

**Summary of the Laboratory Accreditation Body Expert Committee Meeting
Tuesday, May 19, 2015**

1. Welcome and Roll Call

Carl opened the meeting and the roll was called. Those present are noted in Appendix A. Minutes from March 17, 2015, were re-approved. (NOTE: Lynn forgot these were already approved by email in April.)

2. Updates since the March 17 Meeting – Five Year Review of Volume 2 Modules

Since the planned April LAB meeting did not occur, there was some urgency to finalize a statement about the committee's five-year review of Modules 1 and 3 of Volume 2 of the TNI Environmental Laboratory Sector Standard, so that the Chair and Vice Chair decided to attempt an email vote on the review conclusion (as well as the March minutes, see above.)

On April 17, Nilda proposed a motion that was seconded by Aurora on April 18, stating that the LAB Expert Committee has reviewed the V2M1 and V2M3 standards and finds the contents are consistent with ISO 17011. EL-V2-2009, Modules V2M1 and V2M3 are approved by the LAB committee as suitable for continued use. Voting was initiated on April 20 and concluded with four of seven committee members voting "yes", that same day. This approved motion was transmitted to the CSDEC on April 22, and is recorded here for the permanent record within TNI.

3. Policy for the NELAP AC

As noted above, the Laboratory Accreditation Systems Executive Committee has referred one of the needed Accreditation Council policies to LAB for drafting. The policy request originated with an AC discussion and submission of a Standards Interpretation Request about whether an Accreditation Body will assess all methods or a representative sampling of methods. The wording referred from the AC is as follows:

On-site assessment – to what extent must all methods be assessed, and what level of detail is required. The AC earlier agreed to honor EPA OGWDW's request that all drinking water methods be assessed individually, but other fields of accreditation need to be addressed with at least minimum requirements. The starting resource may be the 2003 NELAC Standard, Chapter 3, Appendix C .4, and possibly information in Modules 1 and 3 of the TNI Environmental Laboratory Sector Standard (ELSS) Volume 2. (V2M3 6.3.5 is the appropriate reference for the TNI standard.)

Carl drafted language to form the basis of this policy, which was circulated before the meeting and discussed during the meeting. The original language, as proposed by Carl, is included as Appendix B of these minutes.

During discussion, participants wanted to add a reference to V2M3 §6.13.2 to the list of other references to the standard in the draft. That will be done and the revision redistributed to committee members, accompanying these minutes. Carl asked that committee members please send him any additional comments prior to the June LAB meeting, so that the draft can be offered for committee approval at that time.

Lynn noted that TNI policies typically do not include citations to the standard but rather are about operational practice. Carl declared that he is comfortable with citing the standard as the basis for policy.

4. Notice to TNI Membership about Revision of V2M1 and V2M3

Carl had also prepared and circulated a draft notification, for publication on the TNI website, which LAB is preparing to revise the AB operations modules of Volume 2, as required by the current and recently revised Standards Development SOP 2-100. After some discussion, it became obvious that the plan to offer a draft of the consolidated modules was premature, and that clause was stricken from the draft. See Appendix C, as edited. Lucrina moved and Virginia seconded to approve the revised notice, and it was approved by unanimous vote.

LAB will be the first committee to revise a standard starting with the new SOP revisions.

Participants agreed that, if the draft revision as prepared by Carl will not be distributed until additional input is received and incorporated, that it would be premature to discuss that document at the present time.

Carl thanked everyone for their time and the meeting adjourned at 11:56 am Eastern.

5. Next Meeting

The next meeting of the LAB Expert Committee is scheduled for **Tuesday, June 16, 2015, at 11:00 am Eastern.** A reminder notice will be sent the week before.

The LAB Expert Committee meeting at conference in Chicago will be on Monday morning, July 13. No teleconference line will be available.

Our membership is down to six. Requests for member applications in the TNI newsletter, at conference and to NELAP evaluators have brought no response. Current members are asked to please use their personal connections to recruit additional members to help with the increased workload due to review and revision of the standard as well as the policy and upcoming generic application issues. Lynn noted that we must have an additional member from the "other" stakeholder category before we can add anyone from either the "lab" or "AB" category.

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	No
Nilda Cox, Vice Chair nildacox@eurofinsus.com	12/31/2017	Lab – Eurofins Eaton Analytical Inc.	Yes
Virginia Hunsberger vhunsberge@pa.gov	12/31/2017	AB – PA Department of Environmental Protection	Yes
Lucrina Jones Jones.Lucrina@epa.gov	12/31/2016	Other – EPA Region 9 Laboratory	Yes
Carl Kircher, Chair carl_kircher@flhealth.gov	12/31/2015	AB – Florida Department of Health	Yes
Aurora Shields ashields@lawrenceks.org	12/31/2015	Lab – City of Lawrence, KS	No
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Jeff Flowers, Chair jeff@flowerslabs.com		Lab – Flowers Chemical Laboratories, Inc.	No
Chris Gunning cgunning@A2LA.org		AB – A2LA	No
Doug Leonard dleonard@L-A-B.com		AB – Laboratory Accreditation Bureau	No
Jeff Lowry JeffL@phenova.com		Other -- Phenova (PTP)	Yes
June Main jmain@dep.nyc.gov		Lab – NYC DEP	No
Rebecca Pierrot		LAB -- Eurofins	No
Guests: none			

Appendix B

NELAP Policy on Laboratory On-Site Assessments (Re-assessments)

The NELAP Accreditation Council (AC) highly recommends that all the accredited laboratory Fields of Accreditation be covered and addressed during the regular on-site assessments that are conducted at the accredited Conformity Assessment Body (CAB, environmental testing laboratory) every two years, plus-or-minus six months (as re-assessments).

The applicable Standard in ISO/IEC 17011 Clause 7.5.6 (and TNI V2M3, 6.3.5) says that the assessment team needs to "witness a representative number of examples." The reader should not automatically or necessarily equate "examples" with accredited test methods, to imply that not all test methods need to be covered during on-site assessments. Analytes might also be considered as "examples." Further examples that could be witnessed on a representative basis would be laboratory analysts, test reports, data packages, continuing demonstrations of capability, limits of detection and verifications, and test method standard operating procedures. Taken together, it could be that not all accredited methods will be covered during a CAB's reassessment. However, 100% of the laboratory Quality System must be addressed during the re-assessments of each accredited CAB.

This Standard also specifies "sampling (if applicable)," and there may be instances where sampling only a representative number of methods and analytes during a reassessment is not applicable. An example of this circumstance would be US EPA's expectations for a State Accreditation Body (AB) to maintain Primacy for the Safe Drinking Water Act. Laboratory client expectations, project requirements, and other factors should be taken into account.

With the Standard as currently worded, while all methods of all technologies, test methods, and analytes do not necessarily have to be assessed during the reassessment, the AB is obligated to assure the performance of the laboratory. While the Standard is not prescriptive about how that must be accomplished, the Standards are clear about what the end result must be.

V2M1, 3.7 NOTE: Assessing the competence of a CAB involves assessing the competence of the entire operations of the CAB, including the competence of its personnel, the validity of the conformity assessment methodology, and the validity of the conformity assessment results.

V2M1, 4.2.1: The ... operation of an accreditation body shall be such as to give confidence in its accreditations.

V2M1, 4.2.2: The accreditation body ... shall be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending, and withdrawing of accreditation.

V2M1, 7.7.2: The accreditation body shall establish procedures and plans for carrying out ... reassessments at sufficiently close intervals to monitor the continued fulfillment by the accredited CAB of the requirements for accreditation.

If the Accreditation Body considers that reassessments should be identical with initial assessments (rather than "similar"), then the following Standard is also applicable:

V2M3, 6.9.1: The assessment team shall conduct the assessment of the conformity assessment services of the CAB at the premises of the CAB ... to gather objective evidence that the applicable scope the CAB is competent and conforms to the relevant standard(s) and other requirements for accreditation.

If not all methods and analytes are covered during the routine reassessment, the laboratory may need reassessments at intervals more frequently than every two years plus or minus six months.

Each recognized Accreditation Body on the NELAP Accreditation Council (AC) should consider that confidence in its laboratory accreditation decisions needs to be instilled in many affected parties, inclusive of laboratory clients, officials making environmental protection and public health decisions, users of laboratory test results, the laboratory community seeking competent subcontractors, NELAP AC members granting secondary accreditations, and (last but not least) The NELAC Institute.

Appendix C

Notice of Consensus Standard Development (ELS Volume 2, Modules 1 and 3)

Pursuant to The NELAC Institute's SOP 2-100 on consensus standard development, notice is hereby given that the Laboratory Accreditation Body Expert Committee (hereinafter called Lab AB Committee) seeks to consolidate Modules 1 and 3 in Volume 2 of the Environmental Laboratory Sector (ELS) standards into one module.

Modules 1 and 3 were formerly the responsibility of two separate expert committees. However, the former On-Site Assessment Committee is now merged with the Lab AB Committee, so that the latter-named committee now has responsibility for both modules.

The existence of separate modules has created some confusion and problems for the NELAP Accreditation Bodies (ABs) that are recognized by TNI when evaluated to these standards. Overlapping requirements are found in both Modules 1 and 3, while some key requirements are found in Module 3 but not Module 1, and vice versa.

Volume 1, which is applicable to the accredited environmental testing laboratories, has benefitted from having all the quality management system requirements in ISO/IEC 17025 incorporated, in order, into Module 2. The proposed combined module for Volume 2 will thus benefit NELAB ABs by having all the ISO/IEC 17011 requirements incorporated, in order and in one place, along with the additional normative requirements added by TNI. ~~A copy of the proposed draft has been prepared and is available to all stakeholders who have paid the copyright fees and are licensed to own the TNI ELS Volume 2 standard.~~

The Lab AB Committee actively seeks input from stakeholders and stakeholder groups who may subsequently adopt this standard as accreditation bodies, be accredited to the standard, or use data from accredited entities. This Committee also has several openings for interested TNI Members to nominate themselves and be seated as voting members on the Committee.

Further information about this proposed consensus standard development may be directed to the Lab AB Committee Chair, Carl Kircher, at phone number 904-791-1574 and through e-mail to <carl.kircher@flhealth.gov>.