The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on June 14, 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.

Silky introduced the newest member of the committee, Eugene Klesta, who briefly outlined his experience and expertise. She then announced that the request for interpretations 112, 115, and 116 were complete and forwarded back to Illona. She asked again if anyone had any suggested revisions to ISO 17025 and requested that any suggestions be forwarded to Carl Kircher and her as soon as possible.

The Action Items were reviewed. All were completed with the exception of items 3, 4 and item 9. Items 3 and 4 are ongoing, as the committee has not yet identified an EPA representative. Fred was not present to report on any suggested changes to 17025.

The committee began work on the request for interpretation 119, 120, 122, and 123.

Item 119 is identical to the previous item 112, and the identical response was added. The committee agreed that this was appropriate.

Item 120 is an interpretation that must be asked to the state regulatory agency. The response as worded, was accepted by the committee.

Item 122 resulted in a lively discussion as to what an appropriate matrix would be. The committee felt that a Demonstration of Capability (DOC) should be based on the preparation/cleanup/determinative method for the type of biological tissue. As an example, if the same combination was used for both fish and shellfish, only one DOC would be required.

The batch QC, however must use a CRM/QC sample that is similar to the tissue matrix. In the example above, the batch QC for fish would be different from the batch QC for shellfish.

Eugene will draft a response to be circulated to the committee members.

Item 123 refers to items in the PT chapters. The question was forwarded back to Illona for appropriate routing.

Item 125 resulted in some discussion. However, the committee unanimously agreed that the laboratory must obtain Certificates of Analysis when available for all chemicals, standards, reagents, media and reference materials. The committee emphasized that the laboratory may need to request such information from the manufacturer, and agreed that copies (paper or electronic) must be retained by the laboratory.

Item 126 is a question that the laboratory must have answered by the client or the regulatory authority. The committee agreed on the written response. The committee agreed that the datum must be flagged or identified in some way to indicate that the value was outside the calibration range.

Once a proposed revision to Item 122 is received, the entire set of interpretations will be routed to the committee for one final review and vote.

Revisions to the TNI Standards

Silky introduced the revisions by stating that the revisions that were being made were

1. The Tentative Interim Amendment to the Radiochemistry Technical Module
2. Changes to consolidate and clarify the intent of the standard. A list of the changes is attached as Appendix E.

The proposed additions to the definitions were reviewed. The definitions for “analyte” and “parameter” were added to clarify the use of the terms in the standard. In addition, where applicable, the term ”analyte” was substituted for similar terminology (compound of interest, parameter, etc.)

The definition of “reference method” was removed from the body of the document and placed in the definitions.

Silky reviewed the changes related to 5.4.4 Non Standard Methods, and 5.4.5 Validation of Methods. The original iso language was inserted into the Module 2 and the similar language was deleted from the technical module (3-7). Each of the technical modules were revised to reference the relevant sections of 5.4.4 and 5.4.5.

The final change was in response to a comment in 4.1.7.2 a) regarding whether or not the technical manager needed to be a full-time position, It was pointed out that item e) required that the substitute technical manager be a full-time staff member. The committee agreed that the status of technical managers (permanent or temporary) needed to be the same.

While the standard precludes a technical manager from acting in that role for multiple accredited laboratories, in some states the individual acts as technical director for multiple laboratories (one accredited and the other non-accredited). Further, because of the volume of work, some smaller laboratories may not be open full-time, and the director is hired on a part-time basis to be present when the laboratory is open. In view of the scenarios, the committee agreed to strike “full-time” from item e).

A comment was made that some of the microbiology language did not make sense to a microbiologist, and should be changed. Silky noted that as long as the changes did not change the intent of the standard, that suggested changes would be considered. Gil and Robin will review and determine what changes might be considered

The committee was asked to review all revisions and provide comments prior to the next meeting.

As the last item of business, Silky announce that the information for the meeting in DC was on the web and that registration was open. She encouraged early registration for the meeting and the hotel. Quality Systems will be meeting on Thursday afternoon. She also polled the members for attendance. Four of the five accrediting authorities indicated that they would not be able to attend. A suggestion was made that the committee arrange a teleconference for those that were not in attendance. Silky will follow up with Jerry for the arrangement.

The meeting was adjourned at 2:30 pm EDT. The next teleconference will be on July 12, 2010 starting at 1:00 pm EDT.

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

June 14, 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 *June 14. 2010*)

Old Business:

Roll Call	All	5 Minutes
Action Items (attached)	All	5 Minutes
Member Status	Silky	2 Minutes
Status of 112. 115, 116	Silky	2 Minutes
Revisions to ISO 17025	All	5 minutes

New Business:

Working Draft Standard V1, M2,3,4,5,6,7	All	40 minutes
Requests for Interpretation , 119, 120, 122, 123, 125,126 (attached)	All	40 minutes
Summer Conference	All	10 Minutes

APPENDIX B - ACTION ITEMS

TNI Quality Systems Committee Meeting

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	
12	6-14-10	All – review revisions and provide relevant comments	7-12-10	
13	6-14-10	Silky to follow-up with Jerry on arranging teleconferencing capabilities during the August meeting	7-12-10	6-15-10
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APPENDIX C - PARTICIPANTS

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Attachment D
Requests for Standards Interpretation
119, 120, 122, 123, 125,126

#119

Section (e.g. C.4.1.7.4)	TNI V1M4, Section 1.7.4.c
Describe the problem:	What was the intent of the QS Committee in requiring "results reported from analyses with surrogate recoveries outside the acceptance criteria shall include appropriate data qualifiers"? The wording suggests that the sample data be qualified as is required for toerh QC failures. Since there has never been any 1 to 1 relationship established between surrogates and targets, is it an "all or nothing qualification"? Is the lab free to develop its own policy for qualficiation of results? This provision need clarification.
Comments	
Response	The NELAC standard requires that the laboratory report any data performance issues to the client that may impact the data quality. However, there is no set protocol for handling surrogates that applies universally, and comments on how individual surrogate apply to individual analytes is beyond the scope of the NELAC standard. Therefore in the “evaluation for the effect” of a surrogate failure, the laboratory should consider compliance with client requirements, compliance with the method requirements and compliance

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Section (e.g. C.4.1.7.4)	Appendix D.1.2.1 (c)
Describe the problem:	For ICP analyses when using a "0" std and a single point std- may the determined LOQ, or Report limit, however named, be considered to be a minmum level of Calibration (ML). In short, our permit has required ML's. does a LOQ constitute an ML for ICP work?
Comments	2003 NELAC Standards
Response	The Quality Systems Expert Committee cannot respond to this question. The question must be posed to the inquirer’s regulatory authority and their interpretation of the relationship between LOQ as defined by NELAC and ML as defined by the regulatory authority.

#122

Section (e.g. C.4.1.7.4)	Appendix A - Glossary, Matrix & 2003 Standards, 5.5.4.2.2
Describe the problem:	FoA Matrix states, "these matrix definitions shall be used when accrediting a laboratory"... "Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin." And, from the 2003 standards, Section 5.5.4.2.2 "Prior to acceptance and institution of any method, satisfactory demonstration of method capability is required. (See Appendix C and 5.5.2.6.b) In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean quality system matrix sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., drinking water, solids, biological tissue and air." The statement, "such samples shall be grouped according to their orign", confuses categorization. If a lab seeks accreditation for biological tissue matrix, is a DOC required for shellfish, plant, fish tissue, etc.? (Assuming the lab will be analyzing various types of biological tissue.) Extending to batch QC, is the lab required to use a shellfish CRM for shellfish samples, a fish CRM for fish samples, etc.?
Comments	Note, while the FOA matrix and Quality System Matrix use the same definition for biological tissue, the inquirer should be aware of the difference between the two. Section 5.5.4.2.2.a of the 2003 NELAC Standard states: *Prior to acceptance and institution of any method, satisfactory demonstration of method capability is required. (See Appendix C and 5.5.2.6.b) In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean quality system matrix sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., drinking water, solids, biological tissue and air. In addition, for analytes which do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples*
Response	When all real world materials contain target analytes and/or interferences, a “representative” matrix may be used for a given test method and analyst. If the test method as defined by the combination of preparation, cleanup and determinative

	methods for a given biological tissue is different from the test method (preparation, cleanup and determinative method) for another biological tissue, then separate DOCs are expected. With regard to batch QC, it is highly improbable that CRMs exist for all biological tissues that could be analyzed. However, when available a CRM that matches the tissue type (e.g., shellfish, fish, etc.) should be used. A representative material may be used for laboratory control spikes as long as the material used follows all steps of the test method.

#123

Section (e.g. C.4.1.7.4)	D.9. , A.4.7
Describe the problem:	We are looking to develop a "Laboratory Ethics" workshop/course for individuals wanted to meet the NELAC/NELAP standard. What are the requirements for such a course?
Comments	These references are from the PT chapter
Response	No Response

#125

Section (e.g. C.4.1.7.4)	5.5.6.4
Describe the problem:	For subsection a), I would like an interpretation of the requirement to obtain the manufacturer's Certificate of Analysis for reagents. Does this mean just "ready-made" reagents (e.g. the color reagent for a test) or does this also include pure chemicals (e.g. a bottle of sodium chloride crystals)?
Comments	a) The laboratory shall retain records for all standards, reagents, reference materials and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), ...
Response	The standard requires that Certificates of Analysis be obtained for all reagents. This does not mean that the C of A is automatically supplied. In some cases, you may need to request such information from a manufacturer. This includes both "ready-made" and pure (neat) chemicals.

#126

Section (e.g. C.4.1.7.4)	5.5.5.2.2.1 h)
Describe the problem:	In the analysis of samples for pH...our buffer range is 2 through 12. Does that mean we need to flag any values outside this calibration range? Is "J" appropriate? or a flag identified as "out side calibration range"? FYI - our analyst found a reference that states that negative values for pH are possible...and she actually got a sample like that last week from mine waste.
Comments	NELAC 5.5.10.3
Response	The use of flags to report data is dependent on the client requirements and the state regulatory requirements. The committee cannot comment on appropriate use, as the use of qualifiers varies from state to state. In all cases, the value must be identified with either a flag to indicate the value as

	being outside the calibration range or a narrative describing the condition.

Appendix E

Summary of Changes

June 14, 2010

Definitions:

Analyte

Parameter

Reference Method

Proposed permanent change to the Radiochemistry Module (TIA)

Substitute “Analyte” for Parameter (where applicable) or “compound of interest”, etc.

Need to discuss adding “full-time” to laboratory technical director. (4.1.7.2)

5.4.4 Added ISO Clause 5.4.4

5.4.5 Added ISO Clause 5.4.5

5.4.5.4 Added reference to each of the technical modules for specifics.

In each of the technical modules:

1.4 – Method Selection: Points to Sections 5.4.2, 5.4.3, 5.4.4 and deletes redundant language.

1.5 – Method Validation: Points to 5.4.5 and deletes redundant language