

Summary of the Laboratory Accreditation Body Expert Committee Meeting
Tuesday, June 15, 2021 1:00 pm Eastern

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The meeting agenda (Attachment 2) was modified to add a discussion about the agenda for the LAB session at conference, and then approved by acclamation. The minutes of May 18 were approved unanimously.

2. Agenda for Conference Session

The LAB session will be on Monday morning, August 2, as part of the hybrid conference week. The time will be 9 am PDT until noon PDT (so, starting at noon Eastern), with a mid-morning break. Participants agreed to the following agenda:

Welcome and Roll Call
Approval of Agenda
Approval of July minutes
Discussion of Select Comments on V2M1 Draft Standard
New Business
Adjourn

Carl plans to travel to Bellevue, but Mei Beth and Lynn will participate remotely. Carl intends to identify comments from the most problematic or controversial sections of the Draft Standard – assessor training, timelines and possibly other areas – to present for discussion during the session. Other committee members registered for conference may participate either in person or remotely, depending on their arrangements.

As with previous virtual conference sessions, all participating committee members and associates will be able to speak, as well as participants in the room (both committee members and audience), and someone will be assigned to read comments from the WebEx “chat” as part of the meeting. The chat comments will be captured for further consideration at later committee meetings, as well.

3. Continued Consideration of Comments on Draft Standard V2M1

A complete spreadsheet of all comments submitted, sorted in sequential order to align with the Draft Standard, was distributed to committee members, and this spreadsheet will be where the formal record of how comments were addressed. The portions of the spreadsheet addressed at each meeting will be included as an attachment to the minutes in addition to being recorded in the permanent spreadsheet. This spreadsheet is based on the template provided in the Standards Development SOP 2-100. (See Attachment 3, below.)

As the details of the vote on whether or not a comment is persuasive and how it should be addressed if persuasive are not needed for commenters or the public to consider the actual outcome of the discussion for each comment, those details are not included in the formal Response to Comments spreadsheet, but will be noted in the minutes for the meeting(s) where comments are addressed. NOTE: the comment numbers in the table below refer back to the order of submission, so that when the spreadsheet is sorted by comment number, all comments from each submitter will be clustered, but for addressing the comments, it works best to follow the sequence of the standard itself.

<u>Comment Number</u>	<u>Section Number</u>	<u>Proposed Decision</u>	<u>Motion Made</u>	<u>Motion Seconded</u>	<u>Vote</u>
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		(P/NP/editorial as determined)			
45/77/83/86	4.4.11	All persuasive, add note using wording suggested in comment #83	Mei Beth	Alia	unanimous
46	4.4.12.a	Persuasive	Mei Beth	Nilda	Unanimous
9	4.4.12.d	Persuasive	Bill	Nilda	Unanimous
10	4.4.13	Non-persuasive	Mei Beth	Bill	Unanimous
74	4.4.3	Non-persuasive	Bill	Alia	Unanimous
32	4.4.5	Persuasive/editorial	Mei Beth	Nilda	Unanimous
75	4.4.5	Non-persuasive	Mei Beth	Alia	Unanimous
8	4.4.9	Non-persuasive	Mei Beth	Nilda	Unanimous
11	6.1.2.8	Non-persuasive	Mei Beth	Bill	Unanimous
16	6.1.3.2.b	Persuasive	Mei Beth	Zaneta	Unanimous

Comment numbers 11, 12, 29, 35, 47, 48, 49, 50, 72, 78, 79 and 82 all pertain to assessor training in section 6.1.2.9. Consideration of these comments was postponed so that they can all be reviewed at one time. Mei Beth volunteered to consolidate them for ease of review, and will have this consolidation available for the July meeting.

3. New Business

No new business was offered. Bill moved and Nilda seconded that the meeting be adjourned at 2:15 pm.

4. Next Meeting

The next teleconference meeting will be **Tuesday, July 20, 2021, at 1:00 pm Eastern.** 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	1/30/2023	Other – Alger Consulting & Training	No
Socorro Baldonado sbaldonado@mwdh2o.com	1/30/2023 (1 st term)	Lab – Metropolitan Water District, La Verne, CA	Yes
William Batschelet wbatsche@aol.com	1/30/2022 (2 nd term)	Other – Retired from US EPA R8	Yes
Nilda Cox nildacox@eurofinsus.com	1/30/2022 (1 st term)	Lab – Eurofins Eaton Analytical LLC	Yes
Catherine Katsikis catherinekatsikis@gmail.com	1/30/2022 (2 nd term)	Other – Laboratory Data Consultants	No
Carl Kircher, Chair carl_kircher@flhealth.gov	1/30/2022 (3 rd term, extended)	AB – Florida Department of Health	Yes
Marlene Moore mmoore@advancedsys.com	1/30/2022 (2 nd term)	Other – Advanced Systems, Inc., Newark, DE	No
Michael Perry michael.perry@lvvwd.com	1/30/2023 (1 st term)	Lab – Southern Nevada Water Authority	No
Zaneta Popovska zpopovska@anab.org	1/30/2022 (1st term)	AB – ANAB	Yes
Alia Rauf arauf@utah.gov	1/30/2021 (1st term)	AB – Utah Department of Health	Yes
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com	1/30/2022 (2 nd term)	Other – Shepherd Technical Services	Yes
Nicholas Slawson nslawson@a2la.org	1/30/2022 (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	Yes
Scott Haas shaas@etilab.com		Lab – Environmental Testing, Inc., and Chair, FAC	No
Sviatlana Haubner Sviatlana.Haubner@cincinnati-oh.gov		LAB – Cincinnati Metropolitan Sewer District	No
Paul Junio paulj@nslab.com		LAB – Northern Lake Services	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 – LAB Expert Committee Meeting Agenda, June 15, 2021

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (May minutes attached)
- *ADDED PRIOR TO APPROVAL*: Agenda for Conference Session
- Continue Review of Comments on Draft Standard (comments spreadsheet sorted sequentially and cleaned-up Draft Standard attached)
- New Business, if any
- Adjourn

Attachment 3 – Committee Decisions on Comments for June 15, 2021

Title -- V2M1 comments on Draft Standard, 12/1/2020 thru 3/30/2021

Comment Number	Vote & Justification (Persuasive/non-persuasive)	Editorial (Y/N)	Section/Clause	Comment	Committee Action	Date Addressed	Committee Comment
45	P		4.4.11	<p>4.4.11 This is new ISO language. Its requirement cannot always be met if it conflicts with the establishment in state regulation of a state as an accrediting body within the same division as the state laboratory (or other listed service, such as provider of proficiency testing). ISO language does not over-rule state regulatory requirements. This could be a cause for veto from one or more state ABs, since many ABs are situated within government structures that include testing, or, in one case, providing proficiency testing. Suggested solution: A NOTE is needed that exempts states from this requirement if state structure is established in conflict with the ISO language. (Note: numerous impartiality requirements in 4.4 still apply to these ABs and these ABs will need to demonstrate risks for impartiality have been identified and managed.) Suggested language (formatted from note already existing in 4.4.12): NOTE: An accreditation body and related bodies within a Government department or entity might provide</p>	<p>This is one of 4 comments on this section. All are persuasive. Language suggested in comment 83 was deemed the best language to add to the Draft Standard.</p>	6/15/2021	

				conformity assessment activities as directed by Government.			
77	P		4.4.11	<p><i>TNI V2M1 section 4.4.11</i> <i>The accreditation body and any part of the same legal entity shall not offer or provide any service that affects its impartiality, such as: a) those conformity assessment activities covered by accreditation which include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification; b) consultancy....</i> <u>Comments:</u> The laboratory accreditation program like most programs are under federal approval in environmental testing for public health concerns which may provide services to the citizens of the state</p>	<p>This is one of 4 comments on this section. All are persuasive. Language suggested in comment 83 was deemed the best language to add to the Draft Standard.</p>	6/15/2021	

				<p>that involve personnel in testing, inspections and or processes and services. Suggest note to be added: <u>Suggested language</u>: “Note: Governmental bodies in which are associated with public health may require personnel to be indirectly or directly involved with testing, inspections and/or other processes or services for the health and safety of their citizens.”</p>			
83	P		4.4.11	<p>4.4.11 This is new ISO language. Its requirement cannot be met as it conflicts with the establishment in state regulation of this state as an accrediting body within the same division as the state laboratory. ISO language does not over-rule state regulatory requirements. This could be a cause for major concern from one or more state ABs, since many ABs are situated within government structures that include testing, especially in situations where they are located in Health Departments. Suggested solution: A NOTE is needed. Suggested Edit (formatted from note already existing in 4.4.12): NOTE: An accreditation body and related bodies within a Government department or entity might provide conformity assessment activities as directed by Government. In such cases, the accreditation body must</p>	<p>This is one of 4 comments on this section. All are persuasive. Language suggested in this comment (83) was deemed the best language to add to the Draft Standard.</p>	6/15/2021	

				have effective measures to manage impartiality risks.			
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86	P		<p>4.4.11.a</p> <p>Section 4.4.11.a: The requirement that the conformity assessment activities such as testing not be offered by the accreditation body nor any part of the same legal entity is not appropriate for all government agencies. Typically, the testing services and accreditation services are both performed by the same government agency. As such, state Accreditation Bodies (ABs) that reside in an agency that also has a laboratory could not conform to this standard. Additionally, if Section 4.4.12 was intended to apply to state ABs, it would not apply as they are not “linked” to a body undertaking testing, but rather are a part of the same legal entity. Therefore, only Section 4.4.11.a would apply. We suggest adding a note in Section 4.4.11.a that governmental entities that also perform testing are considered to meet this requirement if effective mechanisms to prevent any influence on the outcome of any accreditation activity are employed. Section 4.4.11.a: The requirement that the conformity assessment activities such as testing not be offered by the accreditation body nor any part of the same legal entity is not appropriate for all government agencies. Typically, the testing services and accreditation services are both performed by the same government agency. As such, state Accreditation Bodies (ABs) that reside in an agency that also has a laboratory could not conform to this standard. Additionally, if Section 4.4.12 was intended to apply</p>	<p>This is one of 4 comments on this section. All are persuasive. Language suggested in comment 83 was deemed the best language to add to the Draft Standard.</p>	6/15/2021	
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				<p>to state ABs, it would not apply as they are not “linked” to a body undertaking testing, but rather are a part of the same legal entity. Therefore, only Section 4.4.11.a would apply. We suggest adding a note in Section 4.4.11.a that governmental entities that also perform testing are considered to meet this requirement if effective mechanisms to prevent any influence on the outcome of any accreditation activity are employed.</p>			
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46	P		4.4.12.a	<p>4.4.12.a This is not new ISO language but is language conveying a requirement that cannot always be met in state agencies when the regulation specifies the duties and structure of an agency. Different “top management” is not always possible. Suggested solution: A NOTE is needed that exempts states from this requirement if state structure is established in conflict with the ISO language. (Note: numerous impartiality requirements in 4.4 still apply to these ABs and these ABs will need to demonstrate risks for impartiality have been identified and managed). Suggested language (formatted to match note already existing in 4.4.12): NOTE: An accreditation body and related bodies within a Government department or entity might not have different top management. [Section 4.4.12 would now have NOTE 1 and NOTE 2.]</p>	add note as suggested	6/15/2021	
9	P		4.4.12.d	<p>4.4.12 d) Note – This Note is in direct conflict with 4.4.12 c. Comment 1 – a Note is note enforceable. Comment 2 – this Note, even if made an enforceable non-Note, creates a direct conflict wherein the Standard says that if the AB offers the services in 4.4.11, it shall have a different name, logo and symbol, by saying that they ‘might not’ have a different name, logo and/or symbol. You can’t do that. The Note and the statement contained therein must be removed or the Standard is in conflict with itself and must be rejected.</p>	remove this note but keep the new note added from comment #46 above	6/15/2021	

10	NP		4.4.13	4.4.13 uses the term 'scheme owner'. This term also appears in a note to a definition (3.33). Please define this term, as it is unclear what it means.		6/15/2021	definition can be found at www.iso.org with browser search for PUB100439.pdf , not needed here
74	NP		4.4.3	TNI V2M1 section 4.4.3 " <i>It shall document and make public an impartiality policy which includes the importance of impartiality in carrying out its accreditation activities, managing conflict of interest, and ensuring objectivity of its accreditation activities.</i> " <u>Comments:</u> This language requires the accrediting authority to publish its standard operations which is usually internal for laboratories under V1M2. States do have ethics laws publicly available in which they are to conduct themselves impartially, and all state employees are held to uphold. Suggested language would eliminate the need to publication such specific operational procedures but if requested will be supplied. <u>Suggested language:</u> "Note: Governmental bodies are under the authority of state's regulation for publish ethical rules of conduct which are available."		6/15/2021	language already exists in state law or regulation and applies to all state employees, so the information is already public.
32	P	x	4.4.5	4.4.5, 6.3, 7.6.2: These clauses refer to "ISO/IEC 17011:2017(F)." I suspect "F" is a typo that should be "E."	edit made	6/15/2021	

75	NP		4.4.5	<p><i>TNI V2M1 4.4.5 The accreditation body shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating. <u>Comments:</u> Governmental bodies are required to involve public comments and governed through public councils and boards which may not be able to safeguard balanced representation. A note should be included for this clarification. The state Oklahoma has public comment through a council and board which may not be balanced through the selection of representatives appointed by legislative bodies. <u>Suggested language:</u> "Note: Governmental bodies involved in public participation, comments through public meetings, councils, and boards may not have balanced representation in a specific program through regulations that appoint representation."</i></p>	The fact that rulemaking comments can be submitted by everyone covers the need for "balance". This section does not require that every single group involved in the process be balanced.	6/15/2021	
8	NP		4.4.9	4.4.9 – It seems that this section on impartiality is addressed toward the AB. It should be made clear that this is a reflection on the AB and THEIR impartiality, resulting in the AB not being impartial and thus not be able to offer accreditation.		6/15/2021	this module is entirely devoted to ABs so the desired outcome is already obvious.

11	NP		6.1.2.6	6.1.2.6 Note 2 has been stricken. Is it the intent of the Standard to eliminate the ability of an assessor to communicate through a translator or interpreter?		6/15/2021	The standard is silent on the use of translators or interpreters, thus their use is allowed.
16	P		6.1.3.2.b	6.1.3.2 b) Note states "...allowing the assessor to conduct some parts of the assessment independently". Comment – Notes aren't enforceable, so if this is presumably clarification an making this allowance, it is in direct conflict with 6.1.3.2.1, which requires that "Before an assessor is allowed to perform unsupervised assessments for an accreditation body, the assessor shall have performed a minimum number of assessments under the supervision of an assessor whose competence has been qualified by the accreditation body." If you intend to set the minimum number of unsupervised assessments to zero by allowing unsupervised assessments as in the note in 6.1.3.2 b, then delete 6.1.3.2.1. I suggest that the note in 6.1.3.2.1 b be deleted.	the note will be removed.	6/15/2021	