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

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on September 13, 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 welcomed Kristina as the newest member of the committee.

Silky reviewed and updated the action items (attached). Items 3 and 4 are closed pending receipt of an application. Item 9 was cancelled.

The committee is still one member short. Tamara is no longer with the State of Utah, leaving an accrediting authority vacancy. The committee agreed that in order to maintain geographic balance among the accrediting authorities, that one should be selected from the mid-United States. Minnesota, as the newest accrediting authority may bring different perspectives to the committee. Silky will contact Susan Wyatt about nominating someone from her state.

The committee reviewed the changes that were made to the standard after the August meeting in Washington, DC. These changes were:

1. Addition of the following definitions: Data Integrity, Physical Parameter (in module 4), Source Water (in module 5)
2. Clarifying the LOD exceptions in Module 4
3. Clarifying how LOQ may be determined and defining exceptions in Module 4
4. Clarifying the diluents for preparing solutions for a demonstration of capability in Module 5.

Several definitions for data integrity were proposed. Dorothy Love contributed one used by her laboratory. After some discussion, Silky stated that she would incorporate all definitions, and the committee would vote on the one to be used in the draft standard. Response must be received before the end of the month so that a Voting Draft Standard can be prepared for consideration at the October meeting. She stressed that all committee members must attend the October meeting so that a vote on the voting draft standard could be completed.

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

1. SIR 129 – The Committee agreed that the proposed language was the correct interpretation. Silky will forward the interpretation to Jane as final.
2. SIR 130 – The committee agreed that only demonstrations of capability (i.e. initial demonstration of capability) required the use of the form in Appendix C to document satisfactory completion.

The laboratory is free to the form to document continuing demonstrations, but it is not required. Silky will draft a response that reflects the committee's discussions.

3. SIR 132 and 133 – Robin and Gill will propose responses for committee consideration in October.
4. SIR 135 – The committee agreed that reference cultures are reference materials. Therefore the requirements for reference materials must be followed. Silky will draft a response for consideration in October.

The committee briefly discussed the Quality Manual template. Silky has completed the draft of the section on method validation, etc. She asked that the committee begin reviewing the language to ensure that only standard requirements are discussed. She also asked for committee members to begin collecting examples of certain procedures to be included with the template. Currently the following are assigned:

Asbestos – Laurie
Microbiology – Gil and Robin
Radiochemistry – Bill Ray (associate member)
Toxicity – Robert
Chemistry – Dorothy

Other examples will be assigned at future meetings.

The next meeting is scheduled for October 11, which is a holiday for some of the state accrediting authorities. Silky will send a detailed agenda, with an exact time for voting on the voting draft standard so that states could participate for the short period of time needed to complete the vote.

The meeting adjourned at 14:21 EDT.

Appendix A

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

September 13, 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 *July 12. 2010*)

Old Business:		
Roll Call	All	5 Minutes
Action Items (attached)	All	10 Minutes
Member Status	Silky	2 Minutes
Revisions to ISO 17025	All	5 minutes
Status of Revisions	Silky	2 minutes
Review of Revisions to Standard	All	1 hour
New Business:		
Need for Accrediting Authority Member	All	10 minutes
Review of Standards Interpretation Request 129	All	10 minutes
Review of SIR 130,132,133,135	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	
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

Appendix C - Participants

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Ms Robin Cook City of Daytona Beach 3651 LPGA Blvd Daytona Beach FL 32124T P: (386) 671-8856 E: cookr@codb.us	p	Ms Tamara DeMorest E: tamara.demorest@gmail.com	a
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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	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: dmlove@lancasterlabs.com	p
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Associate Members:
Gary Dechant
Patsy Root
Bill Ray

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	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." 5.5.4.2.1.a is modified by the statement "unless it is not appropriate or possible to do so." Therefore, is a method is requested or mandated (NELAC 5.5.4.2.1.b), it is not appropriate to use the most recent editions of the method. Therefore, 1.b supersedes 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	

#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	

#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	

#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	