

**Summary of the TNI NELAP Board Meeting  
January 5, 2009**

1. Roll call

The NELAP Board met at 1:30 EST on January 5, 2009. Those members in attendance are listed in Attachment 1.

2. Approval minutes

All present voted in favor of approving the minutes for December 15, 2008. The program administrator was directed to post the minutes.

3. Extension requests

The holidays have caused a delay in completing the technical reviews in the second round of AB renewals. All teams in the second round have requested and received 20 day extensions for completion of the technical review.

4. Miami Meeting

Dan reviewed the agenda and assignments item for the Miami meeting.

Agenda items for the Miami meeting include:

2008 accomplishments – Dan Hickman  
White paper on new ABs– 30 minutes – Ken Jackson  
Associate/affiliate AB recognition– 30 minutes – Joe Aiello  
Fees for ABs – Dan Hickman  
QAO report – Paul Ellingson  
TNI Board Resolution on SW-846 – Aaren Alger  
Priorities for 2009 – Dan Hickman

Dan asked Carol to review past minutes and provide him with a list of NELAP Board accomplishments since the summer meeting.

5. Standards Interpretation Requests

The NELAP Board considered and acted on the following standards interpretation requests:

#11 – the consensus was to send this back to the LASC and request that language be added about training and documentation of training.

#14 – approved

#19 – Modify the 1<sup>st</sup> sentence in the last paragraph to say “when required by the method or regulation, the LDR must also.....

In the next to last paragraph, modify to say “requires an **acceptable** LOD check..... Delete everything after “However....

#20 – approved

#21 – approved

#26 – tabled for further discussion

#28 – this appears to be a lab/AB dispute. Actions by the PT board have likely fixed this issue.

#31 – approved

It was pointed out that the current NELAP Board voting procedure is too cumbersome for dealing with standards interpretation requests efficiently. The board will discuss an amendment to the procedures at a future meeting.

## 8. Adjourn and next meeting

The next meeting will be January 13, 2009, at the Miami meeting. Following Miami, the next meeting is Feb. 2, 2009.

## Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: <a href="mailto:gkulasin@dhs.ca.gov">gkulasin@dhs.ca.gov</a>	Yes
	Alternate: Jane Jensen <a href="mailto:jjensen@dhs.ca.gov">jjensen@dhs.ca.gov</a>	
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: <a href="mailto:steve_arms@doh.state.fl.us">steve_arms@doh.state.fl.us</a>	Yes
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: <a href="mailto:scott.siders@illinois.gov">scott.siders@illinois.gov</a>	No
KS	Jack McKenzie T: (785) 296-1639 F: (785) 296-1638 E: <a href="mailto:imckenzi@kdhe.state.ks.us">imckenzi@kdhe.state.ks.us</a>	Yes
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-219-3310 E: <a href="mailto:Paul.Bergeron@la.gov">Paul.Bergeron@la.gov</a>	Yes
	Alternate: Cindy Gagnon E: <a href="mailto:Cindy.Gagnon@la.gov">Cindy.Gagnon@la.gov</a>	

LA DHH	Louis Wales T: (225) 342-8491 F: (225) 342-7494 E: <a href="mailto:lwales@dhh.la.gov">lwales@dhh.la.gov</a>	Yes
	Alternate: Ginger Hutto <a href="mailto:ghutto@dhh.la.gov">ghutto@dhh.la.gov</a>	
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: <a href="mailto:whall@des.state.nh.us">whall@des.state.nh.us</a>	Yes
	Alternate: Jeanne Chwasciak	
	<a href="mailto:jcchwasciak@des.state.nh.us">jcchwasciak@des.state.nh.us</a>	
NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 <a href="mailto:joseph.aiello@dep.state.nj.us">joseph.aiello@dep.state.nj.us</a>	No
	Alternate : TBD	
NY	Kenneth Jackson T: (518) 485-5570 F: (518) 485-5568 E: <a href="mailto:jackson@wadsworth.org">jackson@wadsworth.org</a>	Yes
	Alternate: Dan Dickinson <a href="mailto:dmd15@health.state.ny.us">dmd15@health.state.ny.us</a>	
OR	Dan Hickman T: (503) 229-5983 F: (503) 229-6924 E: <a href="mailto:hickman.dan@deq.state.or.us">hickman.dan@deq.state.or.us</a>	Yes
	Alternate: Raeann Haynes <a href="mailto:haynes.raeann@deq.state.or.us">haynes.raeann@deq.state.or.us</a>	
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: <a href="mailto:aaalger@state.pa.us">aaalger@state.pa.us</a>	Yes

	<p>Alternate: Bethany Piper  <a href="mailto:bpiper@state.pa.us">bpiper@state.pa.us</a></p>	
TX	<p>Stephen Stubbs  T: (512) 239-3343  F: (512) 239-4760  E: <a href="mailto:sstubbs@tceq.state.tx.us">sstubbs@tceq.state.tx.us</a></p> <p>Alternate: Steve Gibson  <a href="mailto:jgibson@tceq.state.tx.us">jgibson@tceq.state.tx.us</a></p>	Yes
UT	<p>David Mendenhall  T: (801) 584-8470  F: (801) 584-8501  E: <a href="mailto:davidmendenhall@utah.gov">davidmendenhall@utah.gov</a></p>	Yes
	<p>Alternate: Kristin Brown  <a href="mailto:kristinbrown@utah.gov">kristinbrown@utah.gov</a></p>	
	<p>Program Administrator:  Carol Batterton  T: 830-990-1029 or 512-924-2102  E: <a href="mailto:carbat@beecreek.net">carbat@beecreek.net</a></p>	Yes
	<p>Evaluation Coordinator:  Lynn Bradley  T: 202-565-2575  E: <a href="mailto:Bradley.lynn@epa.gov">Bradley.lynn@epa.gov</a></p>	Yes
	<p>Quality Assurance Officer  Paul Ellingson  T: 801-201-8166  E: <a href="mailto:altasnow@gmail.com">altasnow@gmail.com</a></p>	Yes

## Attachment 2

<b>STANDARDS INTERPRETATION REQUEST (11)</b>	
<b>Section (eg. C.4.1.7.4)</b>	5.4.2.6
<b>Describe the problem:</b>	<p>Could you please give an example, clarification of proper data integrity procedure documentation by senior management.</p>
<b>FINAL RESPONSE:</b>	<p>(Technical Assistance Committee / NELAP Board, 1-x-09)</p> <p>Section 5.4.2.6. of the 2003 NELAC Standard specifies the elements required in a laboratory's ethics and data integrity procedure and states that "The data integrity procedures shall be signed and dated by senior management."</p> <p>The standard allows flexibility of how to meet the requirement. The laboratory may address the ethics and data integrity procedure in their Quality Manual and/or in SOPs that are signed and dated by senior management. The procedure may also be addressed in the annual management review which is then signed and dated by senior management. Another approach may be to have a stand alone sign-off sheet for the data integrity and ethics procedure which includes references to all laboratory documentation associated with the ethics and data integrity procedures. An example is provided below.</p> <p style="text-align: center;"><b>Documentation example Management Approval</b></p> <p>Documents:            Quality Manual – Effective Date: 1/1/08            Code of Ethics - Effective Date 09/27/08            Data Integrity Training Presentation – Effective Date 09/27/08</p> <p>The above referenced documents (attached) have been reviewed and approved for laboratory use.</p> <hr style="width: 50%; margin-left: 0;"/> <div style="display: flex; justify-content: space-between;"> <span>XXXXXX Laboratory Manager</span> <span>Date</span> </div>

	<hr style="width: 100%;"/> XXXXXX <span style="float: right;">Date</span> Laboratory Deputy Manager
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**STANDARDS INTERPRETATION REQUEST (14)**

<b>Section (eg. C.4.1.7.4)</b>	Appendix C-C.1e)
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<b>Describe the problem:</b>	<p>Demonstration of Capability Issue -          We seem to have a difference of opinion in our lab.          We have a manager that feels that the Table 2 of the EPA Method 548.1 give the criteria to be used for %Recovery for DOCs          They are stating that the Concentration used 100 shows a 95% recovery - they are trying to change their acceptance to 95% +/- 20%          Section 9.3 of the method states to use the R value from this table 2. Aren't these only suggestions of R values?          At the moment it is +/- 20% of the mean recovery</p>
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<b>FINAL RESPONSE:</b>	<p>(Technical Assistance Committee / NELAP Board, 1-x-09)</p> <p><i>Note: Laboratories should attempt to reconcile all differences in the interpretation of the NELAC 2003 standards and/or analytical methods with the applicable EPA Program, Regional Office and/or NELAC accreditation body. The following is an opinion of the current TNI Technical Assistance Committee and NELAP Board.</i></p> <p>In reviewing EPA Method 548.1, Revision 1.0, section 9.3 it is our interpretation, which concurred with one of EPA's Cincinnati's Chemist, that the laboratory's mean recovery +/-20% with an RSD of 30% is acceptable for the IDOC, then the laboratory may use the same values or tighter for DOCs in accordance with Chapter V, Appendix C, 1.e.</p> <p>Table 2 of the method was developed only using 7 replicates, therefore it would be best for a laboratory to adhere to limits for accuracy and precision developed using their own mean recovery.</p>
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**STANDARDS INTERPRETATION REQUEST (19)**

<b>Section (eg. C.4.1.7.4)</b>	D.1.2.1
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<b>Describe the problem:</b>	The standard allows a lab to forgo the MDL determination if they do not report outside the calibration range unless the
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	<p>method requires it. Since the determination of the MDL and the LDR are pointless exercises for labs that do not report outside their calibration range, I believe that the MUR of 3/12/07 allows a lab to delete these requirements from method requirements since it does not change the chemistry, it does not change the determinative step, and it does not change the performance of the method. Agree? Disagree?</p>
<p><b>FINAL RESPONSE:</b></p>	<p>(Technical Assistance Committee / Quality Systems Committee / NELAP Board, 1-x-09)</p> <p><i>Laboratories should attempt to reconcile all differences in the interpretation of the NELAC 2003 standards and/or analytical methods with the applicable EPA Program, Regional Office and/or NELAC accreditation body. The following is an opinion of the current TNI Technical Assistance Committee, Quality Systems Committee and NELAP Board.</i></p> <p>The Quality Systems Committee and the Technical Assistance Committee feels that the MUR does not allow the lab to delete non-determinative steps from the method.</p> <p>The MUR does not allow QC to be deleted. 136.6 (b)(i) stipulates that the requirements of paragraph (b)(2) be met for modified methods; (b)(2) states that QC acceptance criteria, both initial (start up) and ongoing must be equivalent to the approved method. This includes MDLs and linear range determinations where required.</p> <p>Since the NELAC Standard requires an annual LOD check, this is acceptable in place of annual MDLs, <b><u>UNLESS</u></b> otherwise specified by the method or Program (i.e., SDWA methods require annual MDLs). However, if the LOD check does not pass, the the MDL study must be performed. (Note – this also does not remove methods requirements that MDLs must be performed anytime the method or instrument type changes.)</p> <p>The LDR must also be performed on initial method start-up. Conformance to the LDR can also be demonstrated if a lab does not report outside their calibration range, and analysis of the high standard is no more than 10% of the true value (LDR criteria). In this case, the lab has demonstrated that they continue to operate with their LDR</p>



**STANDARDS INTERPRETATION REQUEST (20)**

<b>Section (eg. C.4.1.7.4)</b>	D.1.6a)
<b>Describe the problem:</b>	Not sure if this is the applicable section for this question. This question has to do with method 524.2 section 11.2.1 which talks about desorb time of about 4 minutes. If DOC and MDL studies show that a 2 minutes desorb time achieves equal or greater method performance as the 4 minute desorb time, will this method modification meet NELAC requirements for drinking water volatile analysis.
<b>FINAL RESPONSE:</b>	<p>(Technical Assistance Committee / NELAP Board, 1-x-09)</p> <p><i>Note: Laboratories should attempt to reconcile all differences in the interpretation of the NELAC 2003 standards and/or analytical methods with the applicable EPA Program, Regional office and/or NELAC accreditation body. The following is an opinion of the current TNI Technical Assistance Committee and NELAP Board.</i></p> <p>The following is an excerpt of an email regarding the allowable changes to purge time for EPA Method 524.2, Rev. 4.1, received in 11/07 by one State program from EPA Cincinnati:</p> <p><i>The statement in the method of "about 4 minutes" was to avoid issues with people demanding that desorb time be exactly 4.00000 minutes. It should be interpreted as times that could be rounded to 4, such as 3.5 to 4.4. It was not meant to permit people to have drastically shorter times.</i></p> <p>Modification to methods should be confirmed with the applicable EPA ATP program and Accreditation Program. DOC and MDL studies alone do not necessarily meet the requirements of an allowable method modification.</p> <p>For further consideration please refer to the 40 CFR, Part 141, Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures, Federal Register / Vol. 73, No. 107 / Tuesday, June 3, 2008 / Rules and Regulations.</p> <p>During the TNI Laboratory Forum Conference in Miami, scheduled for January 2009, the Assessment Forum (1/13/09) will include topics on <i>What is a Non-Standard Method?</i></p>

	<i>When do Standard Methods become non-standard modified methods?</i>
<b>STANDARDS INTERPRETATION REQUEST (26)</b>	
<b>Section (eg. C.4.1.7.4)</b>	Chapter 2
<b>Describe the problem:</b>	<p>I have been recently inspected by the State of Florida DOH. The inspection was very well done and along NELAC standards.</p> <p>The auditor indicated that if we were certified for compound 1,2,4-trichlorobenzene for 8260 we would be required to perform the PT if 1,2,4-trichlorobenzene was offered for any group. It is not currently in the 8260/624 volatile grouping as offered by WIBBY or NIS. It is however listed in the base neutral grouping. We were advised that we would have to perform the volatile analysis using the base neutral sample. We are not currently certified for 8270.</p> <p>If we put this base neutral PT on the volatile instrument we would ruin the column with the very first PT.</p> <p>I emailed Steve Arms the program director at the State of Florida and got a similar response.</p> <p>This is just an example of one parameter there are others that fall into this issue Thank you for your time.</p>
<b>FINAL RESPONSE:</b>	<p>(Proficiency Testing Board / NELAP Board, 1-x-09)</p> <p>In the absence of a written policy from the previous NELAC PT Board regarding proper interpretation of the FOPT table analyte analysis requirements, the TNI PT Board can not comment on what may or may not have been the intent of the NELAC PT Board in this regard. Without previous PT Board policy, interpretation to date of analyte analysis requirements for the FOPT tables has been left to an AB's (Accrediting Body's) discretion.</p> <p>The TNI PT Board believes that there has been a general lack of clarity within the community on how the FOPT tables should be interpreted. The TNI PT Board consensus is that group headers in those FOPT tables must hold significance, and group headers must be utilized to classify when an organic analyte is required to be processed and analyzed using extractable and/or purgeable technologies.</p>

	<p>The TNI PT Board is currently working to add this clarification to the FOPT tables.</p> <p>Until such time as the revised FOPT tables become available, the requirement for a PT by the AB must take into consideration current FOPT table group headers and whether TNI approved PT providers offer that analyte in their routinely offered products for volatile analysis. It must not be required by an AB that a PT product specifically designed and packaged by a PT vendor for extraction (semivolatile) methods be analyzed by purgeable (volatile) analysis. If volatile analysis of an analyte listed under a FOPT Base/Neutral grouping is required by an AB, the analyte must be readily available (from at least the majority of TNI approved PT providers) in PT vendor products that have been designed and marketed to be used for volatile method analysis.</p>
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**STANDARDS INTERPRETATION REQUEST (28)**

<b>Section (eg. C.4.1.7.4)</b>	2.4.1 (2003 Standard)
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<b>Describe the problem:</b>	<p>We are respectfully asking for an expedited review of this request, due to an immediate and significant financial impact on the laboratory; details are given in the last paragraph of this note. Thank you.</p> <p>“Our lab” attempted to obtain accreditation for the Analyte = E. coli, Technology = Colilert+ QuantiTray , Matrix = Drinking Water during it's initial accreditation (received July 1, 2007; Florida DOH). During the assessment, and during conversations/discussions prior to and following the assessment and receipt of accreditation, the laboratory was told that, since a PT was not available for this Analyte/Technology/Matrix, that the AB would only provide accreditation if the laboratory used the available PT for Analyte = E. coli, Matrix = Drinking water, and Technology = Colilert, BUT actually using the Technology Colilert + QuantiTray, but reporting only presence/absence (as if the QuantiTray had not been used). We declined to do that, for various reasons. With the publication of the new FoPT tables, it is now evident that a PT does not and has never existed for the Analyte/Technology/Matrix cited above, and our position is that we should have been allowed to apply for accreditation initially, as we had requested, and that we should be allowed to apply for accreditation immediately, on the basis of our assessment for the Analyte/Technology in the Matrix = Non-Potable Water, for</p>
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which we were accredited in July, 2007. (Please note that for reading convenience, we are citing only one technology, but several do exist and are widely used).

To further support our position, we would like to note three factors:

1. We took, and passed with an almost perfect quantitative score, the new PT (E. coli in Source Water, as provided by ERA) listed on the 2009 FoPT tables.

2. The AB New Jersey DEP has been accrediting laboratories for the quantitative Analyte/Technology/Matrix cited above by requiring successful accomplishment of two PTs exactly as have been added to the FoPT, which have been available for years from at least one vendor.

3. We would also note that accreditation for this particular combination of Analyte and Matrix, by a set of Technologies that are quantitative rather than qualitative, is a requirement for analysis of source waters as mandated by the Long Term 2 Enhanced Surface Water Treatment Rule (LT2). Unfortunately for the laboratory community, the language of this regulation is ambiguous regarding certification, and has required a Clarification Memorandum from the EPA (Clarification - Approved laboratories for E. coli analysis under the LT2 Rule. August 1, 2006). When we did not obtain the specific certification for quantitative analysis of E. coli in drinking water through NELAC, we relied on the fact that the EPA considered and listed ASI as an approved laboratory, based on our combination of certifications (Analyte = E. coli; plus Matrix = DW with Technology = Colilert, and Matrix = NPW with Technology = Colilert+QuantiTray)

LT2 is implemented in two phases and four "schedules" for the regulated community. The Schedule 4 public water suppliers (PWS's) must begin a year of quantitative monitoring of E. coli in their source water on an every-other week basis starting on Oct. 1. Our home state, Vermont, has quite recently decided that the Drinking Water Certification Officer cannot list ASI as a certified laboratory for the enumeration of E. coli in drinking water because that is not what appears on our NELAC certificate. And the EPA, which has listed ASI as approved for the Schedule 1-3

	<p>PWS's, will not be the data recipient for Schedule 4 monitoring; instead, the states have been designated as the data recipient. So we suddenly and unexpectedly must have this listing on our NELAC certificate to continue to service our main client base, the LT2-regulated PWS's. Hence our request for an expedited review.</p> <p>We extend our thanks for your consideration of this issue.</p>
<p><b>FINAL RESPONSE:</b></p>	<p>(Proficiency Testing Board / NELAP Board, 1-x-09)</p> <p>Section 2.4.1 of the 2003 NELAC standard states that to be accredited initially and to maintain accreditation, a laboratory shall participate in two single blind, single concentration PT studies, where available, per year for each field of proficiency testing.</p> <p>Section 2.1.3 of the 2003 NELAC standard states “Current NELAC fields of proficiency testing are located on the NELAC website”.</p> <p>The current FoPT Table for Drinking Water posted on the TNI website (01/01/08), (which replaced the NELAC website) lists Total Coliform as an FoPT. However, the FoPT is footnoted to indicate that this FoPT is specifically applicable to the presence/absence (P/A) qualitative test. There is not an FoPT listed in the FoPT table for Total Coliform for the quantitative method, thus per Section 2.4.1 of the 2003 NELAC Standard, no PT (either qualitative or quantitative) is currently required for initial or continued accreditation for the quantitative method.</p> <p>In 2007-2008, the TNI PT Board established the Microbiology Fields of Proficiency Testing Subcommittee. The primary task of the subcommittee was to evaluate the FoPT for microbiology and proposed changes to the FoPT as needed to ensure PT requirements were consistent with regulatory expectations, including those specified in the LT2 Rule. The subcommittee recommended several changes to the FoPT and one of those changes includes the addition of a FoPT for Total Coliform by a quantitative method. This recommendation was approved by the PT Board and the NELAC Board and the new FoPT requirement becomes effective January 1, 2009. Prior to the effective date of the FoPT, an AB cannot require a laboratory to successfully analyze a PT as a</p>

	<p>condition for accreditation nor can they withhold accreditation until the effective date of the FoPT, nor can the AB impose an alternative PT requirement as a condition for NELAC accreditation. The AB may require additional PT not listed as NELAC fields of proficiency testing in order to determine laboratory eligibility to report data to a state program, but the AB may not impose those added state PT requirements for granting initial or continued accreditation.</p> <p>The January 1, 2009 effective date was set to allow sufficient time for proficiency test providers and laboratories to prepare for the new PT requirement in accordance with the time frames set in the 2003 NELAC Standard. Nevertheless, the PT Board recognizes that when new regulations are promulgated and these regulations prompt a needed change for proficiency testing, the effective date of the regulation should be taken into account when determining the effective date for the new FoPTs and the PT Board will work on creating a mechanism to ensure this is done.</p>
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**STANDARDS INTERPRETATION REQUEST (31)**

<b>Section (eg. C.4.1.7.4)</b>	Chapter 2, Section 2.6
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<b>Describe the problem:</b>	<p>1. 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.</p> <p>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 it 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</p>
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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.

**FINAL RESPONSE:**

(Proficiency Testing Board / NELAP Board, 1-x-09)

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.