The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on October 11, 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.

Silky reviewed and updated the action items (attached) and updated the committee on the status of vacancies for an accrediting authority and EPA. Candidates for both have been identified and are going through the process. The minutes from the September 2010 meeting were reviewed and accepted for posting.

The committee was asked for any additional comments on the proposed changes. None were provided. Silky then asked for an individual by individual vote on whether to move the standard to a Voting Draft Standard. All committee members in attendance were in favor of moving the standard forward.

The committee began discussions on the Standard Interpretation Requests (SIR) 79, 129, 130, 132, 133, 135, 137 and 138.

1. SIR 79, 129, 130, 133, 135 and 137 – The committee agreed that the proposed language for each was the correct interpretation. The SIRs will be forwarded to Jane for review.
2. SIR 132 – the requirement for testing pH is a Standard Methods requirement, and the committee cannot make interpretations on a method requirement. The interpretation needs some wordsmithing before posting. Silky will edit and circulate for approval
3. SIR 138 – The committee discussed the various uses of “source” in the citation. The confusion concerning “source” will be explained in the proposed clarifications to this section. This language will be included in the response. In addition, the committee agreed that the intent of the exception to monitoring for residual chlorine in every sample was predicated on the fact that the laboratory had control of the containers they provide including the requisite tests for chlorine removal. The response will be redrafted and submitted for final discussions at the November meeting.

Illona Taunton joined the meeting to discuss the Quality Manual Template. She explained the difference between the “yellow boxes” and the “gray boxes”. She further stressed that the document was confidential and should not be distributed until the product has been finalized. Silky noted that some sections were longer than others, and will assign sections so that each committee has approximately the same number of pages to review. The committee is targeting mid-December for the complete review.

The next meeting is scheduled for Monday, November 8. The meeting adjourned at 14:45 EDT.

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

October 11, 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 *October 11, 2010*)

Old Business:		
Roll Call	All	5 Minutes
Action Items (attached)	All	10 Minutes
Minutes from September	All	5 minutes
Member Status	Silky	2 Minutes
New Business:		
Discussion and Voting on the Voting Draft Standard Sent in separate email	All **(Voting is scheduled for 1:30 edt)**	30 minutes
Review of Standards Interpretation Request 129	All	10 minutes
Review of SIR 130,132,133,135	All	10 minutes
Discussion of SIR 137 and 138	All	10 minutes
Discussion of SIR 79	All	20 minutes
Discussions of examples for template	All	30 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 standard	10-05-10	10-05-10
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		
23	10-11-10	Silky to forward the completed SIRs to Jane for proofing		
24	10-11-10	Silky to make review assignments on the quality manual template		

Appendix C - Participants

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	a	**Ms Laurie Carhart** NYS DOH ELAP PO Box 509, ESP Albany, NY 12201 P: (518) 486-2538 E: ljc09@health.state.ny.us	p
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Associate Members: Larry Penfold

Appendix D - Request for Interpretations

#129

Section (eg. C.4.1.7.4)	5.5.4.2.1.a, 5.5.4.2.1.b, 6.7.b.2
Describe the problem:	There are many obsolete methods on the TNI method codes list. For example, EPA Method 200.7, a final rule method, was last revised in 1994, yet TNI has listed the previous three versions. I am requesting an interpretation to resolve the problem: 1. NELAC 5.5.4.2.1.a states that "the laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so." NELAC 5.5.4.2.1.b states that "when the use of specific methods for a sample analysis are mandated or requested, only those methods shall be used." Which of these standards supersedes the other?, and 2. If EPA prohibits the use of older versions of this or other Final Rule methods, then should the accreditation bodies be listing these methods in the fields of accreditation document (NELAC 6.7.b.2) and should these methods be removed to a TNI archived method list? Thank you for your assistance.
Comments	Comment from Aaren: I think QS can answer the question about "most recent edition of the standard". As for the method codes and what the ABs list on their scopes, that is a regulatory issue and I think it is up to the AB. Lastly, the method code list must include old versions for record-keeping.
Response	NELAC 5.5.4.2.1.a states that "the laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so." NELAC 5.5.4.2.1.b states that "when the use of specific methods for a sample analysis are mandated or requested, only those methods shall be used." 5.5.4.2.1.a is modified by the statement "unless it is not appropriate or possible to do so." Therefore, if a method is requested or mandated (NELAC 5.5.4.2.1.b), it is not appropriate to use the most recent edition of the method and the laboratory must use the mandated or requested method. 1.b supersedes (or modifies) 1.a.

#130

Section (eg. C.4.1.7.4)	5.5.2.6.c.3, 5.5.4.2.2.d, Chapter 5 Appendix C.1, Chapter 5 Appendix C.2
Describe the problem:	A laboratory accredited by our program asserts that the form in NELAC Chapter 5 Appendix C.2 is needed only for documentation initial demonstrations of capability and not continuing demonstrations of capability. It cites the language from NELAC 5.5.4.2.2.d "in all cases, the appropriate forms such as the Certification Statement" and from NELAC Chapter 5 Appendix C.1 "It is the responsibility of the laboratory to document that other approaches to DOC are adequate." Other language in the same appendix prescribes the use of the form, for example C.1 "All demonstrations shall bee documented through the use of the form in this appendix" and C.2 "The following certification statement shall be used to document the completion of each demonstration of capability." I am requesting an interpretation to resolve the question, is the Chapter 5 Appendix C Certification Statement required for documentation of continuing demonstrations of capablity? Thank you for your assistance.
Comments	
Response	C.2 of Appendix C states that “The following certification statement shall be used to document the completion of each demonstration of capability” This statement refers only to the demonstration of capability, not continuing demonstrations of capability. The laboratory may choose to use the form to document continuing demonstrations, but it is not required.

#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	The 2003 NELAC standard outlines the need to monitor the

	water quality for residual chlorine, specific conductance and heterotrophic plate count monthly. The requirement for monitoring pH is a method requirement that the committee cannot address. 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. Based on the requirements in the TNI standard, the committee recommends the following: If the water is used for only blanks, then only sterility needs to be checked at a frequency of once per lot. 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.

#133

Section (eg. C.4.1.7.4)	Appendix D.3.8(b)(6)(i) to NELAC Chapter 5
Describe the problem:	The laboratory has free standing incubators that are not used every day for testing and turns them turned off and on with use. There would be times when the laboratory does not have temperatures documented twice per day with at least 4 hours apart for days of use. The incubators take about 30 minutes to 1 hour to reach the correct temperature. If the laboratory records the temperature when the samples are put in the incubator and when the samples are taken out, would this meet the standard? The laboratory would continue to record the normal morning and afternoon temperatures along with the times the samples were place in and taken out of the incubator.
Comments	
Response	The requirement to monitor the temperature while in use is two times daily at least 4 hours apart. The requirement has been met. The procedure as described is acceptable.

#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.

New SIRs

#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	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. 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. A verification performed after use 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.

#138

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.5.b
Describe the problem:	Regarding microbiological samples and especially the potentially reduced frequency of checks for absence of chlorine residual for potable water sources (including source water): 1. What are the definitions of "source" and "source water" in this context? 2. What constitutes a unique "source"? Some considerations are: a. A water body (stream or lake) as a source vs. discrete segments (i.e., random or recurring sampling locations) of the water body as unique sources of source water. b. Individual wells producing source water. c. A common aquifer with multiple wells producing source water from that aquifer.

	d. A water distribution system as a source vs. individual sampling locations specified in the sampling plan for the distribution system as unique sources. It seems like the intent of this section was to perform checks to verify removal of chlorine residual from samples from all new potable water sources and random checks for routine samples submitted by long-term customers whose samples satisfy all four conditions in 1.7.5.b.i to iv. 3. What constitutes sufficient documentation or objective evidence that "the laboratory can 'show' that the received sample container are from their laboratory?" For example, IDEXX containers provided by various laboratories to customers are indistinguishable, unless a laboratory marks the containers to show they came from a specific laboratory in a large nationwide chain of laboratories.
Comments	
Response	1. What are the definitions of "source" and "source water" in this context? “Source water” is defined by EPA as “Untreated water from streams, rivers, lakes, or underground aquifers, which is used to supply private and public drinking water supplies” A “source” as defined by Merriam Webster as “a point of origin or procurement”. “Source” when used as a noun refers to origin or point of procurement. 1. What constitutes a unique "source"? Some considerations are: a. A water body (stream or lake) as a source vs. discrete segments (i.e., random or recurring sampling locations) of the water body as unique sources of source water. Check influent point if for drinking water b. Individual wells producing source water. c. A common aquifer with multiple wells producing source water from that aquifer. d. A water distribution system as a source vs. individual sampling locations specified in the sampling plan for the distribution system as unique sources. It seems like the intent of this section was to perform checks to verify removal of chlorine residual from samples from all new potable water sources and random checks for routine samples submitted by long-term customers whose samples satisfy all four

	conditions in 1.7.5.b.i to iv. Correct – however the check is made on **sample containers** received by the laboratory, regardless of how they were collected. 3. What constitutes sufficient documentation or objective evidence that "the laboratory can 'show' that the received sample container are from their laboratory?" For example, IDEXX containers provided by various laboratories to customers are indistinguishable, unless a laboratory marks the containers to show they came from a specific laboratory in a large nationwide chain of laboratories. The intent of this requirement is to ensure that the laboratory is supplying containers with sufficient dechlorination reagent. For the example described above, each laboratory is responsible for verifying their individual supply of containers. Therefore, it is logical to presume that the laboratory has a procedure to ensure that they can identify containers that were provided by their laboratory.

#79

Standard	2003 Standard
Section (eg. C.4.1.7.4)	5.5.10.
Describe the problem:	X's question for TNI concerns the documentation of the laboratory's scope of accreditation in the test report. In this situation, our laboratory is licensed for a small number of tests in the State of Minnesota, which is adopting the NELAC Standard. Our laboratory is licensed for a full scope of parameters in the State of Arizona, a non-NELAC state. In Section 5.5.10 of the 2003 NELAC Standard, is there a requirement for qualifying data that is not included in the laboratory's scope of accreditation? If there is a requirement (either directly or implied), how should the laboratory indicate the lack of NELAC licensure on the Arizona-only parameters in order to comply with the NELAC Standard? Is it sufficient to include a disclaimer on the cover page of the reports for Arizona-only work that indicates the data may only be used for compliance purposes in the State of Arizona and not in NELAC states?
Comments	5.5.10.1: "The results of each test . . . carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively . . ." 5.5.10.2 m) requires: "Laboratories accredited to be in compliance with these standards shall certify that the test results meet all requirements of NELAC or provide reasons

	and/or justification if they do not.”
Response	Based on the standards quoted above, if the laboratory is issuing a NELAC-compliant report and the report has results that are not accredited under NELAC, you must identify those methods that do not meet the NELAC requirements (i.e., methods certified by another accrediting body). The committee cannot comment on reports that are issued for Arizona compliance purposes.