Summary of the Laboratory Accreditation Body Expert Committee Meeting

Tuesday, May 21, 2019

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The minutes of April 16, 2019, were approved.

2. Agenda for Jacksonville Conference

The LAB session in Jacksonville is scheduled for Thursday morning, August 8. Participants agreed on the following agenda:

Welcome and Roll call
Approval of Minutes
Consideration of Comments Received on the Outline of Proposed Changes and the Draft Revised V2M1
Adjourn

3. Status of Publication of the Draft Revised Module for Comment

The "Request for Comments on a Draft Revision of the 2009 TNI Environmental Sector Standard Volume 2 Module 1, General Requirements for Accreditation Bodies Accrediting Environmental Laboratories" was posted as a news item on the TNI home page on April 17. The comment period closes on June 16.

4. Review of Accumulated Comments

Comments received at all previous public sessions have been recorded in a Response-to-Comments spreadsheet, just as the formal comments on the published draft are being recorded. As previously agreed, all comments will be reviewed and addressed, although for the public sessions, the identity of commenters was not recorded.

This meeting was devoted to review of comments received during the public session in Houston, in January 2017. The comments and the final decisions on how to handle them are in Attachment 2, below.

5. Next Meeting

The next teleconference meeting will be **Tuesday, June 18, 2019, at 1:00 pm Eastern.** An agenda and documents will be distributed prior to the meeting. The primary agenda item will be to begin reviewing comments collected from all public sessions over the past several years.

Attachment 1

LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
William Batschelet Batschelet.william@epa.gov	12/31/2021 (2nd term)	Other – US EPA R8, Lab QAO	Yes
Nilda Cox nildacox@eurofinsus.com	12/31/2021 (1st term)	Lab – Eurofins Eaton Analytical LLC	No
Charles Hartke Charles.hartke@sgs.com	12/31/2020 (1st term)	Lab – SGS Accutest, Dayton, NY	No
Oommen Kappil okappil@emsl.com	12/31/2019 (1st term)	Lab – EMSL Laboratories, Inc.	No
Catherine Katsikis catherinekatsikis@gmail.com	12/31/2021 (2nd term)	Other – Laboratory Data Consultants	No
Carl Kircher, Chair carl_kircher@flhealth.gov	12/31/2021 (3rd term, extended)	AB – Florida Department of Health	Yes
Marlene Moore mmoore@advancedsys.com	12/31/2021 (2nd term)	Other – Advanced Systems, Inc., Newark, DE	No
Zaneta Popovska zpopovska@anab.org	12/31/2021 (1st term)	Other – ANAB	No
Alia Rauf arauf@utah.gov	12/31/2020 (1st term)	AB – Utah Department of Health	Yes
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com	12/31/2021 (2nd term)	Other – Shepherd Technical Services	No
Nicholas Slawson nslawson@a2la.org	12/31/2021 (1st term)	AB – A2LA	Yes
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Yumi Creason ycreason@pa.gov		AB – Pennsylvania	Yes
June Main jmain@dep.nyc.gov		Lab – NYC DEP	No
Bill Ray bill_ray@williamrayllc.com		Other – William Ray Consulting, LLC	No
Aurora Shields Aurora.Shields@kcmo.org		Lab – Kansas City, MO	No
Ilona Taunton Ilona.taunton@nelac-institute.org		Other – TNI Program Administrator	No

Attachment 2

No.	Vote	Section / clause	Comment	Committee action	Date comment considered	Committee comment -- these comments are from the initial discussion, 4/18/17, prior to shift to 2017 revision of ISO/IEC 17011, and do not reflect the final decision, which is noted under "committee action"	Submitter
1	N/A		Commenter 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.	the term surveillance is now obsolete	5/21/2019	anticipated change to require that each lab be provided with a custom "accreditation cycle" seems likely to make this issue obsolete	Aaren Alger
2	N/A		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.	draft published for comments retained the 2 years ± 6 months, which accommodates current practice and regulations	5/21/2019	anticipated change to require that each lab be provided with a custom "accreditation cycle" seems likely to make this issue obsolete	
3	N/A	§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	made the proposed edit to the draft V2M1, prior to shift to 2017 version of 17011, and transferred the normative language ("shall") into the published draft	3/21/2017	Participants agreed that “may” is inappropriate in the standard, but believe that the last sentence of this section should be converted to a note, and become “Note #1” placed ahead of the existing note.	N/A
4	N/A	§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	paradigm shift in ISO 17011:2017 addressed this	5/21/2019	Keep this section for now, with expectation to delete it when transferring to the new 17011, as it appears that §8.1.1 – 8.1.4 will address the issue with ISO language	N/A

5	N/A		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	retained the 2 yrs ± 6 months. 3 years is considered to present higher risk	5/21/2019	Await wording of new ISO language concerning accreditation cycles, and then consider whether two years plus/minus 6 months is riskier than three years (plus/minus one month?) In current V2M1, this would be language in §7.11.3.1. As it stands now, the AB might have to do an additional site visit if the cycle is lengthened to three years, but with "customized" assessment programs (new 17011, §7.9) there may be other possibilities.	N/A
6	N/A		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	§7.6.6.b.1 retained the 30 day timeframe in the published draft	5/21/2019	it appears that the revised ISO 17011 will permit an AB to specify its own timeframes	N/A
7	N/A		In the expected 17011 revisions, any findings different from those discussed during the assessment's exit briefing must be explained.	§7.6.6.c (ISO language) addresses this	5/21/2019	it appears that the revised ISO 17011 will make this a requirement	N/A
8	N/A	§7.8.3.4	should be reworded but no	see comment #3	5/21/2019	addressed in #3 above	N/A

			suggestions about how				
9	N/A		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.	These requirements are in §4.2, and also 4.3 and 4.4 (ensuring that labs are impartial)	5/21/2019	this section, or what remains of it, will be in §4.2 of the revised 17011. When that is available, LAB will need to address this issue somehow. There may be a holdover lab requirement in V2M2 (PT module) -- should check with PT Expert Committee eventually.	N/A
10	N/A		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.	not something LAB can control	4/18/2017	resolution will be done by CSDEC and TNI's Executive Director	N/A
11	N/A		§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.	the language is not in ISO 17011:2017, but PT is considered an "assessment technique". V2M2 addresses the AB's requirements	5/21/2019	it appears that this language will not exist in the revised 17011	N/A
12	N/A		All 17011 references will need to be verified and updated during this revision process.	done prior to publication of draft	5/21/2019	when the revised language is available, this will be addressed	N/A
13	N/A	"parking lot" issue - remote assessments	About remote assessments – by the new 17011 definition, TNI standard should specify “electronic means.”	this is included in the definition of remote assessment (ISO §3.26)	5/21/2019	cannot be addressed until new 17011 language is available	N/A
14	N/A	"parking lot" issue - remote assessments	Labs without electronic records are not easy to assess with remote assessment. It’s really only viable with cloud storage of information.	it is up to the AB to determine whether remote assessments will be used	5/21/2019	cannot be addressed until new 17011 language is available	N/A
15	N/A	"parking lot" issue - remote	Individual ABs would need to have procedures for ways to perform assessments and report findings	ISO clause 7 addresses this	5/21/2019	cannot be addressed until new 17011 language is available	N/A

		assessments	whether done on-site or remotely.				
16	N/A	"parking lot" issue - remote assessments	Consider possible use of a webcam for assessing laboratory equipment.	it is up to the AB to determine whether remote assessments will be used	5/21/2019	cannot be addressed until new 17011 language is available	N/A
17	N/A		If people want to cheat, they can do so with remote assessments.	no action, but see §7.2.4 & 7.11.2	5/21/2019		N/A
18	N/A		A strong recommendation was made for NOT using remote assessment for a lab's initial assessment.	clause 7 appears to require an on-site assessment	5/21/2019		N/A
19	N/A		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.)	comment noted, but decision up to the AB	5/21/2019		N/A
20	N/A		General consensus formed that using remote assessments for familiar labs would be easily done.	comment noted, but decision up to the AB. §7.9.3 is relevant	5/21/2019		N/A
21	N/A		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	so long as this is allowed by the AB's documented procedures, it would be okay, but note that an immediate request could not have been covered in the required assessment plan for the lab	5/21/2019		N/A
22	N/A		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."	observation noted	5/21/2019		N/A

23	N/A		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."	PT is not mentioned in ISO 17011 but is addressed in V2M2	5/21/2019		N/A
24&25	N/A	§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.	addressed in §7.11.1.2 and 7.11.1.2.8 of ISO 17011 language	5/21/2019		N/A
26	N/A		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?	This was already addressed in V2M1	5/21/2019		N/A
27	N/A		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.	this is not in the 2009 standard modules, and was not added	5/21/2019		N/A
28	N/A		Frequency of reporting should be every 2 weeks or whenever there are changes	this is not in the 2009 standard modules, and was not added	5/21/2019		N/A

29	N/A		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.	the 2 years ± 6 months accreditation cycle was retained	5/21/2019		N/A
30	N/A		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.	observation noted. §4.4 and especially 4.4.7 addresses impartiality and the ISO language seems adequate for the purpose of addressing this risk	5/21/2019		N/A
31	N/A	§3.20	there is no note in the ISO language, although the handout seems to indicate one – this needs verification.	the old language was about suspending or withdrawing accreditation; related definitions in ISO 17011:2017 address it	5/21/2019		N/A
32	N/A	§5.9	section "e" from the ISO language should be on a separate line.	this was fixed	5/21/2019		N/A

33	N/A	§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.”	disputes are not addressed in the standard, so that ISO did not see a need to address "dispute" separately from complaint. No action taken, since presumably "complaint" encompasses dispute. The NELAP Dispute Resolution SOP pertains only to the evaluation and recognition of ABs, which is not addressed in the standard	5/21/2019		N/A
34	N/A		Consider whether and how enforcement actions should be required in the standard and whether/how they should become part of the evaluation process	this is covered in §7.11	5/21/2019		