Summary of the TNI NELAP Board Meeting
November 10, 2008

1. Roll call

The NELAP Board met at 1:30 EST on November 10, 2008. Those members in attendance are listed in Attachment 1. Jerry Parr took minutes substituting for Carol Batterton and Ilona Taunton was present as a representative of LASC.

2. Approval of November 3 minutes

Move to approve by Ken Jackson with addition of adding the electronic vote tally to the vote on New York.

Second by Steve Arms

Pass with no negative votes.

3. Update on AB evaluations

California, Florida and New Jersey are in progress. All of the current round should be complete by January 12. All in next round have requested extension until week after Thanksgiving.

4. New Accreditation Body White Paper

Will be discussed in Miami. Concern over conditional AB granting interim accreditation that would then be recognized by other ABs. Concern over having two evaluations within three-years.

Side Note: TNI can likely provide travel support for one individual from each AB. Those interested should get a request to Carol.

4a. Side bar discussion on TNI standards.

The LASC review of Quality Systems, On-Site Assessment and Accreditation Body volumes and modules have been completed and are on-track to have a comprehensive report provided to the NELAP Board with recommendations in December. Some editorial changes may be needed but it is unlikely the standard will need to be revised. Several issues have been identified with the PT volumes/modules and it is unlikely the PT Expert Committee can complete their work before the Miami meeting. The tentative interim amendment process may need to be used for the PT standards.

5. Letter from ACIL on SW-846 Methods

The NELAP Board reviewed the second draft of the letter to ACIL and had no comments. Anyone not participating in the call should send comments to Jerry Parr by Thanksgiving.

6. Resolution of the TNI Board on SW-846 Methods

The NELAP Board reviewed the TNI Board resolution and will add this issue to their agenda for Miami.

7. AB Standards Interpretation Panel in Miami

Those ABs that will be in attendance in Miami will be asked to participate in the panel session on Tuesday afternoon.

7. Standards Interpretation Requests

The NELAP Board affirmed that all standard interpretation requests need to be voted on as accreditation business and thus the vote for items 29, 30, 34, 8, 13, and 16 will occur at the next meeting. The Board was in general agreement with the responses to questions 29 and 34.

The NELAP Board did not agree with the answer to question 30 and this question has been referred back to the Quality Systems Committee.

After extensive discussion on the interpretation of section 5.5.4.2.1, the NELAP Board decided question 8 involved a dispute between a laboratory and an accreditation body and recommends this question not be considered an interpretation request.

Based on discussion, the responses to questions 13 and 16 have been reworded. See attachment 2.

7. Adjourn

After a motion by Steve Arms and a second by Steve Stubbs, the Board adjourned at 2:33 pm.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@dhs.ca.gov	Yes
	Alternate: Jane Jensen jjensen@dhs.ca.gov	
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	
	Alternate: TBA	
KS	Jack McKenzie T: (785) 296-1639 F: (785) 296-1638 E: jmckenzi@kdhe.state.ks.us	Yes
	Alternate: Dennis L. Dobson 785-291-3162 ddobson@kdhe.state.ks.us	
LA DEQ	James Brent T: 225-219-9800 F: 225-219-9898 E: James.Brent@la.gov	
	Altérnate: Paul Bergeron E: Paul.Bergeron@la.gov	Yes

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	
NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 joseph.aiello@dep.state.nj.us Alternate : TBD	Yes
NY	Kenneth Jackson T: (518) 485-5570 F: (518) 485-5568 E: jackson@wadsworth.org 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	
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	
	Evaluation Coordinator: Lynn Bradley T: 202-565-2575 E: Bradley.lynn@epa.gov	
	Quality Assurance Officer Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	Yes

Attachment 2

STANDARDS INTERPRETATION REQUEST (29)	
Section (eg. C.4.1.7.4)	5.5.5.10
Describe the problem:	The following comments and concerns are base on actual practices observed in laboratories based on possible interpretations of the NELAC standard. Section 5.5.5.10 begins with the statement “When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by continuing instrument calibration verification with each analytical batch. The following items are essential elements of continuing instrument calibration verification:” This is a forward looking statement meaning that the pass/fail status of the CCV standard being run is evaluated only in light of its impact on the samples which follow the CCV standard. Section 5.5.5.10 e) reads “If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate acceptable performance after corrective action with two consecutive calibration verifications, or a new initial instrument calibration must be performed.” The corrective action language in the standard only address what is necessary to proceed with analysis without recalibration. I referred to this evaluation as being “forward looking”. There is no interpretation given regarding any additional considerations, or limitation on corrective actions for nonconforming CCV events where they occur in the middle or the end of a sequence that requires acceptable bracketing CCVs such as in GC analysis without the use of internal standards. The following practices have been observed in NELAC accredited laboratories: • A laboratory routinely will set up two consecutive CCVs during an automated sequence. If the first CCV passes, the laboratory will not evaluate the second. However if the first CCV fails and the second one passes the laboratory will report all preceding and trailing samples as being bracketed by an acceptable CCV. • In an "attended" continuous sequence it has also been observed that a laboratory will perform instrument maintenance such as changing an inlet liner etc. in between CCVs and again treat the second passing CCV as the acceptable bracketing CCV for the

	preceding samples. Comment: these practices constitute the "priming" of an instrument before running a CCV, the treatment of QC samples differently from the associated samples, and the "cherry picking" of QC that passes over QC that fails. However, there is no language in the standard that clarifies the CCV evaluation regarding their potential impact on the preceding samples. In the above cases the laboratory has argued that the NELAC standard allows for this. It is requested that clarification be provided regarding the impact on a failing CCV on the preceding samples during a continuing sequence where acceptable bracketing CCVs are required.
FINAL RESPONSE:	(Quality Systems Expert Committee/NELAP Board, 10-x-08) Running a second CCV in a sequence is not the intention of the standard. The practice of running two CCVs routinely would require that the laboratory evaluate each of them on every occasion. There must be a form of corrective action (i.e., instrument maintenance) prior to the second CCV being evaluated. Since no corrective action is being taken between the two CCVs, the laboratory is failing the requirement in 5.5.5.10 e of performing routine corrective action (unless it can be documented that something occurred in the first CCV, such as poor sample introduction, that did not occur in the second CCV), and cannot use the second CCV to alleviate the failing of the first.

STANDARDS INTERPRETATION REQUEST (30)	
Section (eg. C.4.1.7.4)	5.5.5.2.2.1.d
Describe the problem:	My question concerns the definition of a second source standard. What input variables (analyte lot, solvent lot, balance, operator, etc) must change in order for a second lot of standard to be considered to be prepared independently? Thanks for your help.
FINAL RESPONSE:	(Quality Systems Expert Committee/NELAP Board, 10-x-08) 5.5.5.2.2.1 d requires that the laboratory be able to verify that the second lot of standard is prepared independently from other lots. If this can be demonstrated, there are no other requirements in the standard. It would be a good practice to change the operator, at a minimum. Any other changes introduce additional variables that the second source is not attempting to verify.

STANDARDS INTERPRETATION REQUEST (34)	
Section (eg. C.4.1.7.4)	C.3.1.b
Describe the problem:	It is felt that the LOD validation procedure in the 2003 NELAC Standard is ambiguous and can result in two different interpretations. By using the relevant standards (C.3.1.b, D.1.2.1.a) as well as definitions in the glossary especially for terms such as a quality system matrix, you can construe two different procedures. One interpretation is that the LOD must be determined only in the matrix of the sample. In other words, if a lab is analyzing wastewater effluent samples, the LOD must be validated only in a wastewater effluent matrix. Not only is this not practical but not possible for many analytes. This is a challenge to the practical and second interpretation which allows for the LOD to be validated in a reagent water matrix. As someone who is engaged in quality assurance work, whenever an alternative interpretation is brought to me, I must evaluate objectively all viewpoints and I feel there is merit to the alternative argument. With respect to the two choices, we like to hear from you as to which choice is right and as stated we like to alert you that they may be an ambiguity issue with the LOD procedure.
FINAL RESPONSE:	Response: Reagent water (however named) is accepted as the quality systems matrix used for the determination of LOD for wastewater analyses.

#8 Submitted 7/8/08

Name	
Email	
Phone	
Organization	
Address	
Section (eg. C.4.1.7.4)	5.5.4.1
	Our laboratory recently was cited with deficiency because the general chemistry Standard Method editions are not 20th edition. Our response is as follows, and we seek assistance in this interpretation.
Describe the problem:	Section 5.5.4.1 of the 2003 NELAC standard states that "The laboratory shall use appropriate methods and procedures for all environmental tests within its scope." By appropriate, ENCO interprets that the method will satisfy our client's regulatory needs. According to the Methods Update Rule of March, 2007, the 18th edition of Standard Methods is an approved version

for regulatory needs, and thus is appropriate.

Section 5.5.4.1 of the NELAC standard goes further to state that "All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 5.4.3)." Section 5.4.3 of the standard refers specifically to document control. We feel that the interpretation of this section of the NELAC standard to refer to the latest update of Standard Methods is excessive and can lead to undesirable results. For example, the 21st edition of Standard Methods is the most recent available, but the methods in this edition are specifically not included in the Methods Update Rule.

From Assessment Forum, 8-12-08:

Discussion:

- The SM edition should correlate to the SOP.
- We would only cite this if there was a discrepancy been SOP and what is being used.
- Accreditation available for many methods. ABs offer accreditation for many variations. Labs must selected method based on regulation or permit or client request.
- Secondary accreditations can become a problem.

STATUS

Response:

This appears to be a dispute between the lab and the AB and not a standards interpretation request. Any disputes between a laboratory and their AB regarding accreditation are to be handled through the appropriate appeals process established by applicable state laws and regulations.

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Date E-mailed:

FINAL RESPONSE:

Response:

#13 Submitted July 22, 2008

Name	
Email	
Phone	
Organization	
Address	
Name	
Email	
Name	
Email	

Section (eg. C.4.1.7.4)	5.4.12.2.2
Describe the problem:	This section of the standard talks about observation, data and calculations recorded at the time they are made. Currently our lab has a policy in place to mark the preservation checks for each sample separately. Example a specific sample has a pH of less 2 and chlorine result of zero. Would it be sufficient to document the pH and chlorine checks by a general statement for example "all samples extracted in the batch had a pH less than 2 and chlorine result of zero"? Final Response To Be Prepared By: NELAP Board
STATUS	**Preliminary Response:** No. 5.4.12.2.1 requires observations to be recorded at the time they are made. 5.4.12.2.5.1 requires date/time of sampling to be recorded, so as to demonstrate compliance with holding times. 5.5.8.3.1(2) states the laboratory shall implement procedures for checking chemical preservation prior to or during sample preparation or analysis. 3(b) requires the results of these checks to be recorded. 5.5.8.3.1(d)(2)(iv) requires comments resulting from inspection for sample rejection to be linked to the laboratory ID code. So, the lab could, for example, use a check box on a sample receipt form to indicate a sample's preservation was checked and the result was less than 2 and chlorine was zero as long as the observation was unequivocally linked to each sample checked. The lab could not simply preprint this statement on an analytical report or document preservation after-the-fact in an extraction log because doing so would not comply with requirements to record observations at the time they are made and link the results of preservation checks unequivocally with sample identification numbers.
	Date E-mailed:
FINAL RESPONSE:	Response:

#16 Submitted 7/31/08

Name	
Email	
Organization	
Address	
Section (eg. C.4.1.7.4)	5.5.10.2(i)

Describe the problem:	The standard states the report should note whether the sample result was calculated on a wet weight or a dry weight basis. The narrative that accompanies every analytical report out of our laboratory states "all sample results are reported on an "as-received" basis unless otherwise noted". My question is why does the report have to note whether it is dry or wet weight a second time, when we have already noted "as-received"? Final Response To Be Prepared By: NELAP Board
STATUS	**Preliminary Response:** 5.5.10.2(i) requires identifying whether data are calculated on a dry weight or wet weight basis Recording sample result as being calculated on the basis of 'as received' does not indicate wet or dry weight basis. As or more importantly, identifying results as having been calculated on an 'as received' basis would not comply with requirements in 5.5.10.1 to report results unambiguously. The laboratory could have a statement: “All results are wet weight unless otherwise noted.”
FINAL RESPONSE:	Date E-mailed: Response: