The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on January 10, 2011 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), the committee reviewed and updated the action items (attached). The minutes from the December 2010 meeting were reviewed and accepted for posting.

The committee reviewed Standard Interpretation Requests (SIRs) 27 and 92. These were approved for forwarding to the LASC.

The committee charter was reviewed (Appendix E) and accepted with a few minor corrections. The Charter will be forwarded to the Consensus Standards Development Executive Committee.

The committee reviewed the TNI Quality Manual and made these comments which will be forwarded to Jerry Parr for consideration by the writers:

1. The program descriptions in II of the manual need to be revised to that all are presented in a consistent format.

2. The committee was not sure how “diversity” affects the quality of the system, and questioned whether or not discussions concerning this topic should be included in this document.

3. Page 13 Line 8: The committee felt that all corrective actions (regardless of why they were initiated) need to be included. Examples are complaints, preventive measures, and management review. This should also be included in the table on page 16.

The committee began discussions on the new Standard Interpretation Requests (SIR) 148 and 151 (appendix D).

SIR 148 – The committee agreed to respond with the language from the first and last paragraph of the proposed language.

SIR 151 – The committee agreed on the language as proposed.

Both will be forward to LASC for processing.

Final plans for the upcoming Savannah Forum were discussed. Since the discussions on comments require at 2/3s vote to determine if the comment is persuasive or non persuasive, Silky will arrange for a teleconference line during the meeting. She urged all that will not be attending the Savannah Forum to join by conference all.

The next meeting is scheduled for Savannah, February 1, 2011. The meeting adjourned at 14:14 EST.

Appendix A

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

January 10, 2011 1:00 pm EST
1 Hour, 55 Minutes
Conference Call

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

Your Participant Access Code is: 816895

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 *January 10, 2011*)

Old Business:		
Roll Call	All	5 Minutes
Action Items (Appendix B)	All	10 Minutes
Minutes from December (Separate Email))	All	5 minutes
Final review of SIRs 27 and 92 (appendix D)	All	10 minutes
Committee Charter (Appendix E)	All	10 minutes
TNI Quality Manual (sent 12-10-2010)	All	45 minutes
New Business:		
Review of SIR 148 and 151	All	30 minutes
Voting Comments on TNI Standard Revisions	all	

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
25	11-8-10	Silky to forward completed SIRs to Jane for proofing	12-13-10	12-10-10
26	11-8-10	Silky to begin reorganizing checklist		Ongoing
27	12-13-10	Silky to check into terms of current membership.	1-10-11	1-6-11
28	12-13-10	Forward completed sections of Quality Manual Template review to Ilona	ASAP	12-16-10
29	12-13-10	Provide comments on the TNI Quality Manual	1-6-2011	Ongoing

Appendix C - Participants

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Appendix D - Request for Interpretations

Final Review

STANDARDS INTERPRETATION REQUEST (27)	
Standard	2003 NELAC Standard
Section (eg. C.4.1.7.4)	D.3.1.a.5
Describe the problem:	How are other AB's interpreting this standard: "5) A sterility blank shall be performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with non-selective growth media." Are you requiring a sterility check with non-selective growth media for any dilution water (i.e. Deionized, distilled, etc.) or just those dilution waters whose preparation is described in microbiological procedures, like phosphate buffer water or peptone water?
Comments	
Response	If sterility is required for use (whether in-house or purchased), then sterility must be checked prior to use. If the water is being used to prepare media or buffered water, then a sterility check is not needed until after the reagent has been prepared. A sterility check must be performed on any dilution water.

STANDARDS INTERPRETATION REQUEST (92)	
Section (eg. C.4.1.7.4)	D.1.1.2.1.c
Describe the problem:	With regards to the requirement of spiking all targeted components over a 2-year period, is this an overall requirement per ANALYTE or per METHOD? As an example, we analyze pesticides by EPA 525.2 and EPA 8270C. Can we spike all target analytes for one method and cover the other? Or must we spike all for both methods?
FINAL RESPONSE:	(Quality System Expert Committee/NELAP Board, 2-x-10) The standard for multi-analytes tests requires that that all targeted components be included in a spike mixture for evaluation during a 2-year period and includes any reported analyte (whether detected or not).The committee noted that the preparation for 525.2 and 8720C are different, and spike

	results could differ. Therefore, each method requires a separate spiking schedule. Methods 624 and 8270, which use the same preparation procedure, could use the same spiking study.

NEW

#148

Standard	2009: V1M4 1.5.4
Section (eg. C.4.1.7.4)	5.D.1.5.b
Describe the problem:	Since PTs are supposed to be treated like "real environmental samples",[1] 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 [3]" and therefore 2nd column confirmation is not required?
Comments	**Relevant Standard Citations** **[3]EPA "600 series methods"**: "When this method is used to analyze unfamiliar samples for any or all of the compounds above, compound identifications should be supported by at least one additional qualitative technique." **[3]Standard Methods:** "When analyzing unfamiliar samples for any or all of these compounds, support the identifications by at least one additional qualitative technique. **V1M1 5.1.1** The laboratory shall analyze PT samples in the same manner as used for routine environmental samples using the same staff, sample tracking, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures and acceptance criteria. **[1]V1M2 3.1: "Proficiency Test Sample (PT):** A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria." **V1M4 1.5.4** Evaluation of Selectivity The laboratory shall evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors. **V1M4 1.7.3.6 Selectivity** The laboratory shall document selectivity by following the checks established within the method.

	NELAC D.1.5 Selectivity a) The laboratory shall evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors. [3]b) A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. All confirmation shall be documented.
Response	The question provides references from the TNI and NELAC Standards. The response for both standards are discussed below: The TNI standard requires that confirmations be performed according to the method. Standard Methods and EPA methods require confirmation on "unfamiliar samples." A PT sample (unknown composition) is a sample that is "unfamiliar" to the laboratory and therefore requires confirmation per method requirements

#151

Standard	2003 NELAC Standard
Section (eg. C.4.1.7.4)	NELAC 2003, Section C.3.2.c
Describe the problem:	Is it acceptable to demonstrate the accuracy and precision at the Limit of Quantitation (LOQ) using a concentration that is less than the LOQ, including down to ½ the LOQ?
Comments	NELAC C.3.2.c) "The validity of the LOQ shall be confirmed by successful analysis of a QC sample containing the analytes of concern in each quality system matrix 1-2 times the claimed LOQ."
Response	The standard requires concentrations that are 1-2 times the claimed LOQ. A concentration below the LOQ may not have the same accuracy and precision and therefore could not be used to verify the LOQ.

Appendix E

Committee Charter

Standards Development

The committee will develop a standard based on public input, as well as the expertise of the committee and subcommittees. This standard should be universally accepted, not interfere with emerging technologies and ensure that the Laboratory Quality System will produce data of known and documented quality. The standard will be based on a module concept which includes a management plan to be used by all disciplines in conjunction with one or more technical modules

The management plan will have ISO 17025(2005) references, comply with applicable requirements and establish requirements that apply to environmental testing laboratories

The technical modules will be based on the NELAC 2003 Chapter 5 Appendix D disciplines (ie, Chemistry, Microbiology, Asbestos, Toxicology, and Radiochemistry).

ISO language will be referenced and relevant requirements for testing laboratories will be included. The modules will be renumbered.

The document developed is a functioning standard that is adopted and required by Accrediting Bodies.

Based on the SIRs (see below), new technology or requests, the committee will periodically update the standard to incorporate revisions or add new technical modules.

Technical Assistance

The committee will provide technical assistance on issues related to the adopted standard or tools that will be used to facilitate implementation of the standard. These activities will include responses to Standard Interpretation Requests (SIRs) and development of documents such as a Quality Manual Template and Assessor Checklists.