Summary of the Laboratory Accreditation Body Expert Committee Meeting
National Environmental Monitoring Conference, Thursday, August 8, 2019

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting and welcomed the audience. Attendance is recorded in Attachment 1. The minutes of July 19 were approved unanimously.

2. Discussion of Comments on Outline of Proposed Changes and Draft of V2M1

Carl explained that the committee would discuss the comments in the order of the draft document, but with the comments expected to be controversial in the first part of the session (before break) and then moving to the less controversial comments after the break. Time did not permit all comments in either category to be discussed. The conclusions of the discussion are summarized in the table in Attachment 2, below.

One new comment from participants concerned training for assessors. One AB requested that the standard specify requirements for training of assessors, and perhaps for qualifications of assessors, as well, somewhat similar to the Technical Director qualification language being discussed in Quality Systems. These specifications should also take into consideration the requirements of the Drinking Water Certification Manual. Another AB noted that states set qualifications for hiring, but at least one state could not require a bachelor's degree because that is not in the standard, and while state regulations would override the standard, they may not apply to third party assessors. Aaren Alger agreed to submit draft language for committee consideration.

There was also brief discussion of whether confidentiality is addressed (yes, in the ISO language), and about the requirement for "public review" of documents (§4.6.2) and also "public perception" (§4.4.6) in the section on accreditation schemes (rulemaking processes satisfy those requirements).

3. Next Meeting

The next teleconference meeting will be **Tuesday, September 17, 2019, at 1:00 pm Eastern.** An agenda and documents will be distributed prior to the meeting.

LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
William Batschelet Batschelet.william@epa.gov	12/31/2021 (2nd term)	Other – Retired from US EPA R8	yes
Nilda Cox nildacox@eurofinsus.com	12/31/2021 (1st term)	Lab – Eurofins Eaton Analytical LLC	Yes
Charles Hartke Charles.hartke@sgs.com	12/31/2020 (1st term)	Lab – SGS Accutest, Dayton, NY	Yes
Catherine Katsikis catherinekatsikis@gmail.com	12/31/2021 (2nd term)	Other – Laboratory Data Consultants	Yes
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	Yes
Zaneta Popovska zpopovska@anab.org	12/31/2021 (1st term)	Other – ANAB	Yes
Alia Rauf arauf@utah.gov	12/31/2020 (1st term)	AB – Utah Department of Health	No
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com	12/31/2021 (2nd term)	Other – Shepherd Technical Services	Yes
Nicholas Slawson nslawson@a2la.org	12/31/2021 (1st term)	AB – A2LA	No
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Yumi Creason ycreason@pa.gov		AB – Pennsylvania	No
Scott Haas shaas@etilab.com		Lab -- Environmental Testing, Inc., and Chair, FAC	No
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 – KC Water	No
Ilona Taunton Ilona.taunton@nelac-institute.org		Other – TNI Program Administrator	No

Attachment 2 – Comments Received from Posting of Outline and Draft, with Summary of Discussion

Comments Submitted on the outline of proposed changes and the draft module V2M1 April 17-June 16, 2019

Disclaimer: The NELAC Institute (TNI) accepts no liability for the content of any comment on a standard. Any views or opinions on a standard are solely those of the commenter and do not necessarily reflect those of TNI.

	Section/clause	Comment	Committee action	Committee comment
1		The **Introduction** to ISO/.IEC 17011 is not all stated. At least the following needs to be added to Volume 2: "In this document, the following verbal forms are used: — “shall” indicates a requirement;— “should” indicates a recommendation;— “may” indicates a permission;— “can” indicates a possibility or a capability."	address in private session	put in §1 and include the term "must"
2		The wording from ISO/IEC 17011:2017 **Scope** is not included in this version of the Volume 2. “This document specifies requirements for the competence, consistent operation and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies."	ISO language cannot be omitted	change title also
3	normative references	**Normative References**: Remove the note for ISO 9000:2015 since this is not listed in either 17011 and 17025. Please add the correct title for the VIM in Note 2 as used in 17025:2017. This must be a normative reference that is used by the AB and listed as it is in ISO/IEC 17025 2017. So add this reference to the standard.	fix the title and change to "latest edition"	okay to remove ISO 9000 reference
4	3.4	**3.4 Conformity assessment body**: Note 2 and 3 must use the input from the task force related to field activities. These two notes seem to contradict each other. These notes must be place in 7.4.4 for Volume 2.		agree that notes 2&3 do not belong. Keep only the first sentence of Note 2 there. Consider relocating other text

151	3.6	The definition of Fields of Accreditation in section 3.6 and again in Section 7.8.3.d. For the purposes of accreditation, why are we using “technology”? A Field of Proficiency Testing is based on Technology, however, a field of accreditation is not. The accreditations granted by the ABs are based on methods, so to add technology here seems to be incorrect.	retain technology, keep language as is	
168	3.7	Flexible scope of accreditation. This definition needs a note with regard to NELAP accreditations, or preferably a statement that flexible scopes of accreditation are not applicable. (My notes indicate that “not applicable” was the conclusion in the Milwaukee discussion.) If we determine that this is an applicable option, we need a comment expressing the limitations determined by the AC and other interested parties to this consensus standard. (And these limitations will need discussion with input from all ABs.)	add note saying this is Not applicable to TNI	
####	3.26	Revised comment: Would like to see a note with clear requirements on what constitutes a remote assessment and what can and can't be reviewed remotely and include requirements on the number of remote assessments that can be performed without having an acutral onsite assessment. Original comment: I would like to see clear requirements on what constitutes a remote assessment and what can and can't be reviewed remotely and include requirements for an actual on site assessment on predefined time periods.	no change to §3.26. Sections 7.6.1, 7.6.2, 7.6.6.a, 7.9 & 7.3 address the issue	

####	4.2 (first sentence)	I will need to discuss further with management and MDH legal on the terms "legally enforceable" and how that will work for our program.	no response needed	it is up to the accreditation body to figure out how to comply
169	4.2.a	"… This includes agreement to adapt to changes in the requirements for accreditation." The former TNI Standard / ISO language stated this: "… This includes agreement to adapt to changes in the requirements for accreditation, as set out in 8.2.4." This revision excludes the reference to 8.2.4 but the requirements of 8.2.3 and 8.2.4 (regarding notifications of changes to requirements with stakeholder input) are still in the ISO language. Omission of the reference to those other sections in this section may be problematic (how can an AB require a lab to "agree to adapt to changes in the requirements for accreditation" if those changes have not yet gone through public comment?). I suggest a note that clarifies that an AB demonstrating compliance with 8.2.3 and 8.2.4 is meeting this requirement, otherwise I am concerned this might be a legal / regulatory stumbling block for some states, even though the requirement is still being met.	no note needed	the standard must be read as a whole. It is not possible to cross-reference every detail.
####	4.2.e	Revised comment: Can a note be added to clarify this requirement as I have no idea what it is saying? Original comment: What does 4.2 e) mean?	no note needed	the AB must have access, even if it's a mobile lab on a client site. If no access, there can be no accreditation
146	4.4.12	**4.4.12 Note 3** should not be numbered that is-- with Note no number	this will be fixed	

152	6.4.6 note 3	**6.4.6 Note 3** Is an incorrect statement of outsourcing, Outsourcing is following the management system of your own organization not another system. You can contract with a person or with a company to follow the ABs management system - this is an internal resource.		(this is out of order, need to return to it)
147	4.4.14	**4.4.14** "The accreditation body also shall require accredited CAB's to maintain impartiality and integrity. [from V2M1, 4.3.3.1] " This is a CAB requirement that must be in Volume 1 not Volume 2.	delete this language and renumber subsequent sections	the AB has to do this anyway, but the CAB requirement should go in Volume 1
166		**There are a few areas where I am not sure how the ABs would carry out a particular requirement. Without knowing how to enforce it, I'm not sure why it would be included in the standard. Specifically:**		
166	4.4.14	4.4.14. How would an AB require accredited laboratories to maintain impartiality and integrity?	from comment number 147, "delete this language and renumber subsequent sections"	
170	4.4.14	AB shall "require CABs to maintain impartiality and integrity." [TNI Language]. This needs to be removed. It's a requirement of labs (which means it does not belong in Volume 2) and it's covered in Volume 1 by data integrity / ethics requirements. Other than verifying the data integrity / ethics requirements are being met, and that complaints are being addressed appropriately, ABs really do not have any other means to "require" [detect / monitor / evaluate] this, even if it stays in the standard.	from comment number 147, "delete this language and renumber subsequent sections"	
167	4.4.15	4.4.15. I'm not sure why this statement is in the standard. What is the value added?	remove it	might be old language that didn't get deleted

158	V2M3, 6.12.1	FOLLOW-UP REQUEST FROM SIDERS WITH SPECIFIC LANGUAGE: V2M3, 6.12.4The CAB shall provide to the accreditation body a plan of corrective action to address findings in the assessment report within thirty calendar days from its receipt. The accreditation body shall present to the CAB within thirty calendar days a response to the plan of corrective actions. The CAB shall then provide the accreditation a revised second plan of corrective action to address any corrective action deemed by the accreditation body to be unacceptable within thirty calendar days from its receipt. The accreditation body shall present to the CAB within thirty calendar days a response to the revised second plan of corrective actions. If the revised second plan of corrective action is deemed not acceptable then the accreditation body shall make a decision within 30 calendar days regarding suspension or reducing of the CAB's accreditation, in whole or part. Failure by the accreditation body to achieve the requirements within 6.12.4 shall require the accreditation body to take corrective action and inform without undue delay the CAB of the actions being taken to address the non-conformity.	add to §7.6.9 as normative language	TX stated that it needs 45 days for corrective action review but the labs get only 30 days. Other ABs say that sometimes the corrective actions are "dreadful" and take much longer than 30 days to review. Also, state laws govern suspension and revocation timelines and those would override the standard anyway. Some site reports have critical findings, different than repeat findings
161	7.6.6.b	Section 7.6.6.b – I would suggest adding language about what must be included in an assessment report by the AB. This will help ensure consistency in recordkeeping/reporting and assist with the Secondary accreditation of NELAP accredited laboratories. For example, add requirements for structure or content of the report to include:	discuss in expert committee the final details and add specifics to the language	the next assessment team needs to know what was assessed. All drinking water methods must be assessed (per EPA). Prep method assessment information is needed in the site report for secondary accreditation purposes (where prep methods are not accredited separately)
		Assessment Date(s)		

		Laboratory Name and Physical Address		
		Laboratory ID number (as assigned by the AB)		
		Applicable Matrices		
		Applicable Methods, including preparation methods when separate or different from the analytical method		
		Key Laboratory Personnel at the time of the assessment (such as technical manager, QA officer, etc.)		perhaps this is not mandaatory, possibly just list personnel interviewed instead
162	7.6.6.b.1	Sections 7.6.6.b.1 and 7.7.5.1.11 include the word “on-site” was this intentional? Most other places in the standard the term is “assessment” not “on-site assessment”.	if remote assessment is possible or applicable, then "on-site" should not remain	eliminate "on-site" in 7.6.6.6.1, 7.7.5.1.8 7.7.5.1.11 & 7.7.5.1.5. Keep in 7.7.5.1.10. SEARCH THROUGHOUT DOCUMENT FOR TERM "on-site" AND CHANGE AS NECESSARY
		The PA-DEP has an Environmental Hearing Board that handles all appeals, the Laboratory Accreditation Program does not manage them in any way. All decisions are made by the court. To say that the AB is required to be responsible for the decisions at all levels (Section 7.13.3) is impossible and a violation of the PA laws.		
####	7.6.6.b.2	ADD a requirement. All ABs should be required to communicate deficiencies in the issued reports in terms of what requirement from the standard was not met. Although we may “assume” an AB will always provide the specific citation to the Standard, which has not been met, we need to clearly communicate this expectation to all ABs.	include in list of mandatory inclusions for report contents (comment 161)	a question arose whether the report can cite to a method. Answer is to cite the regulation/method along with the requirement of the standard to comply with the method

####	7.6.6.a	The obligation to provide nonconformities in writing at a meeting at the end of the assessment is impractical. If the meeting is conducted during the onsite assessment, assessors do not generally have access to printing equipment. In addition, it will extend the time required to conduct the assessment because the nonconformities will have to either be typed or hand-written prior to the meeting. This is an unnecessary additional cost to the lab and burden on the AB. Assessors do provide the nonconformities verbally to the laboratory during the meeting. There is no advantage to providing the nonconformances in writing as the nonconformities are preliminary until a review has occurred offsite. The laboratory is provided the final nonconformances in writing upon issuance of the final report. If this requirement remains, ABs will be forced to either invest in portable printing equipment and increase the time/cost of assessments or conduct the meetings remotely, which does not improve the assessment process.	discuss further in committee, likely will need additional TNI language	most prefer that all reports should be issued by the AB, not by the assessor. Okay to leave the draft report. | One committee member argues that the closing meeting should not occur until all SOPs and data packages are reviewed, which likely would mean a teleconference closing meeting -- the closing meeting should happen when all findings can be discussed. This would require calling the meeting at the end of the assessment/on-site by some other name. | At least one AB currently reviews site reports AFTER the assessor has delivered it to the lab (FL), since the report is sent to lab and AB simultaneously. || Need to define "end of assessment" -- end of site visit or closing conference? PA requests removal of "authorized representative" language and insists that only the AB can issue a report. | An amended report would reset the clock from when the "authorized rep" delivered the report (for lab response time). | Sometimes the SOP in use will not be what was submitted, which requires additional review time after the assessment itself

####	7.6.6.b.1	The issuance of the assessment report within 30 days in not always feasible. If accreditation is being revoked/denied as a result of the onsite assessment report, the report may have to be reviewed by the AB's legal department. This review time is outside the control of the AB and generally causes the final report date to be greater than 30 days. There needs to be some flexibility in the 30-day requirement.	failure to meet the 30 days would require corrective action upon internal audit; add a requirement that the AB must notify the lab if the report will be delayed beyond 30 days.	extended discussion: if cannot meet 30 day time, document the exception and the extenuating circumstance causing it, and notify the lab of delay (before 30 days is up). Remove "on-site" term.
####	7.6.6.c	The AB is required to provide the laboratory an explanation if the outcome of the assessment in bullet "b" differs from the outcome delivered at the meeting in bullet "a". However, it is unclear what is meant by "outcome" of the assessment. Is this referring to findings/nonconformities or an overall outcome of the assessment? Bullet "a" states that the assessment team shall report on the findings identified and detail any nonconformances. Bullet "b" requires a written report on the outcome of the assessment and identifies nonconformities as one of the items the report shall contain. If the intent is that ABs must provide an explanation for any finding/nonconformances that changed from the exit meeting, this is going to cause unnecessary work for assessors. This should only apply if the findings/nonconformances identified in the exit meeting are not identified as preliminary. If the nonconformances are identified as preliminary, the purpose of the review process is to ensure that the preliminary findings are accurate. There should not be an expectation from the laboratory that the findings are final, and thus no need for an explanation of the differences.	no clarity attained -- need additional discussion in committee.	What is the "outcome" -- is it the assessment findings or the recommendation for accreditation? The assessment is a gathering of objective evidence. Note that after "c", outcome is used as a definitive action. Need to clarify what the expectations are. Any new or additional nonconformance must be explained in writing. Recommend to make the language normative