comments
email w.delong@apgqa.com
Phone Number 740-423-4200
Date 7/31/2007
Details
Response: Not Applicable. The elimination of reporting to the PTRL is a deliberate change made by the committee. The purpose of the change is 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 have been 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 no negative impact to laboratories.

Comment Number 367
First Name Wade Last Name DeLong
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.2
Comment w/Rationale for Change 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 simple 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.
Proposed Change Suggested resolution: Delete it section as vague, unclear and unnecessary.
Uploaded Document
vote No + Comments
email w.delong@apgqa.com
Phone Number 740-423-4200
Date 7/31/2007
Details
Response: Non-Persuasive. The committee believes it is necessary for laboratories to know how PT samples are evaluated, thus a reference to the volumes that describe PT scoring and evaluation are included.

Comment Number 368
First Name Mike Last Name Haller
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.2
Comment w/Rationale for Change 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.

Proposed Change 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.
Uploaded Document
vote No + Comments
email m.haller@apgqa.com
Phone Number 740-423-4200
Date 7/31/2007
Details
Response: Non-Persuasive. The definition of Field of Accreditation includes matrix, technology/method and analyte combinations and all ABs should be applying this definition consistently when offering fields of accreditation. A note has been added to clarify this requirement.

Comment Number 389
First Name James Last Name Broderick
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5
Comment w/Rationale for Change This note is located in the wrong place and makes little sense. Why would an AB ask a lab to perform a PT that is not required in the FOPT, especially if the AB has to accept the result even when the lab fails the non-FOPT test? This adds nothing for the AB, and actually creates a tenuous legal position for an AB (granting accreditation to a lab when it failed the PT).
Proposed Change Delete Note.
Uploaded Document
vote No + Comments
email jdb10@health.state.ny.us
Phone Number 518-573-7548
Date 8/1/2007
Details
Response: Persuasive. The note has been removed.

Comment Number 391
First Name James Last Name Broderick
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.1, 4.2.3, 6.2.B
Comment w/Rationale for Change The concept of Experimental PTs is of no value to a lab (being required to do work without being evaluated or held accountable for the answers), the accreditation body (who has to try to identify which PTs really count towards accreditation and which don't), or PT providers (who have to do a lot of work for samples with no value to labs or ABs). The PT Board should decide whether or not an analyte belongs on the FOPT or not. This is a non-essential burden (and source of confusion) to all involved, will not enhance acceptance of NELAP, and does not promote creation of better data.
Proposed Change The standard should have all references to Experimental PTs removed.
Uploaded Document
vote No + Comments
email jdb10@health.state.ny.us
Phone Number 518-573-7548
Date 8/1/2007
Details
Response: Hold until Next Revision. The topic of experimental PTs is under discussion with the TNI PT Board. So long as the FoPT tables include experimental FoPTs the term experimental PTs and their requirements need to be included in the standard.

Comment Number 405
First Name Kenneth Last Name Jackson
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.1
Comment w/Rationale for Change Requiring a laboratory to analyze experimental PTs, but not using their score in the accreditation process is meaningless. The requirement does nothing to assure the quality of a lab. Therefore, it should be removed from the standard and placed in policy, as a voluntary exercise for labs, if the PTB really wants to continue having labs do this. Also as an AB, I would have a problem allowing a lab to continue operation if its experimental PT was reported as "less than" when I knew the sample contained a high concentration of that analyte. I would be powerless to take any action agianst the lab, but I would also be turning a blind eye to a situation that could adversely affect the public health of the citizens in my state.
Proposed Change Remove all reference to experimental PTs
Uploaded Document
vote Yes + Comments
email jackson@wadsworth.org

Date 8/1/2007
Details
Response: Hold until Next Revision. The topic of experimental PTs is under discussion with the TNI PT Board. So long as the FoPT tables include experimental FoPTs the term experimental PTs and their requirements need to be included in the standard.

Comment Number 406
First Name Kenneth Last Name Jackson
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.3
Comment w/Rationale for Change Requiring a laboratory to analyze experimental PTs, but not using their score in the accreditation process is meaningless. The requirement does nothing to assure the quality of a lab. Therefore, it should be removed from the standard and placed in policy, as a voluntary exercise for labs, if the PTB really wants to continue having labs do this. Also as an AB, I would have a problem allowing a lab to continue operation if its experimental PT was reported as "less than" when I knew the sample contained a high concentration of that analyte. I would be powerless to take any action agianst the lab, but I would also be turning a blind eye to a situation that could adversely affect the public health of the citizens in my state.
Proposed Change Remove
Uploaded Document
vote Yes + Comments
email jackson@wadsworth.org
Phone Number 518-485-5570
Date 8/1/2007
Details
Response: Hold until Next Revision: The committee has taken the comment under consideration and the proposed change will be held until the next revision as this topic (experimental PTs) is currently under discussion with the TNI PT Board. The TNI PT Board is the body that establishes FoPT. The committee has determined that such a change is a substantial change to the PT program that cannot be made at this time.

Comment Number 408
First Name Kenneth Last Name Jackson
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 6.2
Comment w/Rationale for Change Requiring a laboratory to analyze experimental PTs, but not using their score in the accreditation process is meaningless. The requirement does nothing to assure the quality of a lab. Therefore, it should be removed from the standard and placed in policy, as a voluntary exercise for labs, if the PTB really wants to continue having labs do this. Also as an AB, I would have a problem allowing a lab to continue operation if its experimental PT was reported as "less than" when I knew the sample contained a high concentration of that analyte. I would be powerless to take any action agianst the lab, but I would also be turning a blind eye to a situation that could adversely affect the public health of the citizens in my state.
Proposed Change Delete the paragraph: "The laboratory's PT performance....."
Uploaded Document
vote Yes + Comments
email jackson@wadsworth.org
Phone Number 518-485-5570
Date 8/1/2007
Details
Response: Not Applicable and Hold until Next Revision. The comment was made for section 6.2, which has been removed from this module, however the rationale of the comment pertains to experimental PTs. The PT committee has decided to hold all comments regarding experimental PTs until the next revision because this topic currently under discussion with the TNI PT Board.

Comment Number 411
First Name Kenneth Last Name Jackson
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5
Comment w/Rationale for Change This refers to the "note". This is not a standard. It tells me the AB can request analysis of a PT sample, but cannot require it. Also, it opens the door for some ABs to put pressure on a lab to analyze PT samples that other ABs don't require. This can only lead to an unlevel playing field between states. The standard requires labs to analyze PTs only if there is a TNI FoPT, and language should not be added that makes this "fuzzy".
Proposed Change Remove the note
Uploaded Document
vote Yes + Comments
email jackson@wadsworth.org
Phone Number 518-485-5570

Details
Response: Persuasive. The note has been removed.

Comment Number 412
First Name Kenneth Last Name Jackson
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 8.2
Comment w/Rationale for Change An evaluation is made by the PT provider, and any appeal should go to the PTPA. However, an accreditation decision should be appeealed to the NELAP Board. Reqwording is in order
Proposed Change Change 8.2 to read: "When an accreditation decision, by the primary AB, that results from unsatisfactory PT scores provides sufficient cause to question the validity of the decision, the laboratory may appeal the decision of the AB to the NELAP Board."
Uploaded Document
vote Yes + Comments
email jackson@wadsworth.org
Phone Number 518-485-5570
Date 8/1/2007
Details
Response: Persuasive. The reference to the NELAP Board has been removed and replaced with a reference to the TNI appeals process policy which will define the appropriate authorities.

Comment Number 438
First Name Dave Last Name Mendenhall
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section M1 8.2
Comment w/Rationale for Change 8.2 When a laboratory receives a not acceptable evaluation by the Primary AB and there is sufficient cause to question the validity of the evaluation, the laboratory shall appeal the evaluation to the primary AB. If the primary AB is not able or is unwilling to resolve the evaluation, the laboratory shall appeal to the National Environmental Laboratory Accreditation Program (NELAP) Board, which is the body that approves the NELAP ABs.

The NELAP board doesn't seem to be the proper body to deal with complaint resolution of this type. An interpretation may take a different path than a unique AB program need. In some cases an AB decision may be a determining factor to their continuing to be an AB and others may be less significant.
Proposed Change Either eliminate the following sentence [prefered] or choose a different body to take on the appeal and resolution.

If the primary AB is not able or is unwilling to resolve the evaluation, the laboratory shall appeal to the National Environmental Laboratory Accreditation Program (NELAP) Board, which is the body that approves the NELAP ABs.
Uploaded Document
vote Yes + Comments
email davidmendenhall@utah.com
Phone Number 801-584-8470
Date 8/2/2007
Details
Response: Persuasive. The reference to the NELAP Board has been removed and replaced with a reference to the TNI appeals process policy which will define the appropriate authorities. It should be noted that Ken Jackson, Chair of the Consensus Standard Development Board indicated that the NELAP Board is the group with the proper authority to handle these appeals.

Comment Number 467
First Name Jenny Last Name Scifres
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.2, 4.2.1.d, and general comment for all volumes
Comment w/Rationale for Change V1M1 5.1.2 Holding accreditation for missing an analyte by one method and hitting it by another is disincentive for a lab to seek accreditation for new or alternative technologies. It is also not fair to revoke accreditation when the lab may be experiencing problems in one area, but the other area is working fine (e.g., ICP vs. ICP-MS).

V1M1 4.2.1.d This can be a very hard criteria to meet. Labs always time the PTs less than 7 months apart.
Proposed Change General Comment: The proposed standard is a huge step backwards from the 2003 NELAC Standard. The way these are written require the use of more than one document and is an added expense. This is such an inconvenience that the whole standard should be rewritten leaving out the ISO language. This can be done- ISO cannot copyright the ideas, just the language. So much time has been spent on writing these standards and will be spent on these standards that this would be worth the effort.

vote No + Comments
email scifres.jenny@epa.gov
Phone Number 706-355-8812
Date 8/2/2007
Details
Response to Section 5.1.2: Hold for Next Revision. This change cannot be made at this time as this would be substantial change to the Program and need further consideration by the full TNI membership.

Response to Section 4.2.1 (d): Non-Persuasive. The language specifies that analysis dates of PT samples for continued accreditation shall be no more than 7 months apart and at least 15 days apart. The time-frame did not change from the 2003 standard which specified approximately 6 months apart. The new language defines "approximately six months" apart as 5 to 7 months with an exception given for PT samples used for corrective action or for removal of suspension. The language change is actually more flexible than the 2003 standard.

Comment Number 496
First Name Gary Last Name Ward
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.4
Comment w/Rationale for Change With different AB able to specify different months for the PTs, the laboratory ends up doing PT studies in multiple months in order to have accreditation for all the needed parameters. It is very costly and inefficient.
Proposed Change AB can suggest months for participation but not require it as long as there are 2 studies per year; or all ABs should provide accreditatiion for the same FOTs to eliminate the need to get specific parameters from different states.
Uploaded Document
vote Yes + Comments
email gward@caslab.com
Phone Number 360-501-3371
Date 8/3/2007
Details
Response: Non- Persuasive. The requirement was removed from the laboratory volume as this is not a laboratory requirment. However, ABs are permitted to specify the months in which laboratories participate as required by their regulation and thus the proposed change cannot be made at this time.

Response: Not Applicable. The proposed change that all ABs offer the same parameters for field of accreditation cannot be addressed by the TNI PT Committee.

Comment Number 510
First Name Dale Last Name Piechocki
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5, 4.2.1(d), and 7.2(b)
Comment w/Rationale for Change These three sections should read similar. The analsis date between PT studies should be used to track PTs. The analysis date is already collected by PT vendors along with the analyst name. The analysis date and analyst name should be printed on the Final PT Report to make it easy for the State Regulators to track.

or - PT Vendors could set the time between PT Studies to no less than 15 days. Currently there are is less than 15 days between the close date of ERA's PT Studies and the opening date of the next study. A lab would have to skip a PT Study and participate in the following month in order to meet the 15 day separation requirement.

or -Another good compromise may be to use the close date and ship date between PT Studies. Using the ship date would allow labs to use the next months study and simply delay shipment to meet the 15 day separation time, if necessary.
Proposed Change "There shall have been at least fifteen calendar days and not more than 7 months between the analysis date of each consecutive study for the same FoPT."
Uploaded Document
vote No + Comments
email dale.r.piechocki@us.ul.com
Phone Number (574) 472-5523
Date 8/3/2007
Details
Response: Persuasive. All sections of the standard that provide dates and/or time-frames for tracking PT samples have been changed to analysis date.

Comment Number 513

First Name Dale Last Name Piechocki
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.2
Comment w/Rationale for Change Analyte method combinations of reporting results should be scored separately regardless if the technology is the same between the two different methods. Failing an automated ion selective elcetrode method (Tech-380-75WE) and passing a manual ion selective electrode method (SM4500F-C) should not result in two failures.
Proposed Change Delete the last sentence in the paragraph.
Uploaded Document
vote No + Comments
email dale.r.piechocki@us.ul.com
Phone Number (574) 472-5523
Date 8/3/2007
Details
Response to Section 5.1.2: Hold for Next Revision. This change cannot be made at this time as this would be substantial change to the Program and need further consideration by the full TNI membership.

Comment Number 514
First Name Dale Last Name Piechocki
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.0
Comment w/Rationale for Change Clarification is needed to define the differences between Suspension and Revocation and should be provided in section 3.0.
Proposed Change Add definitions for Suspension and Revocation
Uploaded Document
vote No + Comments
email dale.r.piechocki@us.ul.com
Phone Number (574) 472-5523
Date 8/3/2007
Details
Response: Persuasive. The terms “suspension” and “revocation” have been added to this section.

Comment Number 515
First Name Theresa Last Name Zielke
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5, 4.2.1(d), 7.2(b)
Comment w/Rationale for Change These sections should be consistent. There should be 15 days between analysis, do not use the study dates. The analysis dates can easily be tracked if the final PT reports include this information.
Proposed Change There shall be at least fifteen calendar days and not more than 7 months between analysis dates of each consecutive study for the same FoPT.
Uploaded Document
vote Yes + Comments
email theresa.j.zielke@us.ul.com
Phone Number 574-472-5515
Date 8/3/2007
Details
Response: Persuasive. All sections of the standard that provide dates and/or time-frames for tracking PT samples have been changed to analysis date.

Comment Number 516
First Name Theresa Last Name Zielke
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.2
Comment w/Rationale for Change Analyte method combinations of reporting results should be scored separately and not effect another result regardless if the methods use the same technology.
Proposed Change Delete last sentence.
Uploaded Document
vote Yes + Comments
email theresa.j.zielke@us.ul.com
Phone Number 574-472-5515
Date 8/3/2007
Details
Response to Section 5.1.2: Hold for Next Revision. This change cannot be made at this time as this would be substantial change to the Program and need further consideration by the full TNI membership.

Comment Number 517
First Name Theresa Last Name Zielke
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.0
Comment w/Rationale for Change Clarification is needed to understand the difference between suspension and revocation.
Proposed Change Add definitions of suspension and revocation.
Uploaded Document
vote Yes + Comments
email theresa.j.zielke@us.ul.com
Phone Number 574-472-5515
Date 8/3/2007
Details
Response: Persuasive. The terms “suspension” and “revocation” have been added to this section.

Comment Number 542
First Name Rodney Last Name Reininger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 1.2 Scope
Comment w/Rationale for Change This section, or at least the contents of this section at the present time, does not seem to be applicable to laboratory requirements. The contents of this section at the present time seem only applicable to the requirements of the PT provider.
Proposed Change Remove contents of this entire section.
Uploaded Document
vote Yes + Comments
email rreininger@tmilab.com
Phone Number (217) 698-0642
Date 8/3/2007
Details
Response: Persuasive. The language of this entire section has been removed and replaced with language applicable to laboratories.

Comment Number 543
First Name Rodney Last Name Reininger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 3.0 Definitions
Comment w/Rationale for Change Need to define the term "Accreditation Body". Several references are made to the term, but it is not really defined as far as I could tell.
Proposed Change Define term "Accreditation Body".
Uploaded Document
vote Yes + Comments
email rreininger@tmilab.com
Phone Number (217) 698-0642
Date 8/3/2007
Details
Response: Persuasive: The term “accreditation body” has been added to this section.

Comment Number 545
First Name Rodney Last Name Reininger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section Section 5.1.3 d)
Comment w/Rationale for Change Need to add the word "provider" to the end of this statement ("attempt to obtain the assigned value from PT").
Proposed Change Add the word "provider".
Uploaded Document
vote Yes + Comments
email rreininger@tmilab.com
Phone Number (217) 698-0642
Date 8/3/2007
Details
Response: Persuasive. The sentence has been corrected to specify PT Provider.

Comment Number 547
First Name Rodney Last Name Reininger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing

Section Section 7.2 b) and d)
Comment w/Rationale for Change Combine the statements contained in Section 7.2 b) and d). They appear to me to contain the same idea, and therefore, seem redundant.
Proposed Change Combine Section 7.2 b) and d)
Uploaded Document
vote Yes + Comments
email rreininger@tmilab.com
Phone Number (217) 698-0642
Date 8/3/2007
Details
Response: Persuasive. Item b has been deleted.

Comment Number 558
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.1
Comment w/Rationale for Change Why would the laboratory need to analyze the PTs before they apply? The AB would probably not have a system to track PTs of a laboratory that is not in their system.
Proposed Change delete this requirement.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Persuasive. It was not the intent of the committee to require labs to complete PT studies before they applied for accreditation. The language has been revised accordingly.

Comment Number 559
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.1.5
Comment w/Rationale for Change 4.1.5-The NOTE in this section does not make sense. The FoPT Tables dictate which PTs are required for NELAP accreditation. How could an AB require a laboratory to obtain and analyze a PT that does not exist?
Proposed Change 4.1.5-Delete this requirement
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Persuasive. The note has been removed.

Comment Number 560
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 4.2.1
Comment w/Rationale for Change 4.2.1.d- I suggest some clarification language for this item. It says no more than 7 months apart, but then in item a) it says to analyze at least two PT samples per year. 2 PT samples that meet item d) would not necessarily meet item a). Additionally, what is the penalty for not analyzing 2 successful PTs more less than 7 months apart?
Proposed Change 4.2.1.d- Include explanation that if the laboratory does not successfully analyze a second PT within 7 months from the closing date of the first study, a failure is recorded in the laboratory's PT record. The key date for the failure should be on the sixth month. Then the next PT (third study) would be requried seven months from the date the failure was recorded.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Non-Persuasive: This section describes 2 separate requirements for continued accreditation. The first requirement is analysis of 2 PT samples per year for each accreditation FoPT. The second is that the analysis dates of successive PTs be at least 5

not meet the 2 samples per year requirement. Similarly, if a lab analyzes the first PT in January and the second in August, that lab has not met the time-frame requirement. If a lab analyzes the first PT in February and the second PT in July, the lab has met both requirements. If a laboratory fails to meet the PT frequency requirement or any other requirement of the module, the requirements of the standard are not met and the AB should take action as specified in the AB volume. The committee determined that the consequences of not meeting the requirements of the standard are understood. Additionally, the requirements for performance and evaluations of laboratories are functions of the ABs and the PT Providers.

Comment Number 564
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 8.2
Comment w/Rationale for Change The primary AB does not evaluate the PT for "Acceptable" and "Not Acceptable". The provider makes the designation. In addition, why would the laboratory appeal to the NELAP Board? It is not their job to deal with PT provider issues.
Proposed Change If the laboratory has a problem with the evaluation by the provider, then they should take it up with the provider or the PTOB.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/6/2007
Details
Response: Non-Persuasive. The primary AB is the body that makes final decisions about when a laboratory has met the requirements of the standard. When a laboratory fails to comply with the standard, the laboratory's evaluation is not acceptable, even if the laboratory received an acceptable score from a PTP. Section 8.1 describes the procedure for when the laboratory has issue with the PTP. Section 8.2 describes the procedure for when the laboratory has an issue with any decisions made by the AB.

Comment Number 568
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.1.6
Comment w/Rationale for Change The NOTE in this section does not apply. I has no regulatory requirement. Especially since section 4.2.2 states that the AB may not impose additional requriements on the laboratory.
Proposed Change Delete the note
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Non Applicable. The comment refers to section 5.1.6, which does not exist.

Response: Persuasive. The committee believes that the comment is meant for section 4.1.5, in which case, the comment is Persuasive. The "note" has been removed from this section.

Comment Number 570
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 5.2.3
Comment w/Rationale for Change I suggest some clarification language for this item. It says no more than 7 months apart, but then in item 5.2.1 it says to analyze at least two PT samples per year. 2 PT samples that meet item 5.2.3 would not necessarily meet item 5.2.1. Additionally, what is the penalty for not analyzing 2 successful PTs more than 7 months apart?
Proposed Change Include explanation that if the laboratory does not successfully analyze a second PT within 7 months from the closing date of the first study, a failure is recorded in the laboratory's PT record. The key date for the failure should be on the sixth month. Then the next PT (third study) would be requried seven months from the date the failure was recorded.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Non-Persuasive: This section describes 2 separate requirements for continued accreditation. The first requirement is

months apart and no more than 7 months apart. If a laboratory waits until June to analyze their first PT sample; the laboratory will not meet the 2 samples per year requirement. Similarly, if a lab analyzes the first PT in January and the second in August, that lab has not met the time-frame requirement. If a lab analyzes the first PT in February and the second PT in July, the lab has met both requirements. If a laboratory fails to meet the PT frequency requirement or any other requirement of the module, the requirements of the standard are not met and the AB should take action as specified in the AB volume. The committee determined that the consequences of not meeting the requirements of the standard are understood. Additionally, the requirements for performance and evaluations of laboratories are functions of the ABs and the PT Providers.

Comment Number 571
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 6.2
Comment w/Rationale for Change The laboratory should have a penalty for the failure to analyze the PTs in accordance with 6.1
Proposed Change I suggest adding that the AB shall reconsider the PT study and determine it invalid in the laboratory's PT history. And then make the necessary accreditation changes, effective within the next month after the discovery of the inappropriate action.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Not Applicable. This section has been removed as it describes procedures for the PTP or the AB and is not applicable to laboratories.

Comment Number 573
First Name Aaren Last Name Alger
Section Number Item 1 VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing
Section 7.1
Comment w/Rationale for Change What about studies that are acceptable and thus, upgrade the laboratory's accreditation status?
Proposed Change Include acceptable studies in this section.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/6/2007
Details
Response: Not Applicable. The comment is not applicable to section 7.1. It is most likely associated with section 6.0 which described requirements for evaluation of PT samples. Section 6.0 has been removed from the laboratory volume as it does not specify requirements for laboratories. Procedures for the upgrade of a laboratory's accreditation status should be included in Volume 2, Module 1.