The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on November 14, 2011 via teleconference. No agenda was published, but the purpose of the meeting was to finalize all comments submitted on the working draft standard. The attendees are listed in Appendix A and the comments are hyperlinked to PDF files in Appendix B.

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

1. Larry Penfold: proposed language will be used.
2. Tom McAninch: Source water will be further defined to state that the definition is used for purposes of drinking water compliance.
3. Art Clark: Corrected as noted.
4. Email string on definition of Demonstration of Capability – changes accepted
5. Jerry Parr/Jack Farrell: Revert back to the NELAC 2003 language. Committee is unsure of why it was changed.
6. Steve Arms: added an explanatory statement indicating that the reference method definition is to be used to determine the extent of method validation.
7. Richard Burrows: Proposed definition accepted.
8. Elizabeth Turner:
    a. V1M2 4.13.3 – language is a requirement from the NELAC 2003 standard. Tabled for future consideration
    b. V1M5 1.7.3.7 b ii– Requires a change (not a clarification) to the TNI standard. Tabled for future consideration.
    c. V1M5 1.7.3.7 b vi- language is a requirement from the NELAC 2003 standard. Tabled for future consideration
    d. V1M5 1.7.5 – the committee does not understand how reducing chlorine checks to once a month per client is a hardship.
9. Comments from Steve Gibson: Situation 2 will be incorporated into the standard.

The committee reviewed the suggested changes to a document sent by Carol Batterton to the committee. While the committee was unsure of the audience for the position statement, the suggested changes were approved for forwarding to Carol

Silky also discussed additional options for incorporating a calibration standard into the Quality System standard. The issue has not been resolved, and the committee will continue with the process for finalizing the current revisions. A copy of the revised standard and the outstanding comments will be circulated before the December meeting. If the committee votes to move these forward to a voting draft standard, the proposed revisions will be posted before December 29, so that comments to the revisions can be discussed in Sarasota.

The meeting was adjourned at 2:22 EST, with the next meeting scheduled for December 12, 2011.

**Appendix A - Participants**

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|---|---|---|---|
| **Ms. Katie Adams**<br>USEPA Region 10<br>Manchester Laboratory<br>7411 Beach Drive East<br>Mail Code: LAB<br>Port Orchard, WA 98366<br>P: (360) 871-8748<br>E: Adams.Katie@epamail.epa.gov | P | **Ms Silky S. Labie**<br>Env. Lab Consulting & Technology, LLC<br>PO Box 13324<br>Tallahassee, FL 32311<br>P: (850) 656-6298<br>E: elcat-llc@comcast.net | P |
| **Mr. Brian R Boling**<br>Oregon Dept. of Environmental Quality<br>3150 NW 229th Suite 150<br>Hillsboro, OR, 97124<br>P: (503) 693-5745<br>E: boling.brian@deq.state.or.us | A | **Ms Dorothy M. Love**<br>Lancaster Laboratories, Inc.<br>2425 New Holland Pike,<br>P.O. Box 12425<br>Lancaster, PA 17605-2425<br>P: (717) 656-2300 x1204<br>E: dmlove@lancasterlabs.com | P |
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| **Ms Robin Cook**<br>City of Daytona Beach<br>3651 LPGA Blvd<br>Daytona Beach FL 32124T<br>P: (386) 671-671 8885<br>E: cookr@codb.us | P | **Mr. Fred S. McLean**<br>NAVSEA 04XQ(LABS)<br>1661 Redbank Road<br>Goose Creek, SC 29445-6511<br>P: (843) 764-7266<br>E: fred.mclean@navy.mil | A |
| **Ms Tamara DeMorest**<br>Utah Department of Health<br>4431 South 2700 West<br>Salt Lake City, UT 84119-8600<br>P: 801-965-2541<br>E: tdemorest@utah.gov | A | **Ms Michele Potter**<br>NJDEP<br>9 Ewing Street, 2nd Floor<br>Trenton, NJ, 08625<br>P: (609) 984-3870<br>E: Michele.Potter@dep.state.nj.us | A |
| **Mr. Gil Dichter**<br>IDEXX Laboratories<br>One Idexx Dr<br>Westbrook, ME 04092<br>P: (207) 556-4687<br>E: gil-dichter@idexx.com | P | **Mr. Randall Querry**<br>A2LA<br>5301 Buckeystown Pike, Suite 350<br>Frederick, MD 21704<br>P: (301) 644-3221<br>E: rquerry@a2la.org | P |
| **Ms. Stephanie Drier**<br>Minnesota Department of Health<br>P.O. Box 64899<br>601 Robert Street North<br>St. Paul, MN 55164-0899<br>P: (651) 201-5326<br>E: stephanie.drier@state.mn.us | A | **Ms. Kristina Spadafora**<br>Frontier Global Sciences<br>414 Pontius Avenue North<br>Seattle, WA 98109<br>P: (206) 957-1423<br>E: kristinas@frontiergs.com | P |
| **Mr. Eugene Klesta**<br>110 South Hill Street<br>South Bend, IN 46617<br>P: 574-472-5580<br>eugene.j.klesta@us.ul.com | A | **Ms. Michelle L. Wade**<br>Kn Dept of Health and Environment<br>Forbes Field, Building 740<br>Topeka, KS 66620<br>P: (785) 296-6198<br>E: mwade@kdheks.gov | P |

Associate Members:
Larry Penfold
Eric Denman
Paul Junio
Bill Ray

Appendix B
Comments (from September Meeting_

**Comment on EL-V1-M3-2011**

Concern: On August 1, 1994, the EPA announced in the Federal Register that EPA/600/R-93/116 provides clarification and improvements to the 1982 protocol and recommended that it serve as a preferred substitute method. However, a 2010 federal court ruled (United States v. San Diego Gas & Electric, Co.) that the EPA did not go through required administrative rulemaking to replace the 1982 method with the 1993 method and that results produced by the 1993 method were not allowed in court deliberations.

Recommendation: Replace "EPA/600/R-93/116, July 1993" with "EPA 600/M4-82-020 (1982)", as detailed below:

1.7.7.1.3 Bulk Samples
a) The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized (e.g., ~~EPA/600/R-93/116, July 1993)~~ EPA 600/M4-82-020 (1982).

1.7.7.3 Polarized Light Microscopy
1.7.7.3.1 The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized (e.g., ~~EPA/600/R-93/116, July 1993)~~ EPA 600/M4-82-020 (1982).

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Additional Comments

**From:** aex
**To:** "Jerry Parr"; elcatllc@centurylink.net
**Subject:** RE: CCV
**Date:** Monday, August 01, 2011 12:06:18 PM

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Sorry for the delay in getting back to you folks....as you can imagine I have some strong feeling and technical opposition to weakening the standard by allowing two CCV before considering corrective action. It opens up a number of potential issues for labs to run two CCV as a routine process and pick and choose what is acceptable without a conscious decision being make on why a particular CCV failed. If we look at most methods, it is pretty clear that if calibraration or calibration verification fails...corrective action needs to be taken, now that can be running another standard or other CA, but and to me this is the critical point....it needs to be a conscious decision on the part of the analyst AFTER review of the failure to determine the cause and appropriate corrective action...I firmly believe that the final response provided by the NELAP AC to the 2003 standard is right on...and we should keep this approach and philosophy...and maybe clarify that it needs to be a conscious technical decision, not an automatic "mulligan"...its a slippery slope at best....

Hope this helps...

Jack Farrell
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-----Original Message-----
From: Jerry Parr [mailto:jerry.parr@nelac-institute.org]
Sent: Tuesday, July 26, 2011 10:20 AM
To: elcatllc@centurylink.net
Cc: aex@ix.netcom.com
Subject: CCV

Silky:

This is the other issue I mentioned. Note the striking difference in language between 2003 NELAC and 2009 TNI and the strong statement in the SIR supporting the 2003 language.

I do not really care which way this is, trust consensus of the committee, but wanted to make sure this was a conscious decision of the committee and not a slip up given the strong response in the SIR.

jerry

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**TNI Position Statement**

**Demonstration of Method Competency**

TNI believes a laboratory must demonstrate its competency for every test method used by the laboratory and ensure the competency for ~~every~~ each analyst(s) who is responsible for performing all or part of the test method.~~and for every test method used by the laboratory~~.

**Background**

A laboratory test method, along with other components such as appropriate quality control activities, adequate instrument calibration, and suitable reagents, is one of the key components for ensuring reliable laboratory analyses. The laboratory performing the analysis must demonstrate that it can generate data suitable for its intended purpose.

TNI has expanded this fundamental concept into two sets of activities termed Method Validation and ~~Initial~~ Demonstration of Capability ~~and Continuing Demonstration of Capability~~(initial and continuing. Method Validation demonstrates that the laboratory is capable of performing a test method to a predetermined set of standards. A Demonstration of Capability (DOC) is used to document the competency of analysts who perform the method. Both a method validation and DOC must be successfully completed before reporting data for the method. In addition, each analyst must continually demonstrate competency in performing the method (continuing DOC). ~~TNI's accreditation standard requires the laboratory, and each analyst involved in using the test method, demonstrate its competency before any samples are analyzed and then on an on-going basis.~~

**Challenges or Intended Audience**

Training in performing a method is not the same as demonstrating competency to conduct analyses by ~~that~~ a given method. Both are necessary and both need to be documented for each analyst. Many EPA methods require a laboratory to perform "an initial demonstration of method capability." However, this requirement is not tied to each individual analyst, nor is there any requirement to demonstrate continued proficiency in performing the method.

**References**

Quality Assurance of Chemical Measurements, John Taylor, 1983

ISO/IEC Standard 17025: *General requirements for the competence of testing and calibration laboratories*, Second Edition, 2005

TNI Standard ELV1, *Management and Technical Requirements for Laboratories Performing Environmental Analysis*, 2009