

**Summary of the NELAP Accreditation Council Session
Forum on Laboratory Accreditation, Columbus, Ohio
Tuesday, January 23, 2024 1:00 pm Eastern**

1. Welcome and Introductions

Kristin welcomed everyone to the meeting and asked the Council members who were present to introduce themselves.

Although special arrangements had been made for audio feed into the WebEx recording, it was very difficult to hear anyone speaking who was not directly in front of the laptop displaying the presentation. Many thanks to Michele for taking good notes on the discussion, as her efforts make this summary possible.

2. Changes to NELAP Accreditation Body Activities

Kristin invited participants to provide updates on their state. Three states responded, as follows:

KS – Carissa noted that their regulation to update to the 2016 Standard is in the state Attorney General’s office, that KS is now using the generic application.

MN – Stephanie explained that they are working with the state legislature to secure funds for hiring additional personnel to assist with database updates and CECs (PFAS).

IL – Millie explained that state legislation to adopt the draft solid waste and wastewater methods is under consideration and that she is hiring assessors due to losing all three staff positions due to retirements in the past year.

OR – Kristin explained that Travis Bartholomew is leaving ORELAP and his replacement will be Steve Jetter. For now, labs and ABs wishing to contact ORELAP’s program manager should use the email orelap.info@oha.oregon.gov.

Information provided after conference, for inclusion in these minutes:

FL is now offering Draft 4 of EPA Method 1633, as they are updating laboratories as the drafts are published. Labs sign attesting that they acknowledge that after obtaining certification for a draft, they must change to the updated draft method as it changes. After a request from EPA Region 4, FL is not offering the older draft versions of this method. FL is now including the latest method and analyte codes from TNI LAMS in its Scopes of Accreditation, but still has concerns about the codes and other states that are using older or obsolete codes in their Scopes of Accreditation. They continue to update Scopes of Accreditation to comply with MUR 2021.

Discussion

Steve Arms, NELAP Lead Evaluator, asked if there’s a policy for how AC gets notified when personnel changes occur. Yes, there is, it’s in POL 3-101, Changes to AB Operations. Notifications are not required for any scope changes. Steve also inquired whether all ABs are operating under the 2016 Standard for AB operations, and that is so because it does

not require rulemaking.

Dan Hautman, Director, EPA OGWDW Technical Support Center, provided a status update on the Method 1633 draft, explaining that it's wastewater but since he knew, he would share that he has heard that the wastewater program plans to publish the final version the end of this month.

3. Possible Ways to Revise the AB Evaluation Process

The LAB Expert Committee and NELAP Evaluators groups are both contributing to the development of what will become a proposal to the Council for revising both the evaluation process for renewals and the current evaluation schedule.

As the only member of both groups present at this session, Cathy gave update on what changes are under consideration our AB evaluations. She explained the scheduling issues for evaluations, and consideration of how to adjust the schedule (again), likely to be based on the previous, most recent evaluation date rather than the current renewal schedule of one application requested every two months starting at the beginning of the cycle (October of every third year).

Cathy then explained how LAB is trying to make the evaluation process more efficient to alleviate backlog in future and to reduce duplicate reviews of AB documentation (statutes, regulations, SOPs and quality system documentation), so that evaluators need only to review documents that have been revised instead of all previously reviewed documents, then focusing more on the implementation of the processes documented. For new AB applicants, or if a new AB operations module (Volume 2) is implemented, all documentation would be thoroughly reviewed, as is done now.

Some of the possible options under consideration are:

- Looking to revise checklist for our renewals,
- Key performance indicators,
- Possibly standardizing an internal audit format,
- More extensive interviews with staff, and
- Focus on outcomes rather than procedures.

Discussion

AB comments – MN expressed support for the changes being considered and OK favors standardizing requirements as well as streamlining the renewal process to be more effective.

One participant asked about considering a risk-based approach for different types of lab audits, but Kristin clarified this is for AB evaluations, not lab audits. That participant then suggested another approach of doing spot audits to look at all aspects of operations over 3 years instead of one large audit once every three years – so everything is looked at over 3 years.

Another participant asked if our changes to the evaluation process would be part of the Standard and would they be voted on, as the changes discussed seem to be less restrictive. This commenter questioned why the ABs are we allowed to change how they are evaluated, and pointed out that we must be careful about how proposed changes are presented so that they don't appear to be less stringent than before.

There was no response to possibly expanding the evaluation teams to include other outside groups, except for MN's comment that the Region 5 Certification Officer will now be joining the evaluation teams for that region.

4. Status of the AB Operations Module V2M1

The LAB Expert Committee did not meet during this conference. They are voting on persuasiveness of comments received on the V2M1 Draft Standard Revision 1, but no decisions have yet been made about revisions to the draft language.

LAB is looking for additional committee members if anyone is interested, as there are several openings on that committee.

5. Open Discussion

Certificates of Accreditation

EPA has raised its concerns about identifying the primary AB for each method/matrix/analyte combination, as not all AB's lab certificates differentiate primary from secondary accreditations. Additionally, there are concerns that a scope could be mistaken for a primary scope when it is actually secondary accreditation, and thus passed along to a non-NELAP certification body as a primary accreditation when the laboratory's certificate is presented.

Ed. NOTE: The entire mutual recognition system used by NELAP (and also ILAC) is based on ensuring that laboratory accreditations done by one AB are equivalent to those done by any other AB within the mutual recognition system, but somehow, "secondary" accreditations (where one NELAP AB accepts another's assessment of a laboratory) are somehow perceived as different or lesser than "primary" accreditations issued by the AB that actually conducted the assessment. Information about which AB accredited (i.e., conducted the primary assessment) a lab for any particular method is readily available on the LAMS database, which is public and accessible to anyone with a computer online.

The discussion at conference revolved around what information is specifically part of the laboratory certificate, and the apparent request from EPA to have the primary AB identified on the certificate for each method/matrix/analyte combination, including all that are "secondary" accreditations in the state issuing the certificate. Michella, EPA Liaison to the Council, stated the problem goes beyond the NELAP ABs, and that non-NELAP ABs are granting certifications off of NELAP certificates, and that EPA wishes to have those non-NELAP certifications traceable in case of "problems", so they know which state was the assessing organization.

Several possible "fixes" were discussed:

- list the primary state or just list that the accreditation is based on some other state's assessment
- Not listing the state doesn't show who did the audit, would still need to contact the lab to determine which AB.
- MN states it's easier to get such a change to the certificates implemented if it's required in the Standard rather than just as a NELAP policy.

- NH mentioned that LAMS has the ability to identify the primary and secondary ABs.
- LAMS is not easy to sort through, but it is easy to download the LAMS file for a lab into an Excel spreadsheet and then do a sort of the data.
- Steve Arms mentioned there's nothing in the Standard that requires this, presently.
- We should also consider requiring that the certificate state what version of the Standard is being implemented for traceability. This is actually already required in the Standard but how can we make it more clear – for example, KS is actually accrediting to the 2016 Standard but its rule says 2003 NELAC, so rule conflicts with the certificate.
- One participant stated that it makes sense for us in the TNI community, but for labs, it may be difficult to explain to customers that primary and secondary accreditations are no different. This individual does not want a distinction between primary and secondary accreditations on lab certificates, and prefers just stating the AB that performed the assessment. This individual also commented that putting the Standard version on the certificate would lead to labs having to explain the differences in the Standards and that there is a “rolling implementation” when a new Standard is implemented. Steve Arms agreed that it leads to people thinking there are multiple tiers – said that's why FL originally didn't designate the Standard on its certificate.
- Another participant suggested stating that the audit was performed by XXX/AB instead of listing primary/secondary would be more clear, while yet another proposed listing the state but not list primary/secondary.
- Michaela recommended that putting such requirement in the Standard would be preferable to policy, as that would have more weight for implementation and would be subject to public comment prior to actual implementation.
- MN asked how does EPA plan to address with other non-NELAP labs. EPA responded that it could be included in their Certification Manual revision and also be included in the regions' evaluations for state primacy. Michella would also include the requirement in their training materials.

Questions without answers:

- Dan Hautman asked what happens if a lab is decertified, and whether such language is in the rule. Another participant believed this being addressed in the revision to Standards.
- If a second primary exists, what happens if one AB pulls the certificate but the other doesn't, is the lab still accredited for the other items?
- There was some confusion about whether labs are only allowed to have 1 primary and all others are secondary; one primary is responsible for demographics in LAMS and typically that AB does the quality system assessment. We need to determine whether this is actually in the Standard, or if it should be.
- Where is the requirement for who (besides the lab itself) must be notified when a suspension or withdrawal of accreditation is issued?

Kristin also noted that there is a widespread misperception that NELAP issues “TNI Accreditations” and expressed a desire to have the Advocacy Committee help with clarifying that inaccurate view.

6. Next Meeting

The next teleconference meeting of the NELAP AC is scheduled for **Monday, February 5,**

2024, at 1:30 pm Eastern. An agenda and documents will be provided in advance.

Attachment 1 – Remote participation was not available for this conference session

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