



## **The NELAC Institute (TNI) Quality Systems Expert Committee**

### Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on September 14, 2009 at 1:00 PM EST by conference call. The action items are listed in Appendix A and the attendees listed in Appendix B.

A summary of the closing session of the meeting in San Antonio was discussed, as follows:

The Environmental Standard is complete. NELAP will be voting on its acceptance at its next call, which is scheduled for 8/24. Their voting process allows for two weeks to get votes placed, so don't get concerned if there's no announcement on that day.

People are concerned about using the term "Guidance Document". There's a fear that "documents" will be used to set policy and become part of the standard. States can't enforce guidance, so there's concern that these CAN'T be requirements. This is one of the reasons that the Expert Committees were opposed to creating them in the first place. With this clarification in place, it's less of an issue for us. The Policy committee is working on how Guidance should be created and distributed. Guidance must not be mandatory and may not contain direct or implied requirements.

ISO Copyright issues are almost a non-issue at this point. There were a pair of copyright lawyers that attended the meeting on Tuesday, and they discussed a case that applies to the states that would be using copyright language. Essentially, if they use the ISO language in their state regulations, the right of people to know what's in law would trump Copyright law. This wouldn't alleviate copyright issues for anyone who would distribute state regulations, though. If they cite the ISO language, then they need only have the ability to let people see the language if they come looking for it. Also, labs will need to have a copy of the TNI Standard that includes the ISO language to protect themselves from copyright issues, as opposed to having the ISO-free version along with a copy of ISO.

A clean copy of the standard will be available once the NELAP Board votes to adopt it.

Experimental PT Tables are supposed to be retired by December.

Policies are needed yet for recognition and "home state" requirements. The TNI Board recognized that these don't currently exist, but figured it made sense to get the standards done first. Now, they'll get these issues done.

Next meeting locations - Winter 2010 - Chicago; Summer 2010 - Washington DC; Winter 2011 - either Tampa, Jacksonville, or Savannah; Summer 2011 - either Denver, San Francisco, or Seattle

TAC will be focusing its work on training session on the TNI Standard at the next two meetings.

Other notes: The comparison of the TNI Standard and the Drinking Water Manual wasn't meant to be a one way street. Either side could change to make the two "more similar".

EPA will be funding regional workshops to get the word out about the TNI Standards.

The PT Frequency Report doesn't support either 2 or 1 PTs per year - the data are inconclusive.

TIA's don't really affect state regulations. The states will adopt the standard as it appears right now. If the TNI Standard is changed in the future, that won't force the states to make a similar update. Essentially, while TIA's can only exist for 2 years within TNI, they last indefinitely in state regulations.

Timeline:

August '09 - Adoption of the standards (adoption and implementation date are two different votes)

October '09 - initiate regulatory changes in state laws

Spring '10 - training and outreach sessions

Summer '10 - replace the NELAC Standard

Lem Walker intends to update 40CFR so that the latest version of a method is the only version. The people from SW846 are less likely to work out the method revision issues now than they sounded like in January.

Modules 2 through 7 of Module 1, as corrected by TIA and editorial changes, was distributed to committee members in advance of the call, as was the QS Checklist. For the next call, committee members are to review the checklist as a 'complete' checklist, looking for any items that may have been divided that don't need to be, or items that should have been divided that weren't.

Any committee members willing to volunteer some time to help with Checklist formatting should contact the QS Chair.

Guidance items should be in a presentable format for the meeting in Chicago. Any ideas for such items should be brought to the committee's attention.

Finally, Aaren Alger has resigned from the committee due to her position as the new TNI Board Chair. We will look for a replacement, hopefully from among the ABs.

Next Meeting is scheduled for Monday, October 12, at 1:00 PM EST.

## APPENDIX A - ACTION ITEMS

### TNI Quality Systems Committee Meeting

Item No.	Date Proposed	Action	Date to be Completed	Date Completed
1	02/09/09	Request feedback from CSDB on the format and process of Guidance Documents	02/12/09	04/09/09
2	03/09/09	Distribute decisions on Standards Interpretation to assure the decision is appropriately relayed; awaiting Radiochemistry clarifications	03/20/09	05/04/09
3	03/09/09	Any items that could be used in support of the new Quality manual Template should be distributed to the Committee for comment; permission will be sought to distribute the existing Manual for comparison and inspiration	04/10/09 04/17/09	04/17/09
4	03/09/09	Submit versions of the edited Modules to Committee members delayed until the editorial changes in the Modules have been approved as being "as described"	03/27/09 04/30/09?	09/14/09
5	04/13/09	Contact Jack Farrell regarding participation on a Checklist subcommittee, and for any other ideas	04/21/09	04/22/09
6	04/13/09	Provide tentative schedule for San Antonio meeting to aid in scheduling QS Working session	04/21/09	05/04/09
7	05/11/09	Request clarification with CSDB regarding timeframe of adopted standards	05/14/09	09/14/09
8	05/11/09	Request clarification regarding QM Template – is it starting from scratch or revising the old one	05/14/09	
9	06/08/09	Determine process for revising a TIA	06/11/09	06/10/09
10	06/08/09	Find out if paraphrased ISO language can be used in the Quality Systems Checklist	06/25/09	09/14/09
11	07/13/09	Each member of the Committee will need to prepare a portion of the checklist	07/31/09	08/10/09
12	09/14/09	Review the checklist as a total document for any possible changes	12/31/09	
13	09/14/09	Provide any guidance issues that should be addressed by Quality Systems	12/31/09	

## APPENDIX B - PARTICIPANTS

<p><b>Ms Aaren Alger</b> DEP–Bureau of Laboratories Laboratory Accreditation Program 2575 Interstate Drive Harrisburg, PA 17110 P: (717) 346–8212 E: <a href="mailto:aaalger@state.pa.us">aaalger@state.pa.us</a></p>	Excused	<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>	Excused
<p><b>Ms Laurie Carhart</b> NYS DOH ELAP PO Box 509, ESP Albany, NY 12201 P: (518) 486–2538 E: <a href="mailto:ljc09@health.state.ny.us">ljc09@health.state.ny.us</a></p>	Present	<p><b>Mr. Patrick Conlon</b> Environmental Standards 1140 Valley Forge Road PO Box 810 Valley Forge, PA 19482–0810 P: (610) 955–8319 E: <a href="mailto:pconlon@envstd.com">pconlon@envstd.com</a></p>	Absent
<p><b>Ms Robin Cook</b> City of Daytona Beach 3651 LPGA Blvd Daytona Beach FL 32124T P: (386) 671–8856 E: <a href="mailto:cookr@codb.us">cookr@codb.us</a></p>	Present	<p><b>Ms Tamara DeMorest</b> Utah Department of Health PO Box 142109 Salt Lake City, UT 84114–2109 P: (801) 538–9372 E: <a href="mailto:tdemorest@utah.gov">tdemorest@utah.gov</a></p>	Present
<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>	Present	<p><b>Ms Michelle Henderson</b> USEPA, ORD 26 W ML King Dr. MS 207 Cincinnati, OH 45268 P: (513) 569–7353 E: <a href="mailto:henderson.michelle@epamail.epa.gov">henderson.michelle@epamail.epa.gov</a></p>	Present
<p><b>Mr. Paul Junio</b> Test America 602 Commerce Drive Watertown, WI 53094 P: (920) 261–1660 x127 E: <a href="mailto:Paul.Junio@testamericainc.com">Paul.Junio@testamericainc.com</a></p>	Present	<p><b>Ms Silky S. Labie</b> Env. Lab Consulting &amp; Technology, LLC PO Box 13324 Tallahassee, FL 32311 P: (850) 656–6298 E: <a href="mailto:elcat-llc@comcast.net">elcat-llc@comcast.net</a></p>	Absent
<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>	Present	<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>	Present
<p><b>Mr. Fred S. McLean</b> NAVSEA 04XQ(LABS) 1661 Redbank Road Goose Creek, SC 29445–6511 P: (843) 764–7266 E: <a href="mailto:fred.mclean@navy.mil">fred.mclean@navy.mil</a></p>	Excused	<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>	Present
<p><b>Mr. Randall Query</b> A2LA 5301 Buckeystown Pike, Suite 350 Frederick, MD 21704 P: (301) 644–3221 E: <a href="mailto:rquery@a2la.org">rquery@a2la.org</a></p>	Present	<p><b>Ms Jane M. Wilson, M.P.H.</b> Director of Standards NSF International P: (734) 827–6835 E: <a href="mailto:Wilson@nsf.org">Wilson@nsf.org</a></p>	Absent

### Associate Members Attending:

Patsy Root