

## Summary of the Laboratory Accreditation Body Expert Committee Meeting

Tuesday, June 18, 2019

### 1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The minutes of May 21, 2019, were approved.

Lynn noted that Oommen Kappil is no longer a TNI member and no longer works for EMSL. He has been removed from the committee roster, leaving the committee composed of five “other”, three “AB” and two “lab” stakeholders. This still qualifies as “balanced”, but we would benefit from an additional member of the AB or lab stakeholder category, to ensure that balance can be maintained through the final stages of revising V2M1.

Also, June Main is retiring and will no longer remain an associate member.

### 2. Consideration of Changed Session Time for Conference in Jacksonville

The preliminary program showed the LAB session as Thursday morning, August 8, but Jerry notified Lynn and Carl that it had been shifted to Thursday afternoon for unspecified reasons, saying that there was a room available if we preferred to have the morning time slot on that day. Carl and another member mentioned needing to depart early in the afternoon, so that the original morning time would be better. Lynn has informed Jerry and he confirms that LAB will be assigned a room for a morning session.

### 3. 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. Carl stated that he wants to begin reviewing the comments on the published draft during the LAB session in Jacksonville, rather than in teleconference sessions such as this one.

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

### 4. Next Meeting

The next teleconference meeting will be **Tuesday, July 16, 2019, at 1:00 pm Eastern.** An agenda and documents will be distributed prior to the meeting. The primary agenda item will be to continue 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 <a href="mailto:Batschelet.william@epa.gov">Batschelet.william@epa.gov</a>	12/31/2021 (2 <sup>nd</sup> term)	Other – US EPA R8, Lab QAO	Yes
Nilda Cox <a href="mailto:nildacox@eurofinsus.com">nildacox@eurofinsus.com</a>	12/31/2021 (1 <sup>st</sup> term)	Lab – Eurofins Eaton Analytical LLC	Yes
Charles Hartke <a href="mailto:Charles.hartke@sgs.com">Charles.hartke@sgs.com</a>	12/31/2020 (1st term)	Lab – SGS Accutest, Dayton, NY	No
Catherine Katsikis <a href="mailto:catherinekatsikis@gmail.com">catherinekatsikis@gmail.com</a>	12/31/2021 (2 <sup>nd</sup> term)	Other – Laboratory Data Consultants	Yes
Carl Kircher, Chair <a href="mailto:carl_kircher@flhealth.gov">carl_kircher@flhealth.gov</a>	12/31/2021 (3 <sup>rd</sup> term, extended)	AB – Florida Department of Health	Yes
Marlene Moore <a href="mailto:mmoore@advancedsys.com">mmoore@advancedsys.com</a>	12/31/2021 (2 <sup>nd</sup> term)	Other – Advanced Systems, Inc., Newark, DE	No
Zaneta Popovska <a href="mailto:zpopovska@anab.org">zpopovska@anab.org</a>	12/31/2021 (1st term)	Other – ANAB	No
Alia Rauf <a href="mailto:arauf@utah.gov">arauf@utah.gov</a>	12/31/2020 (1st term)	AB – Utah Department of Health	Yes
Mei Beth Shepherd, Vice Chair <a href="mailto:mbshep@sheptechserv.com">mbshep@sheptechserv.com</a>	12/31/2021 (2 <sup>nd</sup> term)	Other – Shepherd Technical Services	Yes
Nicholas Slawson <a href="mailto:nslawson@a2la.org">nslawson@a2la.org</a>	12/31/2021 (1st term)	AB – A2LA	No
Program Administrator: Lynn Bradley <a href="mailto:Lynn.Bradley@nelac-institute.org">Lynn.Bradley@nelac-institute.org</a>	N/A		Yes
<b>Associate Members:</b>			
Yumi Creason <a href="mailto:ycreason@pa.gov">ycreason@pa.gov</a>		AB – Pennsylvania	Yes
Bill Ray <a href="mailto:bill_ray@williamrayllc.com">bill_ray@williamrayllc.com</a>		Other – William Ray Consulting, LLC	No
Aurora Shields <a href="mailto:Aurora.Shields@kcmo.org">Aurora.Shields@kcmo.org</a>		Lab – Kansas City, MO	No
Ilona Taunton <a href="mailto:Ilona.taunton@nelac-institute.org">Ilona.taunton@nelac-institute.org</a>		Other – TNI Program Administrator	No

<b>ATTACHMENT 2</b>						
Results of LAB discussion of comments from public session in Washington, DC						
comment number	Section/clause	Issue	Comments from Session	Committee action	Date comment considered	Committee comment
35	never addressed after removal from 2003	Assessing all methods versus selected methods for drinking water and other fields, at initial and subsequent on-site assessments (subject of SIR 254 and policy currently before LASEC)	-Policy is currently in development, so no need to consider adding to the standard	no action	6/18/2019	planned policy dropped by NELAP AC. Issue should be addressed by AB in its assessment plan for each lab
36	never addressed after removal from 2003	Assessing all methods versus selected methods for drinking water and other fields, at initial and subsequent on-site assessments (subject of SIR 254 and policy currently before LASEC)	-Policy is currently in development, so no need to consider adding to the standard	no action	6/18/2019	planned policy dropped by NELAP AC. Issue should be addressed by AB in its assessment plan for each lab
37	never addressed after removal from 2003	How to assess different Fields of Accreditation	Part of policy currently in development	no action	6/18/2019	planned policy dropped by NELAP AC. Issue should be addressed by AB in its assessment plan for each lab
38	never addressed after removal from 2003	Accreditation of "prep methods" and accommodating the varied approaches by Accreditation Bodies (ABs)	Part of policy currently in development	no action	6/18/2019	planned policy dropped by NELAP AC. Issue should be addressed by AB in its assessment plan for each lab
39	never addressed after removal from 2003	Using technologies as the basis for PT samples and Fields of Proficiency Testing (FoPT) tables	-This is an issue for the PT program, not for LAB committee module	no action	6/18/2019	not within LAB purview

40	never addressed after removal from 2003	Assessing laboratory accreditation scopes by matrix/method/analyte (by governmental and nongovernmental ABs)	-This is a substantial issue not fully addressed within the "onsite assessment" policy being developed. -Also, NGABs are not bound by the drinking water program's requirement to fully assess all methods. - Request that the issue of assessing to analyte level versus technology/method level be included in "on-site assessment" policy -This is an industry-wide problem (such as for asbestos), and cannot be solved by the NELAP ABs	no action	6/18/2019	planned policy dropped by NELAP AC. Issue should be addressed by AB in its assessment plan for each lab
41	never addressed after removal from 2003	What to do about PT requirements for scopes where there are no approved PT providers (such as Biological Tissues as a matrix and DW Asbestos)	-This is an issue for the PT program, not for LAB committee module	no action	6/18/2019	not within LAB purview
42	never addressed after removal from 2003	NELAP policy on AB conformance to the current V2M3, Section 6.3.5 (current ISO/IEC 17011, Clause 7.5.6)	should be covered in the policy under development	no action	6/18/2019	planned policy dropped by NELAP AC. Issue should be addressed by AB in its assessment plan for each lab
43	never addressed after removal from 2003	Allowance to grant interim accreditation status to laboratories	-This issue needs to be resolved within the NELAP AC, but trying to address it in the standard is likely to bring a veto from one side or the other	no action	6/18/2019	some ABs have no option to grant interim accreditation but others wish to keep the option. Not addressed at all in ISO/IEC 17011 or in additional TNI language at this time

Results of LAB discussion of comments from public session in Washington, DC			
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44	never addressed after removal from 2003	Allowance to extend deadlines in any standard through which timeframes are specified	<p>-Two separate issues – deadlines for AB completion of site reports <u>and</u> deadlines for lab responses with corrective actions - Should deadlines even be in the standard? They currently are. General agreement that deadlines ought not to be in a policy - AB deadline for site reports should more reasonably be 45 days (instead of 30) - NELAP ABs advise not including language permitting exceptions to deadlines in the standard; at most, state that an AB can decide on a case-by-case basis if extraordinary circumstances warrant extending deadline(s)</p>	defer decision to consideration of comments submitted during formal comment period (comment 157)	6/18/2019	defer decision to consideration of comments submitted during formal comment period (comment 157)
45	never addressed after removal from 2003	Requirement for the laboratory to seek NELAP Primary Accreditation in the state in which it resides, if that state has a Recognized NELAP AB for the fields of accreditation requested	<p>-This is currently in the NELAP Mutual Recognition Policy 3-100 -Not all NELAP state regulations require this -Consider for inclusion in the standard, since it is not enforceable as part of the policy -Not applicable to NGABs - Consensus that when a lab has dual primaries (to obtain scopes not available from first primary or in-state AB), only one AB should normally perform the quality system assessment. The second primary ought only to assess the additional method(s) - Demand from NELAP that a lab in non-NELAP state should obtain every scope possible from a single</p>	no action	6/18/2019	this issue is actually not addressed in the NELAP Mutual Recognition Policy POL 3-100. It is embedded in some NELAP states' regulations but not in others, but in actual practice, the concept continues to be honored.

			primary, and not be allowed to pick and choose which AB for which scope -Agreed-upon exception is that EPA regional labs should use an AB outside of their region (to avoid conflict of interest)			
46	never addressed after removal from 2003	Allowance for NELAP Recognized ABs' personnel to perform accreditation functions for each other	-Consensus was not to include this in the standard – “allowing” actions begins a slippery slope. -ABs currently work this out informally when needed	no action	6/18/2019	

Results of LAB discussion of comments from public session in Washington, DC						
47	never addressed after removal from 2003	Process for expanding the scope of recognition for each NELAP AB to offer as Primary Accreditation to applicant laboratories	-This was in 2003 NELAP standard but is not currently addressed in documentation -ABs typically authorize themselves to expand their scopes, subject to review during the evaluation process - Some ABs drop items from their scope, which creates a problem for labs that then need an additional primary AB Recommend that the standard include requirement for the AB to have a documented process for modifying its scope Need a procedure to ensure that all possible scopes are addressed by the first primary AB as scopes shift Labs need to know that they can request a scope even if it's not listed as available – some ABs will agree	no additional action needed	6/18/2019	there are five items in this comment and all are addressed in the relevant sections of ISO/IEC 17011:2017

48	never addressed after removal from 2003	Communication policy to allow advance notice to other recognized NELAP ABs of cost increases or other changes in the AB's program	-Should be in the standard, but ought not to reference cost increases, just other changes such as scope adjustments - Consider more fully in committee discussions -Note that the new §8.2.3 mentions "notice" but does not say to who(m)	no action	6/18/2019	ISO/IEC 17011 adequately addresses this (§4). The standard discusses general communications and is not specific to other ABs in the same accreditation scheme [NELAP is an accreditation scheme], but presumably other NELAP ABs would be "interested parties". NOTE: the standard does not mention fees in any way
49	never addressed after removal from 2003	Policy on secondary accreditation to mobile laboratories	-There is presently too much disagreement among ABs about how these are handled for it to be included in the standard. Danger is that it would bring a veto vote Consider setting some kind of baseline for (in?) the standard -Discuss with TNI Field Activities Committee (which is revising its standard, too)	no action	6/18/2019	A NEFAP Task Group that includes NELAP AB representation is addressing this issue for coverage in the NEFAP standard. For now, it would be inappropriate to preempt the Board's effort in creating this Task Group by trying to include it in this standard
50	never addressed after removal from 2003	Generic accreditation application form that will be used or acceptable to all recognized ABs	-Objections to requiring this in the standard -Probably not even ready for a NELAP policy yet – too early in the development -States are handling on an individual basis	no action	6/18/2019	NOTE: a few ABs are experimenting with this tool
51	never addressed after removal from 2003	Requirements on the content and frequency for updating information to LAMS (the National Database) on NELAP accredited labs	-This is in Mutual Recognition Policy 3-100 Not all NELAP ABs are capable of reporting FOAs to LAMS -Policy does not cover NGABs	no action	6/18/2019	NOTE: not all NELAP ABs have technological capability to perform automated reporting into LAMS and manually inputting FOAs is unreasonable

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52	never addressed after removal from 2003	Policy on secondary accreditations (scope of accreditations)	-Commenters recommend developing tools and writing a policy about this, but not including in the standard	no action	6/18/2019	The NELAP Mutual Recognition Policy addresses this for the NELAP scheme. NGAB accreditations are not presently recognizable within NELAP for secondary accreditation
53	never addressed after removal from 2003	Timeframes for ABs to require of laboratories to complete corrective actions to non-conformances identified during on-site assessments	-See also comments on timelines above - Maybe set a maximum time limit -2009 TNI standard has no requirement that an actual CA be completed, only that a plan for one be submitted The timeline should be in Volume 1, not V2. Quality Systems has this in its "parking lot" to address with next revision -17011 requires a "satisfactory response" -Consider more fully in committee discussions	no action	6/18/2019	§7.6 addresses the completion of corrective actions
54	never addressed after removal from 2003	Policy outlining qualifications and credentials needed for contract assessors or ALL	-Discuss fully in committee	no action in LAB	6/18/2019	we understand that some discussions have taken place in other groups within TNI
55	never addressed after removal from 2003	AB assessors Scope of Accreditation definitively defined (at a minimum) as matrix-method (technology?)-analyte (or analyte group, or not at all?)	-Issue varies in how PTs are handled among different NELAP ABs	no action	6/18/2019	PT issues are not within the purview of LAB committee
56	never addressed after removal from 2003	Minimum requirements for training courses to train and qualify assessors (and accreditation decision makers?)	-Former TNI On-site Assessment Committee prepared guidance for training courses	no action	6/18/2019	we understand that some discussions have taken place in other groups within TNI



