Comment Number 8
First Name Bob **Last Name** Di Rienzo
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section All
Comment w/Rationale for Change Same comments that I made on Volume 1 Module 1 as applicable
Proposed Change Same comments that I made on Volume 1 Module 1 as applicable
Uploaded Document
vote Yes + Comments
email dirienzo@datachem.com
Phone Number (801) 266-7700
Date 6/28/2007
Details
Response: Persuasive. The committee will make every effort to be consistent between the two standards.

Comment Number 53
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 1.3.3
Comment w/Rationale for Change Section 1.3.3: Language in this section refers to "an appendix to this volume (3)"; the Committee could not determine what this appendix is. Does it refer to the Volume 3 standard for PT Providers? The Committee recommends the appropriate revisions to this section for clarity.

(Uniformity of Standards Committee)
Proposed Change Section 1.3.3: Language in this section refers to "an appendix to this volume (3)"; the Committee could not determine what this appendix is. Does it refer to the Volume 3 standard for PT Providers? The Committee recommends the appropriate revisions to this section for clarity.
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vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Persuasive. Language has been removed since there will be either Volumes and Modules or Policies and SOP's.

Comment Number 54
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 3.7
Comment w/Rationale for Change Section 3.7: In the definition of proficiency testing provider, the definition 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: In the definition of proficiency testing provider, the definition 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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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Persuasive. Refers to PTPA as the full title.

Comment Number 55
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 3.8
Comment w/Rationale for Change Section 3.8: The Committee recommends that the PTPA be defined as "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 PT Committee define the term "NELAP Board."

(Uniformity of Standards Committee)
Proposed Change Section 3.8: The Committee recommends that the PTPA be defined as "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 PT Committee define the term "NELAP Board."
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vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Persuasive. The wording has been accepted.

Comment Number 56
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 3.8
Comment w/Rationale for Change Section 3.8: The Committee recommends that the PTPA be defined as "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 PT Committee define the term "NELAP Board."

(Uniformity of Standards Committee)
Proposed Change Section 3.8: The Committee recommends that the PTPA be defined as "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 PT Committee define the term "NELAP Board."
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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Persuasive. The wording has been accepted.

Comment Number 57
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 3.10
Comment w/Rationale for Change Section 3.10: In the definition of proficiency testing sample, there is no acronym specified as "PT Sample." The other definitions include an acronym such as PT study after the term is stated (e.g., Proficiency Testing Study (PT study)). This is not done for this definition, but the acronym PT sample is used later in the standard. The acronym should be added at the end of the term at the beginning of the definition.
Proposed Change Section 3.10: In the definition of proficiency testing sample, there is no acronym specified as "PT Sample." The other definitions include an acronym such as PT study after the term is stated (e.g., Proficiency Testing Study (PT study)). This is not done for this definition, but the acronym PT sample is used later in the standard. The acronym should be added at the end of the term at the beginning of the definition.
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vote Yes + Comments
email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Persuasive. The wording has been accepted.

Comment Number 58
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 5.1.1
Comment w/Rationale for Change Section 5.1.1: The Committee believes that the wording of this section can be more accurately worded as follows: "The Primary AB shall require that a laboratory seeking initial accreditation for a field of accreditation successfully analyze two PT samples for the corresponding Field of Proficiency Testing (FoPT) in which the laboratory seeks accreditation."

(Uniformity of Standards Committee)
Proposed Change Section 5.1.1: The Committee believes that the wording of this section can be more accurately worded as follows: "The Primary AB shall require that a laboratory seeking initial accreditation for a field of

the laboratory seeks accreditation."
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Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Persuasive. The wording has been accepted.

Comment Number 59
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 5.1.6
Comment w/Rationale for Change Section 5.1.6: This section refers to a "close" date for a PT study. Section 3.13 defines it as the "closing" date. The term in this section should be revised to "closing" to be consistent with the definition.
Proposed Change Section 5.1.6: This section refers to a "close" date for a PT study. Section 3.13 defines it as the "closing" date. The term in this section should be revised to "closing" to be consistent with the definition.
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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Not Applicable. This (renumbered) section now refers to analysis dates.

Comment Number 60
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 7.1
Comment w/Rationale for Change Section 7.1: Similarly, the Committee also recommends changes in the wording at the end of the section, so as to say the following: ". . . determine the accreditation status for any field of accreditation for which Not-Acceptable evaluations were assigned for the corresponding FoPT."

(Uniformity of Standards Committee)
Proposed Change Section 7.1: Similarly, the Committee also recommends changes in the wording at the end of the section, so as to say the following: ". . . determine the accreditation status for any field of accreditation for which Not-Acceptable evaluations were assigned for the corresponding FoPT."
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email carl_kircher@doh.state.fl.us
Phone Number 904-791-1574
Date 7/3/2007
Details
Response: Persuasive. The wording has been accepted.

Comment Number 61
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 7.2
Comment w/Rationale for Change Section 7.2: The statement currently reads "The Primary AB shall consider the analytical result for a FoPT acceptable when the result reported by the laboratory for the FoPT is evaluated acceptable by the PT Provider." The Committee recommends that the PT Committee consider the proper course of action (and add the appropriate language) if, during an on-site assessment, the laboratory was found to be analyzing PT samples with the wrong method and reported the wrong method number to the PT Provider.

(Uniformity of Standards Committee)
Proposed Change Section 7.2: The statement currently reads "The Primary AB shall consider the analytical result for a FoPT acceptable when the result reported by the laboratory for the FoPT is evaluated acceptable by the PT Provider." The Committee recommends that the PT Committee consider the proper course of action (and add the appropriate language) if, during an on-site assessment, the laboratory was found to be analyzing PT samples with the wrong method and reported the wrong method number to the PT Provider.
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Date 7/3/2007
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Response: Non-Persuasive. This appears to be an onsite assessment concern and thus is not covered in this standard. Refer to section 7.3.c of this Volume and Module.

Comment Number 62
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 8.0
Comment w/Rationale for Change Section 8.0: The corrective action section of this section does not use the term "corrective action PT sample" as is used in Section 7.0. In the interest of uniformity, the Committee suggests that the relevant expert committee consider whether the term "Corrective Action PT Sample" should be defined in this Module.

(Uniformity of Standards Committee)
Proposed Change Section 8.0: The corrective action section of this section does not use the term "corrective action PT sample" as is used in Section 7.0. In the interest of uniformity, the Committee suggests that the relevant expert committee consider whether the term "Corrective Action PT Sample" should be defined in this Module.
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Date 7/3/2007
Details
Response: Persuasive. The Committee will re-phrase this term since these are: 'PT samples used for corrective action purposes'. The committee agreed that it will be less confusing as there would be less terms. Also some laboratories choose quick turn supplemental PT's and others choose regular PT studies to serve there needs to demonstrate the corrective action has been successful.

Comment Number 63
First Name Carl Last Name Kircher
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section Section 8.2(c)
Comment w/Rationale for Change Section 8.2(c): For clarity the Committee recommends adding the following parenthetical explanation at the end of the sentence: ". . . for the same FoPT (see Sections 3.11, 3.12, 3.16, and 3.17 for the differences of opening dates and closing dates between regular PT studies and supplemental PT studies).

(Uniformity of Standards Committee)
Proposed Change Section 8.2(c): For clarity the Committee recommends adding the following parenthetical explanation at the end of the sentence: ". . . for the same FoPT (see Sections 3.11, 3.12, 3.16, and 3.17 for the differences of opening dates and closing dates between regular PT studies and supplemental PT studies).
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Phone Number 904-791-1574
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Response: Not Applicable. The Committee has defined 15 days as the necessary prescribed wait time before a laboratory can run another PT to insure that the corrective action that has been implemented is effective after a reasonable amount of time. 'Laboratory analysis time' will be added to Volume 3 requirements for reporting and used to assess that the corrective action has been successful.

Comment Number 172
First Name Thomas Last Name Coyner
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 4.1.1
Comment w/Rationale for Change I have several comments on the Standard. This comment is being supplemented with written comment to TNI and copied to the PT Committee.

This section should have timeframes associated with sections 4.1.1 e) and f).
Proposed Change See written comments for suggestions.
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email t.coyner@apgqa.com

Date 7/24/2007
Details
Note: The Comments have been addressed in the separate document supplied by Mr. Coyner.

Comment Number 192
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 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. (This and some others of my comments have counterparts for other modules and should be addressed where applicable across all modules.)
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.
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email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/25/2007
Details
Response: Not Applicable. The Committee has defined 15 days as the necessary prescribed wait time before a laboratory can run another PT to insure that the corrective action that has been implemented is effective after a reasonable amount of time. 'Laboratory analysis time' will be added to Volume 3 requirements for reporting and used to assess that the corrective action has been successful.

Comment Number 193
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.2
Comment w/Rationale for Change There needs to be a specific location of the PT listing. Otherwise, this clause is too ambiguous to enforce. (Also needs to be corrected in V1, M1)
Proposed Change Add to 5.1.2 Note: This listing is posted on The NELAC Institute website.
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Date 7/25/2007
Details
Response: Persuasive. The standard will reference the website.

Comment Number 194
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.4
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 5.1.4.
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email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/25/2007
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

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. The Committee has chosen to use analysis time and have added that as a requirement for reports to AB's.

Comment Number 195
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.6 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 5.1.6 in its entirety.
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email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/25/2007
Details
Response: Persuasive. The Note has been deleted in its entirety.

Comment Number 197
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2 and Table of Contents
Comment w/Rationale for Change Inconsistent terminology
Proposed Change Replace "Continuing" with "Continued" for consistency in 5.2 and Contents (either word is fine, just use the same one throughout all modules).
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email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/25/2007
Details
Response: Persuasive. The Committee will use 'Continued' consistently throughout the document.

Comment Number 199
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2.3
Comment w/Rationale for Change The intervals allowed between studies should be the same regardless of study type or purpose, and they should be clearly defined and measurable.
Proposed Change In 5.2.3, strike the words "approximately six months apart and". Add the sentence: "The closing date of one study for a given FoPT and the opening date of any successive study for the same FoPT shall be no less than fifteen days apart." ("opening" here is only appropriate if the change to 3.12 that I suggested is made; otherwise, use "shipment". This is also true for the corresponding comment made for V1, M1.)
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email steve_arms@doh.state.fl.us
Phone Number 9047911502
Date 7/25/2007
Details
Response: Not Applicable. The Committee has defined 15 days as the necessary prescribed wait time before a laboratory can run another PT to insure that the corrective action that has been implemented is effective after a reasonable amount of time. 'Laboratory analysis time' will be added to Volume 3 requirements for reporting and used to assess that the corrective action has been successful.

Comment Number 200
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 6.1(f)

Comment w/Rationale for Change Laboratories are required to treat PT samples just the same as environmental samples. The wording in this clause is not consistent with that requirement.
Proposed Change Change 6.1(f) to read: "the laboratory has procedures in place for the analysis of environmental and PT samples when the concentration range of the samples is outside of its normal range of measurement".
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Response: Persuasive. Adopted the wording.

Comment Number 201
First Name Stephen Last Name Arms
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing Section 8.1
Comment w/Rationale for Change Reword for consistency with V2, M2, 6.1 (g).
Proposed Change Add the word "root" before "cause".
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Phone Number 9047911502
Date 7/25/2007
Details
Response: Not Applicable. The committee has decided to use the words "corrective action" in both sections.

Comment Number 220
First Name Roger Last Name Kenton
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing Section 4.1.3
Comment w/Rationale for Change Sections 4.1.3, 4.2.1.c), and 4.2.2 require that labs obtain PT samples from a PTPA accredited PT provider. If the sentence in question addresses experimental parameters, then this needs to be clarified. Otherwise, the sentence appears to be unnecessary.
Proposed Change Delete "For FoPTs for which PT samples are not available from a PTPA recognized PT provider, a Primary AB may accept PT results from non-recognized PT providers."
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Phone Number 903-237-6882
Date 7/26/2007
Details
Response: Non-Persuasive. To further improve the accreditation program, AB's may choose to have laboratories participate in non-NELAC studies including Experimental PT samples that may be available from a variety of providers. However, the wording has been changed for further clarification.

Comment Number 221
First Name Roger Last Name Kenton
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing Section 7.3.d)
Comment w/Rationale for Change The laboratory PT result should not be considered unacceptable if the lab in good faith analyzes a PT sample for which it is determined after the study closes that the PT sample is not valid (e.g., stability testing). Instead, the result should be viewed as "Not Useable". This does not relieve the lab of the responsibility of completing another PT study for the affected parameter(s). However, under such circumstances the lab should not be considered as failing a PT study.
Proposed Change (1) Delete "and/or the PT sample does not meet the requirements for a valid PT sample as defined elsewhere in this Standard or by the program under which the laboratory is accredited." from "the laboratory submits analytical results for a FoPT from a PT provider that is not accredited by the PTPA and/or the PT sample does not meet the requirements for a valid PT sample as defined elsewhere in this Standard or by the program under which the laboratory is accredited."

(2) Add the following:

7.4) If the laboratory submits analytical results for a FoPT from a PTPA recognized provider and it is determined that the PT sample does not meet the requirements for a valid PT sample as defined elsewhere in this Standard or by the

Useable".
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Details
Response: Persuasive. The Committee agrees that the wording leads to confusion. The Committee has new wording to better capture the intent of the standard. TNI, AB's or other interests within TNI (PT Board) may have reasons to include additional PT's to further the scope of the programs.

Comment Number 226
First Name Jeff Last Name Flowers
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 4.2.2
Comment w/Rationale for Change AB's should actually adhere to the standard and not intimidate CAB's with additional requirements. The current requirements are strong enough already.
Proposed Change The Secondary AB shall not impose additional requirements for proficiency testing that are not included in this Standard as a requisite for initial or continued accreditation, ever.
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email jeff@flowerslabs.com
Phone Number 407 339 5984
Date 7/29/2007
Details
Response: Non Persuasive. This is informational for the Secondary AB's. Enforcement of the standard belongs with the NELAP Board.

Comment Number 227
First Name jeff Last Name flowers
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2.1
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 PTâ€™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) PTâ€™s, but now, the same methods are referenced. In order to attract more participating labs and ABâ€™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. Doughertyâ€™s May 14 2007 Memorandum on Drinking Water Laboratory Program Oversight.

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 PTâ€™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 PTâ€™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.

This idea will cut the time and costs to both labs and ABâ€™s.
Proposed Change The Primary AB shall have a process that checks that the laboratories analyze one PT sample for the FoPT per year maintaining a history of at least one successful analyses for the FoPT out of the most recent two attempted when a...
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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 321
First Name Chuck Last Name Wibby
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.6
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.
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email cwibby@wibby.com
Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Persuasive. The Note will be deleted in its entirety.

Comment Number 323
First Name Chuck Last Name Wibby
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2.1
Comment w/Rationale for Change The first sentence ("The Primary AB shall have a process that checks that the laboratories analyze two PT samples for the FoPT per year maintaining a history of at least two successful analyses for the FoPT out of the most recent three attempted when a laboratory has been granted accreditation for a field of accreditation that is also a FoPT, in order to maintain continued accreditation for the field of accreditation.") does not clearly address the issue of what the Primary AB shall do and should be rewritten.

The second sentence ("When PT samples are not available for the FoPT from any PTPA recognized PT provider at least twice per year, the Primary AB shall require the laboratory to analyze the PT samples in the minimum timeframe in which the PT samples are available from any PTPA recognized PT provider.") in Section 5.2.1 does not clearly address the issue of what the primary AB shall require if PT samples are not available twice each year.
Proposed Change The first sentence should be rewritten as follows. "The Primary AB shall have a process that checks that accredited laboratories analyze two PT samples for the FoPT per year and maintain a history of at least two successful analyses for the FoPT out of the most recent three attempted. "

The second sentence should be rewritten to clearly state what the Primary AB is required to do when PT samples are not available twice each year.
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Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Persuasive. The wording has been changed and is consistent with the intent of the standard especially for micro and WET and possibly Air samples in the future.

Comment Number 324
First Name Chuck Last Name Wibby
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2.2
Comment w/Rationale for Change
The language in this section ("The Primary AB shall require a laboratory which has been granted accreditation for a field of accreditation that is also an Experimental FoPT to analyze two PT samples for the Experimental FoPT per year in order to maintain continued accreditation for the field of accreditation.") is inconsistent with the frequency requirements found elsewhere in the standard.
Proposed Change The language should be rewritten to be consistent with that found in other sections of this standard, e.g., "The Primary AB shall require a laboratory which has been granted accreditation for a field of accreditation that is also an Experimental FoPT to analyze PT samples for the Experimental FoPT approximately six months apart and no longer than seven months apart."

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email cwibby@wibby.com
Phone Number 303-940-0033
Date 7/31/2007
Details
Response: Not Applicable. The frequency and spacing requirements for the experimental FOPTs are the same as for regular FoPTs (that is no less than 5 months and no greater than 7 months apart).

Comment Number 326
First Name Chuck Last Name Wibby
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 6.3
Comment w/Rationale for Change The language in this Section ("The Primary AB shall allow the laboratory to analyze the same PT sample using different technologies and/or multiple test methods for any FoPT. If a laboratory reports more than one test method per technology per 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 Primary ABs using this standard accredit laboratories by technology only and not by method.
Proposed Change Change the language in this section to read "If a Primary AB 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. This is what the AB's asked to be added to aid them in scoring laboratories that continue to report multiple PT results for the same technology. The exception will be Drinking Water matrix samples that must be scored by method.

Comment Number 355
First Name Paul Last Name Junio
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 6.1
Comment w/Rationale for Change The entire Standard is considered the minimum. I suggest deleting "At a minimum".
Proposed Change The Primary AB shall require the laboratory records to demonstrate that:
Uploaded Document
vote Yes + Comments
email Paul.Junio@testamericainc.com
Phone Number 920-261-1660
Date 7/31/2007
Details
Response: Persuasive. The wording has been removed.

Comment Number 366
First Name Wade Last Name DeLong
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 6.2
Comment w/Rationale for Change Section 6.2 As has been repeated and repeated in NELAC for many years, neither NELAC nor TNI has any control over how PT providers promote materials which are not TNI specific PT samples. ABâ€™s may require labs to not run QC samples specifically with PT samples but they have no right to be involved in the sale of QC materials by the PT providers. This section is absolutely inappropriate.
Proposed Change Suggested resolution: Delete this section.
Uploaded Document
vote No + Comments
email w.delong@apgqa.com
Phone Number 740-423-4200
Date 7/31/2007
Details
Response: Non Persuasive. The AB's requested that this wording be added to the standard to reflect what they agreed upon under the current program. This is a requirement of all AB's to act through the PTPA to address PT Providers.

Comment Number 369
First Name Mike Last Name Haller

Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 7.3.d
Comment w/Rationale for Change This section makes the lab responsible for errors by the PT provider which is inappropriate. In the spirit of the standard, the laboratory has not generated unacceptable result and their accreditation status should not be in jeopardy. The lab may be performing the test to the best of their abilities, and should not be penalized when a PT Provider makes a mistake (or losses their accreditation).
Proposed Change Establish seperate contingency/interim "status" for laboratories with no evaluation or unacceptable results linked direclty to PT Provider accrediation or sample design/reporting issues. The details should be established by the labs and AB's to give the labs an opportunity to resolve the issue with negatively impact their business. This may a 60 to 90 day window to obtain a new test.
Uploaded Document
vote No + Comments
email m.haller@apgqa.com
Phone Number 740-423-4200
Date 7/31/2007
Details
Response: Persuasive. This wording has been changed to be similar to this proposed wording.

Comment Number 399
First Name James Last Name Broderick
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.6
Comment w/Rationale for Change As noted in V1, this note is not in the right place and offers no benefit.
Proposed Change Delete clause.
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 deleted in its entirety.

Comment Number 400
First Name James Last Name Broderick
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2.2
Comment w/Rationale for Change As noted in V1, Experimental is a burden on all parties involved, and offers no benefits. It also may put an AB into a bad legal position of approving a lab that failed to pass PTs.
Proposed Change Delete all references to Experimental.
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 proposal to either eliminate or change the frequency of Experimental PT samples was not supported by the Committee or the TNI PT Board. Further discussion is warranted and the Committee will continue to address Experimental PT samples immediately after the January 2008 meeting. Any proposed change must include a robust discussion of the entire membership.

Comment Number 401
First Name James Last Name Broderick
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 4.1.1.f
Comment w/Rationale for Change As written, Primary ABs have to notify all Secondary ABs of the revocation of a lab. Without the implementation of the national database, the Primary AB may be unaware of the lab's secondary ABs. Also, in reality, this should be happening any time a lab loses an analyte, not just when the entire lab is revoked. I think this standard is premature, in that it is difficult to implement, and doesn't really target what we desire (instant cascading of Primary suspensions to all secondary accreditation bodies).
Proposed Change As a minimum add, "After implementation of the national database, ..."
Uploaded Document
vote No + Comments
email jdb10@health.state.ny.us
Phone Number 518-573-7548

Details
Response: Non-Persuasive. The AB's decided that at a serious level e.g. revocation, the AB's need to communicate.

Comment Number 416
First Name Kenneth Last Name Jackson
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 1.3.2
Comment w/Rationale for Change This module does apply to experimental FoPTs. They are found in 1.3.3, 3.1, 5.1.2, and 5.2.2.
Proposed Change Either remove the last 8 words in 1.3.2, or better get rid of experimental PTs in the standard (please see my other comments on this).
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 proposal to either eliminate of change the frequency of Experimental PT samples was not supported by the Committee or the TNI PT Board. Further discussion is warranted and the Committee will continue to address Experimental PT samples immediately after the January 2008 meeting. Any proposed change must include a robust discussion of the entire membership.

Comment Number 418
First Name Kenneth Last Name Jackson
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 4.1.1 f)
Comment w/Rationale for Change Presumably this clause refers only to revocation as a result of PT failure? If so, I would add suspension as well as revocation. Having said that, revocation of accreditation does not really belong in this module. It belongs in V2M1, and I believe it will be in a NELAP policy. current
Proposed Change Remove
Uploaded Document
vote Yes + Comments
email jackson@wadsworth.org
Phone Number 518-485-5570
Date 8/1/2007
Details
Response: Non-Persuasive. The committee believes that ABs need to be required to communicate with each other regarding the laboratory's accreditation status only when there is a serious problem with the laboratory's PT sample analyses that results in the revocation of the laboratory's accreditation. The committee hopes that these types of serious problems would happen infrequently and thus not pose a burden to the ABs.

Comment Number 420
First Name Kenneth Last Name Jackson
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.6
Comment w/Rationale for Change This refers to the note. Please see my similar comment on V1M1, 4.1.5.

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
Date 8/1/2007
Details
Response: Persuasive. The Note has been deleted in its entirety.

Comment Number 421
First Name Kenneth Last Name Jackson
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 1.3.3

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 proposal to either eliminate or change the frequency of Experimental PT samples was not supported by the Committee or the TNI PT Board. Further discussion is warranted and the Committee will continue to address Experimental PT samples immediately after the January 2008 meeting. Any proposed change must include a robust discussion of the entire membership.

Comment Number 422
First Name Kenneth Last Name Jackson
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 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
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 proposal to either eliminate or change the frequency of Experimental PT samples was not supported by the Committee or the TNI PT Board. Further discussion is warranted and the Committee will continue to address Experimental PT samples immediately after the January 2008 meeting. Any proposed change must include a robust discussion of the entire membership.

Comment Number 423
First Name Kenneth Last Name Jackson
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.2
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 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 proposal to either eliminate or change the frequency of Experimental PT samples was not supported by the Committee or the TNI PT Board. Further discussion is warranted and the Committee will continue to address Experimental PT samples immediately after the January 2008 meeting. Any proposed change must include a robust discussion of the entire membership.

Comment Number 424
First Name Kenneth Last Name Jackson
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2.2
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 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 proposal to either eliminate or change the frequency of Experimental PT samples was not supported by the Committee or the TNI PT Board. Further discussion is warranted and the Committee will continue to address Experimental PT samples immediately after the January 2008 meeting. Any proposed change must include a robust discussion of the entire membership.

Comment Number 520
First Name Carol Last Name Schrenkel
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 4.1.2
Comment w/Rationale for Change This needs to be clarified a little better. If a lab in good standing drops out of a study for cause (instrument problems, analyst sick, etc) the non-reported FoPTs are considered failed. If the lab is still passing 2 of the most recent 3 (counting this failed study), they should still be accredited without having to purchase additional PTs. The last sentence leads me to believe the lab could be suspended anyway because they havenâ€™t met the semi-annual requirement.
Proposed Change add: However, if the lab is still passing 2 of the most recent 3 attempted for that FoPT and participates in their next regularly scheduled study, then the continuing accreditation requirements will be considered to have been met.
Uploaded Document
vote Abstain + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 8/3/2007
Details
Response: Non-Persuasive: The current language says that a laboratory may drop out of any study but must maintain the expectation of doing a PT sample every six months for any field of accreditation for which it expects to be maintain accreditation.

Comment Number 523
First Name Carol Last Name Schrenkel
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 4.1.3
Comment w/Rationale for Change How can a PT for a particular FoPT not be available from ANY PTPA accredited provider? And if all accredited providers are not accredited for a particular FoPT, I would question the data from a non-accredited provider.
Proposed Change delete the second sentence.
Uploaded Document
vote Abstain + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 8/3/2007
Details
Response: Non-Persuasive. To further improve the accreditation program, AB's may choose to have laboratories participate PT studies that may be available from a variety of non-PTPA approved PT Providers where there are no approved PT Providers. These are beyond Experimental PT samples and may include Air, WET or other matrices. The ABs need the flexibility to use non-approved PT Providers until all FoT's are covered by FoPT's.

Comment Number 526
First Name Carol Last Name Schrenkel

Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.1.6 Note
Comment w/Rationale for Change This cannot be allowed to happen if this is to be a National Standard. Pass/fail isn't an issue - what is an issue is that some labs may be required to spend time, resources, and money on something other labs do not have to do.
Proposed Change delete
Uploaded Document
vote No + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 8/3/2007
Details
Response: Persuasive. The Note has been deleted in its entirety.

Comment Number 530
First Name Carol Last Name Schrenkel
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 5.2.1
Comment w/Rationale for Change see comment to 4.1.2 and 4.1.3. A lab should be allowed to not report (fail) one round as long as they still maintain 2 of the most recent 3.

The last sentence: How can a matrix/method-technology/analyte make it to being an FoPT, and not be available from any accredited PT provider? Shouldn't having them available twice per year be part of their accreditation?
Proposed Change delete the last sentence
Uploaded Document
vote Abstain + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 8/3/2007
Details
Response: Persuasive. This requirement has been removed.

Comment Number 532
First Name Carol Last Name Schrenkel
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 6.1 f)
Comment w/Rationale for Change This makes absolutely no sense since PTs are to be treated as routine samples. What does the lab do if routine samples are outside the normal range of measurement? Are you suggesting there be a separate procedure for PTs?
Proposed Change delete
Uploaded Document
vote Abstain + Comments
email schrenkc@lionvillelab.com
Phone Number (610) 280-3013
Date 8/3/2007
Details
Response: Persuasive. Wording change has been accepted to read: "the laboratory has procedures in place for the analysis of environmental and PT samples when the concentration range of the samples is outside of its normal range of measurement".

Comment Number 566
First Name Aaren Last Name Alger
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 4.1.1.f
Comment w/Rationale for Change Does this requriement mean that it is the responsiblility of the AB to notify every other AB of a laboratory's accreditation status each and every time it is upgraded or downgraded based on PTs? This would be a never ending job and way too difficult for a system that is not managed by a single database.
Proposed Change this requirement should definitely be deleted.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Persuasive. The language was meant to reflect the agreement between AB's to notify each other when a laboratory has been revoked and not just suspended for PT sample failures.

Comment Number 574
First Name Aaren Last Name Alger
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 9.2
Comment w/Rationale for Change WHat does this mean? It seems to imply that the AB is responsible for evaluating the "acceptable" and Not Acceptable" results. THis is the PT provider's job. Do you mean evaluating the Laboratory's accreditation status based on the results of the PT study?
Proposed Change If so, change the wording. Otherwise, delete the section
Uploaded Document
vote No + Comments
email aaalger@state.pa.uss
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Non-Persuasive. Since the standard requires that the PT Providers only grade the acceptable range it is left to the AB to determine whether the laboratory correctly reported the matrix/technology or method/analyte properly. This was requested by the ABs as important language.

Comment Number 575
First Name Aaren Last Name Alger
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 10.1.b
Comment w/Rationale for Change The laboratory requriements state that the corrective action report must be made available to the AB. Not submitted to the AB. I, as an AB do not want the laboratory to be submitting the corrective actions for every single PT study. This would make our files and records unmanageable.
Proposed Change Delete this section. Allow the ABs that want the reports to require them. PA does not want them
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Non-Persuasive. The ABs were responsible for adding this language to this standard and the standard clearly states that the laboratory has to provide a corrective action report only “upon request of such report”. So the AB will get the report only when it specifically asks for it.

Comment Number 577
First Name Aaren Last Name Alger
Section Number Item 8 VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing
Section 10.4
Comment w/Rationale for Change The NOTE does not make sense? I thought the ABs were not allowed to impose additional requirements on the laboratories?
Proposed Change This NOTE should be deleted.
Uploaded Document
vote No + Comments
email aaalger@state.pa.us
Phone Number 717-346-8212
Date 8/3/2007
Details
Response: Non-Persuasive. This note acknowledges the fact that States have their own processes for suspension and revocation. The standard language (in Section 10) are the conditions that the States need to address in their implementation of these standards relative to when laboratories lose accreditation status.