# Summary of the NELAP Accreditation Council Meeting Monday, April 1, 2024 1:30 pm Eastern

#### 1. Welcome and Introductions

In Kristin's absence, Michele welcomed everyone to the meeting. Attendance is recorded in Attachment 1. The agenda is included in Attachment 2. Both the agenda and the minutes of March 4 were approved by unanimous consent.

### 2. Vote on Utah Recommendation

This recommendation was tabled from the March meeting. There was no discussion requested. Taryn moved and Paul Bergeron seconded to accept the recommendation of the evaluation team to renew the recognition of Utah as a NELAP AB. Nine votes were cast during the meeting and the remaining votes were cast by email in response to a request from the Program Administrator. The vote tally is presented in the table below with the dates given for email voters.

State AB	Vote		State AB	Vote	
FL	Yes		NY	Yes	
IL	Yes (4/9/24)		OK	Yes	
KS	Yes (4/1/24)		OR	Yes	
LA	Yes		PA	Yes (4/1/24)	
MN	Yes		TX	Yes (4/1/24)	
NH	Yes		UT	Abstain (4/4/24)	
NJ	Yes		VA	Yes	
13 votes in favor, 1 abstention –					
Renewal approved, April 9, 2024					

### 3. Discussion with LAB Expert Committee

After introducing Aaren and Yumi, Michele invited Aaren to lead the discussion of topics for which the LAB Expert Committee seeks input.

## Who Can Deliver Assessment Reports to the Laboratory?

Aaren explained that this issue comes from comments on §6.4.1.1 of the draft V2M1. In response to Revision 0, a comment requested that the section state explicitly that the assessment report should be presented to the lab by the AB, and that change was deemed persuasive and language added to so state, and was included in Revision 1 when published.

Then, LAB received a comment on Revision 1 that Florida objects to the change, because FL's contracts with third party assessors require that the assessors send the final report to the AB at the same time the assessor delivers it to the laboratory. Florida explained that changing its contracts would be very difficult. Importantly, at a later point in the discussion, Carl noted that Florida's statute requiring the use of third party (contract) assessors essentially mandates outsourcing the entire accreditation process, so that the AB must delicately balance the EPA's requirement for the AB to make all accreditation decisions with its law requiring outsourcing.

Aaren asked the Council for input about how to proceed – whether to remove the AB-issues-report language, or if perhaps extending the timeframe for delivery of the report to the laboratory (perhaps 5 to 15 days longer) would resolve the issue. Comments from the discussion are summarized below.

- LDEQ endorses issuing the report on the AB's letterhead, but as they sometimes struggle to meet the 30-day deadline, a longer timeframe would be welcomed.
- FL explained that the AB staff cannot write the report, as the assessor did all of the assessment, and that would not change with a time extension. Occasionally (possibly 10%), reports are amended by the AB to fix typos or clarify citations, with time extensions for the modified portions where appropriate.
- MN receives draft reports from its contract assessors, reviews the reports and then sends them to the labs. They require submission of draft reports within 7 days after the assessment, and any corrections are made prior to the AB issuing the report by the 30-day time limit, but they would not object to a longer timeline.
- FL noted that they could write changes into renewed contracts, if required. Its contracts are for 3 years, with an optional 3-year renewal, after which time an entire new request for application is repeated.
- VA's program manager reviews staff-written reports and may ask questions, discuss
  the report and possibly request revision, and would prefer that Florida's reports (the
  10%) be corrected prior to delivery to the lab. FL responded that until new contracts
  are in place, they cannot request reports from assessors earlier than 30 days, and
  that the contract requires that the assessor to deliver the report directly to the lab.
- OR explained that it occasionally uses third party/contract assessors, and it requires that the assessor submit materials (checklists, etc.) which are input into ORELAP's database from which all assessment reports are generated.
- NJ favors AB review before issuance of reports, even if the report later requires amendment or revision.
- EPA Liaison noted that the authority to certify labs is delegated to the state as part of state primacy, and cannot be further delegated. Its position is based on an earlier decision by the US Department of Justice, about EPA's radiochemistry assessment reports, that EPA must issue the report, not the assessor. The Agency understands that DOJ thus interprets the Safe Drinking Water Act to say that the state as the certification authority must issue the report. Lynn requested a copy of that opinion, but it was some years ago, issued to EPA Region 8, and Michella is uncertain whether it can be located, but referred to 40 CFR 142.10 (b) (see <a href="https://www.ecfr.gov/current/title-40/chapter-l/subchapter-D/part-142/subpart-B/section-142.10">https://www.ecfr.gov/current/title-40/chapter-l/subchapter-D/part-142/subpart-B/section-142.10</a>) as stating that the state with primacy must issue the decision. Florida responded that it makes the accreditation decision.

Some additional discussion transpired about the desirability of extending the timeline regardless of who issues the report, and that if the AB's timeline is extended, the time allowed for a lab to respond should be similarly extended. At that point, Aaren declared that she will take this information back to LAB and invited all Council members to participate in its discussion of this issue on April 16 at 1 pm Eastern. Anyone desiring to participate should notify Lynn and Aaren.

### What Limits Should Be Put on Remote Assessments?

Aaren explained that the Proposed V2M1, based on ISO 17011:2017, does not specify that in-person on-site assessments are required. Prior to the pandemic emergency declaration,

TNI's requirement was every 2 years ± 6 months, but remote assessments were used by many ABs during the emergency. Now, some ABs still use fully remote assessments sometimes while in some cases, uncertainty exists about whether those can even be mutually recognized now that the emergency has officially ended. LAB is discussing whether to specify that, if fully remote assessments are used, they should be alternated with in-person site visits and also that every initial assessment must be on-site. She asked for feedback from the Council about this issue.

- FL noted that §7.9.3 of the draft revision states that the time between consecutive assessments cannot exceed 2 years. However, the ISO language does allow for techniques other than an in-person site visit to be counted, such as PTs.
- EPA has no formal policy about remote assessments but prefers that an on-site assessment happen every 3 years with remote assessments used only in emergency circumstances. No revision of the Certification Manual is envisioned, however.
- LDEQ does not recognize remote assessments, per its regulations and/or statute.
   They are exploring whether that can be changed but for now, could not accept fully remote assessments for secondary labs.
- OR recommends that, if remote assessments are permitted, they never be used for initial assessments and that the best practice be acknowledged as not performing consecutive remote assessments.
- OR requests that a hybrid approach be allowed, with some of the assessment team on-site and others working remotely (to also include remote document reviews).
- MN requested that remote assessments be used only for assessing technologies currently on the lab's scope of accreditation, not to add technologies
- In the current draft revision, §7.9.4.1 allows for reassessments at 2 years ± 6 months. §7.9.4 requires that the reassessment plan use information from the prior assessment(s).
- LDEQ wants to keep the 6 month window in the timeframe for reassessments.
- MN inquired about the definition of reassessment; it is defined in V2M1 as a renewal. MN's regulation defines assessments as being "in person".
- Aaren noted that the standard needs to be perfectly clear about what is allowed, for assessments and reassessments, so that no AB can argue. She also stated that, in her experience as a consultant, labs actually like in-person assessments, so that they can be face-to-face with their assessors. LAB has also learned that TNI can "strike" (remove) ISO language from its standard, if necessary.
- NH noted that limits on remote assessments could be problematic for extraordinary assessments, but those would not apply as reassessments anyway.
- MN wants the flexibility to allow remote assessments for adding new methods/matrix/analytes for technologies already on a lab's scope so that they could be used in-between the 2 year cycle of reassessments.
- Regarding hybrid assessments, Aaren explained that LAB believes the standard allows for those, so long as some portion of the assessment is physically on-site. Document reviews done off-site are already acceptable. One AB asked that the standard clarify this position.

Aaren asked for a "survey" of personal opinions about the maximum interval between onsite visits. Seven ABs want 2 years  $\pm$  6 months or 3 years between on-sites, one wants permission to use remotes for every other reassessment (with the same 2.5-3 year interval), with one of those ABs specifying that 2 years  $\pm$  6 months is acceptable so long as PTs are required every 6 months but if PT frequency is reduced to annual, then an on-site

should be required every year. One AB stated that its statute requires reassessment every 2 years, but that they would be happy to have an additional 6 months of flexibility for "good labs". Based on that response, Aaren proposed drafting language for Council review to clarify what constitutes a reassessment.

## What, If Any, Language Changes Are Needed to Address Changing Certificate Requirements?

This topic was discussed at several Council meetings and at conference in Columbus, and seems to have originated with EPA OGWDW's concern that they have seen "tertiary certifications" – a state granting "mutual recognition" based on what turned out to be a certificate from a different state that intermingled primary and secondary certifications. EPA seeks to have clear documentation of the origin of the assessment for each method/matrix/analyte combination. This information is available in LAMS but not necessarily easy to find, and some NELAP evaluations have apparently demonstrated a lack of clarity about what methods were actually accredited (as primary) by which AB.

A secondary issue, corollary to this one, is that the version of the Standard used to accredit the lab should be identified. Because of "rolling implementation", this is not necessarily always the latest version.

Lab representatives have been very clear that they do not want to see the terminology of primary and secondary accreditations used on certificates, as "secondary" connotes "less than", which is very difficult to explain to clients/customers.

NJ and PA now list the primary state for each item in the Scope of Accreditation, but some other ABs use databases that are not capable of carrying that level of detail when accreditations are granted and certificates issued. Thus, if the standard were to impose additional requirements for certificates, an unknown amount of additional time would be needed for those states to update their IT systems to meet the new requirements. That timeframe could be lengthy.

Several ABs offered that they are happy to provide whatever information is necessary, and track down whatever is needed through their own internal processes. In response, EPA stated that they cannot identify the primary AB (establish traceability) by using 14 AB's internal processes. For instance, if a lab misses 2 PTs, they want to know which AB should have suspended the accreditation for that method. EPA also cited one instance where a secondary accreditation was based on an Arizona certification, while Arizona does not recognize any other states' accreditations and is not part of NELAP.

EPA has indicated that they can accept some other method of identifying the primary AB, such as a letter accompanying the certificate that specifies the AB that issued the "original" (primary) accreditation for each method/matrix/analyte in the scope.

One additional point was raised, that if a NELAP state were ever to decide to accept NGAB accreditations for secondary, at some point in the future, the result could be a fiasco.

Yumi offered to work with Michella and the Council to draft language for the standard, to address this issue.

## 4. Update on Credentials Committee

With time expired, Lynn quickly shared that the next role to be addressed for credentialing will be the Technical Specialist.

### 5. New Business

Taryn asked about the process for expanding its accreditation offerings -- OK wants to add a new technology but in an existing matrix. The response was to just add it, and it will be evaluated during the AB's next evaluation, but to make certain that training for assessors is documented and that Paul Junio is notified so that the expansion can be included in LAMS.

## 6. Next Meeting

The next teleconference meeting of the NELAP AC is scheduled for <u>Monday</u>, <u>May 6</u>, <u>2024</u>, <u>at 1:30 pm Eastern</u>. An agenda and documents will be provided in advance.

## Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Carl Kircher E: carl.kircher@flhealth.gov	Yes
	Alternate: Vanessa Soto  E: Vanessa.sotocontreras@flhealth.gov	No
IL	Millie Rose T: 217-557-0220 E: mildred.rose@illinois.gov	No
KS	Carissa Robertson Carissa.Robertson@ks.gov (785) 291-3162	No
	Alternate: Paul Harrison  paul.harrison@ks.gov  (785) 296-1656	No
	For information purposes: Amy Suggitt  Amy.Suggitt@ks.gov	No
	For information purposes: Matthew Jones Matthew.jones@ks.gov	Yes
LA DEQ	Tramecha Rankins E: tramecha.rankins@la.gov 225-219-3247	No
	Paul Bergeron E: paul.bergeron@la.gov	Yes
MN	Windsor Molnar Windsor.Molnar@state.mn.us 651-201-3702	Yes
	Alternate: Lynn Boysen E: lynn.boysen@state.mn.us	No
	For Information only: Stephanie Drier T: 651-201-5326 E: stephanie.drier@state.mn.us	Yes
NH	Brian Lamarsh (603) 271-2998 F: (603) 271-5171 Brian.M.Lamarsh@des.nh.gov	Yes
	Alternate: Bill Hall T: (603) 271-2998 E: george.hall@des.nh.gov	No

NJ	Michele Potter T: (609) 984-3870 F: (609) 777-1774 E: michele.potter@dep.nj.gov	Yes
	Alternate : Rachel Ellis E: rachel.ellis@dep.nj.gov	No
NY	Amy Steuerwald 518-473-0748 E: amy.steuerwald@health.ny.gov	Yes
	Alternate: Gretchen Welfinger Gretchen.Welfinger@health.ny.gov	Yes
	For Information only: Derek Symula derek.symula@health.ny.gov	No
OK	Taryn Hurley Taryn.hurley@deq.ok.gov (405) 702-1006	Yes
	Alternate: Ryan Lerch Ryan.Lerch@deq.ok.gov (405) 702-1020	No
OR	Steve Jetter T: 503-505-2672 E: steven.jetter@oha.oregon.gov	Yes
	Alternate: Lizbeth Garcia 971 865 0443 E: Lizbeth.garcia@dhsoha.state.or.us	No
	Included for information purposes: Ryan Pangelinan E: Ryan.pangelinan@dhsoha.state.or.us	No
PA	Annmarie Beach E: anbeach@pa.gov T: 717-346-8212	Yes
TX	Jody Koehler (512) 239-1990 <u>Jody.Koehler@tceq.texas.gov</u>	No
	Steve Gibson (512) 239-1316 Steve.Gibson@tceq.texas.gov	Yes
UT	Kristin Brown T: (801) 965-2540 F: (801) 965-2544 E: kristinbrown@utah.gov	No
VA	Cathy Westerman T: 804-648-4480 ext.391 E: cathy.westerman@dgs.virginia.gov	Yes

	Alternate: Shane Wyatt shane.wyatt@dgs.virginia.gov	No
PA and EC	Lynn Bradley T: 540-885-5736 E: <u>lynn.bradley@nelac-institute.org</u>	Yes
	Michella Karapondo Karapondo.michella@epa.gov	Yes
	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
	Christopher Hand Christopher.Hand@Waterboards.ca.gov	Yes
F	Michael Antoine mantoine@ndep.nv.gov	No
	Aaren Alger, Chair, LAB Expert Committee, <u>aaren.s.alger@gmail.com</u> Yumi Creason, Vice Chair, LAB Expert Committee, <u>ycreason@pa.gov</u>	

### Attachment 2 – Agenda for April 1, 2024, Meeting

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (March minutes attached)
- Vote on Utah Recommendation for Renewal (sent February 22)
- Discussion with LAB Expert Committee about possible revisions to V2M1 (draft module as published attached, fyi)
  - who can deliver assessment reports to the lab, and would changing the timeline help with resolution
  - o what limits (if any) should be put on remote assessments
  - what, if any, language changes are needed to address changing certificate requirements
- Update on Credential Committee's Next Effort
- New Business, if any
- Adjourn