The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on May 10, 2010 at 1:00 PM EST by conference call. The agenda is attached as appendix A, action items are listed in Appendix B and the attendees listed in Appendix C.

As a quorum was not present, the Committee could not finalize any pending actions. Silky announced that Michelle Wade from Kansas has been confirmed as a committee member and is now a member of the Quality Systems Committee.

Silky reported that additional candidates to represent EPA were needed. Several names were mentioned, and members are to follow up with names and emails so that the individuals can be contacted.

A list of candidates and their credentials were circulated among the expert committee members. Silky will resend the list as an email vote. Any comments on the candidates must be shared with the committee via email.

The Committee worked on a recent standards interpretation request. The resulting version is attached as Appendix D.

112 – After a lengthy discussion, the committee decided that the original draft needed to be modified to make it more generic. Pat Conlon volunteered to draft language. (Note, language is included in the attached language.)

115 – The committee agreed that the stated requirement could be met by having a copy of the NELAP certificate that identifies the accredited tests. However, if the primary laboratory's client is requesting additional information, the laboratory should be prepared to provide the requested information under NELAC 5.4.7.

116 – The committee agreed in principle with the proposed response. Additional wording concerning following any additional manufacturer's instructions was added. The committee also agreed that "adjustment feature" is not an acceptable approach, because it changes the original calibration.

All three requests will be routed for final review and vote by e-mail

The committee began discussion on the email and attachment sent by Jerry Par on 4-8-10. Items number 1 and 2 met with agreement from participating committee members.

Item 3 – The Committee determined that the standard states that an IDOC for each analyst must be completed. Once the IDOC has been established for one analyst, subsequent IDOCs could be done on the same samples by different analysts, or over time (using LCS spiked with the analyte) as long as any affected data are reported under the supervision of the individuals that were identified in original IDOC.

Based on the information provided by Jerry, the committee felt that the final item (4.1.4 and 1.5.3) will need a TIA to add the missing ISO language and to make the appropriate references in each of the technical modules. Silky will draft language to be considered at the next meeting

The final item on the agenda was the email sent by Jerry on 4-20-10 concerning changes to ISO 17025. In general, the committee feels that it is premature to suggest changes since the standard has not been implemented. Carl Kircher, as the representative to ANSI ICAC explained voting choices he had on the issue. The committee will poll others concerning the issue, and will revisit the issue at the June Meeting.

The meeting was adjourned at 2:30 EDT.

Appendix A – 5-10-2010 Agenda

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

May 10, 2010 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: 52518

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 *Date of Call*)

Old Business:

Roll Call	All	5 Minutes
Meeting Minutes (attached)	All	5 Minutes
Action Items (attached)	All	5 Minutes
Member Status	Silky	5 minutes
Requests for Interpretation , 112, 115,116 Attached	All	30 minutes

New Business:

Jerry's Memo (emailed in April)	All	45 minutes
Summer Conference	All	

APPENDIX B - ACTION ITEMS

TNI Quality Systems Committee Meeting

Item No.	Date Proposed	Action	Date to be Completed	Date Completed
1	5-10-10	Circulate April Minutes for email approval	6-14-10	
2	5-10-10	Circulate May Minutes for email approval	6-14-10	
3	5-10-10	Provide additional names from EPA for consideration	6-14-10	
4	5-10-10	Follow up on EPA candidates	6-14-10	
5	5-10-10	Contact current members concerning membership	6-14-10	
6	5-10-10	Complete vote on laboratory member	6-14-10	
7	5-10-10	Pat to draft response for interpretation request 112	6-14-10	5-10-10
8	5-10-10	Silky to draft TIA for non standard methods	6-14-10	
9	5-10-10	Fred to poll others concerning changes to 17025	6-14-10	
10				
11				
12				
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14				

APPENDIX C - PARTICIPANTS

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	Absent	**Ms Laurie Carhart** NYS DOH ELAP PO Box 509, ESP Albany, NY 12201 P: (518) 486-2538 E: ljc09@health.state.ny.us	Excused
Mr. Patrick Conlon Environmental Standards 1140 Valley Forge Road PO Box 810 Valley Forge, PA 19482-0810 P: (610) 955-8319 E: pconlon@envstd.com	Present	**Ms Robin Cook** City of Daytona Beach 3651 LPGA Blvd Daytona Beach FL 32124T P: (386) 671-8856 E: cookr@codb.us	Excused
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	Present	**Mr. Gil Dichter** IDEXX Laboratories One Idexx Dr Westbrook, ME 04092 P: (207) 556-4687 E: gil-dichter@idexx.com	Excused
Ms Silky S. Labie Env. Lab Consulting & Technology, LLC PO Box 13324 Tallahassee, FL 32311 P: (850) 656-6298 E: elcat-llc@comcast.net	Present	**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	Present
Mr. Robert Martino QC Laboratories 60 James Way, Unit 6 Southampton, PA 18966 P: (267) 699-0103 E: RMartino@qclaboratories.com	Absent	**Mr. Fred S. McLean** NAVSEA 04XQ(LABS) 1661 Redbank Road Goose Creek, SC 29445-6511 P: (843) 764-7266 E: fred.mclean@navy.mil	Present
Ms Michele Potter NJDEP 9 Ewing Street, 2nd Floor Trenton, NJ, 08625 P: (609) 984-3870 E: Michele.Potter@dep.state.nj.us	Absent	**Mr. Randall Querry** A2LA 5301 Buckeystown Pike, Suite 350 Frederick, MD 21704 P: (301) 644-3221 E: rquerry@a2la.org	Absent
Ms Jane M. Wilson, M.P.H. Director of Standards NSF International P: (734) 827-6835 E: Wilson@nsf.org	Absent		

Associate Members Attending: **Carl** Kircher, Eric Denman, Meera Neb, Travis Clark

Attachment D
Requests For Standards Interpretation

#112

Section (eg. C.4.1.7.4)	TNI 1.7.4.3.c
Describe the problem:	In going form the 2003 standard to the TNI standard, a "should" has been changed to "shall" with respect to qualifying sample results when surrogate recoveries fail to meet acceptance criteira. The new standard language is very vague and provides little direction for laboratories. What does "evaluated for the effect indicated for the individual sample results" mean? Does it mean if one surrogate fails, all results must be qualified? Does it mean that an relationship must be established between each analyte and each surrogate? Is such a relationship to be based on chemistry or comparable retention times? The qualification of a selected list of analytes form a long list of sample analytes creates a messy reporting situation. any clarification of expectations on this will help.
Comments	Refers to V1M4 (Chemistry)
Response	The NELAC standard requires that the laboratory report any data performance issues to the client that may impact the data quality. However, there is no set protocol for handling surrogates that applies universally, and comments on how individual surrogate apply to individual analytes is beyond the scope of the NELAC standard. Therefore in the "evaluation for the effect" of a surrogate failure, the laboratory should consider compliance with client requirements, compliance with the method requirements and compliance with their own quality system requirements. ~~Each surrogate represents a set of the analytes and has been selected to "reflect the chemistries of the targeted components of the method" (V1M4 1.7.3.3.3). This information is typically found in the method (or method resource citations). The intent of this standard is to identify analytes in the sample that are represented by the failed surrogate and 1) take appropriate corrective actions and 2) report the analytes with appropriate data qualifiers. This applies only to the sample with the failed surrogate, and only to the surrogate associated analytes in that sample.~~

#115

Section (eg. C.4.1.7.4)	5.4.5.4
Describe the problem:	What is the documentation needed as the 'record of evidence of compliance'? Our clients are asking for our NELAP certificate, PT results, insurance certificates and QA manual. But we interpret this statement to mean having the NELAP certificate on file.
Comments	Refers to 2003 NELAC, Subcontracting of Environmental Tests
Response	The requirements outlined in 5.4.5.1 refer to a subcontracted laboratory and the tests to be performed. They are 1) the laboratory is accredited under NELAP for the tests or 2) the laboratory meets the statutory or regulatory requirements for performing the tests. In the case of the first requirement, the NELAP Certificate that identifies the accredited test would meet the requirement. If other statutory or regulatory requirements exist, the laboratory must be prepared to provide document to indicate that these additional requirements have been met. **However,** Under "Service to the Client (NELAC 5.4.7), the laboratory shall cooperate with the client "to monitor the laboratory's performance . . . . provided that the laboratory ensures confidentiality to other clients."

#116

Section (eg. C.4.1.7.4)	5.5.5.2.2.1.b
Describe the problem:	My question is about pre-programmed and calibrated instruments provided from HACH. 1) What is required to "reconstruct" the calibrations when the no official calibration is done? It is already programmed into the instrument. 2) Are Continuing Calibration Checks (verifications) required on these types of instruments, or are the LCS and MS data sufficient?
Comments	The instructions for the Hach instruments imply or recommend that the factory calibration be used.
Response	The manufacturer's instructions should be carefully read to determine if additional steps are required if the factory calibration is used. When an instrument is factory calibrated, and the laboratory decides to use the factory calibration, ~~document~~ its use must be documented in the laboratory records (5.5.5.2.2.1 b). Since the calibration is factory-installed, there will be no records of the original calibration. To document the use of the factory calibration, the laboratory must identify the specific instrument and the concentration range associated with a given factory calibration. Note: upon first use, the calibration must be verified with a second source standard (5.5.5.2.2.1 d). Thereafter, the requirements for continuing calibration (5.5.5.10) must be followed. The LCS could function as a continuing calibration if no prep is needed. Some of the manufacturer's instructions allow for "adjustment" of the factory calibration by using a blank and a standard near the top of the range. A calibration factor, based on the standard is applied to subsequent sample results. Since the factory calibration is considered the initial calibration, results must be quantitated based on the original factory calibration (see 5.5.5.2.2.1 c)), and not from any continuing calibration verification. "Adjusting" the factory calibration with a standard is considred using a continuing calibration standard to change the original curve. ~~*Note for discussion: the manual allow for "adjustment" of the factory calibration using a blank and a standard near the top of the range. A calibration factor (presumably a ratio of the standard concentration vs internal standard concentration) is applied to each sample. Should an adjustment be considered in ICAL, how to document.*~~