Proficiency Testing Expert Committee

Meeting Summary
April 3, 2020

The Committee met via teleconference on April 3, 2020 at 11:00 AM ET. Chair Kirstin Daigle led the meeting. The agenda for the meeting is provided as Attachment 1. Added the agenda item of "PT Studies and the impact of the COVID-19" at the request of Chandra.

Roll call

Nicole Cairns, NYSDOH (Laboratory)	Present
Thekkekalathil Chandrasekhar (Chandra), FLDEP (Laboratory)	Present
Patrick Garrity, KYDOW (AB)	Present
Craig Huff, ERA (Vice-Chair; PT Provider)	Present
Susan Jackson, SC DHEC (Laboratory)	Present
Tim Miller, Phenova (PT Provider)	Present
Reggie Morgan, Hampton Roads San. Distr. (Laboratory)	Present
Rachel Bailey, Advanced Analytical Solutions (PT Provider)	Present
Matt Sica, ANAB (AB)	Absent
Amy Pollard, Occidental Chemical(Laboratory)	Present
Kirstin Daigle, Pace Analytical (Chair; Laboratory)	Present
Sennett Kim, A2LA (AB)	Present
Rachel Ellis, NJ DEP (AB)	Present
Robert Wyeth, Program Administrator	Present

Associate Committee Members Fred Anderson and Audrey Cornell were also present. With a quorum present the meeting proceeded.

Review and approve March 6, 2020 minutes

March 6, 2020 minutes were reviewed and with one editorial change in the spelling of Fred Anderson's name, a motion was made by Craig and seconded by Chandra to accept the minutes. The motion was unanimously approved and will be posted on the TNI website.

Charter Review

Although not required at this time, Kirstin suggested a review of the PTEC Charter. The committee reviewed each section of the 2017 Charter (Attachment 2) and after discussing other possible need to modify the section on "Decision Making" to clarify voting on developing standards for ANS approval, it was decided no changes were needed. The 2017 Charter was accepted by the committee as it is currently written.

2020 Work Plan

Kirstin provided copies of the committee specific SIR summary and a document listing potential topics of concern from previous discussions (Attachment 3). From these documents and other suggestions of the committee, the committee's work plan for 2020 will be derived.

Other topics for future discussion suggested by committee members include the "greater than values" seen primarily in microbiology reporting as well as other methods/procedures. The issue of Aroclor scoring was also suggested as a topic to be addressed by the committee.

After continuing general conversations regarding a work plan, Kirstin asked the committee members to review these documents with the intent to develop a prioritization of topics and development of a detailed work plan during forthcoming meetings.

The SIR previously referred to in the March meeting has not yet been received. Bob will communicate with Lynn regarding the status of this SIR.

Impact of Corona virus on PT Studies

The corona virus pandemic has impacted public and private businesses across the country. Numerous state agencies have been essentially closed as have some laboratories. There are open and on-going PT studies underway and more are scheduled to begin prior to any anticipated resolution to the pandemic. Considering the potential impacts of problems with PT reporting and the subsequent potential for revocation of accreditation of laboratories, the committee is requesting the immediate attention of the AC to this issue. The AC is schedule to meet on Monday April 6, 2020. Bob, on behalf of the committee, will send an email to Lynn requesting that the AC address this urgent concern and bring the issue to some resolution during that Monday call. An ad-hoc group of all potentially impacted parties/committees was also suggested to assist in resolution and/or implementation of a solution. Kirstin was going to contact the chair of the PTPEC and the AC chair to coordinate a conference call as early as next Tuesday (following the AC call) to further address the issue.

The meeting adjourned at 11:45 AM ET on a motion by Tim, seconded by Craig and passed unanimously by committee members present. The next meeting of the PT Expert committee is scheduled for May 1, 2020 at 11:00 AM ET.

Attachment 1

TNI Proficiency Testing Expert Committee Agenda
04/03/20
11:00 AM – 12:30 PM EST

Dial-in using your phone:
United States: **+1 712-832-8330**
Access code: **822 174**

1. Review and approve minutes from previous meetings
   - TNI_PTEC_3-6-2020_draft.2.docx

2. Review Charter
   - 3_PTEC Charter 03-03-17 Final

3. 2020 Work Plan -
   - 5_Comments-Review of PT Standards 11.01.19
   - 14_SIR PT Summary 01.04.19 PTEC Review

4. Impact of Corona virus on PT Studies (added at request of Chandra)

Attachment 2

3_PTEC Charter
03-03-17 Final[7075].

Attachment 3

5_Comments -
Review of PT Standar

Copy of 14_SIR PT
Summary 01.04.19 P

Laboratory Proficiency Testing Expert Committee (PTEC)

Charter (Revised: 03-03-2017)

Mission

Develop and maintain consensus standards for proficiency testing (PT) that support TNI programs and that address the following elements of a proficiency testing program:

- Roles and responsibilities of program participants.
- Manufacturing, validation and verification of PT samples.
- Accreditation and oversight of PT Providers.
- Management and evaluation of PT sample data by PT Providers (PTP), PT Provider Accreditors (PTPAs) and the Proficiency Testing Program Executive Committee (PTPEC).
- Use of PT samples by laboratories, accreditation bodies, and regulatory programs supported by TNI programs.

Composition of the Committee

TNI members representing applicable stakeholder groups; each serving 3-year terms with a maximum of 2 consecutive terms.

- Stakeholder groups include:
  - Laboratory/Field Sampling Measurement Organization (FSMO)
  - PT Provider
  - Accreditation Body (AB) – (includes ABs of Labs/FSMOs/PTPs)
  - Other (i.e. consultants, 3rd party assessors, etc…)
- A Chair and Vice-Chair are elected from among the committee membership; each serving 1-year terms with a maximum of 3 consecutive terms.
- Membership must maintain balance so that no stakeholder group has a majority.
- Associate members are allowed.

Objectives

1. Develop and maintain consensus standards for proficiency testing (PT) that are practical, implementable, and meet the needs of the environmental community.
   - **Success Measure:**
     - Adoption of PT standards by TNI and/or other applicable programs.

2. Develop and maintain consensus standards for the manufacture of PT samples that ensures PT samples provide equal challenge to participants regardless of manufacturer.
   - **Success Measure:**
     - Failure rates as summarized by the PTPAs and evaluated by the PTPEC show consistency across PT Providers.

3. Develop and maintain consensus standards that support PT sample design and scoring criteria (analyte, matrix, concentration and acceptance criteria) appropriate to evaluate a participant's competency in the field(s) of accreditation for which the PT sample was manufactured.
   - **Success Measure:**
     - Successful accreditation of PT Providers showing compliance with design and scoring criteria specified in the standards and on the Fields of Proficiency Testing (FoPT) tables approved by the PTPEC and applicable TNI programs.

4. Support the PTPEC in the successful and consistent implementation of PT standards.
    - **Success Measure:**
        - Successful evaluations of accreditation bodies (including ABs of Labs/FSMOs/PTPs) showing appropriate use and implementation of the PT standard.

5. Serve as a technical resource to TNI membership.
    - **Success Measure:**
        - Prompt response to Standard Interpretation Requests (SIRs).
        - Adoption of guidance documents by TNI that support the PT standards (*i.e.* Small Lab Handbook)

Decision Making

Decisions of the PTEC are generally made by a majority vote in the presence of a quorum during teleconferences, face-to-face meetings, or by electronic voting, unless an alternate voting procedure is determined to be necessary by the committee.

Available Resources

- Volunteer committee members
- Existing national and international consensus-based standards
- TNI website and other TNI support services (administrative, technical editing, etc.)
- Teleconference and web-based services
- Industry experts

Anticipated Meeting Schedule

- Monthly teleconferences (open to all full and associate members and the general public)
- Additional teleconferences as needed
- Face-to-face meetings during the semiannual TNI Forums (open to all full and associate members and the general public)

ATTACHMENT 3

Standard Reference	Comment (Received By)	Address in Next Revision (Yes/No)	Scale of Revision (Minor/Major)	PTEC Comments	Revisions Made to Standard (Yes/No)	New Standard Reference
2016 - V3	Radiochemistry requirements (Bob Shannon)	Yes	Major	Collection of uncertainty by PT Providers; what is the purpose of collection of this data? what will it be used for?		
2016 - ALL	Review and update to latest ISO/IEC standard where applicable in all volumes. ISO/IEC 17011:2017, ISO/IEC 17025:2017, and ISO 17034:2016 (PTEC, Lauren Smith)	Yes	Major	None. Look into including by reference to most current version so that we aren't always out of step with ISO.		
2016 - V1M1, V3?	Standardization of WET PTs and dealing with small data sets (see white paper by Rami)	Yes	Unknown	**HOLD** until WET expert committee comes up with a plan		
2016 - V1M1: 3.0	Add a definition for Secondary AB (PTPEC)	Yes	Minor	**HOLD** until glossary of terms use finalized.		
2016 - V1M1, V3	Breakdown products - how to report and how to score? - i.e. Endrin, DDT (Matt Sica)	Unknown	Unknown	**HOLD** until PTPEC Analyte Breakdown Subcommittee reaches a determination.		
2016 - V1M1, V3	Additional reporting information. Zero (0) values and values associated with greater than (>) Not Acceptable. Micro - consider whether some > reporting is appropriate.	Yes	Major	Work with Micro Expert committee and AC, possible Asbestos. Get AC feedback on using FoPT ranges to dilute appropriately, PT Providers - include info in instructions? Labs must follow PT Provider instructions.		
2016 - V1M1, V2M2, V3	PCB evaluation as a total group vs. individual Aroclors for accreditation.	Yes	Major	**HOLD** for PTPEC and AC outcomes regarding this issue		
2016 - V1M1, V3: 5.4.3.1 - 5.4.3.3	Supplemental PT requirements - qualitative vs. quantitative (lots of grey areas; benzo(b) vs Benzo(k) - if they mis-ID, is this qualitative or quantitative failure?) Do we need these specificiations: What purpose does this serve? Labs don't have to take supplemental PT regain compliance with successful PT frequency history. They can plug along with regular studies (espcially if only one failure). If we keep specific requirements in Volume 3, then we need the labs to be required to comply - currently nothing in lab module about supplemental PTs. (SIR 7 as well).	Yes	Major	Need to work with AC		
2016 - V1M1, V1M4: 1.5.4	Second column confirmation not explicitly required for PT samples. May need to more clearly define PT sample as an "unfamiliar" sample with expectations of treating it as a "real environmental sample", even though PT test ranges, PTRLs, and components are known when purchased. (SIR 12/8/10 - no#).	Yes	Unknown	Getting into the weeds; may not want to adress in PT standard; keep it generic - follow your procedure; should we reach out to the AC; just a procedural thing, not a science thing; very AB dependent		
2016 - V1M1: 4.1.2 and 4.3.4	Definition of FoPT (SIR 266)	Yes	Minor	Clarification		
2016 - V1M1: 4.1.2, V3: 5.5.2	What defines a matrix for an FoPT? (SIR 6/27/11 - no#)	Yes	Minor	Add definition of matrices - confirm with glossary of terms		
2016 - V2M2: 4.1.5 g)	Revocation notifications to secondary ABs (SIR 275)	Yes	Unknown	Work with AC on who is responsible for revocation notifications and to whom. Review if anything in lab volume/AB volumes with regard to revocation notifications.		
2016 - V3: 3.0	PTPA is defined, but not PTPEC - add PTPEC or remove PTPA (PTPEC)	Yes	Minor	**HOLD** until glossary of terms use finalized.		
2016 - V1M1, V3: 3.0	Definition of PTRL is not a great one - could use tweaking (PTPEC)	Yes	Minor	Work with PTPEC on definition.		
2016 - V3: 4.6	Do we need to provide additional detail on why a referee lab would be needed. (PTPEC)	Yes	Minor	Contact PTPEC for further clarification.		
2016 - V3: 5.5.3.4.2	Add "…with the justification for modification(s)." to the end of the phrase as is done in Section 5.7.1.2 (PTPEC)	Yes	Minor	Clarification; is cost prohibitive or not available a technical reason.		
2016 - V3: 5.6.1.7 and 5.6.1.8 a) and b)	Should biased and unbiased verification methods be more clearly defined (PTPEC)	Yes	Minor			
2016 - V1M1: 4.2.3, 4.3.5 and 4.3.7 c), V3	Conflict in less than (<) reporting for non-detected analytes; can report and less than (<) value, not just less than (<) PTRL and be scored acceptable.	Yes	Unknown			
2016 - V1M1, V3	Prep Methods	No	n/a	List of combinations of prep and analytical methods is large; beyond PT; other expert committees need to be involved	n/a	n/a
2016 V1M1, V2M2	Who determines what fields of accreditation have corresponding fields of proficiency testing? Is it the Primary NELAP AB? Does this need to be part of the standard or should be a NELAP AC policy? (Carl Kircher)	No	n/a	Bring this to attention of PTPEC and AC	n/a	n/a
2016 - V3	VHS criteria - would like to have specific criteria/calculations that PTPs must follow and meet for VHS - consistency among PTPs (Donna Ruokonen)	No	n/a	Comment received prior to inclusion of ISO 13528 in V3 for Homogeneity	n/a	n/a

Standard Reference	Comment (Received By)	Address in Next Revision (Yes/No)	Scale of Revision (Minor/Major)	PTEC Comments	Revisions Made to Standard (Yes/No)	New Standard Reference
2016 - ALL	Legionella - would this require updates to standard if new PT (Donna Ruokonen)	No	n/a	PTPEC issue if an ARA received	n/a	n/a

ATTACHMENT 3

#	Date Submitted	2003	2009	2016	Actual Request	Final Response	Jerry's Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
72	6/23/09	Ch 2: 2.2.3	V1M1: 4.1.1	V1M1: 4.1.2	The SCM PT standard for TPH references HEM/SGT on the FoPT. HEM/SGT is a method defined analyte for method to 1664A. The scope and application section of 1664A says that it is for "surface and saline waters and industrial and domestic aqueous wastes". Therefore, the method has to be modified to be performed on solid and chemical materials. Is it appropriate to have a required PT for a non-standard method?	The TNI PT Board does not get involved in questions concerning the appropriateness of methods for specific analytes. Accrediting bodies routinely accredit labs for "non-standard" methods and then require the analysis of PTs included on the FoPT tables. The general answer to your question is, yes, it is appropriate to have a required PT for a non-standard method.	This SIR is valid for the 2009 and 2016 standards.	Yes.	Yes.	Yes.	No, but this topic cannot be addressed in the standard; TNI does not define method suitability of FoPTs. This specific example is no longer an issue - TPH no longer on SW FoPT table; but general question still applies as TPH is on the NW FoPT table.
80	8/7/09	Ch 2: 2.2.3	V1M1: 4.1.1	V1M1: 4.1.2	We are currently accredited for method SW 846 8151, but we want to add Pentachlorophenol by 8151 to our scope. Pentachlorophenol is not listed as requiring PT with the other Herbicides that are analyzed by 8151 that are listed. Therefore, I interpret that as Pentachlorophenol by method 8151 does not require PT. Our Accrediting Body says otherwise. They contend that because Pentachlorophenol is listed under the Acid Extractables (Method 625 or 8270) that require PT, it also requires PT if we want to add it to our 8151 scope.	The ABs are correct in requesting the analysis of PTs where available by analyte/matrix. While the 2003 NELAC Standard defined an FoPT as having all three elements of matrix, method/technology, and analyte/analyte groups, PT data was not available to establish separate FoPTs according to method/technology. The 2003 Standard also specified that sufficient PT data had to be available, specified as at least 10 valid PT studies with at least 20 participant laboratories in each study, in order to establish concentration ranges and acceptance limits for FoPTs. When this SIR was initially submitted for consideration, the TNI PT Program worked to establish additional FoPTs for so-called "dual-purpose" and "overlapping" analytes. The SCM FoPT Table that went into effect on 1/3/2012 added an additional listing for Pentachlorophenol in the grouping with other Herbicides analytes for possible use with methods such as EPA 8151. At that time, insufficient PT data was available to support the addition of Pentachlorophenol to the NPW FoPT Table. The TNI PT Program has no control over the business practices of PT Providers on how they package, market, and distribute their PT samples. Therefore, the only recourse within the auspices of TNI are to petition the PTPEC to add the analyte in question as a separate entry with separate concentration range and acceptance limits. This could be done by submitting an Analyte Request Application to the PTPEC, with a TNI NELAP AB sponsor and supporting PT data justifying the addition of the requested analyte.		Yes.	Yes.	Yes.	No, but this topic cannot be addressed in the standard; TNI does not define method suitability of FoPTs.
96	10/14/09	Ch 2: 2.5	V1M1: 5.1.1 & V2M2: 6.1	V1M1 4.2 & V2M2: 4.1.1	Section 2.5 of the 2003 NELAC standard states "When analyzing a PT sample, a laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as uses when analyzing routine samples." Questions 3 through 11 of the NELAC checklist contain additional details for this section of the NELAC standard. 1. Are these statements an official interpretation? 2. A laboratory analyzes the PT provider companion quality control sample with the unknown PT sample. The laboratory includes all routine QC, such as blanks, LCS, etc, in the batch. In addition to using the routine QC criteria, the companion QC sample is used to determine the acceptability of the batch containing the PT. This is not a routine practice of the laboratory. Is this considered a finding versus Section 2.5 of the NELAC standard?	It is the consensus of the PT Committee that Questions 3-11 are appropriate interpretation of the requirements specified in Section 2.5 of the 2003 NELAC Standard. 2) It is the consensus of the PT Committee that the scenario described in the problem is a finding against Section 2.5 of the NELAC Standard.	The 2009 standard (V2) contains explicit language concerning the routine analysis of PT samples. The 2016 standard (v2) removed most of the laguage in the 2009 standard, but does the AB to report to the PTPA and laboratory than analyzes QC samples along with PT samples. Section 4.2.2 of V1M1states "PT samples shall be analyzed in accordance with the laboratory's established standard operating procedures (SOPs) using the same quality control (QC), acceptance criteria and staff as used for the analysis of routine environmental samples." This SIR is likely obsolete.	Yes.	Yes.	Yes.	Yes, but SIR is still applicable to all standards to provide proper interpretation/clarification of the standard; all standards adequately address the topic of QC with PT samples.
31	10/15/08	Ch 2: 2.6	V3: 10.2.4-10.2.6	V3: 5.9.2.4-5.9.2.6	ILAC Guide 13 in section 3.6.1.7 requires the PT provider to have procedures for dealing with small data sets that may be inappropriate for statistical evaluation. APG has protocol in place for all non-NELAC PT programs that deals with this issue. However, in the case of the NELAC PT program, APG feels strongly that since NELAC evaluation limits are regulatory and are written into State laws that we have no option but to apply the NELAC FOT requirements as written without exception regardless of sample size. However, the A2LA auditors are requiring us to use an alternative evaluation technique based upon our own technical judgment, or prior studies on a case by case basis. While is would be simple to implement a criteria based upon professional judgment it would raise issues of objectivity. Such a procedure would lead to variability in laboratory evaluations, and be in conflict with the NELAC level playing field concept. Such practices would lead to arbitrary and inconsistent evaluations. It would furthermore transfer responsibility for setting laboratory evaluation criteria to the PT provider and removes it from the NELAC PT Board who are responsible party. The NELAC 2003 Standard in Chapter 2 Section 2.6 says: "PT providers shall evaluate results from all PT studies using NELAC mandated acceptance criteria described in Appendix C." It continues: "The PT Board shall provide, and update as necessary, the data acceptance criteria that all providers shall use for all PT studies". Based upon this section APG believe that ILAC Guide 13 Section 3.6.1.7 is not relevant to the NELAC program until the NELAC PT Board provides the necessary acceptance criteria.	The TNI PT Board thinks that the acceptance criteria listed in the various Fields of Proficiency Testing Tables should be adequate to meet ILAC G13 requirements in most cases. For those analytes where the acceptance criteria are based on fixed limits or upon regression equations, these limits and criteria are based on aggregate PT data spanning several years from multiple PT providers. Of course, the NELAP Program requires PT results to be scored acceptable or unacceptable based on these published limits. If the number of participants in the PT study is small, the acceptance limits published in the Tables still need to be used. However, since these limits are based on the aggregate scientific and statistical analyses, the TNI PT Board thinks that using these limits would satisfy ILAC G13 requirements for small data sets. The PT Provider should not have difficulty using this as a justification, and this justification should carry more tangible, defensible weight compared with any other alternatives that could be considered. Nevertheless, there are Fields of Proficiency Testing where the acceptance limits are still based on consensus participant mean and a PT-study specific standard deviation. In these cases, the PT provider would definitely need to formulate an alternate procedure to handle small data sets. However, the TNI PT Board cannot really provide or advocate a specific protocol to use in these instances. In fact, it may be scientifically unsound to do so, since other procedures and statistical models (e.g., Lorentzian, Maxwellian, chi-squared, or Poisson, as opposed to Gaussian) may work better. In addition, the PT Provider may need to adapt or change models and procedures used to accommodate individual circumstances for a given PT study. The TNI PT Board thinks the important thing to do is to document the preferred procedure(s) chosen (to satisfy ILAC G13), implement this procedure for the small data sets as needed, and be prepared to revise the SOP if the results do not work out as expected.	Although these sections have been extensively revised in the 2009 and 2016 standards, the basic response is still valid.	Yes.	No.	No.	Yes. Small data sets were adequately addressed in Section 10.2 of 2009 V3 and Section 5.9.2 of 2016 V3.

ATTACHMENT 3

#	Date Submitted	2003	2009	2016	Actual Request	Final Response	Jerry's Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
7	06/27/08	Chapter 2: 2.7.3.1 d	V3: 8.4.2 & 8.4.3	V3: 5.4.3.1-5.4.3.3	"For corrective action supplemental studies, the assigned values for all analytes requested by the laboratory must not be equal to zero with the exception of the qualitative PCB group and qualitative microbiology." For years we have been ordering corrective action supplemental studies for PCB's by asking for specific arochlors (that were missed in the original PT sample) and have been allowed to do so. Recently our provider could not fill an order and I went to a different provider. They told me that I could not specify an arochlor for a supplemental study. When I inquired about why I could not do so they told me that I should talk to someone at the LDEQ and they would explain. Before I called them I thought that there must be something in the standard that I was over looking and I found the above citation. I talked to several people at the LDEQ, they were not aware of this citation and they seemed to be easy persuaded either way. My interpretation of the standard is that we should have never been allowed to specify arochlors for supplemental studies. If this is true then I seem like a big dilemma, because I have not been able to find a single person who already knew about this and I have talked to a lot of people. We are trying to do the right thing, but we are getting mixed signals and no one seem to be on the same page. There is a specific exception for PCB's, but it is vague and no one is interpreting it the same way. What are we suppose to do?	The PCB group is the exception-a laboratory does not need to specify the specific Arochlor and should not specify a specific Arochlor because a component of challenge of the PCB Group is both qualitative and quantitative detection. In other words, the lab must report the correct quantitative value for a specific Arochlor but also be able to report non- detects for the other Arochlors.	2009 standard does not mention PCBs. 8.4.3 of V3 does indicate micro PTs may be 0. The 2016 standard has a significant rewrite and specifically mentions aroclors and microbiology. The SIR is still valid thru the 2016 standard	Yes.	Yes.	Yes.	No. The difference between a supplemental PT needed for quantitative vs. qualitative failures was not fully addressed for analyte groups.
75	7/27/09	Ch 2: 2.2.1 & C.3	V3: 10.3.1	V3: 5.9.3.1	The result for EDB of <0.500ug/L was scored "not acceptable", against the true value of 0.299ug/L and limits of 0.179-0.419ug/L. This result is not identified as consideration for unacceptable criteria. We disagree, and feel that this result should be scored acceptable. 0.299ug/L is less than 0.500ug/L.	Based upon current acceptance criteria, the lab result for the analyte provided in the problem statement was correctly scored as not acceptable. Acceptance criteria for this analyte are currently based on the PT acceptance requirements outlined in Chapter 2 and Appendix C of the 2003 NELAC Standard. In addition, the FoPT tables currently include a footnote that states, "NELAC Proficiency Testing Reporting Limits (PTRLs) are provided as guidance to laboratories analyzing NELAC PT samples. These levels are the lowest acceptable results that could be obtained from the lowest spike level for each analyte. The laboratory should report any positive result down to the PTRL. It is recognized that in some cases (especially for analytes that typically exhibit low recover) that PTRL may be below the standard laboratory reporting limit. However, the laboratory should use a method that is sensitive enough to generate results at the PTRL shown..." The laboratory should be aware of and take into account the corresponding PTRL for each analyte before reporting any PT results.	The < value would be valid under the 2009 standard. The 2016 standard reintroduces PTRLs, and this the SIR is still valid for 2016. There are significant differences between the 2003, 2009 and 2016 standards.	Yes.	No.	No.	Yes. Section 5.9.3.1 of 2016 V3 states that a < value reported for any anlayte with an assigned value above the PTRL will be scored as not acceptable.
7	06/27/08	Ch 2: C.3	V3: 10.3.1 & 10.3.2	V3: 5.9.3	Based upon a question from a customer I checked the FOT tables and NELAC Chapter 2 and I can't find a requirement for evaluation of "less than" (<) values. This was in the Criteria Document and I think was supplemented by a NELAC Board policy both or which would be invalid now. If you agree, I think the PT Board needs to implement a Policy on "less than" reporting immediately to fill the gap until the TNI Standard, which is very poor, in this area is implemented.	The TNI PT Board concurs with the need to define a policy, as a stop gap measure until such time as the TNI Standard Volume 3 is implemented, on the evaluation/scoring of PT results reported as "less than" (<) or zero values. This new policy will replace previous policy as outlined in the NELAC BOD Policy #16 (effective 12/14/2000) and the EPA National Standards for Water Proficiency Testing Studies Criteria Document (January 31, 2001). The drafting of a policy document on this topic by the PT Board is now underway. Once completed, this new policy document will be recommended to the Policy committee and TNI Board for adoption.	The 2009 standard has explicit language regarding < values. The 2016 standard reintroduces PTRLs, and has different language regarding < values. There are significant differences between the 2003, 2009 and 2016 standards.	Yes, however the Final SIR response did not provide clarification as the policy document needed was never created.	No.	No.	Yes. Section 5.9.3 of the 2016 V3 addresses the scoring of < and > results.
33	10/15/08	Ch 2: B.2.1 & B.2.2	V3: 7.1.6-7.1.7 & 7.1.8-7.1.10	V3: 5.6.1.6 & 5.6.1.7-5.6.1.9	Finally there appears to be a highly technical issue and conflictet bween sections 2.1 and 2.2 of Appendix B in the 2003 NELAC Standard. Section B 2.1 requires the RSD of a method to be less than 50% of the RSD predicted at the Assigned Value of the sample. The NELAC regression equations predict variable standard deviations and RSD across the NELAC concentration ranges and in many instances NELAC criteria require interlaboratory evaluation limits which vary with laboratory population and concentration range. However, good method development procedures require the RSD of a method to be constant across the calibration range which in most cases is not consistent with the NELAC concentration range. The RSD of a method is controlled by the technique of the method and the variability of the instrument not by the NELAC concentration range. The more important requirement to protect PT sample integrity is in Section B 2.2 and it requires the actual standard deviation of the verification analysis to be within 1.5 times the predicted standard deviation at the Assigned Value of the sample. If a method is capable of insuring that the sample meets the standard deviation requirement of section B 2.2 then it should be considered adequate to meet the requirements of the PT program. If the method is capable of achieving the necessary reliability in terms of meeting the standard deviation requirement of Chapter 2 Appendix B 2.2 then it is fit for use.	Sections B.2.1 and B.2.2 serve different purposes and are not in conflict. The purpose of B.2.1 is to ensure that each analytical method being used is precise enough to effectively detect any bias or inhomogeneity in the sample. Section B.2.2 provides the specific criteria for evaluating the homogeneity of the sample. Both sections must be followed.	Although these sections have been extensively revised in the 2009 and 2016 standards, the basic response is still valid.	Yes.	Yes.	Yes.	Yes. Section 5.6 of 2016 V3: section 5.6.1.6 addresses RSD of the method, section 5.6.1.7-5.6.1.9 addresses verification of assigned value. **NOTE**: The final response to this SIR is actually incorrect. B.2.2 does not provide homogeneity critiera, it provides verification of the assigned value criteria. With that said, B.2.1 and B.2.2 were two different requirements and these separate criteria still exist in both 2009 and 2016. References for 2009 and 2016 are updated to the analytical method RSD critiera and the verification of assigned value criteria to be consistent with sections cited in the original SIR.

ATTACHMENT 3

#	Date Submitted	2003	2009	2016	Actual Request	Final Response	Jerry's Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
32	10/15/08	Ch 2: E.3.2.1	V3: 10.2	V3: 5.9	A similar but more difficult situation occurs with the evaluation of microbiological data sets. In the case of quantitative microbiology, the NELAC 2003 Standard Chapter 2 Appendix E Section 3.2.1 appears to authorize the PT provider to use alternative evaluation criteria where 20 valid data points are not available. The Appendix appears to be in direct conflict with Chapter 2 Section 2.6 noted above which clearly states that there are no exceptions. The APG procedure in this case was to supplement available interlaboratory data with internal testing data run by the same method as the laboratories. The A2LA auditor found this to be inappropriate. We do not disagree with the auditors in this instance; however, Chapter 2 Appendix E Section 3.2.1 requires any alternate procedure to be approved by the PTOB. Clearly, the responsibility to providing acceptable evaluation criteria lies with the NELAC PT Board as noted in Chapter 2 Section 2.6 and not with either the PT provider or A2LA. In an effort to get appropriate guidance from A2LA as to available acceptable alternate procedures, we requested guidance from the A2LA microbiological auditor. She provided no recommendation on alternative acceptable procedures. Similarly, we requested guidance from the statistical auditor whose comment was that other providers have procedures but that he was not allowed to provide consultation. It appears to APG that if an alternative quantitative microbiological evaluation procedure must be approved by the PTOB that they then have an obligation to provide guidance on an acceptable proceed. However, it seems inappropriate for A2LA to accept responsibility for setting NELAC acceptance criteria when that function is vested in the NELAC PT Board by the 2003 NELAC Standard. Therefore, in order to meet the requirement of Chapter 2 Appendix E 3.2.1 alternative guidance must be provided since it is also not the responsibility of the PT provider to establish NELAC evaluation criteria.	The information in specific appendices, i.e. Appendix E for Microbiology, takes precedence over the information in the general standard, where conflicts exist. Therefore, Appendix E 3.2.1 must be followed and states, in the second sentence, "Sample sets of less than 20 data points may be used only with the approval of the PTOB/PTPA." The commentor needs to develop and present an option to A2LA and then work through any feedback until they have an acceptable procedure.	Although these sections have been extensively revised in the 2009 and 2016 standards, the basic response is still valid.	Yes.	Yes.	Yes.	Yes. Small data sets were adequately addressed in Section 10.2 of 2009 V3 and Section 5.9.2 of 2016 V3, but SIR still applies to the fact that it is the PT Providers responsibility to develop their own statisitical procedures for approval by their PTPA.
95	10/13/09	Ch 2: F.2.1, F.2.2 & F.3	V1M1: 4.2.1 e)	V1M1: 5.1.2 & 5.2.2	I am confused about the PT requirements for labs doing WET analysis. The only 'true' PT is the DMRQA - but it runs longer than 45 days - which doesn't meet F.2.2 requirements. I need to know will the DMRQA be allowed and counted as a PT until such a time as the PT providers have other PTs available?	While the DMRQA study containing the WET PT is open for a period longer than 45 days, the laboratory must complete the analysis of the WET PT sample within 45 days of sample receipt in order for the WET PT result to be used to meet 2003 NELAC standard requirements. ***The laboratory would have up to 45 days from sample receipt to analyze the WET sample and then the remainder of the DMRQA study period to report the WET PT analytical results to the PT provider.***	The 2009 standard extended the time period to 90 days. E 2016 standard removes all references to study dates for WET testing. The SIR no longer applies to the 2009 ro 2016 standards.	Yes, however, the response is misleading, if not inaccurate. F.2.2.a) Analyze within 45 calendar days of sample receipt: report results within 45 calendar days of completion. **"within 45 calendar days of completion" ≠ "remainder of the DMRQA study"**	No.	No.	Yes. Section 5.2.2 of 2016 V1M1 for WET testing: To maintain accreditation the laboratory shall participate in one (1) WET PT study per calendar year for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory is accredited. a) This requirement can be met by annual participation in the EPA DMRQA studies for WET, or b) If the laboratory is not participating in an EPA DMRQA study for WET, the closing dates of subsequent PT study samples for WET testing PT studies must be no more than fourteen (14) months apart.
184	9/9/11	Ch 2: 2.7.2	V1M1: 4.2.1	V1M1: 5.2.3	NELAC 2003 2.7.2 says, "For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study." TNI V1M1 4.2.1 says, "The analysis dates of successive PT samples for the same accreditation FOPT shall be at least five months apart and no longer than seven months apart unless the PT sample is being used for corrective action to establish successful history …" There is no language to describe what happens after 7 months have passed. The sentence is missing from TNI that was in NELAC that directed or allowed the addition of a "failed study" when the semiannual requirement was not met. Is it the intent of the standard for ABs to continue treating a failure to meet the semiannual schedule as a failed study? This is a significant enforcement issue since a potential alternative seems to be in V2M2, 10.3: "The Primary AB shall revoke the accreditation of a laboratory for a FoPT when:(a) the laboratory does not participate in the PT program as required by this Standard." This penalty is too severe and problematic for what could be just a missed deadline.	If a laboratory fails to report a single proficiency testing result it is evaluated as "not acceptable" per V2M2 7.3 part b. If the laboratory fails to report results for 2 out of 3 proficiency testing study time frames, then the laboratory's accreditation shall be suspended per V2M2 10.1 for failing to participate in the timeframes specified in the standard.	The language has been clarified in the 2016 standard and the SIR is likely obsolete.	No.	Yes.	No.	Yes. Section 5.2.3 of V1M1 states a laboratory that fails to analyze and report PT studies for a particular field of accreditation with the frequency specified in Sections 5.2.1 or 5.2.2 for which it seeks to maintain accreditation is charged with a failed PT study.

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#	Date Submitted	2003	2009	2016	Actual Request	Final Response	Jerry's Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
266	7/14/2014	Ch 2: 2.1.3	V1M1: 4.0 & 5.1.1	V1M1: 4.1.2 & 4.3.4	I am having difficult interpreting the requirements outlined in 4.0. The main concern is with our metals department where we run methods 200.7, 6010B, 200.8, 6020. If we are analyzing a PT by all four methods and reporting all methods individually, are 200.7/6010B and 200.8/6020 being treated the same? For example, is a failure for Cobalt by 200.8 equivalent to a failure for Cobalt by 6020, even if our PT demonstrates that we passed Co by 6020? These methods have different digestions and different method requirement at the instrument level. For the 200 series we utilize a hot block digestion and the 6000 series utilizes a microwave digestion. At the instrument level, the control limits for MS/MSDs and blank spikes are different. The requirements for same-source and second-source checks are different. These are different methods. Is each metals failure for ICP a failure for all ICP methods and each ICP-MS failure a failure for all ICP-MS methods? If this is the case, are we able to only run by one method and hold the accreditation for both. The standard references FoPT, with is defined by matrix, technology/METHOD, analyte. Not just based on matrix, technology, analyte.	The use of the term "method" within the definition of Field of Proficiency Testing (FoPT) (2009 V1M1, 3.6) is only included to accommodate EPA's drinking water program where PTs are required per method for the drinking water analytes referenced in the Code of Federal Regulations (CFR), specifically 40 CFR 141. The use of the term "technology" within the definition of FoPT (2009 V1M1, 3.6) only refers to the determinative analytical technology; preparative techniques/methods are not part of this definition. In addition, the Note in Section 5.1.1 of V1M1, states the following: "…If the laboratory is accredited for multiple test methods that use the same technology within a field of accreditation, the laboratory is not required to analyze a PT sample for each test method, except for fields of accreditation for the drinking water accreditation matrix for which a PT sample per test method is required…" Therefore, using the example provided, for each analyte in the same matrix, the TNI standard only requires PTs for one ICP method (200.7 or 6010B) to maintain accreditation for both ICP methods and one ICP-MS method (200.8 or 6020) to maintain accreditation for both ICP-MS methods If the laboratory chooses to analyze and report PT results for both methods within a technology (i.e. 200.7 and 6010B for ICP), then an unacceptable score for either of those methods will result in an unacceptable score for both methods due to their shared technology. See the Note in V1M1, Section 5.1.1, which states the following "….When the laboratory reports an analytical result for an accreditation FoPT within the same field of accreditation and accreditation matrix by more than one test method using the	V1M1 of the 2016 standard was revised to include this statement "An unacceptable score for the reported test method will result in an unacceptable score for all test methods for that accreditation FoPT."	Yes.	Yes.	Yes.	No. While Section 4.3.4 of 2016 V1M1 has clarified the scoring of multiple methods within one FoPT, the definition for FoPT has not been clearly defined for the applicability of "method" to the Drinking Water program Only.
181	9/6/11	n/a	V1M1: 4.2.1 a)	n/a	Please clarify the use of "analysis date" in V1M1, section 4.2.1 a) for successive PT samples. The standard states that the analysis date is to be at least 5 months apart and no longer than 7 months apart. TNI defines "analysis date" as the "calendar date of analysis" in the "Terms and Definitions" section. So, if a PT sample is analyzed on March 15, 2011, is the period anytime between August 2011 and October 2011 (5 - 7 months) acceptable, or, must one use the period August 15, 2011 to October 15, 2011 for the next PT sample?	The term "analysis date" is as defined in the Terms and Definitions. The 5 to 7 month window would be as is described above; PTs must be analyzed between August 15, 2011 to October 15, 2011 for evaluation purposes.	Analysis date was removed from the 2016 standard.	No.	Yes.	No.	n/a - Analysis date removed from standard.
	9/12/11	n/a	V1M1: 6.1 b) vs. V2M2: 8.2 c)	n/a	There is a discrepancy between these two sections. V1M1 6.1 b) says 15 days between analysis dates for successive PTs for corrective action. V2M2 8.2 c) still uses the closing date of the previous study	There was an oversight in the V2M2 section 8.2(c) requirements. Section V2M2 5.1.4 refers to time between analysis dates for Initial Accreditation and Section V2M2 5.2.1 refers to time between analysis dates for Continuing Accreditation. PTs used for corrective action are viewed the same as those for continuing accreditation. For consistency within the PT program, the language that is in V1M1 6.1b is the TNI 2009 requirement and should be utilized by the ABs as the requirement for V2M2 section 8.2(c).	The 2016 standard does not discuss PTs for corrective action, but instead refers to corrective action in a general sense and references Module 2.	No.	Yes.	No.	n/a - Corrective Action PT requirements removed.
	12/8/10	Ch 2: D.1.5.b	V1M4: 1.5.4	V1M4: 1.5.4	Since PTs are supposed to be treated like "real environmental samples", must laboratories perform second column confirmation for "hits" in PT samples analyzed by GC methods? Or, would a PT sample be considered "a positive result detected on a sample from a location that has been prevously tested by the laboratory" and therefore 2nd column confirmation is not required?	The 2003 NELAC Standard (Chapter 5, Appendix D.1.5) and the 2009 TNI Standard (V1M4 1.5.4) require the laboratory to perform confirmations according to the method. The approved methods in Standard Methods for the Examination of Water and Wastewater and the applicable U.S. EPA methods require confirmation on "unfamiliar samples." A PT sample (by design, a sample with unknown composition) is a sample that is "unfamiliar" to the laboratory and therefore requires confirmation per method requirements.	The 2009 and 2016 standards are identical.	Yes.	Yes.	Yes.	No. V1M1 of the 2016 Standard does not have language that explicitly requires second column confirmations in the analysis of PT samples. Therefore, SIR still needed for clarification/interpretation.
275	9/25/2014	n/a	V2M2: 4.1.1 f)	V2M2: 4.1.5 g)	V2M2, section 4.1.1 f) states: "notify all Secondary ABs of revocation of accreditation of any laboratory in the program." Does this standard language require not only for a Primary AB to notify all Secondary ABs of a total revocation of a laboratory's accreditation, but to also require notification for a partial revocation? We are requesting this SIR since we are debating the interpretation of this requirement within our own program and because we have only been notified by one other AB in regards to total revocation of a laboratory accreditation. We feel there is a need for clarification on how to interpret/implement this requirement and are uncertain if it is being understood and implemented consistently by other ABs.	This standard clause does not delineate between the types of laboratory accreditation revocations, total or partial. The standard should be implemented such that Secondary ABs are notified of any revocation, total or partial, of a laboratory's accreditation.		No.	Yes.	Yes.	No. Language was not changed between 2009 and 2016 Standard.
	6/27/11	Ch 2: 2.1.3.a, 2.3.3, B.1.3 & B.1.4	V2M2: 5.2.2, V3: 6.2.1 & 6.2.2	V1M1: 4.1.2, V3: 5.5.2	A laboratory in our program has requested accreditation to measure analytes in biological tissue. The question is "If biological tissues are not listed as a matrix for the current NELAC Fields of Proficiency Testing, are proficiency tests of solid and chemical materials acceptable to demonstrate proficiency for testing biological testing?"	Biological tissues are not a matrix in the TNI FoPT tables, as such there would be no proficiency testing requirements for this matrix.	The 2016 standard clearly indicates only analytes in FoPT tables are required.	Yes.	Yes.	Yes.	No. Even though V3 sect 5.2.2 of the 2016 Standard states " The matrix for soil PT samples shall be well-characterized natural soil and shall not contain greater than 90% sand by mass", the standard does not exclude this matrix or FoPT table as a substitute for biological tissue matrices.
	4/1/11	Ch 2: 2.1.3	V2M2: 6.3	V1M1: 4.3.4	Section 6.3 says: 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. If a lab uses 2 different extraction procedures for the same analytical method (e.g. Semi-Volatile GCMS in NPW matrix using Liquid/liquid Extraction sometimes and Solid Phase extraction at other times with any of the same analytes). Would it be acceptable to run a PT sample for each technology/extraction combination as long as they stick with the "fail one/fail both" concept that is in the referenced section? It get a little muddy since the TNI standard does not really recognize preparation methods and only looks at the technology but in reality it is like 2 different test methods.	The interpretation of the standard is that if PTs are analyzed using multiple preparation methods while being analyzed by a single analytical technology per an FoPT, then if one PT fails, all of the groups under that technology fail, regardless of the preparation method. The PT assessment is made by analytical technology per FoPT.	V1M1 of the 2016 standard was revised to include this statement "An unacceptable score for the reported test method will result in an unacceptable score for all test methods for that accreditation FoPT."	Yes.	Yes.	Yes.	No, but this topic cannot be addressed in the standard; TNI does not speak to preparation methods.