Summary of the Laboratory Accreditation Body Expert Committee Meeting Tuesday, May 20, 2014

1. Welcome and Roll Call

Chair Jeff Flowers opened the meeting and the roll was called. Those present are noted in Appendix A. Minutes from April 15, 2014, were approved.

2. Committee Meeting at Conference in Washington, DC

At the end of the previous conference, LAB appeared not to need meeting time for the upcoming conference, but with the discussion of third party assessors now underway, receiving input from conference participants could be beneficial. Fortunately, the Information Technology Committee, which is also working on the generic application, is both willing and able to share its half-day session with LAB, so that the LAB will meet on Monday morning, August 4, 2014, at 10:30 am Eastern.

3. New Committee Member

Lucrina Jones of EPA's Region 9 Laboratory was recommended to us as her replacement by Brenda Bettencourt upon Brenda's resignation from the committee. Lucrina's committee membership application has now been received and was circulated to committee members. After brief discussion, Jeff will forward to Sharon Mertens, Chair of the TNI Board of Directors, our request to add Lucrina to the committee roster. WELCOME. Lucrina!

4. SIR #254 Assigned to LAB

This Standards Interpretation Request was assigned to the LAB Expert Committee. It references V2M3 §6.3.5 and appears to have two parts. First, How must accrediting bodies implement/interpret ISO/IEC 17011:2004 (E), Clause 7.5.6 in the instance where the scope of the CAB only has one field of testing (e.g., Testing-Environmental) and the assessment team is performing a reassessment? And second, do NELAP ABs during a reassessment have to assess: all methods in the CAB's scope of accreditation, all technologies in the CAB's scope of accreditation, or a representative number of methods from the CAB's scope of accreditation as long as it ensure proper evaluation of the competence of the CAB? Some additional language from the submission is omitted here for brevity.

After some discussion of the practices of ABs on the committee and the experience of those who were previously assessors, the consensus was that assessing all methods and all technologies is not required by the standard but the AB can require itself to assess them all by incorporating that into the AB's quality system. The AB is obligated to assure the performance of the laboratory, but the standard is not prescriptive about how that must be accomplished. The citations to the standard that will be included in the interpretation should be V2M1 §7.7, particularly §7.7.2, and V2M3 § 6.3.6 and 6.3.7.

Jeff volunteered to draft language for the interpretation, to bring back to the committee for final approval. NOTE: for completeness, since SIRs are supposed to cite both the old NELAC standard and the "new" TNI standard, the relevant citation from the NELAC

standard is Chapter 3, Appendix C.4.2. However, the interpretation should note that all ABs are being evaluated according to V2 of the TNI Standard, regardless of which standard is officially used for assessing laboratories.

5. Third Party Assessor Credentials

Discussion of Phase 3 of our January 8, 2013, proposal to the TNI Board of Directors continued until the end of the meeting. Jeff explained that, since our April meeting, he has called TX, LA DEQ, FL and NJ Accreditation Bodies to ask if it would be useful to them to have a vetted list of assessors, and all said "yes." They explained that increasingly, the functions of contracting are leaving the program areas and being centralized in "purchasing agents" (however designated) with less knowledge about how to evaluate the contracted assessors. They believe that having the ability to specify criteria will be valuable to protect the programs.

Jeff asked Carl how Florida vetted the credentials of its contract assessors, which was to review evidence provided including the record of the assessor's training and college transcripts. Jeff noted that, whatever program the LAB recommends to the Board, if adopted, will likely be carried out by TNI, not by our committee.

Several participants agreed that labs are required to vet vendor-supplied reagent batches, so it seems only right that the AB should vet its assessors to ensure they are adequate and appropriate for the program. Another analogy was that TNI vets PT providers, so that the labs or purchasing offices do not need to, but there is presently no standard for vetting third party assessors, and creating such a standard could conceivably require reworking the entire NELAP.

This led back to a discussion of layers of vetting, and whether it is adequate to examine the training course certificates or if something more "in depth" is essential. Again, the ABs would like to have TNI perform a thorough vetting that essentially guarantees competence of a body of available third party assessors, and yes, this could become a new TNI program area, even if there are only a dozen people to be vetted, since that is the marketplace we need to serve.

Another participant noted that having assessors governed by a new standard would revolutionize the assessment process, where now the requirements and training of assessors are governed by the individual ABs.

Participants agreed that having a one-page or "straw man" document might help resolve the dichotomy evident within the committee. Jeff appointed a subcommittee of himself, Joe, Rebecca and Lynn to develop this document. Jeff will also contact Carl to see if he's willing to serve on this subcommittee.

Since NJ is developing a contract for third party assessors, Joe was asked about NJ's process. It is now a "procurement" process that includes vetting some requirements to be able to bid on NJ contracts, but the detailed list of qualifications for assessors to have a successful bid has yet to be developed.

We learned that the On-Site Assessment Committee (now merged with LAB) had generated guidance for the technical training of assessors, and that training is now

provided by TNI vendors. This might be useful as LAB develops phase three of our proposal to the Board.

We also noted that additional outreach to third party assessors needs to be conducted, since the first four submitted once the Contract NELAP Assessor page went up have not been joined by any others, despite conversations to assure the additional assessors that they were in fact notified in several ways.

The meeting adjourned about 12:30 pm Eastern.

NOTE added during preparation of 4/15/14 minutes and carried forward for reference --This effort by the LAB Expert Committee is a result of the Board's assignment of one of the tasks from the AB Assistance Task Force's report to us. The language of that assignment follows:

<u>Use of Third-Party Assessors (option 4 of the ABTF Report)</u>

Third-party assessors could help facilitate problems with accreditation, especially for assessments of laboratories located in states that are not NELAP-recognized ABs. Third-party assessors are already used by one-third of the states who responded to a recent survey. Third-party assessors are most often used for radiochemistry in the drinking water program and states often rely upon EPA's contract for this service. Use of third-party assessors will not work in all states because of issues including union labor and laws about use of third-party contractors to replace state employees. Simplification of the contract process for third-party assessors would help some states. Qualification or credentialing of third-party assessors would assist on many levels and should include development of minimum qualifications, verification of training and annual performance reviews.

Next Steps to Implement This Option:

- Develop a process for TNI to qualify third-party assessors.
- Develop a model solicitation template for states to use in contracting.
- Develop a process for performance review of third-party assessors that TNI qualifies.
- Develop a service for a state to contract with TNI to obtain the use of third-party assessors.

AND for reference: Phase 3 from LAB's January 8, 2013, proposal to the TNI Board:

Develop a program in TNI that provides a vetted credentialed community of Third Party Assessors (individuals and/or organizations) found qualified to conduct on-site assessments in support of NELAP Accrediting Body activities. Phase III is the most challenging to produce. The product of this phase could be of several different forms and as of yet has not been determined. It could be in the form of an SOP, an additional TNI Program or some other TNI format.

6. Next Meeting

The next meeting of the LAB Expert Committee will be Tuesday, June 17, 2014, at 11 am Eastern. A reminder will be sent the week before.

Appendix A

LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
Joseph Aiello joseph.aiello@dep.state.nj.us	12/31/2016	AB - NJ State Department of Environmental Protection	Yes
Nilda Cox nildacox@eurofinsus.com	12/31/2014	Lab –Eurofins-Eaton Analytical Inc.	Yes
Jeff Flowers, Chair jeff@flowerslabs.com	12/31/2014	Lab – Flowers Chemical Laboratories, Inc.	Yes
Myron Getman mrg05@health.state.ny.us	12/31/2014	AB – NY Department of Health	No
Chris Gunning cgunning@A2LA.org	12/31/2014	AB – A2LA	No
Virginia Hunsberger vhunsberge@pa.gov	12/31/2014	AB – PA Department of Environmental Protection	Yes
Lucrina Jones Jones.Lucrina@epa.gov	12/312016	Other EPA Region 9 Laboratory	Yes
Carl Kircher, Vice Chair carl_kircher@doh.state.fl.us	12/31/2015	AB – Florida Department of Health	Yes
Rebecca Pierrot @ALSGlobal.com	12/31/2015	Lab – ALS	Yes
Aurora Shields ashields@lawrenceks.org	12/31/2015	Lab - City of Lawrence, KS	Yes
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:	-		
Nirmela Arsem narsem@ebmud.com		Other – East Bay Municipal Utility District (San Francisco Bay area)	No
Doug Leonard dleonard@L-A-B.com		AB – Laboratory Accreditation Bureau	No
Jeff Lowry JeffL@phenova.com		Other Phenova (PTP)	No
Judy Quigley JQuigley@dep.nyc.gov		Lab – NYC DEP	Yes
Guests: none			