The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on December 12, 2011 via teleconference. The agenda is presented in Appendix A and the attendees are listed in Appendix B. Materials on outstanding comments and revised documents were sent by separate email.

After roll call, the committee continued work on the comments that were received on the working draft standard.

1. Gil Dichter – Comments 1 through 3 were incorporated into the standard. After some discussion the committee agreed to drop the examples in 1.7.3.6 b). which removes the concern expressed in the comment. 1.7.5.b will remain as written.

2. Sreenivas Komanduri – The committee was unsure of how to address these comments as they appeared to be changes to the standard. Larry Penfold volunteered to provide recommendations on these comments.

Silky noted that all changes that were made after the publication of the working draft standard are highlighted in green and asked for any comments on the changes. Michelle Potter asked if the monthly chlorine check had been deleted. Silky replied that if it was, it was in error, and will check the standard.

No additional comments were forthcoming. Silky stated that she will send out a standard that incorporates any changes suggested by the committee, and will ask for a vote to move the standard to a voting draft standard. She also explained that during the voting period (once the standard has been posted on the web) it is critical that each committee member must vote on-line to accept or reject the proposed changes.

The adjourned at 1:55 pm est, with the next meeting scheduled for January 9, 2012.

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

December 12, 2011 1:00 pm EDT
1 Hour, 55 Minutes
Conference Call

Please Call Dial-in Number: 1-940-287-4000 (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 *December 12, 2011*)

Old Business:		
Roll Call	All	5 minutes
Outstanding Minutes	All	15 minutes
Continuation of V1M2-7 Review	All	60 minutes
Next Steps	All	5 minutes
New Business:		

Appendix b - Participants

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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	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	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	**Mr. Robert Martino** QC Laboratories 60 James Way, Unit 6 Southampton, PA 18966 P: (267) 699-0103 E: RMartino@qclaboratories.com	A
Ms Robin Cook City of Daytona Beach 3651 LPGA Blvd Daytona Beach FL 32124T P: (386) 671-671 8885 E: cookr@codb.us	P	**Mr. Fred S. McLean** NAVSEA 04XQ(LABS) 1661 Redbank Road Goose Creek, SC 29445-6511 P: (843) 764-7266 E: fred.mclean@navy.mil	A
Ms Tamara DeMorest Utah Department of Health 4431 South 2700 West Salt Lake City, UT 84119-8600 P: 801-965-2541 E: tdemorest@utah.gov	A	**Ms Michele Potter** NJDEP 9 Ewing Street, 2nd Floor Trenton, NJ, 08625 P: (609) 984-3870 E: Michele.Potter@dep.state.nj.us	A
Mr. Gil Dichter IDEXX Laboratories One Idexx Dr Westbrook, ME 04092 P: (207) 556-4687 E: gil-dichter@idexx.com	P	**Mr. Randall Querry** A2LA 5301 Buckeystown Pike, Suite 350 Frederick, MD 21704 P: (301) 644-3221 E: rquerry@a2la.org	A
Ms. Stephanie Drier Minnesota Department of Health P.O. Box 64899 601 Robert Street North St. Paul, MN 55164-0899 P: (651) 201-5326 E: stephanie.drier@state.mn.us	P	**Ms. Kristina Spadafora** Frontier Global Sciences 414 Pontius Avenue North Seattle, WA 98109 P: (206) 957-1423 E: kristinas@frontiergs.com	A

Mr. Eugene Klesta 110 South Hill Street South Bend, IN 46617 P: 574-472-5580 eugene.j.klesta@us.ul.com	P	**Ms. Michelle L. Wade** Kn Dept of Health and Environment Forbes Field, Building 740 Topeka, KS 66620 P: (785) 296-6198 E: mwade@kdheks.gov	P

Associate Members:
Larry Penfold
Eric Denman
Paul Junio

Appendix C – Outstanding comments

Gill Dichter

Module 5: Quality Systems for Microbiological Testing

Robin Cook and I met at the FSEA me to review some of my comments to different parts of this Module Robin indicated that changes were made to some of my comments.

1.0) 1.5d. reference to module 2 section 1.5.4 was deleted since this does not exist

2.0) 1.7.3.5 a) i) 1. Add after from basic ingredients and/or commercial dehydrated powder. End of this sentence. Delete prior to first use and change this to: shall be checked at a minimum with first use

3.0) 1.7.3.5 a) ii Ready to use media: See 1.7.3.5 a) i) 1.

4.0) 1.7.3.6 Selectivity b) My concern with verification by the completed test with BGB is that some coliforms are do not produce gas or turbidity within 48 hours or are slow growing lactose fermenters. Enzymatically, these coliforms will yield a positive reaction. Performing a catalase test and I would add oxidase test to confirm the presence of total coliforms (negative for oxidase and positive for catalase) in lieu of the BGB test

5.0) 1.7.5.b delete (source water) . By definition –see 1.3.1 it is untreated water from streams, rivers, ground water, etc

Thanks
Gil

Sreenivas Komanduri

My comments pertain to Module-6, Radiochemical Testing. Each comment is preceded by the relevant citation from the Module and in bold font.

1.5.2 Detectable Activity

All procedures used shall be documented. Documentation shall include the quality system matrix type. All supporting data shall be retained.

This requirement for Detectable Activity is non-specific. It is unclear exactly what is required. Does it mean calculations? Does it mean raw data or something else? More clarity is needed if it were to be useful.

1.5.2.1 Minimum Detectable Activity

The laboratory shall utilize a method that provides an MDA that is appropriate and relevant for the intended use of the data. MDAs shall be determined by the protocol in the mandated method. If the protocol for determining the MDA is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the method.

The Minimum Detectable Activity outlined in Module-6 'Radiochemical Testing' is not entirely accurate. MDA is a sample specific result obtained under certain conditions. It is really not method specific result as implied here.

MDA has often been compared and confused with MDL (Method Detection Limit) in Chemical Testing. While laboratories traditionally are required to perform MDL by the method once a year, the MDA in radiochemistry is really not a method specific result. There lies the difference.

a) The laboratory shall determine the MDA for the method for each target analyte of concern in the quality system sample matrices. All sample-processing steps of the analytical method shall be included in the determination of the MDA.

This again is sounding as though MDA is method specific which is not accurate entirely accurate.

1.5.5 Evaluation of Selectivity

The laboratory shall evaluate selectivity, if applicable, by following the checks established within the method.

Selectivity as mentioned here is vague and do not convey much of anything substantial. Clarification will be required if it is to serve any purpose. In Radiochemistry, there are selective methods and there are non-selective (or screening) methods. For example, the Gross Alpha Beta Method (EPA 900.0) is a

screening method and obviously non-selective. When once a method is selected, there is not much of a concern for Selectivity within the method. Therefore, Selectivity is an important criterion prior to selection of the method and not after.

1.7.2.6 Selectivity

The laboratory shall evaluate selectivity by following the checks established within the method.

Selectivity is included for a second time in the Module which is plainly redundant.