Summary of the Laboratory Accreditation Body Expert Committee Meeting
Tuesday, May 16, 2023   1:00 pm Eastern

1.   Welcome and Roll Call

Aaren opened the meeting. The agenda was approved by unanimous consent. Michella moved and Zaneta seconded that the minutes of March 21, 2023, be approved, and the vote was unanimous, with Bill abstaining due to his absence. Attendance is recorded in Attachment 1.

The vote to approve the V2M1 Draft Standard Revision 1 for publication with a request for comments was completed with each committee member voting in favor, and every member voting. There were no comments offered that needed to be addressed, and thus the April meeting was not held (as proposed in March).

The individual votes were recorded as follows:

Aaren Alger, Chair	Yes
Socorro Baldonado	Yes
Nilda Cox	Yes
Yumi Creason, Vice Chair	Yes
Bill Hall	Yes
Sviatlana Haubner	Yes
Michella Karapondo	Yes
Michael Perry	Yes
Zaneta Popovska	Yes

2.   Updating the Evaluation Process

At the March meeting, Aaren had explained that a small group of volunteer evaluators would brainstorm ideas for modifying the process, and then those ideas would be brought to the LAB consideration and possible incorporation into the Evaluation SOP, the Technical Review Checklist, and the Initial/Renewal Application for Recognition. The TNI Board was informed that this will be undertaken.

The ideas discussed in among the evaluators are summarized in Attachment 3 at the end of this document, and along with some feedback from a committee member (not included here), were the starting point for the committee's discussion at this meeting.

To begin the discussion, since not everyone had read the summary of the evaluator conversations, Aaren explained that the goal is to streamline the evaluation process, including the checklist and the application form, and improve the value of the evaluation process for the program. Evaluations began to be done remotely during the initial months of the pandemic (with appropriate updates to the evaluation SOP), with evaluators reviewing remotely and via videoconferencing all of the same things that would have been reviewed during an in-person site visit.

The Accreditation Council agreed to continue remote evaluations for the current 2023-2025 evaluation cycle, but long-term, the question of whether in-person site visits are needed for

renewals remains to be settled. All parties have agreed that initial evaluations must include an in-person site visit.

The option of breaking each evaluation into three parts (one smaller portion each year, covering everything in three years as now) was raised and given due consideration. Lead Evaluators have struggled to complete evaluations on schedule, for varied reasons. AB staff workloads sometimes make it difficult for the state evaluators to give full attention to their assigned evaluation activities, and particularly right now, two state program managers are serving on evaluation teams at the same time as their evaluations should be starting, which contributes to further delays in the scheduling. Theoretically, breaking the evaluation into three portions would ease that intense workload although adding two additional time periods to the effort. One suggestion was that the three parts could be A) Regulations/Policy/Procedure review; B) Internal Audit/Management Review/Staff Training review; and C) File reviews. The order of these could vary.

Additional discussion points were as follows:

- Two people per team, for the current evaluation process, is too much work. Additional team members are needed.
- In completing a renewal application (for a Standard already in use), the AB needs only to verify the previous checklist and resubmit the same materials, making it essentially a "paperwork exercise". Can only the changed items be reviewed, with unchanged ones by-passed?
- It would be more effective for evaluators to spend time on internal assessments, assessment records and assessor training materials instead of confirming the existence of a Quality Manual and SOPs – it's more important to establish that assessors are working effectively.
- NELAP should give serious consideration to returning back to evaluating assessor competence through in-person observations of actual assessments, with spot-checks of training records.
- Can we find more people for evaluation teams, whether additional paid staff or additional AB staff volunteers (not just program managers)? Are there any incentives that we can offer, such as reduced AB dues for supplying additional personnel?
- Is it feasible to recruit lab volunteers to help with the evaluation, or just with the checklist reviews, then with the team (LE & state staff) doing interviews and assessment reviews? There was concern about conflict of interest with lab staff evaluating their accreditor, but at least one AB indicated that would not present a problem; lab staff would have far less incentive to evaluate an AB with which they have no relationship.
- Could personnel from the TNI-recognized Non-governmental ABs be utilized in evaluations (if they were interested)?
- Lead Evaluators cannot force AB staff to meet the timelines in the SOP, as they have no such authority. Neither does the Evaluation Coordinator.
- General consensus is that NELAP ABS want peer evaluations, not conducted by "outsiders".
- The Technical Review is the most time-consuming thing for an evaluator, and with only two people on a team, that means half of a 54-page checklist. The universal response was dread and dislike of both completing and reviewing this checklist.
- Can the initial evaluation (or perhaps first evaluation with a new Standard) focus on the checklist with renewals more "action-based"? Even if this requires two separate checklists, with the renewal checklist being shorter/simpler and more focused on operational issues than documentation, it's worth considering.
- Looking at findings and corrective actions from prior evaluations should be a priority.

At this point, the discussion veered back to how to modify the process. Major points were:

- It will be crucial to determine what our desired end product is – detailed compliance with each and every requirement in the Standard or a (somewhat subjective) evaluation of the successful operation of an AB.
- Internal audits are a tool used haphazardly by some ABs and faithfully by others. Several participants suggested that a standardized format for internal audits could make them a highly useful tool for evaluating an AB's operations, but as currently done, they are not a reliable tool for all ABs. Aaren noted that during the Minnesota evaluation, a standard checklist for internal audits was mentioned, and she will request a copy of it (distributed to committee members with these minutes).

Two corollary questions arose. First, how do EPA's drinking water audits compare with the NELAP evaluations and second, how are the non-governmental ABs evaluated. Individuals on the committee representing these two groups offered responses:
- Michella addressed the EPA drinking water audits. She explained that they are not as detailed as the NELAP Technical Review checklist. They look at staffing, training, quality of assessments, travel funding, adequate QA documentation, "shadow audits" as funding permits, PT tracking and lab audit reports. She noted that the EPA audits are not standardized across the ten regions, and also that an annual self-report questionnaire is required of each state by its region.
- Zaneta explained that, for ANAB, the ILAC process (as used by its regional consortia) takes place every three years with a team of multiple evaluators drawn from consortium members and may last a full week, looking at all of the various programs ANAB operates. The TNI evaluation (which is entirely separate from ILAC) is typically two people with at least one day of site visit and additional days of witnessing one or more assessments.

At this point, time was expired. Aaren suggested revisiting this discussion in June, then Lynn offered to draft several options based on the ideas raised. Those options could be vetted by Aaren and Yumi, then discussed with the evaluators at their June meeting, brought back to LAB at its June 20 meeting, and then perhaps presented to the NELAP Accreditation Council at its July meeting, with the possibility of having a broader conversation about evaluations at the Council's session at conference in Minneapolis in August. Aaren agreed to this proposal

3.   New Business

With no new business raised, the meeting was adjourned by unanimous consent.

4.   Next Meeting

The next planned teleconference meeting is scheduled for **Tuesday, June 20, 2023, at 1:00 pm Eastern**. **Aaren asks that committee members unable to attend please notify her and Lynn prior to the meeting date.** 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, Chair Aaren.s.alger@gmail.com	1/30/2026 (2nd term)	Other – Alger Consulting & Training	Yes
Socorro Baldonado sbaldonado@mwdh2o.com	1/30/2026 (2nd term)	Lab – Metropolitan Water District, La Verne, CA	Yes
Nilda Cox nilda.cox@et.eurofinsus.com	1/30/2025 (2nd term)	Lab – Eurofins Eaton Analytical LLC	No
Yumi Creason, Vice Chair ycreason@pa.gov	1/30/2025 (1st term)	AB – Pennsylvania	No
Bill Hall george.w.hall@des.nh.gov	1/30/2026 (1st term)	AB – NH DES	Yes
Sviatlana Haubner Sviatlana.Haubner@cincinnati-oh.gov	1/30/2025 (1st term)	LAB – Cincinnati Metropolitan Sewer District	No
Michella Karapondo Karapondo.michella@epa.gov	1/30/2025 (1st term)	Other – EPA OGWDW TSC/Cincinnati	Yes
Michael Perry michael.perry@lvvwd.com	1/30/2026 (2nd term)	Lab – Southern Nevada Water Authority	No
Zaneta Popovska zpopovska@anab.org	1/30/2025 (2nd term)	AB – ANAB	Yes
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Paul Bergeron Paul.bergeron@la.gov		AB – LDEQ	Yes
Scott Haas shaas@etilab.com		Lab – Environmental Testing, Inc., and Chair, FAC	No
Taryn Hurley taryn.hurley@deq.ok.gov		AB – OK DEQ	No
Paul Junio paul.junio@pacelabs.com		LAB – Pace Labs, Inc.	No
Carl Kircher, Chair carl_kircher@flhealth.gov		AB – Florida Department of Health	No
Ryan Lerch Ryan.lerch@deq.ok.gov		AB – OK DEQ	Yes
Marlene Moore mmoore@advancedsys.com		Other – Advanced Systems, Inc., Newark, DE	No
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com		Other – Shepherd Technical Services	No
Aurora Shields Aurora.Shields@kcmo.org		Lab – KC Water	No
Nicholas Slawson nslawson@a2la.org		AB – A2LA	No
Ilona Taunton Ilona.taunton@nelac-institute.org		Other – TNI Program Administrator	No
Cathy Westerman cathy.westerman@dgs.virginia.gov		AB – VA DCLS	Yes

Guests:		
Amy Steuerwald amy.steuerwald@health.ny.gov	NY	
Steve Arms Arms.steve@comcast.net	NELAP Lead Evaluator	

Attachment 2 – LAB Expert Committee Meeting Agenda, May 16, 2023

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (March minutes attached)
- Discussion of Updating the Compliance Checklist and Possibly Revising the Evaluation Process (see attached summary of Evaluator discussions and Cathy's email comments, plus the current checklist and Carl's draft update of it prior to DS Revision 1 [fyi only])
- New Business, if any
- Adjourn

Attachment 3

Summary of NELAP Evaluator Discussions about Updating the Evaluation Process (April-May, 2023)

These conversations began as "brainstorming" and evolved into more detailed discussion of possibilities during the May meeting. Participants varied, but all involved are active NELAP evaluators. These conversations are being presented to the LAB Expert Committee as background information for its discussions about how the checklist and possibly the Evaluation SOP 3-102 might be modified to make NELAP evaluations more efficient and more effectively reflect successful implementation of the Standard.

April 2023 Discussion

One LE expressed a preference for focusing on assessor observations and what the ABs actually do, with assessments and PT reviews. Another participant noted that CLIA audits do spot checks of reports and auditors every visit. Lynn explained that, over a decade ago, several ABs explained that they were unable to take any action on a report from an outside party about assessor performance and had requested that the observations be restricted to whether or not the documented procedure was followed.

Aaren asked for thoughts about how to re-do the checklist so that it looks for objective evidence that an AB's operations meet the requirements of the Standard, but also noted that defining "objective evidence" will not be easy. Discussion points were as follows:

- Do we want to verify every detail of compliance, or determine overall or general competence of the AB's staff and operations?
- The checklist should be a tool, not the complete evaluation.
- Can we re-think the checklist by dividing it into subsections with fewer details and putting more of the document control oversight into the Evaluation SOP itself? That would make the process easier for the AB as well as for the evaluators.
- It is important to retain consistency across all evaluations, and providing "looser" tools may increase the variability among evaluators, and even for the same evaluator in different evaluations. The value of a checklist is that it does ensure consistency.
- It is not so important to DO the same thing in every evaluation, but rather to accomplish the same goal in every evaluation. [Ed. Note: this is the classic tension between objective and subjective judgements.]
- One can review the online data system records while discussing them with AB managers, rather than just reading electronic files remotely. This gives the evaluator an opportunity to ask, "how do you do that" or "show me on the screen" in real time. [Ed. Note: are there other ways we can incorporate newer technologies?]
- Further discussion of assessor observations raised the point that they can be done remotely, as the site visits are now done.

Ilona recalled having seen some "old" checklists that were not line-by-line requirements from the Standard but that looked to see of particular elements were in compliance with the Standard, and she agreed to make the effort to hunt those down and share them.

May 2023 Discussion

The following discussion points emerged:

- Consider mimicking "surveillance assessments" for ABs with few findings – either a longer interval between evaluations or a reduced (shortened) evaluation
- Could reduce the scope of evaluation to review less documentation, but changing the 3-year interval is probably not advisable
- Require AB to submit "evidence of compliance" such as a data audit, internal audit, results of PT reviews, management reviews, and perhaps do fewer file reviews

- Another option would be more frequent (annual?) evaluations covering partial scope such that full scope is covered during the 3-year period
- Check to see if ILAC signatories do this?
- Could establish two types of evaluations, with the initial evaluation (new AB or after implementation of a new Standard) being "complete", and then for renewals thereafter focusing less on the documentation and more on implementation.
- Initial review must be rigorous and include a site visit plus an observation
- Need criteria for deciding which ABs would be allowed to have the focus-on-implementation evaluations
- For ABs seeking re-recognition (such as CA), those should be treated as initial applicants for recognition
- Reduced focus on documentation might miss inconsistencies across ABs; consistency could be checked with the periodic "full" evaluations to be done
- Verify that standards are being applied the same way by reviewing assessment reports (are findings properly cited and objective)
- Give QA Reviewers criteria to look for

Aaren then shifted the conversation to how the Technical Review checklist could be streamlined for the new V2M1. Again, the discussion points are listed here:

- Look at subsections of the Standard as groups of related requirements, then spot check within subsections for what meets the requirements
- Create a conceptual checklist rather than the verbatim, line-by-line checklist used now
- Present open-ended questions, to be answered by document citations from the AB
- Consider ease of completing the checklist for the ABs
- The current checklist effectively forces the AB to review all of its documentation
- Perhaps a 2-part checklist, with one part identifying documents to meet the requirements of the Standard and the other part being a checklist for document submittals (internal audits, quality manual, etc.)
- Could we lighten the AB's burden while still permitting the evaluators to use the complete checklist if desired?
- Review the training SOP and Quality Manual as whole documents rather than as answers to line items in the checklist
- To create "surveillance evaluations", would need an algorithm to break the checklist into portions for each of the more frequent surveillance evaluations, perhaps "mini-evaluations" annually to constitute a complete evaluation every three years – e.g., training, assessment process, accreditation documentation, so that the AB has incentive to be prepared for all aspects
- This would be less interruption to an AB's on-going work, and would require less time commitment from evaluation team members for each of the (annual) mini-evaluations – a full review done in smaller portions