



The NELAC Institute (TNI) Quality Systems Expert Committee
Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on November 8, 2010 at 1:00 PM EST by conference call. The agenda is attached as appendix A, action items are listed in Appendix B and the attendees listed in Appendix C and Standard Interpretations Requests (SIR) are presented in Appendix D.

After roll call (see Appendix C), Silky reviewed and updated the action items (attached). The minutes from the October 2010 meeting were reviewed and accepted for posting.

Silky presented the credentials of the two candidates and asked for a vote. The committee voted unanimously to accept Katie and Stephanie as new members. A request for confirmation of the selected candidates will be sent to the TNI Board of Directors and both should be confirmed before the December conference call.

Silky reported that the Voting Draft Standard has been sent to Jerry Parr for posting and voting.

The committee began discussions on the Standard Interpretation Requests (SIR) 132, 135, 137, 77, 139 and 141.

SIR 132, 135, 137, 139 and 141 – The committee agreed that the proposed language for each was the correct interpretation. The SIRs will be forwarded to Jane for review.

SIR 77 – The committee did not agree with the suggested change as some laboratories use Class 1 or “S” weights for daily checking. The committee agreed, however, that the laboratory must have a set of weights, traceable to national standards that must be used only for calibration/verification of working weights. The committee will review the changes at the December Meeting

Silky asked about the status of the TNI quality manual template. Most had not begun the review of their assigned sections. Silky reminded the group that the Template committee needed the reviews by mid-December, and that the assignments should be completed by the December meeting.

The committee discussed the LASC comments and suggestions to the TNI checklist. The committee felt it important to retain the original standard language, but agreed that the checklist could be organized along topic lines and redundant questions could be removed (or at least referenced to the same requirement). Silky will begin reorganizing, but asked for suggestions on organization/topic headings. Michelle Wade volunteered to send the Kansas checklist headers.

The committee spent the remaining time in reviewing a TNI response to the recent EPA Method Update Rule. The letter will be sent by Jerry Parr, but he asked for input from the Quality Systems Committee. Changes were made, and the letter will be recirculated before sending back to Jerry.

As a final order of business, Silky polled the committee on suggestions to change the monthly teleconference day. The overall response from the committee was that the 2nd Monday was as good as any other day. Therefore, the meeting day for 2011 will remain the 2nd Monday of each month.

The next meeting is scheduled for Monday, December 13. The meeting adjourned at 14:37 EST.

Conference Call Agenda:



**The NELAC Institute Quality
Systems Expert Committee**

**November 8, 2010 1:00 pm EDT
1 Hour, 55 Minutes
Conference Call**

Please Call Dial-in Number: 1-219-509-8222 (East Coast)

Your Participant Access Code is: 52518

To Associate Members Only: Please RSVP your participation in this call with an email to Silky Labie at elcat-llc@comcast.net (Subject: RSVP for *November 8, 2010*)

Old Business:

Roll Call	All	5 Minutes
Action Items (attached)	All	10 Minutes
Minutes from October (attached)	All	5 minutes
Member Status (see applications)	All	10 minutes
Status of Voting Draft Standard	Silky	5 minutes
Final review of SIR 132, 135 and 137	All	10 minutes
Status of TNI Template Review	All	10 minutes

New Business:

Review of SIR 77, 139 and 141	All	30 minutes
TNI Checklist - Response from LASC (separate email)	Silky	15 minutes
Method Update Rule (separate email)	Silky	15 minutes

Appendix B - Action Items

Item No.	Date Proposed	Action	Date to be Completed	Date Completed
1	5-10-10	Circulate April Minutes for email approval	6-14-10	5-10-10
2	5-10-10	Circulate May Minutes for email approval	6-14-10	5-10-10
3	5-10-10	Provide additional names from EPA for consideration	6-14-10	Ongoing
4	5-10-10	Follow up on EPA candidates	6-14-10	Ongoing
5	5-10-10	Contact current members concerning membership	6-14-10	5-10-10
6	5-10-10	Complete vote on laboratory member	6-14-10	6-13-10
7	5-10-10	Pat to draft response for interpretation request 112	6-14-10	5-10-10
8	5-10-10	Silky to draft TIA for non standard methods	6-14-10	5-17-10
9	5-10-10	Fred to poll others concerning changes to 17025	6-14-10	Ongoing
10	6-14-10	Eugene to draft a response to Item 122	6-17-10	6-21-10
11	6-14-10	Gil and Robin to review the microbiology module for language changes	7-12-10	6-25-10
12	6-14-10	All – review revisions and provide relevant comments	7-12-10	6-30-10
13	6-14-10	Silky to follow-up with Jerry on arranging teleconferencing capabilities during the August meeting	7-12-10	6-15-10
14	7-10-10	Examples for QAM template	12-2010	Ongoing
15	7-10-10	Paul to look at Wisconsin standards for ways to exclude certain parameters from LOD	7-26-10	7-23-10
16	7-10-10	Dorothy to propose a definition for physical measurement	7-26-10	7-16-10
17	7-10-10	Silky to check with Jerry concerning whether conference handout will contain ISO language	7-26-10	7-22-10
18	9-13-10	Silky to contact accrediting authorities to request a nomination for the committee.	10-11-10	10-05-10
19	9-13-10	Silky to redraft definitions of “Date Integrity” and circulate for vote.	9-24-10	9-24-10
20	9-13-10	Silky to complete revisions/changes to standard and circulate a voting draft	10-05-10	10-05-10

		standard		
21	10-11-10	Silky to solicit votes on whether to move the standard forward from members that were absent.		10-12-10
22	10-11-10	Silky to wordsmith SIRs 132, 135 and 137 and recirculate for final approval		11-8-10
23	10-11-10	Silky to forward the completed SIRs to Jane for proofing		10-25-10
24	10-11-10	Silky to make review assignments on the quality manual template		10-22-10

Appendix C - Participants

<p>Mr. Brian R Boling Oregon Dept. of Environmental Quality 3150 NW 229th Suite 150 Hillsboro, OR, 97124 P: (503) 693-5745 E: boling.brian@deq.state.or.us</p>	A	<p>Ms Laurie Carhart NYS DOH ELAP PO Box 509, ESP Albany, NY 12201 P: (518) 486-2538 E: ljc09@health.state.ny.us</p>	A
<p>Ms Robin Cook City of Daytona Beach 3651 LPGA Blvd Daytona Beach FL 32124T P: (386) 671 8885 E: cookr@codb.us</p>	P	<p>Ms Tamara DeMorest Utah Department of Health 4431 South 2700 West Salt Lake City, UT 84119-8600 P: 801-965-2541 E: tdemorest@utah.gov</p>	A
<p>Mr. Gil Dichter IDEXX Laboratories One Idexx Dr Westbrook, ME 04092 P: (207) 556-4687 E: gil-dichter@idexx.com</p>	P	<p>Mr. Eugene Klesta 110 South Hill Street South Bend, IN 46617 P: 574-472-5580 eugene.j.klesta@us.ul.com</p>	P
<p>Ms Silky S. Labie Env. Lab Consulting & Technology, LLC PO Box 13324 Tallahassee, FL 32311 P: (850) 656-6298 E: elcat-llc@comcast.net</p>	P	<p>Ms Dorothy M. Love Lancaster Laboratories, Inc. 2425 New Holland Pike, P.O. Box 12425 Lancaster, PA 17605-2425 P: (717) 656-2300 x1204 E: dmllove@lancasterlabs.com</p>	P
<p>Mr. Robert Martino QC Laboratories 60 James Way, Unit 6 Southampton, PA 18966 P: (267) 699-0103 E: RMartino@qclaboratories.com</p>	A	<p>Mr. Fred S. McLean NAVSEA 04XQ(LABS) 1661 Redbank Road Goose Creek, SC 29445-6511 P: (843) 764-7266 E: fred.mclean@navy.mil</p>	P
<p>Ms Michele Potter NJDEP 9 Ewing Street, 2nd Floor Trenton, NJ, 08625 P: (609) 984-3870 E: Michele.Potter@dep.state.nj.us</p>	P	<p>Mr. Randall Querry A2LA 5301 Buckeystown Pike, Suite 350 Frederick, MD 21704 P: (301) 644-3221 E: rquerry@a2la.org</p>	P
<p>Ms. Kristina Spadafora Frontier Global Sciences 414 Pontius Avenue North Seattle, WA 98109 P: (206) 957-1423 E: kristinas@frontiergs.com</p>	E	<p>Ms. Michelle L. Wade Kn Dept of Health and Environment Forbes Field, Building 740 Topeka, KS 66620 P: (785) 296-6198 mwade@kdheks.gov</p>	A
<p>Ms Jane M. Wilson, M.P.H. Director of Standards NSF International P: (734) 827-6835 E: Wilson@nsf.org</p>	A		

Associate Members: Gary Dechant
Larry Penfold

Appendix D - Request for Interpretations

#132

Section (eg. C.4.1.7.4)	Appendix D.3.6(c)
Describe the problem:	If the lab purchases prepared sterile deionized water in 99 mL bottles to make dilutions for the IDEXX products, is the lab required to test for pH and conductivity on a different 99 mL bottle from the same lot every time the labs needs to make a dilution? What is the correct frequency? The sterile deionized water is not used for media or reagent preparation.
Comments	
Response	<p>The 2003 NELAC standard outlines the need to monitor the water quality for residual chlorine, specific conductance and heterotrophic plate count monthly.</p> <p>The requirement for monitoring pH is a method requirement that the committee cannot address.</p> <p>The standard, as written does not specifically address purchased sources of sterile water. This oversight was rectified in the TNI standard that will become effective in July 2011.</p> <p>Based on the requirements in the TNI standard, the committee recommends the following:</p> <p>If the water is used for only blanks, then only sterility needs to be checked at a frequency of once per lot.</p> <p>If the water is used for serial dilutions, it is considered reagent water and needs to be treated as such. A vendor-supplied Certificate of Analysis for the required tests (the water quality for residual chlorine, specific conductance and heterotrophic plate count) will be acceptable.</p>

#135

Section (eg. C.4.1.7.4)	NELAC 5.5.6.4(c)
Describe the problem:	Are microorganisms considered standards? Does the lab need to assign an expiration date on them? The reference cultures the lab receives from ATCC does not have expiration dates. The lab is following the protocol for microorganism listed in Appendix D3.7.
Comments	

Response	The ATCC reference cultures are “reference materials” and must adhere to the requirements of 5.5.6.4. These requirements include the requirement of having an expiration date whether supplied by the vendor or assigned by the laboratory.
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#137

Standard	2009 TNI Standard
Section (eg. C.4.1.7.4)	5.5.5.10.c.1-4
Describe the problem:	Does this standard require weighing a single weight verification after weighing samples to insure calibration is maintained?
Comments	
Response	<p>The citation above is from the NELAC 2003 standard, and refers to instrument calibration. A balance is considered support equipment and must follow section 5.5.5.2.1.</p> <p>Item d) of this section requires that the balance be checked prior to use on each working day in the expected range of use. To verify the range requires at least two weights.</p> <p>An ending verification is not required, however, if the next verification fails, all samples weighed between the previous acceptable verification and the failed verification are suspect and must be qualified as estimated.</p>

NEW

#139

Standard	2003 NELAC Standard
Section (eg. C.4.1.7.4)	D.1.2.1.b
Describe the problem:	In reviewing an onsite report for metals analyses, the auditor noted that the lab did perform LOD analyses annually but that the LODs for vanadium and arsenic were lower than the blank analysis and that new LODs and LOQs must be reestablished. I see nothing in D1.2.1.b that makes any comparison of an LOD to the blank results. Does an LOD need to be higher than the blank?
Comments	

Response	There is no requirement to compare the LOD with the blank. Theoretically, a blank should have no detectable contaminants. Any detection in a blank must be evaluated according to D.1.1.1d).
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#141

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1,M5
Section (eg. C.4.1.7.4)	1.7.5(a) & (b)(i)(ii)(iii)(iv)
Describe the problem:	<p>Does the temperature of samples at the time of sample acceptance apply to presence/absence tests such as SM 9223-a chromogenic substrate test? The LOD is 1cfu and if the result of a test is present, it does not matter whether there is one or thousands of bacteria present.</p> <p>If purchased vessels are used which contain the required amount of sodiumthiosulfate, is a test for chlorine residual done in the field sufficient?</p>
Comments	
Response	<p>Volume 1 Module 2, section 5.8.7.1 of the TNI standard requires that the laboratory have procedures for verifying and documenting preservation. Therefore, when preservation of a sample requires cooling, the temperature of the sample must be verified upon sample receipt. See Volume 1, Module 5 section 1.7.5 a).</p> <p>The V1M2 standard applies to samples that were treated to remove chlorine. See also Volume 1, Module 5 section, section 1.7.5 b)</p>

Request for Clarification

Then with #77, the response needs to be revised to account for the standard language on page 34 of Chapter 5 where the reference is "...such as class S or equivalent weights....shall be used for calibration only.....",

How about this for a response:

A Class 1 or "S" weight is considered a reference and not a working standard, so the lab can document their calibration procedures as long as there is traceability to a national standard.

STANDARDS INTERPRETATION REQUEST (77)	
Section (eg. C.4.1.7.4)	5.5.6.3.1
Describe the problem:	I'm trying to determine if NELAC requires that the weight sets used to verify balances prior to use MUST be Class 1.
FINAL RESPONSE:	<p>(Quality System Expert Committee/NELAP Board, 2-x-10)</p> <p>A laboratory may use any class to verify the balance if the weights are traceable to a national standard.</p> <p>A Class 1 (or "S") weight is normally considered a reference standard, but may be used as working standard. If the laboratory has designated the weight as a reference standard, the weight may only be used for calibration (i.e. calibrating/checking working standards).</p> <p>Standards that are used for daily calibrations (5.5.5.2.1) must be traceable to NIST. The Class1 or "S" weights can be used to verify the working standards, since these are traceable to NIST</p>

**Appendix E
Member Applications**

State Accrediting Authority

Name	Stephanie Drier
Email	stephanie.drier@state.mn.us
Stakeholder Interest	Accreditation Body
Committee Interest	I am interested in serving on the committees checked below.
Expert Committees	- Quality Systems

Qualifications	<p>Stephanie Drier 10.12.2010.pdf</p> <p>Stephanie Drier is an environmental quality assurance specialist who earned her Bachelor of Science degree in Environmental Science and a minor in chemistry from the University of Wisconsin–River Falls. She has 8 years of experience in the environmental testing and quality assurance industry. She has worked at two governmental agencies serving as a laboratory technician, quality assurance officer and a laboratory assessor. In her current role, Stephanie serves as the Quality Systems Officer (QSO) and a NELAP accredited laboratory assessor for the Environmental Laboratory Accreditation Program in the State of Minnesota (MNELAP). The accreditation program is administered by the Minnesota Department of Health.</p> <p>In her role as MN-ELAP quality systems officer, she assists with the development and maintenance of the quality system and quality documentation. With Stephanie’s assistance, the MN-ELAP program received recognition as an accreditation body by The NELAC Institute (TNI) in 2010. As a quality assurance specialist she continually reviews and implements Statute requirements, communicates with the MN-ELAP, state and federal program partners, and accredited laboratories, to ensure excellence within the environmental community.</p> <p>In addition to her assessor and quality system officer roles, Stephanie is a member of several local and national organizations. She is currently a member of the Minnesota Chromatography Forum’s Education Committee, and is responsible for selecting and coordinating training events. Stephanie is also a member of the American Society of Quality and The NELAC Institute (TNI).</p> <p>To contact Stephanie Drier please email stephanie.drier@state.mn.us or go the following website for MN-</p>
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ELAP information:

<http://www.health.state.mn.us/divs/phl/accreditation/index.html>.

Stephanie is available for questions and can be reached by phone at 651-201-5326.

Reference #1 Name	Susan Wyatt
Reference #1 Organization	Minnesota Department of Health
Reference #1 Email	susan.wyatt@state.mn.us
Reference #2 Name	John Gumpfer
Reference #2 Organization	ChemVal Consulting, Inc.
Reference #2 Email	jgumpfer@chemval.com

EPA Representative:

Katherine Adams

Summary:

- 19 years experience performing inorganic chemical analysis, including Inductively Coupled Plasma - Atomic Emission Spectroscopy (ICP-AES), Inductively Coupled Plasma - Mass Spectrometry (ICP-MS), and Cold Vapor Atomic Fluorescence Spectroscopy (CVAFS).
- Extensive experience providing direction to analytical staff in the roles of Inorganic Technical Lead for the Region 10 Laboratory, the Environmental Services Assistance Team (ESAT) Work Assignment Manager, and the ESAT Inorganic Lead Chemist.
- Drinking Water Certification Officer (DWCO) under SDWA since 2006. Experienced in auditing laboratories against SDWA standards. Has served as an instructor for the inorganic portion of the DWCO training course in Cincinnati, OH.
- Experienced with implementing quality systems such as the NELAP standard into laboratory practice.

Work History:

Inorganic Chemist, EPA Region 10, 1997 - Present

Inorganic Chemist (ESAT), Lockheed Martin, 1996-1997, and ICF Kaiser Engineers, 1992-1996

Filled roles of increasing responsibility, including the Lead Inorganic Chemist for the ESAT team. Performed numerous and complex analyses in support of Regional superfund projects. Reviewed data prior to submission to the EPA client to ensure that necessary quality objectives had been met.

Laboratory Technician, **Cornell University** (at the USDA Plant, Soil, and Nutrition Laboratory), 1991-1992

Performed sample preparation and analysis of multiple sample types, including soil, water, and tissue, using ICP-AES and ICP-MS.

Select Training:

Training course for ICP-AES, Thermo Elemental, 2002

Principles of Radiochemistry Training Course, RSCS, 2006

Metals Speciation Analysis Training Course, NEMC, 2006

A Basic Course in the Fundamentals of Analytical Radiochemistry, EPA NARAL, 2007

Sampling for Defensible Environmental Decisions, Envirostat, 2008

Select Awards:

Bronze Medal: In recognition of work done in the survey of chemical contaminants in fish tissue from the Columbia River Basin, 2002

Bronze Medal: For developing and refining a method for speciating arsenic in seafood.

Bronze Medal: For achieving NELAC accreditation for the EPA Region 10 laboratory, 2005

Seattle Federal Executive Board Public Service Recognition Award, for implementing Multi-increment sampling at the Region 10 Laboratory, 2010

Select Publications and Presentations:

“A Procedure for Extracting and Analyzing Arsenic Species in Seafood”, Stephanie Le, Isa Chamberlain, and Katie Adams, presented at NEMC, 2006

Education:

BA, Chemistry, Oberlin College, May 1989: Highest Honors and Phi Beta Kappa

MS, Chemistry, Yale University, December 1990