



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

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on February 13, 2012 via teleconference. The agenda is presented in Appendix A and the attendees are listed in Appendix B.

After roll call, the committee reviewed the January Minutes and approved them for posting. Silky welcomed the three new members, Paul Junio, Robert Shannon, and Janice Willey. Each provided the committee with an overview of their activities and interest.

The next order of business was the election of a committee chair. Silky stated that while Michelle Wade was absent, she had nominated Paul Junio. The committee voted unanimously to elect Paul as chair of the committee.

Before stepping down as chair, Silky reported the results of the official Committee Vote:

14 of the sixteen members voted; 2 abstained

For Modules 3 through 7, the fourteen members voted affirmatively

For Module 2, the vote was 13 affirmative, and one negative

Silky turned the meeting over to Paul as the chair.

The committee reviewed SIR 191. Silky stated that the original concern came from a "grey box" in the DOD QSM. Janice corrected this by stating that the concern was from an interpretation by A2LA that stated that the second source calibration standard must be from a different manufacturer. The concern is that many vendors use the same manufacturer, or, in many cases, only one manufacturer exists. The committee agreed that the intent was the two standards need to be prepared by independent processes that did not include different manufacturers of the original material. The preferred hierarchy was: standards from two different vendors; standard from the same vendor but different lot numbers, and finally the same lot number, but prepared as two independent standards by the laboratory. The committee felt that the hierarchy should be part of the response. Silky volunteered to reword the response and send to Paul for distribution.

While the committee could not discuss any of the comments that were not discussed in Sarasota, the committee began to discuss how those comments that were discussed to determine how to change/reword the standard.

The first negative vote was on unique container IDs. A lively session ensued. It was proposed that a laboratory should assign unique IDs to containers with different preservation and whether or not there was value in assigning a number to each container. A state assessor stressed that there needed to be traceability for purposes of defensibility and to be able to perform a complete historical reconstruction of the data. Someone asked whether or not the committee vote ruling the comment persuasive meant that the committee voted to change the standard. The response was that the persuasive vote meant only that the committee would discuss the standard in detail before coming to a final decision. Stephanie Drier volunteered to send language from their state rules that stress the necessity of individual container identification.

The meeting adjourned at 2:22 pm EST, with the next meeting scheduled for March 12, 2012 via teleconference.

**Appendix A - Agenda**

**Conference Call Agenda:**



**The NELAC Institute Quality Systems Expert Committee**

**February 13, 2012 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](mailto:elcat-llc@comcast.net) (Subject: RSVP for *February 13, 2012*)

**Old Business:**

Roll Call	All	5 minutes
Welcome New Members	All	10 minutes
Outstanding Minutes sent by separate email	All	15 minutes

**New Business:**

Election of Committee Chair	All
Results of Vote on Voting Draft Standard	Silky
Recap of Sarasota Meeting	All
SIR 191	All

<b>Standard</b>	2003 NELAC Standard
<b>Volume and Module (eg. V1M2)</b>	2003 & 2009 Standard
<b>Section (eg. C.4.1.7.4)</b>	2003 Std Chapter 5, section 5.5.5.2.2.1 d
<b>Describe the problem:</b>	<p>I could not find this same paragraph in the new 2009 standard documents posted on the TNI site.</p> <p>My question pertains to the interpretation of this statement in the 2003 NELAC standard and how it applies to the 2009 TNI standard. We have been informed that Environmental lab auditors are now requiring labs to use a second vendor for their second source calibration standards even when use of a second manufactured lot from the same vendor is allowed by both the 2003 NELAC and 2009 TNI standards. We have even heard that second source from a second manufacturer raw material prepared by the same vendor is being noted as non-compliant in some instances.</p> <p>What is the interpretation of what this standard requires of labs where it applies to non-DoD programs with regard to the following options:</p> <ol style="list-style-type: none"> <li>1. Same vendor/supplier - two independently prepared lots from the same raw material.</li> <li>2. Same vendor/supplier - two independently prepared lots from different manufacturer raw materials when available.</li> <li>3. Two different vendor/suppliers for each of the primary and secondary lot standards.</li> </ol> <p>Thank you</p>
<b>Comments</b>	1.7.1.1.d - all initial instrument calibrations shall be verified with a standard obtained from a second manufacturer or from a different lot. Traceability shall be to a national standard, when commercially available;
<b>Response</b>	The intent of the standard is to verify that the standards used for calibration have been properly prepared, not only the by the laboratory but the vendor. The verification standard must be prepared independently, meaning that the standard (and the original vendor-supplied source) must have been prepared under different circumstances from the original calibration standards. All three of the scenarios mentioned above would be acceptable.

**Appendix B - Participants**

<p><b>Ms. Katie Adams</b> USEPA Region 10 Manchester Laboratory 7411 Beach Drive East Mail Code: LAB Port Orchard, WA 98366 P: (360) 871-8748 E: <a href="mailto:Adams.Katie@epamail.epa.gov">Adams.Katie@epamail.epa.gov</a></p>	A	<p><b>Ms Dorothy M. Love</b> Lancaster Laboratories, Inc. 2425 New Holland Pike, P.O. Box 12425 Lancaster, PA 17605-2425 P: (717) 656-2300 x1204 E: <a href="mailto:dmlove@lancasterlabs.com">dmlove@lancasterlabs.com</a></p>	P
<p><b>Mr. Brian R Boling</b> Oregon Dept. of Environmental Quality 3150 NW 229<sup>th</sup> Suite 150 Hillsboro, OR, 97124 P: (503) 693-5745 E: <a href="mailto:boling.brian@deq.state.or.us">boling.brian@deq.state.or.us</a></p>	E	<p><b>Mr. Robert Martino</b> QC Laboratories 60 James Way, Unit 6 Southampton, PA 18966 P: (267) 699-0103 E: <a href="mailto:RMartino@qclaboratories.com">RMartino@qclaboratories.com</a></p>	P
<p><b>Ms Tamara DeMorest</b> Battelle Memorial Institute 15073 Talons Reach Court Draper, UT 84020 P: 435-602-2667 E: <a href="mailto:tamara.demorest@gmail.com">tamara.demorest@gmail.com</a></p>	A	<p><b>Ms Michele Potter</b> NJDEP 9 Ewing Street, 2nd Floor Trenton, NJ, 08625 P: (609) 984-3870 E: <a href="mailto:Michele.Potter@dep.state.nj.us">Michele.Potter@dep.state.nj.us</a></p>	P
<p><b>Mr. Gil Dichter</b> IDEXX Laboratories One Idexx Dr Westbrook, ME 04092 P: (207) 556-4687 E: <a href="mailto:gil-dichter@idexx.com">gil-dichter@idexx.com</a></p>	E	<p><b>Mr. Robert Shannon</b> Quality Radioanalytical Support, LLC PO Box 774 Grand Marais, MN 55604 P: (218) 387-1100 E: <a href="mailto:bobshannon@boreal.org">bobshannon@boreal.org</a></p>	P
<p><b>Ms. Stephanie Drier</b> Minnesota Department of Health P.O. Box 64899 601 Robert Street North St. Paul, MN 55164-0899 P: (651) 201-5326 E: <a href="mailto:stephanie.drier@state.mn.us">stephanie.drier@state.mn.us</a></p>	P	<p><b>Ms. Kristina Spadafora</b> Frontier Global Sciences 414 Pontius Avenue North Seattle, WA 98109 P: (206) 957-1423 E: <a href="mailto:kristinas@frontiers.com">kristinas@frontiers.com</a></p>	P
<p><b>Mr. Paul Junio</b> Northern Lake Service, Inc. 2420 North Grandview Blvd. Waukesha, WI 53188 P: (262) 547-3406 E: <a href="mailto:paulj@nlslab.com">paulj@nlslab.com</a></p>	P	<p><b>Ms. Michelle L. Wade</b> Kn Dept of Health and Environment Forbes Field, Building 740 Topeka, KS 66620 P: (785) 296-6198 E: <a href="mailto:mwade@kdheks.gov">mwade@kdheks.gov</a></p>	E
<p><b>Mr. Eugene Klesta</b> Underwriters Laboratories, LLC Un110 South Hill Street South Bend, IN 46617 P: 574-472-5580 <a href="mailto:eugene.j.klesta@us.ul.com">eugene.j.klesta@us.ul.com</a></p>	P	<p><b>Janice Willey</b> NAVSEA Programs Field Office Laboratory Quality and Accreditation Office 1661 Redbank Road, Bldg 302, Rm 202A Goose Creek, SC 29445 P: (843) 764-7346 E: <a href="mailto:janice.willey@navy.mil">janice.willey@navy.mil</a></p>	P

Associate Members:

Larry Penfold                      Eric Denman  
Silky Labie                              Robin Cook