Summary of the TNI NELAP Board Meeting
May 4, 2009

1. Roll call

The NELAP Board met at 12:30 PM CST on May 4, 2009. Those members in attendance are listed in Attachment 1. In addition to those indicated, Cathy Westerman from Virginia DCLS also joined the call.

2. Minutes

Minutes from the 4-20-09 meeting were reviewed. The minutes were approved for posting.

3. Update on renewals

First round:
CA – Recommendation to the NELAP Board is scheduled for vote today.

Second round:
IL- Evaluation team will review response to technical review soon.
LADEQ –Onsite scheduled for the week of July 13.
OR – Draft report from the onsite is in preparation
TX – Onsite and lab shadow completed.

New applications:
VA application has been submitted. Initial completeness review by Evaluation Coordinator completed.

4. Vote on CA renewal

Dave Mendenhall moved to accept the evaluation team's recommendation to renew CA's recognition as a TNI accreditation body. Louis Wales seconded. All present voted in favor by roll call vote. LADEQ, NJ, and NY will be allowed to vote electronically.

5. Issues from the TNI Board

During the previous NELAP board meeting, Dan reviewed the responses prepared by Jerry Parr to questions raised by EPA RS&T Directors and EPA regional lab staff regarding NELAP accreditations and communications with the NELAP Board. There was not time to review item # 5. These responses are appended to the minutes from 4-20-09. After discussion, the Board agreed that they had no objection to the proposed response to item #5.

6. Memo from Cynthia Daugherty, EPA OW

The Board reviewed the memo that Cynthia Daugherty, EPA OW recently released outlining roles and responsibilities of EPA regional staff with respect to drinking water primacy and NELAP accreditation evaluations. This memo was provided for information and no action was necessary.

7. SW 846

The Board had additional discussion on the issue of consistency in SW-846 accreditations offered by the NELAP ABs. The option of dropping letter designations or of all ABs using letter designations was re-visited. IL stated that they don't have the resources to change the way they are currently awarding accreditations. NJ says they can only use a method if approved by the regulatory programs. PA is in the process of dropping letter designations. TX is not using letter designations. CA commercial labs are requesting use of letter designations in accreditation. Some of the problem for CA may be non-NELAP states that are requesting letter designations in the method accreditation.

Dan suggested that labs could be accredited without the letter designation, and the labs could add the letter as needed. The database and method codes could be modified to just list the method number with the revision number in a separate field. Dan will explore this option as a possible solution.

8. Standards Interpretation Requests

Dan presented the attached Standards Interpretation Requests (SIR) for action/approval by the NELAP Board. The Board voted to accept the responses to the following SIRs: #'s 6,7,32,31,33,38,39,43,44, and 48.

With respect to # 7 regarding reporting of "less than" (<) values in PT results, the Board requested that the answer be amended to indicate which policy the lab should be following before the new policy is created. The NELAC Board Policy #16 spoke to this same issue. Steve Gibson will forward to all. Carol will report results of voting to Ilona Taunton.

9. Next meeting

The next meeting of the NELAP Board will be May 18, 2009. Agenda items at the next meeting will include:

Update on renewals
SW 846
Standards Interpretations
Guidance on revision of the Evaluation SOP requested by subcommittee

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@dhs.ca.gov	
	Alternate: Jane Jensen jjensen@dhs.ca.gov	Yes
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve_arms@doh.state.fl.us	Yes
	Alternate: Carl Kircher carl kircher@doh.state.fl.us	
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	Yes
	Alternate: TBA	
KS	Dennis L. Dobson 785-291-3162 ddobson@kdhe.state.ks.us	Yes
	Alternate: TBA	
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-219-3310 E: Paul.Bergeron@la.gov	No
	Altérnate: Cindy Gagnon E: Cindy.Gagnon@la.gov	

LA DHH	Louis Wales T: (225) 342-8491 F: (225) 342-7494 E: lwales@dhh.la.gov Alternate: Ginger Hutto ghutto@dhh.la.gov	Yes
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: whall@des.state.nh.us Alternate: Jeanne Chwasciak jcchwasciak@des.state.nh.us	Yes
NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 joseph.aiello@dep.state.nj.us Alternate : TBD	No
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us Alternate: Dan Dickinson dmd15@health.state.ny.us	Yes
OR	Dan Hickman T: (503) 229-5983 F: (503) 229-6924 E: hickman.dan@deq.state.or.us Alternate: Raeann Haynes haynes.raeann@deq.state.or.us	Yes
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@state.pa.us	Yes

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

STANDARDS INTERPRETATION REQUEST (6)	
Section (eg. C.4.1.7.4)	2.7.3.1 d
Describe the problem:	"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 seems 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?
FINAL RESPONSE:	(PT Expert Committee/NELAP Board, 12-x-08) 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.

STANDARDS INTERPRETATION REQUEST (7)	
Section (eg. C.4.1.7.4)	NELAC Chapter 2

Describe the problem:	Question via email to Carl Kircher, May 8, 2008: 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.
FINAL RESPONSE:	(PT Board / NELAP Board, 12-x-08) 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.

STANDARDS INTERPRETATION REQUEST (31)	
Section (eg. C.4.1.7.4)	Chapter 2, Section 2.6
Describe the problem:	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. 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.
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.

STANDARDS INTERPRETATION REQUEST (32)	
Section (eg. C.4.1.7.4)	Chapter 2 Appendix E Section 3.2.1 /Chapter 2 2.6
Describe the problem:	2. A similar (to #31 Request) 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.
FINAL RESPONSE:	(Proficiency Testing Board / NELAP Board, 1-x-09) 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 commenter needs to develop and present an option to A2LA and then work through any feedback until they have an acceptable procedure.

STANDARDS INTERPRETATION REQUEST (33)	
Section (eg. C.4.1.7.4)	Chapter 2 Appendix B Sections 2.1 and 2.2
Describe the problem:	3. Finally there appears to be a highly technical issue and conflict between Sections B 2.1 and B 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.
FINAL RESPONSE:	(Proficiency Testing Board / NELAP Board, 1-x-09) 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.

STANDARDS INTERPRETATION REQUEST (38)	
Section (eg. C.4.1.7.4)	5.5.8.3.1
Describe the problem:	The test method specifies thermal preservation at a temperature of 4 C. The samples are hand delivered on ice to the lab on the same day as they are taken. They are received on ice, but the samples taken at the end of the sampling route may have only been chilling 15 - 30 minutes and may not be at or below 6 C as specified by the test method. The NELAC sample receipt protocol in 5.5.8.3.1 states that such samples may not meet the temperature criteria and that in such cases, the samples shall be considered acceptable. The question has arisen as to whether under these circumstances, documentation of receipt on ice is sufficient to meet the method and preservation documentation as the protocol implies, or does the actual sample receipt temperature still have to be recorded? What is the purpose of recording a temperature that is clearly acknowledged as likely to be outside the acceptance criteria if the sample is clearly deemed acceptable as described above? Would recording such temperature data actually make the data more susceptible to challenge by a third party?

FINAL RESPONSE:	(Quality System Expert Committee/NELAP Board, 12-x-08) The allowance for samples exceeding temperature requirements when delivered shortly after sampling does not alleviate the requirement to record a temperature, even in the presence of ice. No, documentation of receipt on ice is not sufficient to meet method requirements, since methods require the temperature upon receipt. Methods and regulations require that the temperature upon receipt be recorded, regardless of whether that information is in compliance or out of compliance. This should not make the data more susceptible to challenge, since it is clearly allowed as a exception.

STANDARDS INTERPRETATION REQUEST (39)	
Section (eg. C.4.1.7.4)	5.5.5.5
Describe the problem:	Are electronic records sufficient for instrument maintenance? If not, can the electronic records be printed and indexed periodically (perhaps monthly) to satisfy hard copy requirements? We can currently record all maintenance in our LIMS system.
FINAL RESPONSE:	(Quality Systems Expert Committee/NELAP Board, 12-x-08) There is nothing stated in 5.5.5.5 that states that records must be hard copy. If the records are maintained in a secure manner (presumably the LIMS contains audit trails and password protection), all of the items required in 5.5.5.5 are maintained, and any other requirements for records and records maintenance are met, this should be allowed.

STANDARDS INTERPRETATION REQUEST (43)	
Section (eg. C.4.1.7.4)	5.5.8.3.2
Describe the problem:	Is the sample acceptance plan required to be communicated to clients at any particulary frequency, i.e. annually? Thank you.
FINAL RESPONSE:	(Quality Systems Expert Committee / NELAP Board, 1-x-09)

	5.5.8.3.2 states that the 'sample acceptance policy shall be made available to sample collection personnel'. The introduction included in 5.5.8 states 'the following are essential to ensure the validity of the laboratory's data', which would mean that the laboratory can't invoke 5.1.2, which states 'When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply' to avoid having such a policy. However, the Standard makes no mention of any period under which the acceptance policy must be communicated to clients.

STANDARDS INTERPRETATION REQUEST (44)	
Section (eg. C.4.1.7.4)	D.3.1 (Standard Methods 9020)
Describe the problem:	In Standard Methods there is a requirement to do at least one positive sample verification monthly, in some cases 10% etc. Question: What if you do not have any positive samples, should you do a positive verification anyway? I see that for DW (source) even if you do not have any positive samples, a positive verification check is to be done quarterly. How about the other type of waters? For example to check any false negatives? Frequency?
FINAL RESPONSE:	(Quality Systems Expert Committee/ NELAP Board, 1-x-09) Questions involving specific methods should be directed to the writer of the method. For information about the requirements in the NELAC Standard, see D.3.1 b. The requirement for positive controls exists so that the lab can demonstrate that IT isn't the reason there are no positives, i.e., it isn't doing something that causes no growth.

STANDARDS INTERPRETATION REQUEST (48)	
Section (eg. C.4.1.7.4)	5.5.5.2.2.1 d)

Describe the problem:	The section in question states: d) All initial instrument calibrations must be verified with a standard obtained from a second manufacturer or lot if the lot can be demonstrated from the manufacturer as prepared independently from other lots. Traceability shall be to a national standard, when commercially available. Our question is, does the requirement for second source standard include calibration curves for surrogate compounds?
FINAL RESPONSE:	(Quality Systems Expert Committee / NELAP Board, 1-x-09) Surrogates are intended to provide a measure of recovery for every sample matrix (D.1.1.3.3 a). A second source check is designed to assure that the analytes of concern are being correctly identified and quantified. Since surrogates are not analytes of concern, and may be held at a constant level in a calibration curve, they are not required to be verified by a second source.