The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on March 14, 2011 via teleconference. The agenda is attached as Appendix A, the action items are listed in Appendix B, the attendees are listed in Appendix C and the Standard Interpretations Requests (SIRs) are found in Appendix D and the QS Decision Rules are listed in Appendix E. An excel spreadsheet summarizing the decisions made in the Savannah meeting and the minutes of the January and February meetings were sent by separate email.

After the roll was taken, the minutes of the January and February meetings were reviewed and approved for forwarding to the TNI website. Silky briefed the group on the current status of the standard. Because 2/3rds of the committee failed to vote during the open electronic voting, the standard was not passed. The standard is now a working draft standard. Silky stated that she would like to have a working draft posted in time to be discussed at the summer meeting in Seattle, with subsequent publishing and voting on a voting draft standard prior to the Sarasota Meeting next summer. A question was asked about the incorporation of the revisions into the 2009 TNI standard. Silky replied that when the standard was finalized, it would not become effective until two years after its status as a standard. The earliest possible date that the changes could be effective was 2014.

Before continuing review of the comments, the Committee reviewed the SIRs (Appendix D). All were approved during the meeting for forwarding back to the LASC.

Silky introduced a modification to the QS decision rules, which were inconsistent with the voting rules for standards. The previous rules stated that 2/3rds of the members must be present, and a majority must vote favorably. The proposed change is consistent the TNI voting rules, which require at least 2/3rds of the members to vote favorably. No comments were made and the revised rules will be forwarded to the TNI website.

The expert committee began addressing the comments received on the voting draft standard. The committee will determine whether the comments are persuasive or not.

V1M5 Comment 7: This comment voted non persuasive based on the fact that all methods require validation before use. Validation for reference methods requires less information.

V1M5 Comment 10: Vote non persuasive. The added language emphasizes the requirements in Standard Methods for Microbiology, the Laboratory Certification Manual and the newer EPA Methods. The requirement proposes that the procedure be performed once per lot.

V1M5 Comment 11 and 12: From the comments, it appears that the commenters are “over-thinking” the requirement and may be confusing the intent of the method blank vs. a sterility blank. Further, it is not possible to identify all possible materials or supplies that are required to be sterile. The committee voted the comments non-persuasive, but will add language to help clarify the materials and supplies to which this applies.

V1M5 Comment 13: The change from source to client was a deliberate action. While a client may submit samples from multiple sources within a system, the check is to determine whether or not the client continues to properly preserve the samples. Voted non-persuasive.

V1M5 Comment 16: Referring to the previous comment, source and client are not equal. If an existing client provides samples from a new water supply, these samples must be checked. Voted non-persuasive.

V1M6 Comment 1: This comment was made on a section that was not to be considered in the vote. Comment disregarded.

V1M6 Comment 2: Voted non persuasive per previous discussions on this topic.

V1M6 Comment 3: Noted persuasive per previous discussions on this topic.

V1M6 Comment 4a: Voted non persuasive based on previous discussions.

V1M6 Comment 4b: Voted non persuasive based on previous discussions.

V1M6 Comment 4c: Recommended language provides clarity to the intent. Voted persuasive.

Note: V1M2 Section 5.4.5.4 Will be clarified to state that "all methods (whether reference or non-reference) must be validated."

V1M6 Comment 5a: Voted non persuasive based on previous discussions.

V1M6 Comment 5b: Voted non persuasive based on previous discussions.

V1M6 Comment 5c: Voted persuasive per V1M6 comment 4c.

V1M6 Comment 5d: There is no 1.5.d; comment disregarded.

V1M6 Comment 6: The demonstrations of capability can meet the requirement of a validation for a reference method. Voted non-persuasive.

V1M6 Comment 7-8 The committee is not able to address the comments without additional information from radiochemists. Fred McLean will take the lead in approaching other radiochemists.

V1M7 Comment 1: Voted non persuasive based on previous discussions.

V1M7 Comment 2: Voted non persuasive based on previous discussions.

V1M7 Comment 3: Voted persuasive based on previous discussions.

V1M7 Comment 5: Voted non persuasive based on previous discussions.

V1M7 Comment 6: Voted non persuasive based on previous discussions.

V1M7 Comment 8: This comment was made on a section that was not to be considered in the vote. Comment disregarded.

TNI Standard (separate comment): The committee agreed that this comment does not address any of the proposed revisions, but requested a new standard. The comment will be tabled until the committee opens the standard for new requirements.

All comments (except "Positive with Comment") were addressed. Silky will review the spreadsheet to ensure that all negative comments were addressed. She will also begin to make modifications to the proposed language based on the discussions in Savannah and the March Teleconference. A revised working draft standard should be available for discussion by the April teleconference.

The meeting ended at 2:50 PM EDT. The next meeting will be via teleconference on April 11, 2011 from 1:00 to 3:00 PM EDT.

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

March 14, 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 *March 14, 2011*)

Old Business:		
Roll Call	All	5 minutes
Minutes from January and February Meetings (Separate Email))	All	5 minutes
Status of Standard	Silky	5 minutes
Continuation of Comment Review (after new business) Excel Spread Sheet (separate Email)		
New Business:		
Review of SIR 152, 154, 158, 160,and 161 (see Appendix D)	All	30 minutes
QS Decision Rules (Appendix D)	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	
30	3-14-11	Fred to consult with Radiochemistry experts concerning comments made on V1M7.	4-11-11	
31	3-14-11	Silky to review the spread sheet to ensure that all negative comments were discussed.	ASAP	
32	3-14-11	Silky will prepare a new draft standard for review	4-11-11	
33	3-14-11	Silky will forward the January and February minutes to the TNI website, and the finalized SIRS to LASC.	ASAP	

Appendix C - Participants

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Appendix D - Request for Interpretations

#152

Standard	2003 NELAC Standard
Volume and Module	V1M2 and V2M1
Section (e.g. C.4.1.7.4)	4.3.3 and 6.2.1.d
Describe the problem:	A laboratory seeking primary accreditation from our program asserts that it is not required to maintain records for more than five years (as required by our state regulations) if those records are for its clients under the jurisdiction of the secondary accreditation body which has incorporated the NELAC standard requirement of five years in its regulations. I am requesting an interpretation to resolve the questions, 1) if the regulation or authority referenced in 4.3.3 has a requirement more stringent than the secondary accreditation body referenced in 6.2.1.d, which requirement should the laboratory follow and the accreditation body(ies) enforce? and 2) is this enforcement state or jurisdiction dependent on where the laboratory or client is located?
Comments	**VIM2 4.13.3 Additional Requirements** b) The laboratory shall retain all records for a minimum of five (5) years from generation of the last entry in the records. **NELAC Chapter 5.4.12.2.4 Records Management and Storage** b) All records, including those specified in 5.4.12.2.5 shall be retained for a minimum of five years from generation of the last entry in the records. All information necessary for the historical reconstruction of data must be maintained by the laboratory. Records which are stored only on electronic media must be supported by the hardware and software necessary for their retrieval. **NELAC 4.3.3 Record Keeping and Retention** All laboratory records associated with accreditation parameters shall meet the requirements of Chapter 5, Section 5.12 and shall be maintained for a minimum of five years unless otherwise designated for a longer period in another regulation or authority. In the case of data used in litigation, the laboratory is required to store such records for a longer

	period upon written notification from the accrediting authority. Note: Cannot find 6.2.1.d
Response	If the primary accrediting authority's regulatory requirement for records retention greater than five years is applied only to laboratories that are providing data to the state, the requirement must be met. Laboratories with no clients within the state must meet the NELAC.TNI requirement. However, if the longer retention time is a condition of accreditation, the laboratory must meet the requirement if the laboratory is to retain primary accreditation with the state. **Note to Accreditation Council**: Can a state require a more stringent requirement as a condition of accreditation?

#154

Standard	2009 TNI Standard
Volume and Module	EL-V1M2-2011
Section (eg. C.4.1.7.4)	4.2.8.5.r
Describe the problem:	If a lab's QAM defined "signature" on technical records, reports and chain of custodies as the hand written signature or electronic equivalent, would this meet the signature requirement for each of these documents? As we upgrade our LIMS and QC software, we have the ability to electronically sign off on chains and lab documents but want to know if this would be acceptable. Thank you.
Comments	4.2.8.4 r) The quality manual shall contain or reference: policy addressing the use of unique electronic signatures, where applicable 4.13.3 Additional Requirements f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory. viii) analyst's or operator's initials/signature or electronic identification;

	See V1:M2 4.2.8.4(r)
Response	Electronic signatures are acceptable (see references above) provided that the signature is unique to the individual. Some states may have regulatory requirements pertaining to the use of electronic signatures. The laboratory should ensure that state requirements are met.

#158

Standard	2009 TNI Standard
Volume and Module	EL-V1M2-2009
Section (eg. C.4.1.7.4)	4.1.7.2 and 5.2.6.1 (a)
Describe the problem:	At present, our laboratory has a NELAC Lab (Lead) Technical Director who fulfils the NELAC requirements as per referenced sections above. We also have three other Technical Directors whose responsibilities are either for environmental analysis of representative organic analytes or inorganic analytes for which our lab maintains NELAC accreditation. Our laboratory is in process of management change where current NELAC Lab Technical Director will be reassigned to other duties and no longer will have responsibility over the NELAC accredited lab. The annual renewals of the NELAC accreditations with our primary and secondary Accrediting Bodies require a "Certificate of Compliance" to be signed by a Lab Key Staff, often listing a Lead Technical Director as the one who needs to sign this document. The Lead Technical Director is also listed on each NELAC certification we maintain. Although the NELAC standard allows for more than one Technical Director, do we must have a Lead Technical Manager/Director who fulfils above requirements for both inorganic and organic environmental analysis. At this time only our Lead Technical Director fulfils the requirements.
Comments	
Response	There is no requirement for a "lead technical director". The standard requires that the individual (or individuals) who are identified as technical directors meet the applicable credentials for the areas over which he/she has oversight.

#160

Standard	2003 NELAC Standard
Volume and Module	n/a

Section (eg. C.4.1.7.4)	D.3-4
Describe the problem:	If when doing monthly analyst verification using positive controls, one of the analysts is not available to submit his/her results, is the acceptance criteria used to determine the validity of data affected?
Comments	Correct reference is D.3.2
Response	This question must be clarified before the committee can respond: why is the analyst not available to submit results.

#161

Standard	2009 TNI Standard
Volume and Module	v1m4
Section (eg. C.4.1.7.4)	1.7.4.3
Describe the problem:	Under Matrix Duplicates it states that the precision may be expressed as RPD or another statistical treatment. We do not do matrix duplicates, we perform sample duplicates only and use percent recovery. Are we required to run matrix duplicates, or are we okay running sample duplicates only? If we are allowed to run sample duplicates only, do we have to express precision as RPD, or can we stick to percent recovery? If we need to switch to matrix duplicates do we need to use RPD or can we use percent recovery?
Comments	
Response	Any laboratory-duplicated sample (however named) must be evaluated for precision. A percent recovery evaluates accuracy, but not precision. Precision must be evaluated by a statistical technique such as RPD, absolute difference or Percent relative standard deviation (% RSD).

Appendix E

Decision-Making Rules for TNI Quality Systems Expert Committee Operations
Type of Decision Decision-Making Rule

Meeting dates, times	Person-in-charge decides after discussion
Meeting adjournment	Person-in-charge decides after all business is conducted or allotted time expires
Meeting minutes approval	Request for approval by email to all committee members – changes approved if needed from email. No Vote
Meeting cancellations	Person-in-charge decides
Addition of TNIQS Committee members	Two-thirds of committee must vote and simple majority vote
Removal of Expert Committee Members	Person-in-charge decides after discussion
Approval of Standards – any stage (including persuasive/non-persuasive votes)	At least two-thirds of committee must vote in the affirmative
Creation of a new subcommittee	Simple vote of attendees
Election of Committee Chair	Two-thirds of committee must vote and simple majority vote
Standard Interpretation Requests	Simple majority vote of attendees