andSummary of the Laboratory Accreditation Body Expert Committee Meeting
Tuesday, January 24, 2017 8:00 am
Forum on Laboratory Accreditation, Houston, Texas

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting and welcomed all participants. The minutes of January 17 were approved by acclamation.

Carl noted that the committee is seeking another member from the Accreditation Body stakeholder community, and once that person is identified, additional members from any stakeholder group will be welcome. There are presently six open full member positions on this committee.

2. Discussion of Revising Volume 2 of the TNI Environmental Laboratory Sector Standard

Carl explained that this committee now has formal approval to begin revisions to Volume 2 of the TNI standard, now that the 2016 revision has been finalized and accepted as an ANSI standard. He noted that Module 2 has been revised by the PT Expert Committee and is not within LAB's purview.

Unofficially, the committee has been busy preparing a combined single draft from Modules 1 and 3 of the 2009 standard, and Carl distributed a handout with just the TNI-added language of that draft combined module (but without the ISO language.) He explained that the single underlined language was from the original Module 3, moved into Module 1 (M1 being the basis for this combination); double underlined text is newly added and text proposed for removal is shown in strikeout. The handout also included "parking lot" issues from the previous revision plus a listing of comments received at conference in August, 2016.

Carl also discussed the status of CASCO's updating of ISO/IEC 17011, which is expected to be final in May or June of this year. There was general agreement among participants, matching the committee members' earlier consensus, that the LAB's revision should align with and incorporate the new structure and language of ISO 17011. With these changes, the new Volume 2 should be able to be adopted and implemented in time for the next cycle of evaluations (beginning 2020.) This is possible because Accreditation Body (AB) operations are not in regulation, so that the operations are much easier to implement than the laboratory standard, as played out when the 2009 standard was adopted.

Carl has participated in the ANSI group that provides the US representative to CASCO for revising 17011, and thus has the now-draft language available. It aligns closely with the language being developed (on a different timeline) for ISO/IEC 17025, which will take additional months to become final. He noted the following conceptual changes expected for 17011:

- Adding "remote assessments"
- Adding psychometrics for assessor personalities and assessor competence
- Re-ordering and re-numbering sections to align with other standards
- Adding management requirements in a new §9
- Adding a concept of "risk-based" operations – ensuring the impartiality of assessments
- Omitting the concept of "preventive actions" but focusing on improvements.

- Carl also asked if ABs need an update to their operations now. Aaren Alger, chair of the NELAP Accreditation Council, noted that there is a 3-year cycle for AB evaluations but a 2-year cycle for laboratory assessments. She asked that LAB consider what might constitute "surveillance" (with the new remote assessment concept, but keeping the shorter-than 5-year cycle that's permitted in 17011) and that LAB consider shifting to a 3-year cycle for reassessments. One commenter inquired about the potential variability within a 3-year cycle, and suggested plus/minus 30 days, versus the current 6 months allowed with the 2-year cycle.

Carl invited all participants to become associate members of LAB, to help with this revision of Volume 2.

3. Specific Comments on the Draft Combined Module and Future Language

The following specific comments were offered by participants:

- §7.8.3.4 – for the TNI additional language, the "may" clause seems superfluous and thus the last sentence should be dropped, or else state that the AB may require documentation that the corrective action was implemented at any future time

- §7.8.3.5 – FOIA laws override this clause for governmental ABs, but non-governmental ABs are not subject to FOIA. Consider setting a 30-day limit for lab review

- Regarding risk-based thinking – is a 3-year cycle for reassessment riskier than 2 years? There is no time restriction on a surveillance audit based on suspicion, but governmental ABs may not be in the agency/department receiving the data, and not all data collected under the standard are submitted to regulatory agencies

- The 30-day deadline for the lab to deliver the corrective action report and the 30-day deadline for the AB to issue the on-site assessment report should be lengthened. Another commenter noted that the 30 days applies to submission of a plan for corrective actions, but there is no limit on the time to implement those actions. Participants discussed that the early version of the TNI standard did not include timelines, and that perhaps those should go into policy or SOP, rather than the standard. The revised 17011 permits an AB to specify its own timeframes. Another concern would be that the non-governmental ABs might not follow a NELAP SOP for this. One suggestion was to lengthen the timeline to 45 days.

- In the expected 17011 revisions, any findings different from those discussed during the assessment's exit briefing must be explained.

- §7.8.3.4 – should be reworded but no suggestions about how.

- Need to review Volume 2 for lab requirements and get those moved into the quality systems module of Volume 1. The removal from V2 cannot occur until the requirements are in V1, however. The options of a supplement to V1 or some sort of guidance document for labs, about lab requirements in V2 were considered.

- The status of the PT module in V2 (V2M2) needs to be clarified, since the 2016 standard does include the revised PT module in V2. Brief discussion occurred about whether secondary accreditation is still mentioned in V2M2.

- §7.15 – this section of V2M1 needs review, concerning PTs. The Standards Review Council should review it along with V2M2 (note sent to Ken Jackson), and this section

should have a new “note” added, that V2M2 should be consulted for additional PT requirements.

- All 17011 references will need to be verified and updated during this revision process.

4. Parking Lot issues

Comments on these items from the handout follow.

- About remote assessments – by the new 17011 definition, TNI standard should specify “electronic means.”
- Labs without electronic records are not easy to assess with remote assessment. It’s really only viable with cloud storage of information.
- Individual ABs would need to have procedures for ways to perform assessments and report findings whether done on-site or remotely.
- Consider possible use of a webcam for assessing laboratory equipment.
- If people want to cheat, they can do so with remote assessments.
- A strong recommendation was made for NOT using remote assessment for a lab’s initial assessment.
- The assessor would miss incidental or accidental findings with remote assessments, but the remote option would be useful for states where labs are physically remote (either long travel times or out of the country.)
- General consensus formed that using remote assessments for familiar labs would be easily done.
- One AB discussed how, when a lab requested additional scope at the last minute, the assessment team was able to accommodate the request by adding an additional assessor (qualified for that scope) through videoconferencing.
- Treating all labs the same (impartiality) becomes more important when there are remote options. This could be a good way to monitor assessors, observing them “in-house.”
- Participants were unsure whether reasons for suspension were addressed in the PT module. The new 17011 uses terminology of “suspended”, “withdrawn” and “reduced.” Participants noted that even a voluntary request for suspension needs established “rules.”
- §7.13.4.2.8 – perhaps this section should be reworded. What if a lab fails to submit corrective action, or if findings are extreme upon completion of the assessment? (The term from clinical labs is “immediate jeopardy.”) How should this differ from other specifics? One suggestion was “failure to conform to the AB’s procedures for assessment”; another was to add a series of bullets here.

5. Additional Issues

- Should the standard include a requirement to report into LAMS? Participants noted that ABs are equally regulated by NELAP SOPs and policies, but there is no mechanism for requiring non-governmental ABs to use LAMS. (Ed. Note – what about their contracts

with TNI for recognition?) Should LAMS be named specifically or should a more generic reference be used in the standard?

- In addition to the AB reporting into the database (however named), the AB should be required to notify labs of publication of their information and status in the database.

- Frequency of reporting should be every 2 weeks or whenever there are changes.

- Several new concepts will be introduced in the new 17011:
    - accreditation cycle (still no longer than 5 years, per 17011) – the cycle begins on or after the date of assessment. Definition of accreditation cycle will need to be developed.
    - assessment program – for each applicant, an AB must develop an assessment plan for that lab. The accreditation program for a lab must be determined and documented, but there is no requirement for a "universal" aassessment program. Some labs may require more frequent assessments. The assessment plan is for the site assessment while the assessment program ensures that all of the lab is covered during the 5-year accreditation cycle "taking risk into consideration."

- Commenters noted that if TNI's accreditation cycle were to be extended to three years (the maximum permitted by EPA's drinking water program) there would still need to have "something" done at the two-year mark. Reviewing PTs might count as "surveillance" for that purpose. Otherwise, three years between full assessments would satisfy the ISO 17011 requirement as well as the drinking water program, but there could be no additional 6-months window as exists now with a 2-year cycle.

- ABs will need to identify and address risks to impartiality, and the language of the standard will need to address impartiality and "risk-based thinking." It might be necessary to define "top management," also. For instance, when the accreditor is in the same department as the data user, risk exists. Also, allowing a lab to choose its assessor is a risk – perhaps this could be mitigated by requiring that different assessors be chosen so that the same assessor does not perform consecutive assessments.

- §3.20 – there is no note in the ISO language, although the handout seems to indicate one – this needs verification.

- §5.9 – section "e" from the ISO language should be on a separate line.

- §5.9.1 – make certain that disputes are covered somewhere else in the standard? Or else establish that dispute is covered under the more general term, "complaint."

- Ken Jackson, Program Administrator for the Consensus Standards Development Program, gave a brief discussion about the revised Consensus Standards Development SOP 2-100 and noted that a webinar on that SOP is being planned. Two important changes are that LASEC will be involved at the beginning of the development of a new or revised standard, rather than at the end, and the Standards Review Council will review the first draft of the Voting Draft Standard stage, rather than waiting until the final standard is approved.

6. Next Meeting

The next teleconference meeting of the LAB Expert Committee is scheduled for **Tuesday, February 21, 2017, at 1:00 pm Eastern.** A reminder notice will be sent the week before.

Appendix 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	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	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	Yes
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	No
Aurora Shields ashields@lawrenceks.org	12/31/2018	Lab – City of Lawrence, KS	No
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Nishant Bhatambrekar Nishant1.Bhatambrekar@ge.com	12/31/2018	Lab -- GE- Power & Water Engineering	No
Yumi Creason ycreason@pa.gov		AB -- Pennsylvania	Yes
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