Notes from the Laboratory Accreditation Body Expert Committee Session Forum on Laboratory Accreditation, Jacksonville, Florida Wednesday, February 5, 2025 8:00 am Eastern

Aaren welcomed everyone to this meeting. The presentation she used is being distributed with these notes, and will at some point be available as part of the online conference proceedings. Several committee members were also present, and are invited to add their thoughts to these notes.

Aaren reviewed the changes that were presented at the Environmental Monitoring Conference in California during August, 2024. Those changes will not be revisited in these notes, as there was no further discussion about them.

This revised document has been updated with information from notes taken by both Millie and Amy, who were present for the session.

Notes from Discussion of Substantive Comments Still to be Addressed

- §4.2 As this section is about lab requirements, it should be either moved or duplicated in Volume 1. One commenter noted that the same language ought not to be in both volumes, and the consensus was to discuss with QMS Expert Committee moving the language into V1M2.
- §4.4.5 about an AB required to have an "provide opportunity for effective involvement by interested parties for safeguarding impartiality." Some states have an advisory committee that would meet this requirement, but all states use some form of "notice and comment" for administrative rulemaking processes, which would seem to also meet the requirement. NGAB input is needed before making any final decision. Need to ensure that all ABs will be able to comply with this requirement.
- §4.4.4 All state employees are bound by state ethics laws and regulations. Discussion brought in how to handle conflicts of interest, with the point made that a potential conflict does not necessarily rule out attending to any individual's input.
- §4.4.6 risk management. Aaren asked that every AB read this section carefully, and some concerns were expressed about whether governmental agencies could meet this requirement. No resolution was reached.
- §4.6.1 do ABs know what an accreditation scheme is? Is it the 2016 Standard or is it how labs are assessed, and does a lab have multiple accreditation schemes? Is the ISO definition sufficiently clear (§3.8 of Draft V2M1, "rules and processes relating to the accreditation (3.1) of conformity assessment bodies to which the same requirements apply" with a note that scheme requirements are any of the many ISO/IEC standards). Can "scheme" be replaced with "SOPs and policies"? Ensure that Note 2 gets added back in.
- §6.2.2.1 is the first item, "have no interests at play" necessary and if so, is it sufficiently clear? The following list of ethical requirements may be sufficient. Not all potential conflicts of interest rule out an individual's involvement, but they should all be declared.
- §6.2.3.1 "unreasonable" and "adequate" are not enforceable terms, but all agreed that it is important to protect both the lab and the assessor from assessments forced to fit into a timeframe that does not allow for thorough assessment. This may be a point of cost competition, if an insufficient number of assessors or too little time are set by the AB, but the standard cannot set a rigid timeframe, either. Perhaps benchmarks or guidelines could be included in a note, or the AB could be required to have documented procedure(s) for determining the appropriate timeframe and number of assessors. The consensus was that the term "reasonable" should be eliminated with the concept replaced with a requirement for guidelines (to be stated in the standard), and that those guidelines should perhaps include a discussion

between the AB and the laboratory about what is "reasonable". Phrasing such as time to complete a thorough assessments taking into account the scope of the assessment, # of assessors the size of the CAB and the number of nonconformances identified in previous assessment *OR* complete the assessment using resources proportional to the scope of lab and the volume of its work was suggested.

§7.2.5 – governmental ABs are required to provide compliance assistance, so distinguishing that from consultancy (service for payment or advice to ensure compliance) will be important. For instance, a "practice on-site" would be considered consultancy if the lab is charged for it, and many NGABs do offer consultancy under their umbrella of services. Consultancy is defined in §3.34, with three examples, and the suggestion was made that replacing the third example might be helpful. Several NELAP ABs noted that they provide videos for compliance assistance purposes, and were concerned that those might be considered "consultancy". Another question asked about conflict of interest if an assessor provides consultancy services – it's not a conflict of interest if the assessor does not assess labs for which consultancy was provided (separate client bases). Should the definition of "consultancy" (§3.34) be modified to better characterize what is acceptable and what is not?

One comment noted that for §4.4.11, the Note should become a requirement (about an AB accrediting a lab that's part of its same organization).

§7.4.3 – about the AB giving assignments to assessment teams – does this requirement need additional clarification? Should the standard specify what the assignments must address, or should that be left to the discretion of the AB? Should we require that the assignment(s) be documented?

§7.4.5 – the use of the term "sample" in this clause is obviously different than a sample for analysis, but the question was raised about whether the Standard should address EPA's insistence that all drinking water methods must be assessed as a condition of granting state primacy (for certification/accreditation of labs). There was no support for mentioning EPA or drinking water specifically. However, consensus was that the AB should be required to document how it defines "appropriate sampling" and the language from 2016 V2M3 6.3.5 was offered as relevant and useful for this purpose.

§7.11.1.1 – multiple individuals commented that setting a 6 month limit on suspensions is "pointless", but one AB found it helpful in getting management agreement to enforce compliance and another liked the idea of giving a lab time to correct its issues. Others noted that it's far simpler to lift a suspension than to re-accredit the lab. The only resolution offered was suspension for six months or until the end of the period of accreditation; several ABs would be disadvantaged it the six month timeframe were removed. Perhaps require that the AB have a policy about time limits for suspensions, rather than mandating a limit in the standard, since there was definitely not a consensus on retaining this requirement.

Notes from Discussion of ISO Text Proposed for Deletion

 $\S 3.7$ – no objection.

 $\S4.3$ – no objection.

<u>§4.5</u> – a proposal for now, comment not voted, suggestion of a note to state the governmental agencies rely on their budget office for this function, but possibly NGABs need this?

§7.8.3 – keep only 7.8.3.d, as other types of labs are not within the TNI community.

§9.7 – delete all but first sentence of 9.7.3; add 9.7.3.1 to clarify that remote assessments cannot be done for initial assessments at any time, or for renewal assessments unless a governmental emergency order is in effect, and also 9.7.3.2 to clarify that assessments must be performed every 2 years plus/minus 6 months and that while some portions of the reassessment may be done off-site, the personnel interviews, witnessing, and equipment verifications must be done on-site.

Closing Remarks

Aaren noted that the committee's struggle to attain a quorum at its meetings continues. The use of email votes for comments was suggested, but when the voters were not present for discussion, they are not well-equipped to decide on the persuasiveness of some comments. One option is to move the fixed meeting date – this will be a discussion item at the next teleconference meeting.

Aaren expressed her desire to complete the review of comments prior to the St. Louis meeting in August 2025, and then she thanked everyone for participating.

Attachment 1 LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
Aaren Alger, Chair	1/30/2026	Other – Alger Consulting & Training	
Aaren.s.alger@gmail.com	(2nd term)		
Socorro Baldonado	1/30/2026	Lab – Metropolitan Water District, La	
sbaldonado@mwdh2o.com	(2nd term)	Verne, CA	
Sviatlana Haubner	1/30/2025	LAB – Cincinnati Metropolitan Sewer	
Sviatlana.Haubner@cincinnati-oh.gov	(1 st term)	District	
	1/30/2025	Other – EPA OGWDW TSC/Cincinnati	
Michella Karapondo Karapondo.michella@epa.gov	(1st term)	Other – EPA OGWDW TSC/Cincinnati	
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Jody Koehler	1/30/2028	AB – TCEQ	
Jody.koehler@tceq.texas.gov	(1 st term)		
Michael Perry	1/30/2026	Lab – Southern Nevada Water Authority	
michael.perry@lvvwd.com	(2nd term)		
Millie Rose	1/30/2028	AB – IL EPA	
Millie.Rose@illinois.gov	(1st term)	AB ILLIA	
	` '	AD AIV DOLL	
Amy Steuerwald, Vice Chair	1/30/27	AB – NY DOH	
amy.steuerwald@health.ny.gov	(1st term)		
Program Administrator:	N/A		
Lynn Bradley			
Lynn.Bradley@nelac-institute.org			
Associate Members:	•		
Paul Bergeron		AB – LDEQ	
Paul.bergeron@la.gov			
Debbie Bond		LAB – Alabama Power	
dbond@southernco.com			
Kathryn Chang		LAB – Eurofins	
Kathryn.chang@et.eurofins.us			
Nilda Cox		LAB – Eurofins	
nilda.cox@et.eurofinsus.com			
Yumi Creason		Other	
ycreason@pa.gov		AD Novellessandia	
Bill Hall george.w.hall@des.nh.gov		AB – New Hampshire	
		AR OK DEO	
Taryn Hurley taryn.hurley@deq.ok.gov		AB – OK DEQ	
Paul Junio		LAB – Pace Labs, Inc.	
paul.junio@pacelabs.com		LAD - I doe Labs, illo.	
LeeAnn Kline		M J Reider Associates	
Ikline@mjreider.com		C. toldol / tobolidio	
Ryan Lerch		AB – OK DEQ	
Ryan.lerch@deq.ok.gov			
Marlene Moore		Other – Advanced Systems, Inc.,	
mmoore@advancedsys.com		Newark, DE	
Zaneta Popovska		AB – ANAB	
zpopovska@anab.org			
Mei Beth Shepherd, Vice Chair		Other – Shepherd Technical Services	
mbshep@sheptechserv.com			

Nicholas Slawson nslawson@a2la.org	AB – A2LA	
Ilona Taunton Ilona.taunton@nelac-institute.org	Other – TNI Program Administrator	
Cathy Westerman cathy.westerman@dgs.virginia.gov	AB – VA DCLS	

Attachment 2 - Agenda

- Welcome and Introductions
- Status of the Draft Standard V2M1 Revision 2
 - o Progress to date
 - o Revisions agreed upon to date
 - Review of older revisions
 - Revisions since EMS in August 2024
- 10:00 10:30 Break
- Issues Pending Revisions (for discussion)
- ISO Text to be Omitted from TNI V2M1
- Open Discussion (time permitting)
- Adjourn