Summary of the Laboratory Accreditation Body Expert Committee Meeting Tuesday, February 18, 2020 1:00 pm Eastern

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The minutes of January 21 were approved. The committee believed that the minutes of February 5 (the conference session) did not accurately reflect either the discussion with the Drinking Water program representative and that it omitted a discussion of basic assessor training; those minutes were returned for revision.

2. New Member Application

A new member application was received from Aaren Alger. As an "other" stakeholder, her addition will not alter the committee's lack of dominance by any one stakeholder category. Nilda moved and Bill seconded that her membership be approved, and the vote was unanimous; her membership was been approved by the Chair of the Consensus Standards Development Executive Committee, the following day.

3. Election of Vice Chair

At the January meeting, Mei Beth was absent and we did now know whether she would be willing to continue in the Vice Chair position. At this meeting, she stated that she was willing to continue as Vice Chair but that she was open to being replaced in that position if the committee wished. No other nominations were offered. Catherine moved and Nilda seconded that Mei Beth be reelected as Vice Chair, and approval was unanimous.

Continued Discussion of Comments on Outline of Proposed Changes and Draft of V2M1

Comments that were discussed during the LAB session at conference were reviewed for consensus approval and discussion of revised language where necessary. Any changes agreed upon during this February 18 meeting are noted and highlighted in Attachment 2, below.

The discussion ended in the midst of item 181, §7.6.6.b.

Next Meeting

The next teleconference meeting will be <u>Tuesday</u>, <u>March 17</u>, <u>2020</u>, <u>at 1:00 pm Eastern</u>. An agenda and documents will be distributed prior to the meeting.

Attachment 1

LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
Aaren Alger Aaren.s.alger@gmail.com	12/31/2022	Other – Alger Consulting & Training	No
Socorro Baldonado sbaldonado@mwdh2o.com	12/31/2022 (1 st term)	Lab – Metropolitan Water District, La Verne, CA	Yes
William Batschelet Batschelet.william@epa.gov	12/31/2021 (2 nd term)	Other – Retired from US EPA R8	Yes
Nilda Cox nildacox@eurofinsus.com	12/31/2021 (1 st term)	Lab – Eurofins Eaton Analytical LLC	Yes
Catherine Katsikis catherinekatsikis@gmail.com	12/31/2021 (2 nd term)	Other – Laboratory Data Consultants	Yes
Carl Kircher, Chair carl_kircher@flhealth.gov	12/31/2021 (3 rd term, extended)	AB – Florida Department of Health	Yes
Marlene Moore mmoore@advancedsys.com	12/31/2021 (2 nd term)	Other – Advanced Systems, Inc., Newark, DE	No
Michael Perry michael.perry@lvvwd.com	12/31/2022 (1 st term)	Lab – Southern Nevada Water Authority	No
Zaneta Popovska zpopovska@anab.org	12/31/2021 (1st term)	AB – ANAB	Yes
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 (2 nd term)	Other – Shepherd Technical Services	Yes
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
Scott Haas shaas@etilab.com		Lab – Environmental Testing, Inc., and Chair, FAC	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 <u>Ilona.taunton@nelac-institute.org</u>		Other – TNI Program Administrator	No

Attachment 2

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

		Section/ clause	Comment	Committee action	Committee comment
ММ	2/14/2019	4.3.4	1. Section 4.3.4 we should add some TNI language. Each recognized AB must use the symbol as authorized by TNI. I think there is a TNI policy that can be referenced or copied into this section.	Add language stating that "each recognized AB must use the symbol as authorized by TNI" to either clause 4.3.6 or 4.3.3.1 Additional language is not needed	Policy 1-103 addresses this. Use of the accredited lab symbol should be addressed in Volume 1 as part of the accreditation scheme.
148		4.6.6	4.6.6 Add a statement to explain regulatory requirements and the TNI Environmental Laboratory Sector Scheme. Such as:' The accreditation body must assess the requirements of the TNI EL Volume 1 standard and the regulatory requirements of the state and federal programs such as drinking water, wastewater, RCRA and other environmental programs.'	include air and possibly TSCA when defining the scheme for NELAP. Note that "scheme" has replaced "scope of accreditation". Add the proposed language from Marlene with air and TSCA included: "The accreditation body must assess the requirements of the TNI EL Volume 1 standard and the regulatory requirements of the state and federal programs such as drinking water, wastewater, RCRA and other environmental programs." Make no change, there is no additional language to add.	email comment from Marlene, 10/15/19 "Item 148: 4.6.6 Add a statement to explain regulatory requirements and the TNI Environmental Laboratory Sector Scheme. Such as:' The accreditation body must assess the requirements of the TNI EL Volume 1 standard and the regulatory requirements of the state and federal programs such as drinking water, wastewater, RCRA and other environmental programs.' COMMENT: We need to define the scheme of the TNI standard. That is why we must add the references applicable to the requirements of the AB. We may also want to add TNI PT program and TNI NEFAP and SSAS as other schemes the may be referenced by the AB." RECONSIDER IN DISCUSSION OF 7.4 OR 7.6

153	7.4.2 note	7.4.2 Note: Change this to a requirement 'notification is not required for unannounced assessments.' The current note does not forgo the requirement to notify the CAB.	add to 7.4.2.1: "The AB need not notify the CAB of the names of the assessment team for unannounced assessments" and delete the first sentence in the note.	change was made to the draft VDS
·›	6.1.2.9.1	Due to the requirement in the 2009 standard, ABs may have assessors that have not worked in an environmental laboratory. They were deemed to have commensurate experience through performance of verified assessments as required in the standard. The new requirement that the assessor must have worked in an environmental laboratory will cause some assessors currently working for ABs to no longer be qualified. In addition, assessors are hired into state classification positions that have specific minimum requirements. These requirements do not include working in an environmental laboratory. As a result, this requirement would contradict state position classifications.	add language about grandfathering for new ABs, similar to what is used for technical managers in newly accredited labs. Language about the requirement of work in an environmental lab was removed.	Grandfather language would not be adequate, since it would not address new hires, so will not be added.

?	6.1.2.9.4	Section 6.1.2.9.4 – Why would an assessor need to sign a qualification statement? And what is the value of providing signatures and a qualification statement to a lab? The standard outlines the specific requirements that each assessor must have, and the AB is responsible for qualifying their assessors. So, a signature by an assessor is irrelevant and unnecessary. Also, the requirement for an AB to provide these specific statements seems unnecessary. I would suggest that the standard be changed to say that the AB must maintain records of the qualifications (and possibly approvals) of its assessors. A requirement to provide anything related to assessor qualifications to the lab just seems unnecessary to me. However, if someone really thinks providing evidence of qualifications to a lab is necessary, then I think it should be done differently than a "qualification statement".	1-21-20 delete this clause; section 6.3 (ISO language) addresses the issue. Deletion made.	at conference, deletion affirmed.
	6.1.2.9.2 note	holdover from previous discussion	no further action. Remove the 1st note.	still no agreement on whether to specify the 5 modules or the way the testing is broken out in the 2009 standard

143	2	FOLLOW-UP REQUEST FROM XXXX WITH SPECIFIC LANGUAGE: V2M1, 7.5.2 ISO/IEC 17011:2004(E), Clause 7.9.2 The accreditation body shall, without undue delay, make the decision on whether to grant or extend accreditation on the basis of an evaluation of all information received (see 7.8.6) and any other relevant information. The accreditation body shall make the decision on whether to grant or extend accreditation to a CAB within sixty (60) calendar days from receipt of the application for accreditation. Failure by the accreditation body to make the decision within the required sixty calendar days shall require the accreditation body to take corrective action and inform the CAB of the actions being taken to address the non- conformity.	see item 3 in February 5, 2020, minutes. New clause 9.5 addresses this issue	new language needs to be created to address this entire section of comments
143	V2M3, 6.12.1	FOLLOW-UP REQUEST FROM XXXX WITH SPECIFIC LANGUAGE: V2M3, 6.12.1, The accreditation body or its authorized representative shall present to the CAB within thirty calendar days of the last day of the on-site assessment a final assessment report identifying all confirmed findings. Failure by the accreditation body to present a final assessment report to the CAB within required thirty calendar days 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.	ditto	

157		Volume 2 (Modules 2 and 3) of the present 2009 TNI Standard does not appear to address the ongoing performance of accreditation bodies between the three-year evaluation cycles. Especially, the ABs ongoing ability to meet two key requirements and obligations to a CAB presently found in V2M2 and V2M3. That is,	ditto	
157		AB shall complete the assessment of the final evaluation report within sixty (60) days of receipt of each study report and determine the accreditation status for any field of accreditation for which Not-acceptable evaluations were assigned for the corresponding FoPT.	not relevant	
157	V2M3, 6.12.1	 V2M3, 6.12.1, The accreditation body or its authorized representative shall present to the CAB within thirty calendar days of the last day of the on-site assessment a final assessment report identifying all confirmed findings. 	not relevant	
157		While the above two requirements for an AB pale in comparison to the numerous and correctly required obligations of CABs to an AB they are however critically vital to the laboratory accreditation process and afford the CAB with some degree of expectations for performance and accountability from an AB (State or NGAB). Extensive delays or an AB's systematic inability to meet these requirements can and does have negative impacts and consequences for any NELAP Accredited CAB that finds themselves dealing with an AB that is unable to consistently fulfil these two fundamental requirements.		the items mentioned relate to the PT module, over which LAB has no control whatsoever

158	V2M3, 6.12.1	FOLLOW-UP REQUEST FROM SIDERS WITH SPECIFIC LANGUAGE: V2M3, 6.12.4 The 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 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.	ditto	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:	List of required assessment report contents drafted & added as clause 7.6.6(b)(2)	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)	time ended before this discussion could be completed	
		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 mandatory, possibly just list personnel interviewed instead
	7.13.3	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.	add section 7.13.3.1 to read "A governmental regulatory body following its due process is considered to meet this requirement."	

#REF!		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 handwritten 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 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
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#R	EF!	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, 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	New clause drafted & added as 7.6.6(c)(1)	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

				differences.	
				7.4.2 This is not a note. It	
MN	1	2/14/2019	7.4.2 note	must be a statement required for conformance by	pending resolution
				the AB/ Last sentence: "should" (formerly used) is better language. I recommend	
				moving the last sentence to a NOTE and keeping the	
				"should", don't make it a "must". Or, delete the	
?			7.6.4.1	statement in its entirety. The issue is that sometimes	pending resolution
				there's ONLY one way to be compliant with a	F 5
				requirement, and if an assessor tries to be helpful and explain that ONE way,	
				we don't want an issue to be brought against the assessor	
				for wrongdoing based on this wording.	

120	7.4.2.1	preferred language would be "ABs are allowed to conduct" and the text about "initial assessments shall be announced" conflicts with at least one AB's regulations (either PA or VA, notes are unclear) and must be removed. The Chair requested proposed wording for both the note and normative language; the issue was not resolved in the session.		pending resolution
125	7.6.6.b	there was a clear desire to allow exceptions to the 30 day "for good cause" or to consider changing it to accommodate holidays (perhaps 30 business days?) – proposed language was that the "AB may extend the time on request due to unforeseen circumstances. Another participant requested adding language about communicating delays and the reason for them, between the lab and the AB.	see discussion in item 3 of February 5, 2020, minutes	
126	7.6.7.1	The proposed deleted language about report sharing brought comments that TX needs it but it violates PA and FL law/regulations. ABs may need to share for purposes of mutual recognition but there may also be other reasons. ABs might be satisfied with exception language, saying "unless superseded by state regulations". (Aaren Alger agreed to submit draft language.) Also, a cross-reference with §8.1 may provide adequate exception.		still requires resolution

MM	2/14/2019	6.2.9.2	6.2.9.2 = Allows each AB to create its own training course(s). This includes the NGABs. The original NELAC standard required the training to be the same among all ABs. Do we want to have the same training for all ABs?(2) similar training, or (3) an approve TNI course(s) or (4) anyone create a basic assessor class and the technical training classes without oversight?	unresolved	Marlene noted that her Basic Assessor Training course was the original standard for AB assessors but when the NELAC standard shifted to ISO 17025, the concept shifted and ABs now do not have standardized training. One AB participant noted that the Drinking Water Certification Officer course is not "assessor training" even though it is sometimes used as such. Another AB noted that flexibility and accessibility for training are important to ABs training should be consistently offered or else "on-demand" and available to all ABs. Yet another AB was content to leave the language as is. Another party noted that TNI's training program does have the potential to meet this need, and asked that there be some time delay written into the standard to allow for expansions of TNI's training to address assessor needs
ММ	2/14/2019	6.1.3.3	6.1.3.3 and other sections in part 6.1.3 require the AB to define training and qualifications for all staff performing accreditation activities. Do we want to list accreditation activities along with the qualifications and training needed to perform each function of the AB. Such as (1) PT review,(2) decisions on accreditation, (3) reviewing/issuing reports/ (4) reviewing and acceptance of CABs corrective actions if not done by the assessor, (5) scheduling assessment (6) others	this will become a "parking lot" issue for the next revision	

ММ	2/14/2019	7.8.3	Reword 7.8.3: "NOTE: In the context of this Volume in TNI's Environmental Laboratory Sector standards, only ISO/IEC 17011 clause 7.8.3(d) below is applicable".	make this edit universally. Alternatively, refer to the TNI ELS standard in the context of Volume 2 TNI ELS only clauses	
ММ	2/14/2019	7.8.3.e	Clause 7.8.3(e) is applicable to Volume 4 in this Sector. (I am not sure we should indicate which section is applicable to other program)	leave as is for now	
ММ	6/3/2019	7.11.1	7.11.1 deficiencies is no longer used. The correct term is non-conformity. Change the word in this section and do a word search for deficiencies and remove this term. Confuses the CABS.	this was done already by Carl	
ММ	6/26/19	Items 35, 36, 37, 38, 40 & 42 in DC comments worksheet	discuss and write a requirement including these elements, rather than deferring to the assessment plan "It must be in the standard to provide information to the ABs and ensure consistency among the ABs. It does not need to be percriptive but must provide the necessary records or procedures to be addressed by the AB. Volume 2 is part of the program - so if you change this to program then it is correct and should be in Volume 2"	requires resolution	unable to identify the referenced comments in the conference session
ММ	6/26/19	item 41	This is with in the AB program - in order to ensure consistency the standard	V2M2 addresses this	
ММ	6/26/19	item 43	I do not think we should add interim accreditation to the standard now since the process has matured from a federal/state program. The action should be the committee must vote to not include interim accreditation in the standard	there will no longer be reference to interim accreditations in the standard although states may still offer it	

ММ	6/26/19	item 44	Deadlined for labs and ABs must be included in the standard to ensure consistency. There is always an allowed for a lab or AB to not meet the deadline, but this delay must be due to a limited timeframe (new program manager, change to regulation, other changes etc)	addressed in discussion summarized in item 3 of February 5, 2020, minutes	
ММ	6/26/19	item 45	Primary and secondary accreditation must be included in the standard to ensure all state treat primary and secondary the same way. We should include the practince in the standard and not let it be free welling	primary and secondary are used in V2M2. For V2M1, just delete the term primary in the clause 7.6 note	
ММ	6/26/19	item 46	Who agreed to this (how many on the committee agreed? This should be presented in the table. I would like to see this in the standard and indicate assessors can be shared as long as they are deemed competent by the individuals primary AB	unresolved	there is nothing in the standard now about "shared" assessors; there needs to be some assurance to the sharing AB that assessors are competent.
ММ	6/26/19	items 49&52	Volume 2 must include information about secondary as well as primary to avoid any confusion by the labs. The actions by the Task force is not to resolve primary and secondary but about field activities accreditation by NELAP ad NEFAP.	resolved above by deletion of term "primary" in V2M1 7.6 note	
ММ	6/26/19	item 50	The standard has requirements of what are mandatory to be in the application. Other information that states or NGABs require can be added, but the standard must indicate the minimum amount of information	Requirements are in ISO language; the added note to 7.2.1 indicates that ABs may require additional information	

ММ	6/26/19	item 51	Even if not all ABs are making entries into LAMS a system must be part of the ABs program since Vol 2 requires a directory or other means to late a lab and others know who is accredited by the state, We must not avoid this item just because the ABs can't do something. The committee should review the policy and see if it addresses all the concerns and make a general requirement in the standard that reflect the policy.	LAMS is not mentioned in Volume 2. All ABs have listings of accredited labs on their websites	
ММ	6/26/19	item 54	We must ensure the language for the credentials of assessors is clear. What other groups are discussing this? Is a member from LAB in those groups? Are NGABs represented?	not addressed	
ММ	6/26/19	item 55	Is this FOPT fields or Fields of accreditation? The field of accreditation or scope of accreditation requires consistent definition within TNI (matrix, technology/method. analyte) Volume 2 must address these terms and ensure all ABs use the same scope	not addressed	
ММ	6/26/19	item 56	We must address what is needed for technical training-Some ABs use the 2033 standard for their requirements others do not Since i have a conflict of interest in this matter the committee must help to reosolve the wording in the 2009 standard	not addressed	
ММ	12/5/2019	7.6.6.c	How long after the closing meeting must the AB provide additional Nonconformities? Draft Language now reads in 7.6.6.c item 1: (1) If additional noncorformities are identified after the on-site portion of the assessment is concluded, these nonconformities shall be communicated to the laboratory in writing.	not addressed	

ММ	12/5/2019	Where is the definition for finding? (It was in V1 M2 are we using the same definition?) The new glossary does not include finding. The definition for finding that was in the standard indicated this was to be a non conformance to the standard. The definition for finding is not presented in the glossary TNI published last week.	not addressed	Ed until the glossary is included in the standard itself, ABs will not be able to rely upon those definitions, per the NELAP AC
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