

Summary of the NELAP Accreditation Council Meeting

January 25, 2017 10:30 am

Forum on Laboratory Accreditation Houston, Texas

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 10:30 am on Wednesday, January 25, 2017. Those present are listed in Attachment 1. Aaren invited the Council members to introduce themselves to the meeting participants.

Three votes were initiated at the January 9 AC meeting, with each having at least one email vote needed. The email votes closed on January 23 as follows:

- Approval of new NPW and SCM FoPT tables – 13 yes votes with one AB not voting.
- Acceptance of LASEC recommendation concerning edited V1M1 – 12 yes votes with two ABs not voting.
- Approval of Evaluation Team recommendation to remove NJ's provisional status and restore full recognition – 12 yes votes, one AB not voting and NJ abstained.

2. Action Items Pending

None

3. Update on AC Activities and Related Items from Conference

Aaren summarized the major activities of the Council since the previous conference. The NELAP Evaluation SOP 3-102 revisions were reviewed by Policy Committee and endorsed by the TNI Board of Directors. These revisions enhance the evaluation process while reducing costs. Updated training for NELAP evaluators is planned at the end of conference with a webinar to follow in February for those who were unable to travel. The new round of evaluations will again be conducted against Volume 2 of the 2009 TNI Environmental Laboratory Sector Standard.

A new round of evaluations of NELAP ABs is underway, with six renewal letters sent thus far. One AB from the previous round remains to be completed, but all corrective actions have been submitted; only the formal recommendation is pending.

The LAB Expert Committee is undertaking a revision of Volume 2 (V2,) and will consolidate Modules 1 and 3. While the committee is accepting input on desired changes, the final combined module will be based on the revised ISO/IEC 17011, which is expected to be finalized before summer 2017.

The AC met with the Advocacy Committee and the LAB committee to discuss a list of nineteen items that drinking water Certification Officers need answered when they accompany NELAP evaluation teams. While these items are not part of the TNI standard, EPA uses them for making drinking water state primacy decisions. There was general agreement to incorporate those items into the NELAP evaluations, beginning with this current

round, although Ken (TX) expressed reservations, saying he needed to investigate further.

The AC has evaluated the 2016 standard, and found all modules except V1M1 (PT) and V1M4 (Chemistry) to be acceptable. V1M1 has undergone some technical edits and is now accepted, but two of the issues in V1M4 cannot be “fixed” with editorial changes, although several other items will receive minor edits. For this reason, the Chemistry module will be re-opened for limited revision, with only the two affected sections to be revised. These concern the ongoing verification of the LOQ (must have some quantitative limits) and the requirement that $LOQ = 3X$ detection limit (DL.) There was some discussion with EPA representatives about possible ways to resolve the “3X” issue without making revisions but no decision was reached.

Aaren noted that two policies are being developed for the AC by LASEC – one on documentation of prep methods and the other on selection of methods to assess during a lab’s biennial audit. For prep methods, the Council seeks something more than the informal understanding that all are getting assessed but that assessment is being documented in multiple different ways that hopefully can be standardized. For method selection, the Council is looking for a policy to set minimums, not to drive major rewrites of each AB’s on-site assessment SOPs.

4. Comments and Discussion from Audience Participants

Remote Assessments

Referring to Warren Merkel’s presentation about upcoming changes to ISO/IEC 17025, one participant asked about the meaning of remote assessments. Aaren did ask that the LAB committee consider allowing remote or off-site assessments in the V2 revision. Another participant noted that a clear definition of the term “remote assessment” will be needed, with a cost-benefit evaluation of what would be acceptable. One AB related the story of adapting an assessment on short notice to include an additional scope, by using videoconference interviews among an assessor qualified to assess that added scope (in the AB’s office), working with an assessor who was on-site at the laboratory to interview the appropriate staff, and that it worked successfully.

Others noted that where there are dual primary ABs, the second AB might not need a site visit at all, but could do the staff interviews and method review electronically. There was general consensus that all initial audits should include a site visit, not just those that are difficult or expensive travel. One lab representative commented that analysts benefit from having an auditor at the lab, but that it could be one person rather than a full team, and noted that having an assessor physically present makes a difference for both managers and analysts.

A few individuals were uneasy with completely “remote” assessment but were willing to consider ways to shorten the on-site part of an assessment.

Status of 2016 Standard

The 2016 standard has been approved as an ANSI standard, and will be re-submitted for approval with the technical edits to V1M1 and V1M4. However, the NELAP AC will not adopt the 2016 standard, but does expect to adopt the 2017 standard, once revisions to V1M4 are finalized. Once a new standard is adopted, the Council will determine its implementation date.

Several questions arose about use of the 2016 standard. It is, after all, a free-standing document, available to everyone. California, currently a non-NELAP state, plans to adopt and implement the 2016 standard. One AB mused about what if a NELAP AB were to implement the 2016 standard (whether the original or the version with edits). This has not been discussed but could result in loss of reciprocity; for now that is all speculative. One participant was puzzled that the 2016 standard is for sale but is not being adopted by TNI – this drew a parallel with Standard Methods, which typically waits years for EPA to approve its method updates, even though they are published and widely available.

Val Slaven, Chair of the Chemistry Expert Committee charged with revising V1M4, explained that there will be extensive conversations and review of the 2017 modifications to V1M4 prior to putting the revised module up for final vote. Aaren committed to timely turnaround times for review of the modifications. NOTE: AC members were invited to the February 10 meeting of the Chemistry committee, to discuss in person the editorial changes; these will be finalized and approved by Chemistry and then sent to LASEC and the AC for review and approval prior to beginning the formal revision process, so that the edits will not be subject to comment during the revision.

Aaren also explained that the Council is considering a less-than-two-year implementation date, and went on to discuss that states adopting a new standard “by reference” can implement on any chosen date, but that ABs needing to conduct rulemaking procedures to adopt a new standard will, as previously, likely need longer times to get the new standard in place. She advised that all NELAP ABs will maintain reciprocal recognition with no “extra” requirements, regardless of which standard any of the ABs are enforcing.

Bob Wyeth, Chair of the Consensus Standards Development Executive Committee, remarked that the 2017 revision needs to be quick but also correct. He raised the issue of whether it might be better to wait the twelve to eighteen months for the new version of ISO/IEC 17025 to be finalized and then restructure Volume 1 before adopting a new NELAP standard. Otherwise, if the NELAP standard holds to a 5-year revision cycle, 17025 will be undergoing revision again by time the TNI standard reflects the changes underway now. He also noted that groups developing standards now (WET and hopefully, soon, asbestos) should proceed slowly to see what the new 17025 says.

Bob also expressed a desire to find some way to address “big deal” comments at any stage of the standards development process. The current restrictions about what portions of the text are open for comment, depending on the stage of development, actually hinder or prevent correcting problems that are noticed too late in the process to be fixed.

Aaren noted that we need a revision only when there is improvement, based on LASEC’s suitability criteria, not just because five years have passed. TNI’s ANSI accreditation requires that we either revise or reaffirm the current standard every five years. General consensus seems to be that the Quality Systems module (V1M2) will be the most drastically impacted, but that the other modules may not need much change to comply with the new 17025.

Aaren noted that if any lab has questions about the implementation of a new standard, they should ask their AB.

Nicole Cairns, Chair of the PT Expert Committee, noted that while Volumes 3 and 4 (for PT providers and PT provider accreditors) have been approved by the PT Program Executive Committee, they cannot be put in place until the PT module of V1 (V1M1) is implemented.

8. Next Meeting

The next teleconference meeting of the Council will be on Monday, March 6, 2017, at 1:30 pm Eastern time. Teleconference information and meeting materials will be distributed with the meeting reminder.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Carl Kircher E: carl.kircher@flhealth.gov	Yes
	Alternate: Vanessa Soto E: Vanessa.sotocontreras@flhealth.gov	No
IL	Celeste Crowley T: 217-557-0274 F: 217-524-6169 E: celeste.crowley@illinois.gov	Yes
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	For information purposes: Kathy Marshall Kathy.Marshall@Illinois.gov	
	For information purposes: John South John.South@illinois.gov	
KS	Sara Hoffman shoffman@ks.gov	Yes
	Alternate: N. Myron Gunsalus 785-291-3162 E: ngunsalus@ks.gov	Yes
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	Altérnate: TBD	
LA DHH	Steve Martin, stephen.martin@la.gov	No
	Alternate: Errin Rider 225-219-5235 Errin.rider@la.gov	No
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes
	Alternate: Stephanie Drier 651-201-5326 E: stephanie.drier@state.mn.us	Yes (phone)

NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	Yes
	Alternate: Tyler Croteau Tyler.Croteau@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	Victoria Pretti 518-485-5570 victoria.pretti@health.ny.gov	No
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OR	Scott Hoatson Agency Quality Assurance Officer Oregon Department of Environmental Quality 503-693-5786 E: hoatson.scott@deq.state.or.us	Yes
	Lizbeth Garcia Lizbeth.garcia@dhsosha.state.or.us	No
	Included for information purposes: Stephanie Ringsage, Manager, Laboratory Compliance Section 503-693-4126 stephanie.b.ringsage@state.or.us	No
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@pa.gov	Yes
	Alternate: Yumi Creason E: ycreason@pa.gov	Yes
TX	Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov	Yes
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UT	Kristin Brown T: (801) 965-2540 F: (801) 965-2544 E: kristinbrown@utah.gov	Yes

	Alternate: Jill Jones T: (801) 965-3899 E: jilljones@utah.gov	No
VA	Cathy Westerman T: 804-648-4480 ext.391 E: cathy.westerman@dgs.virginia.gov	Yes
	Alternate: Ed Shaw T: 804-648-4480 ext.152 E: ed.shaw@dgs.virginia.gov	No
NELAP AC PA and EC	Lynn Bradley T: 540-885-5736 E: lynn.bradley@nelac-institute.org	Yes
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Oklahoma	David Caldwell E: David.Caldwell@deq.ok.gov	No
Guests:	none	