The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on July 11, 2011 via teleconference. The agenda is attached as Appendix A, the action items are listed in Appendix B, and the attendees are listed in Appendix C and recently received Standard Interpretation Requests (SIRS) are listed in Appendix D.

The roll was taken and the action items reviewed and updated. The June minutes were approved with no changes.

Silky announced that the committee voted to move the standard to a working draft standard. As a result, the standard was posted on the TNI Website for public comments. The committee will begin to respond to comments during the Seattle meeting. She also stated that arrangements were made for QS members to call into the meeting.

The committee began working on responses to the SIRs:

166: The committee agreed with the proposed response

169: The idea of continual improvement was stressed, and will be clarified with the current revisions to the standard.

170: The committee stressed that each laboratory may determine how to ensure that the competency of each individual is demonstrated. Work cells may be used.

172: The committee agreed that if requirements of a method are “different”, the method must be followed.

173: Use of QC data may characterize analytical uncertainty.

174: The committee agreed that further information would be needed to provide a specific response to the problem.

175: The committee clarified the intent of “outside source”.

The meeting adjourned at 2:49 pm EDT. The next meeting will be at the TNI meeting in Seattle.

**Conference Call Agenda:**

# The NELAC Institute Quality Systems Expert Committee

**July 11, 2011 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: 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 *July 11, 2011*)

| **Old Business:** | | |
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| Roll Call | All | 5 minutes |
| Action Items | All | 5 minutes |
| Review of June Minutes | All | 5 minutes |
| Results of voting | All | 5 minutes |
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| **New Business:** | | |
| Seattle Meeting | All | 10 min |
| SIRs 166-169-170-172-173-174-175 | All | 45 min |
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**Appendix B - Action Items**

| Item No. | Date Proposed | Action | Date to be Completed | Date Completed |
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| 30 | 3-14-11 | Fred to consult with Radiochemistry experts concerning comments made on V1M7. | 4-11-11 | 4-11-11 |
| 31 | 3-14-11 | Silky to review the spread sheet to ensure that all negative comments were discussed. | ASAP | 4-11-11 |
| 32 | 3-14-11 | Silky will prepare a new draft standard for review | 4-11-11 | 4-11-11 |
| 33 | 3-14-11 | Silky will forward the January and February minutes to the TNI website, and the finalized SIRS to LASC. | ASAP | 3-17-11 |
| 34 | 5-9-11 | Silky to send out the TNI checklist | ASAP | 5-17-11 |
| 35 | 5-9-11 | Silky to send out revised standard for final review | ASAP | 5-17-11 |
| 36 | 5-9-11 | Silky to schedule a July teleconference | ASAP | 6-5-11 |
| 37 | 6-13-11 | Silky to make changes discussed during the meeting and send out the standard for electronic voting | ASAP | 6-14-11 |
| 38 | 6-13-11 | Comments on checklist due by June 27. | | 6-27-11 |
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**Appendix C - 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 | e | **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 | e | **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 |
| **Ms Laurie Carhart**<br>NYS DOH ELAP<br>PO Box 509, ESP<br>Albany, NY 12201<br>P: (518) 486-2538<br>E: ljc09@health.state.ny.us | e | **Mr. Robert Martino**<br>QC Laboratories<br>60 James Way, Unit 6<br>Southampton, PA 18966<br>P: (267) 699-0103<br>E: RMartino@qclaboratories.com | a |
| **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 | a | **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 |

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| **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: Carl Kircher
Eric Denman
Larry Penfold
Bill Ray

**Appendix D**
SIRs

#166

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| **Standard** | 2009 TNI Standard |
| **Volume and Module (eg. V1M2)** | V1M2 |
| **Section (eg. C.4.1.7.4)** | 5.4.2 |
| **Describe the problem:** | I am not sure what section, but my question refers to a statement that was made at a FSEA meeting October 27 - 29, 2010 at Palm Beach Gardens, Fl. A statement was made in reference to everyone must use the most recent version of Standard Methods. For clarification, I wanted to know if this is for the most recently EPA approved version of Standard Methods? Currently some EPA approved methods go as far back to the 18th ed. of Standard Methods.<br>Thank you for your time. |
| **Comments** | 5.4.2 Selection of Methods (*ISO/IEC 17025:2005(E), Clause 5.4.2)*<br>*The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.. . . . . . . . . .The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.* |
| **Response** | The key is the highlighted phrase from 5.4.2. The latest edition of a method must be used unless it is not appropriate or possible to do so. Therefore, if a method from an earlier edition of a published document (such as Standard Methods) is mandated for use by a regulatory agency, it is not appropriate to use the most recent method. |

#169

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| **Standard** | 2009 TNI Standard |
| **Volume and Module (eg. V1M2)** | V1, M4 |
| **Section (eg. C.4.1.7.4)** | 1.6.3 |
| **Describe the problem:** | Does not specify a frequency for CDOC. It does imply |

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| | annually for those who choose to go the 4 x LCS route(1.6.3.2(c)); but there should be a more general requirement for annual CDOCs in 1.6.3.1 |
| **Comments** | 1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC. The analyst(s) shall demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate. |
| **Response** | The key words are “demonstrate on-going capability”. The intent is that each analyst should be continuously demonstrating their competence. The standard does not limit the laboratory to looking at a single event during the year (2003 NELAC Standard), but emphasizes the need to maintain competency on an on-going basis. A proposal to clarify this clause has been posted in the QS working draft standard. |

#170

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| **Standard** | 2009 TNI Standard |
| **Volume and Module (eg. V1M2)** | V1M4 |
| **Section (eg. C.4.1.7.4)** | 1.6.2 and 1.6.3 |
| **Describe the problem:** | Current Situation: Currently our laboratory uses Work Groups for IDOC and DOC of the sample preparation methods (i.e., EPA 3005, EPA 3510, ... etc.) and the we perform IDOC and CDOC on individual analysts for the test methods (i.e., EPA 6020, EPA 8270, ... etc.). This represents well our actual practice of having a formalized group of employees performing sample prep as a team effort, and then subsequent actual instrument analysis is performed by an individual.<br><br>Question: Because the 2009 Standard has been revised to no longer explicitly describe work groups, will it be required to DOC our prep group personnel individually under the 2009 Standard, or are these types of work groups still allowed to be DOCed as a formal team?<br><br>As an alternative, under the 2009 Standard is it permissible to maintain DOC on the analyst as the individual responsible for the sample(s) for that test, with the prep team working under that DOCed analyst’s oversight? This essentially wraps the sample prep and analysis together under a designated analyst who utilizes “assistant” individuals within the process. |

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| | Thank you.<br><br>Robert E. Waite<br>QA Manager<br>Clean Harbors Kimball Laboratory |
| **Comments** | |
| **Response** | Each individual analyst must have documentation on file that indicates that he/she is competent to independently perform the portion of the analysis for which he/she is responsible.<br>Work cells may be used. The laboratory needs to define how the concept is used to demonstrate individual competence. |

#172

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| **Standard** | 2003 NELAC Standard |
| **Volume and Module (eg. V1M2)** | 2003 Standard: Quality Systems |
| **Section (eg. C.4.1.7.4)** | Sppendix D, section D.1.1.1.C) |
| **Describe the problem:** | The composition of a method blank shall consist of a quality system matrix that is similar to the associated samples and known to be free of analytes of interest.<br>No reference could be found in SW-846 Methods 5035, 8000, and/or 8260 that require a VOA method blank to contain a solid matrix. In fact, in method 5035 section 8.2 it is stated before processing samples to analyze an organic-free water method blank.... Nothing about adding a solid matrix is mentioned.<br>Adding a solid matrix to a VOA method blank would only potentially add contamination and not be reflective of the cleanliness of the analytical system. Also if one adds a solid matrix (even if it does not contain analytes of interest) to a VOA method blank, should not the same solid matrix be added to all the samples as well?<br>Basically, is it necessary to add a solid matrix to a VOA method blank when analyzing low level soil samples?<br>Is it the intent of NELAC's definition of a method blank to overrige what is presented in the method?<br>Thank you for your response. |
| **Comments** | |
| **Response** | A blank is required to be free of the analytes of interest. Therefore, an appropriate blank for a solid matrix should not contribute contamination.<br>5.9.3 c) provides the following statements concerning the difference between 5035 and TNI: “The laboratory |

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| | shall ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed." Since the composition of the blank is "different", follow the requirements outlined in 5035. |

#173

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| **Standard** | 2009 TNI Standard |
| **Volume and Module (eg. V1M2)** | V1M2 |
| **Section (eg. C.4.1.7.4)** | 5.10.3.1d |
| **Describe the problem:** | "Where applicable,…. information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit."<br>V1M2 5.10.3.1d<br><br>Isn't the uncertainty always relevant to the validity of tests results?<br>How does TNI expect labs to express uncertainty of tests on analytical reports? Should it be like +/- x% ?<br>Could TNI provide guidance on calculating and expressing uncertainty? |
| **Comments** | V1M2 5.4.6 Clause 5.4.6 of the *ISO/IEC/IEC 17025:2005(E)* concerning calibration testing does not apply. The following requirement replaces the *ISO/IEC Clause*. Environmental testing laboratories shall have a procedure(s) for estimating analytical uncertainty. Quality control measurement data may be used to determine analytical uncertainty. |
| **Response** | There may be some instances where uncertainty is not critical such as presence/absence of a given chemical analyte.<br>The statement in V1M2 5.4.5 allows the use of the QC data to characterize analytical uncertainty. |

#174

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| **Standard** | 2003 NELAC Standard |
| **Volume and Module (eg. V1M2)** | Section 5.5.10 |
| **Section (eg. C.4.1.7.4)** | 5.5.10 |
| **Describe the problem:** | A laboratory client insists that their assessor has told |

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| | them that the requirements of section 5.5.10 include reporting the LOD for all analytes for which determination of LOD is possible. I can see nothing in this section that would indicate reporting of the LOD is required. Can you clarity? |
| **Comments** | **C.3.1.**c) An LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature, or, when test results are not to be reported to the LOD (versus the limit of quantitation or working range of instrument calibration), according to Appendices D.1.2, D.4.5, D.5.4, and D.6.6. Where an LOD study is not performed, the laboratory may not report a value below the Limit of Quantitation. |
| **Response** | The word “detection” is not found in 5.5.10. The reference above does not require an LOD study if test results are not reported to the LOD.<br>Any further interpretations would require the exact standard citation used by the assessor. |

#175

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| **Standard** | 2003 NELAC Standard |
| **Volume and Module (eg. V1M2)** | V1M4 1.5, 1.6 |
| **Section (eg. C.4.1.7.4)** | C.1.a, C.3.1, C.3.2 |
| **Describe the problem:** | A laboratory in our program has requested clarification that the term "outside source" has the same or a different meaning from the term "secondary source." The laboratory understands that a "secondary source" should be used for instrument calibration per NELAC 5.5.5.2.2.1.d but this is not required for demonstration of capability or determination of LOD or determination of LOQ. The question is "Is 'outside source' the same as 'secondary source'?" Thank you for your assistance. |
| **Comments** | |
| **Response** | In some cases, the QC samples are obtained from a vendor. This would be considered an “outside source”. If the laboratory prepares the QC sample, the source of the standard must be from stocks that are prepared independently from those used for calibration. This does not imply a second source, but separate preparation. |