The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on February 8, 2010 at 1:00 PM EST by conference call. The action items are listed in Appendix A and the attendees listed in Appendix B.

At the close of the call, it was announced that the Chair of the Committee would be stepping down effectively immediately. The remaining committee members will need to select a new chair. Each member should respond via e-mail to the entire committee whether or not they are interested in assuming the role of Committee Chair. A potential replacement has been identified, but all members should respond via e-mail by February 19.

Minutes from the January 27 session at the TNI Meeting in Chicago were discussed by those on the call, and were approved. Those minutes will be sent to the website for posting.

The meeting in Chicago was summarized. Among the items of note – future plans call for the Winter Meeting to be the primary working meeting, while the summer meeting would be pressing items as well as training sessions; the committee has been asked to capture the spirit of the discussion regarding Standard Interpretation Requests (SIRs) to keep the process as transparent as possible; Cryptosporidium may be added to the Microbiology Module as an Appendix; the committee or TNI should request an interpretation from EPA regarding the requirement in certain methods to perform an MDL Study every 6 months, especially as it relates to data that aren't reported below a low standard.

The Committee plans on having a Working Draft Standard ready for discussion at the summer meeting in Washington DC. The only parts of the Standard that will be open are those previously addressed via TIA (Module 6, Sections 1.7.1 c) and 1.7.1 c) iii). In addition, the inclusion of ISO language in the Method Validation parts of Modules 3 through 7 needs to be addressed, either through the inclusion of a definition and expanded guidance in each module, through the use of additional ISO language in Module 2, or some combination thereof. The affected sections are: Module 2, Section 5.4.5; Module 3, Section 1.5; Module 4, Section 1.5.1; Module 5, Section 1.5; Module 6, Section 1.5.1; and Module 7, Section 1.5.

The Committee discussed 4 SIRs. The draft responses are presented below. Please keep in mind that these are only draft responses, and should not be considered a final decision.

#101

Section (eg. C.4.1.7.4)	5.4.3.1
Describe the problem:	Identification of controlled documents. Is instrument software (or any other software) considered a controlled document? Are equipment manuals considered controlled documents?
Draft Response	Software is among the items listed in Section 5.4.3.1 as a document that must be controlled. While equipment manual are not explicitly listed as a document that must be controlled, 5.4.12.2.4 a) states "All records (including those pertaining to test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client."
Committee Comments	The committee agreed with the draft response. It was pointed out that equipment manuals are similar to SOPs in that they may address what or how an instrument should be operated. For that reason, they should be controlled, although this may not be the best citation available.

#104

Section (eg. C.4.1.7.4)	5.4.12.2.5.3
Describe the problem:	I have a question as to just how much information is required to be tied to analytical records. For instance, if a reagent used for part of an analysis requires it to be dried prior to weighing, do you really have to record the particular oven used, balance used, time/temp in oven and time/temp out of oven and reference these records in your final analytical record for analysis?
Draft Response	5.4.12.2.5.3 i) indicates that reagent preparation must be associated with an analysis. If the lot of reagent is noted with the analytical records, and the information on how the reagent is prepared is included in the laboratory SOP, that should be sufficient to comply with this requirement.
Committee Comments	The committee agreed with the draft response. The records that are maintained should be tied to due diligence, but need not necessarily be tied to the analytical report.

#108

Section (eg. C.4.1.7.4)	5.4.13.1
Describe the problem:	In the description of internal audits, it states "The internal audit program shall address all elements of the quality system, including the environmental testing activities." Does this mean that every method has to be audited yearly? For Labs that are running 300 or more methods this doesn't seem reasonable.
Draft Response	The Internal Audit that is required in 5.4.13 is of the laboratory's quality system. It is possible to assess a laboratory's quality system without auditing to every SOP.
Committee Comments	Section 5.4.2.1 states 'The laboratory shall establish implement and maintain a quality system based on the required elements in this chapter and appropriate to the type, range and volume of environmental testing activities it undertakes.' It isn't too high a standard to expect that each method would be audited once per year. It is possible that there wouldn't be a complete, exhaustive audit if there are no problems in the past. There could be more than a review of SOPs to qualify as a method review, and it is likely that a more in depth review would be required if issues were uncovered. The laboratory must determine how it will conduct is assessment of its environmental activities, and the lab must establish its procedure for doing this.
Revised QS Response	The Internal Audit that is required in 5.4.13 is of the laboratory's quality system. It is possible to assess a laboratory's quality system without auditing to every SOP. Similar to the concept of marginal exceedances, the schedule of audits is dependent on the number of methods and analytes for which the laboratory maintains accreditation.

#109

Section (eg. C.4.1.7.4)	C 3.1 (b)
Describe the problem:	LOD verification: For our lab, MDL is the LOD. Once an acceptable LOD is established via MDL, if the spike used meets the LOD spike concentration criteria (2-3X the LOD of the single analyte), is it necessary to prep and analyze another sample, or can one of the replicates analyzed for the MDL determination itself can be considered as a verification of the LOD?
Draft Response	C.3.1 b) only states that the LOD must be verified on each instrument used for reporting data. It doesn't place a limit on when that must happen. Therefore, if one of the replicates analyzed for the MDL determination meets the

	applicable criteria for LOD verification, that would meet the intent of the Standard.
Committee Comments	The committee agreed with the draft response, but felt some additional clarification would help. It is important to point out that the level of the spike being used to verify the MDL must be at 2-3x the MDL, not that the recovery of the spike must be at 2-3x the MDL (i.e., if the MDL is 1, then the verification spike must be made at 2-3, not at some higher level that recovers at 2-3).
Revised QS Response	C.3.1 b) only states that the LOD must be verified on each instrument used for reporting data. It doesn't place a limit on when that must happen. Therefore, if one of the replicates analyzed for the MDL determination meets the applicable criteria for LOD verification, that would meet the intent of the Standard. The value of the spike used to calculate the MDL must be at no more than 2-3x the calculated MDL. It is expected that all of the replicates in such a study would show a recovery to be used to calculate the MDL.

SIRs 108 and 109 need approval of the Committee prior to being returned to the Program Administrator. SIRs 101 and 104 have been sent to the Program Administrator.

The Draft Guidance Documents on LOD and LOQ were submitted to those on the call for personal review and comment. Any comment on these should be directed to Richard Burrows and/or Brooke Connor.

A new Bulletin Board has been added to the TNI website. It is set up as a discussion point for the TNI Standards. Each committee is expected to review it at least monthly so that any appropriate discussions may be dealt with during Committee meetings.

APPENDIX A - ACTION ITEMS

TNI Quality Systems Committee Meeting

Item No.	Date Proposed	Action	Date to be Completed	Date Completed
1	02/08/10	e-mail all committee members expressing either interest in, or no interest in, becoming the next Chair	02/19/10	
2	02/08/10	Approve or comment upon the revised response to SIRs 108 and 109	02/26/10	
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APPENDIX B - 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	Excused	**Ms Laurie Carhart** NYS DOH ELAP PO Box 509, ESP Albany, NY 12201 P: (518) 486-2538 E: ljc09@health.state.ny.us	Present
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	Present
Ms Tamara DeMorest Utah Department of Health PO Box 142109 Salt Lake City, UT 84114-2109 P: (801) 538-9372 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 Michelle Henderson USEPA, ORD 26 W ML King Dr. MS 207 Cincinnati, OH 45268 P: (513) 569-7353 E: henderson.michelle@epamail.epa.gov	Present	**Mr. Paul Junio** Test America 602 Commerce Drive Watertown, WI 53094 P: (920) 261-1660 x127 E: Paul.Junio@testamericainc.com	Present
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:

Chip Clark, Brooke Connor, Gary Dechant, Eric Denman, Carl Kircher, Eugene Klesta, Patsy Root