

**Summary of the Laboratory Accreditation Body Expert Committee Meeting
Forum on Laboratory Accreditation, Washington, DC
Thursday, August 10, 2017 9:00 am**

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Committee members present were asked to introduce themselves; attendance is recorded in Attachment 1. The minutes of June 20 were approved.

2. Status Update on Committee Activities

Carl discussed the committee's progress since conference in Houston. All comments from the public session there are included in the formal response-to-comments document, although the individual commenters are not noted, and these committee's decisions about these comments (and those from today's session as well) will be formally tracked along with the required tracking and response to comments from the voting on the later versions of our draft revised standard in accordance with the Consensus Standard Development SOP 2-100.

Carl presented the outline structure of the revisions to ISO 17011, which should be final later this year, and noted that the restructured international standard will form the basis of the revised module of Volume 2 for the TNI Environmental Laboratory Sector Standard. All ISO standards going forward will have this same standard structure. The outline for ISO 17011 is:

- Clause 1: Scope
- Clause 2: Normative References
- Clause 3: Terms and Definitions
- Clause 4: General Requirements
- Clause 5: Structural Requirements
- Clause 6: Resource Requirements
- Clause 7: Process Requirements
- Clause 8: Information Requirements
- Clause 9: Management System Requirements
- Annex A (Informative): Required Knowledge and Skills for Functions in the Accreditation Process

The new TNI V2M1 will be a combination of the TNI language from the old modules (as merged, including the earlier version of 17011), the new 17011, the outcome of issues itemized for discussion (below) plus any additional comments from within TNI, whether they arise from the solicitation of comments document (to be published, based on Attachment B) or from discussions at conference or other correspondence. He also noted that the comments from Houston were examined by the committee, but they cannot be addressed until the exact language of the final ISO 17011 is available.

Carl also explained that the delay in finalizing revisions to ISO 17011 comes from an appeal by ANSI to language about evaluating the competency of an Accreditation Body. As originally approved by CASCO, the evaluation of competency made no reference to criteria for such evaluation, and ANSI asked that the standard explicitly refer to evaluation according to ISO 17011. The process for making this change requires both approval of the change and then a final vote of approval for the revised standard.

Marlene Moore noted that she will be presenting a talk on ISO 17011 in the Thursday afternoon session about revised ISO standards. She also advised that Annex A of the revised ISO 17011 is "informative" (i.e., not mandatory) and recommended against trying to incorporate material from the Annex into the TNI standard. She explained that no one quite knows how to audit against the

information in Annex A, and that proving knowledge of all items described as needed for assessor competency in general and for specific fields of accreditation.

Carl then noted that the LAB Expert Committee has room for additional members and invited those interested to apply for membership.

3. Individual Items Considered for Inclusion in the Revised Volume 2

The discussion of the concepts itemized below was planned to focus on whether those items belong in the standard itself or whether there should be a requirement in the standard that ABs (or the NELAP Accreditation Council) have policies or processes to address the issues. It is important to note that the Non-governmental ABs (NGABs) are not bound to honor any NELAP policies, and this factor needs to be considered.

Discussion points made during this public session are noted beneath the policy statement itself. If no comments are noted, then none were made.

- Assessing all methods versus selected methods for drinking water and other fields, at initial and subsequent on-site assessments (subject of SIR 254 and policy currently before LASEC)
 - Policy is currently in development, so no need to consider adding to the standard
- How to assess different Fields of Accreditation
 - Part of policy is currently in development
- Accreditation of “prep methods” and accommodating the varied approaches by Accreditation Bodies (ABs)
 - Part of policy is currently in development
- Using technologies as the basis for PT samples and Fields of Proficiency Testing (FoPT) tables
 - This is an issue for the PT program, not for LAB committee module
- Assessing laboratory accreditation scopes by matrix/method/analyte (by governmental and nongovernmental ABs)
 - This is a substantial issue not fully addressed within the “on-site assessment” policy being developed. Also, NGABs are not bound by the drinking water program’s requirement to fully assess all methods. Request that the issue of assessing to analyte level versus technology/method level be included in “on-site assessment” policy
 - This is an industry-wide problem (such as for asbestos), and cannot be solved by the NELAP ABs
- What to do about PT requirements for scopes where there are no approved PT providers (such as Biological Tissues as a matrix and DW Asbestos)
 - This is an issue for the PT program, not for LAB committee module
- NELAP policy on AB conformance to the current V2M3, Section 6.3.5 (current ISO/IEC 17011, Clause 7.5.6)
 - Covered under responses to the first, second, third, and fifth bullets above.
- Allowance to grant interim accreditation status to laboratories
 - This issue needs to be resolved within the NELAP AC, but trying to address it in the standard is likely to bring a veto from one side or the other
- Allowance to extend deadlines in any standard through which timeframes are specified
 - Two separate issues – deadlines for AB completion of site reports and deadlines for lab responses with corrective actions
 - Should deadlines even be in the standard? They currently are. General agreement that deadlines ought not to be in a policy
 - AB deadline for site reports should more reasonably be 45 days (instead of 30)

- NELAP ABs advise not including language permitting exceptions to deadlines in the standard; at most, state that an AB can decide on a case-by-case basis if extraordinary circumstances warrant extending deadline(s)
- Requirement for the laboratory to seek NELAP Primary Accreditation in the state in which it resides, if that state has a Recognized NELAP AB for the fields of accreditation requested
 - This is currently in the NELAP Mutual Recognition Policy 3-100
 - Not all NELAP state regulations require this
 - Consider for inclusion in the standard, since it is not enforceable as part of the policy
 - Not applicable to NGABs
 - Consensus that when a lab has dual primaries (to obtain scopes not available from first primary or in-state AB), only one AB should normally perform the quality system assessment. The second primary ought only to assess the additional method(s)
 - Demand from NELAP that a lab in non-NELAP state should obtain every scope possible from a single primary, and not be allowed to pick and choose which AB for which scope
 - Agreed-upon exception is that EPA regional labs should use an AB outside of their region (to avoid conflict of interest)
- Allowance for NELAP Recognized ABs' personnel to perform accreditation functions for each other
 - Consensus was not to include this in the standard – “allowing” actions begins a slippery slope.
 - ABs currently work this out informally when needed
- Process for expanding the scope of recognition for each NELAP AB to offer as Primary Accreditation to applicant laboratories
 - This was in 2003 NELAP standard but is not currently addressed in documentation
 - ABs typically authorize themselves to expand their scopes, subject to review during the evaluation process
 - Some ABs drop items from their scope, which creates a problem for labs that then need an additional primary AB
 - Recommend that the standard include requirement for the AB to have a documented process for modifying its scope
 - Need a procedure to ensure that all possible scopes are addressed by the first primary AB as scopes shift
 - Labs need to know that they can request a scope even if it's not listed as available – some ABs will agree
- Communication policy to allow advance notice to other recognized NELAP ABs of cost increases or other changes in the AB's program
 - Should be in the standard, but ought not to reference cost increases, just other changes such as scope adjustments
 - Consider more fully in committee discussions
 - Note that the new §8.2.3 mentions “notice” but does not say to who(m)
- Policy on secondary accreditation to mobile laboratories
 - There is presently too much disagreement among ABs about how these are handled for it to be included in the standard. Danger is that it would bring a veto vote
 - Consider setting some kind of baseline for (in?) the standard
 - Discuss with TNI Field Activities Committee (which is revising its standard, too)
- Generic accreditation application form that will be used or acceptable to all recognized ABs
 - Objections to requiring this in the standard
 - Probably not even ready for a NELAP policy yet – too early in the development
 - States are handling on an individual basis

- Requirements on the content and frequency for updating information to LAMS (the National Database) on NELAP-accredited labs
 - This is in Mutual Recognition Policy 3-100
 - Not all NELAP ABs are capable of reporting FoAs to LAMS
 - Policy does not cover NGABs
- Policy on secondary accreditations (scope of accreditations)
 - Commenters recommend developing tools and writing a policy about this, but not including in the standard
- Timeframes for ABs to require of laboratories to complete corrective actions to non-conformances identified during on-site assessments
 - See also comments on timelines above
 - Maybe set a maximum time limit
 - 2009 TNI standard has no requirement that an actual CA be completed, only that a plan for one be submitted
 - The timeline should be in Volume 1, not V2. Quality Systems has this in its “parking lot” to address with next revision
 - 17011 requires a “satisfactory response”
 - Consider more fully in committee discussions
- Policy outlining qualifications and credentials needed for contract assessors or ALL AB assessors
 - Discuss fully in committee
- Scope of Accreditation definitively defined (at a minimum) as matrix-method (technology?)-analyte (or analyte group, or not at all?)
 - Issue varies in how PTs are handled among different NELAP ABs
- Minimum requirements for training courses to train and qualify assessors (and accreditation decision-makers?)
 - Former TNI On-site Assessment Committee prepared guidance for training courses

At this point, lunch was served and the session was adjourned.

4. Next Meeting

The next teleconference meeting of the LAB Expert Committee is the session at conference, scheduled for Wednesday, September 19, 2017, at 1 pm Eastern. The agenda and any documents needed will be sent by email, prior to the meeting.

Attachment A

LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
William Batschelet Batschelet.william@epa.gov	12/31/18	Other – US EPA R8, Lab QAO	Yes
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	No
Oommen Kappil okappil@emsl.com	12/31/19	Lab – EMSL Laboratories, Inc.	No
Catherine Katsikis ckatsikis@ldcfl.com	12/31/2018	Other – Laboratory Data Consultants	No
Carl Kircher, Chair carl_kircher@flhealth.gov	12/31/2018	AB – Florida Department of Health	Yes
Marlene Moore mmoore@advancedsys.com	12/31/2018	Other -- Advanced Systems, Inc., Newark, DE	Yes
Mei Beth Shepherd mbshep@sheptechserv.com	12/31/2018	Other -- Shepherd Technical Services	Yes
Aurora Shields ashields@lawrenceks.org	12/31/2018	Lab – City of Lawrence, KS	Yes
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Yumi Creason ycreason@pa.gov		AB -- Pennsylvania	No
June Main jmain@dep.nyc.gov		Lab – NYC DEP	No
Donna Ruokonen donna.ruokonen@microbac.com		Lab -- Microbac	No
Bill Ray bill_ray@williamrayllc.com		Other – William Ray Consulting, LLC	No