

Summary of the NELAP Accreditation Council Meeting
November 17, 2014

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EST on Monday, November 17, 2014. The minutes from November 3, 2014, were approved. Those members in attendance are listed in Attachment 1.

2. Action Items Pending

- Certificates of Recognition and letters to EPA Regional staff affirming renewals for IL, UT, LA DHH and PA (Lynn and Aaren, Paul to sign the PA certificate)
- Lynn to return SIRs to LAS EC as discussed
- All but one of the outstanding votes on SOP 3-103 (Standards Acceptance) were cast. The final total was 13 “yes” votes with one AB not voting. Lynn is working to have Policy Committee review this SOP quickly, due to the need to have procedures in place for reviewing pieces of the upcoming revisions.

3. Updates on CA Discussions

On November 13, Aaren, Steve and Jerry Parr talked with Christine Sotelo and other CA representatives. Christine had asked for the call, both as a general introduction and to address CA’s need to identify some options for how to address its now-expiring “interim” accreditations. Aaren and Steve discussed the possibilities of recognizing other NELAP accreditations or hiring contract assessors, and Jerry mentioned that they could even recognize accreditations to the TNI Standard performed by non-governmental ABs. In response to questions, Steve was willing to share contract language, and Jerry shared an older PowerPoint presentation about pricing structures in the various NELAP states. All agreed to continue working towards the goal of CA returning into NELAP in the future.

4. Resolution of Issue about Assessing All Drinking Water Methods

On Friday, November 14, Donna provided a statement from EPA’s Drinking Water Program that clarifies the expectation that all methods will be assessed every three years. This statement was shared with the AC as well as all ten EPA regional offices and their respective Certification Officers. The statement is included as Attachment 2.

Donna indicated that further documentation about procedures for ensuring that all methods are assessed is planned by the Agency. She also asked that the EPA requirement to assess all drinking water methods be written into the TNI Standard. In his role as Vice Chair of the Laboratory Accreditation Body Expert Committee, Carl suggested that she send that committee language that could be incorporated when Volume 2 Module 3 is next revised.

Scott stated that IL agrees to assess all drinking water methods, and that IL will send a written statement to the Evaluation Team declaring that to be so. When asked about IL’s timeframe for implementing this procedure, Scott stated that one assessment scheduled in early December will not have adequate time, as it was planned under the old procedure, but that IL is now studying how to stretch its resources so that all future assessments can comply with

the “all methods assessed” expectation for drinking water methods.

5. Vote on IL Evaluation Team Recommendation

Following the above discussion, Aaren asked whether it would be necessary to have IL submit a new corrective action response to the Evaluation Team (ET) for review. One participant noted that IL’s affirmative commitment will be captured in these minutes but another questioned whether it would be appropriate to vote on the IL recommendation until that corrective action’s documentation is completed and the practice put in place, thus holding an AB to a different standard than the ABs require of labs. But, the issue of assessing all drinking water methods was recorded in the site report as an “observation” and not a finding. Observations do not require corrective actions.

At that point of the discussion, Paul moved and Bill seconded that the AC accept the recommendation of the ET for the renewal of IL’s Certificate of Recognition. There was no official discussion and of the 11 ABs present, IL abstained and there were ten “yes” votes.

NOTE: by the following day, Tuesday, November 18, the remaining three votes were cast by email, with all three being “yes” votes. The final outcome is 13 “yes” votes and one abstention. IL’s renewal stands approved.

6. Protozoan FoPT Table

Lynn reported that Carrie Miller, EPA drinking water program, had inquired about the recently approved Protozoan Field of Proficiency Testing (FoPT) table. This is posted under “other” FoPTs, with an approval date of October 6, 2014. Carrie inquired whether it had been approved by the AC. This table requires two PTs/year, consistent with other TNI PTs, because that is what the Drinking Water program determined to require for crypto accreditations.

Because this table was not requested by an AB, it was not offered to the AC for approval. Jerry has contacted the Chair of the PT Program Executive Committee (PTPEC) to ask that it be submitted to the AC, since there are labs accredited for crypto in the LAMS database. Through her role as staff for the Policy Committee, Lynn committed to ensuring that this oversight is addressed in the comments from Policy about the PTPEC’s FoPT SOP, which was just reviewed in October.

Carrie also expressed some hope that the AC could help with encouraging another PT provider to create crypto PT samples, but that issue was deflected to the PTPEC.

7. Upcoming Working Draft Standards Webinars

Aaren noted that the Working Draft Standard for Detection and Quantitation has been approved by the Chemistry Expert Committee, and that a webinar on the WDS is scheduled for December 12. This document was circulated with the agenda for today’s AC meeting but is also available on the TNI website, in the “News” section. Aaren recommended that all ABs read this short document carefully, and plans a discussion about it before the end of the formal comment period (30 days after the webinar.)

Aaren also pointed out that the Radiochemistry Modified WDS is available and a webinar about that is scheduled for December 5, to open the comment period.

Finally, Aaren reminded the Council of the December 1 Assessor Call, led by NY, about method modifications.

8. Development of Policies Needed to Support AC Operations

Additional suggestions for policies that might be needed to support the AC's operations were submitted by several ABs. The draft list is shown in Attachment 3. Paul sent a number of possibilities after fully reviewing the NELAC standard, and several others have been added by others.

Participants were invited to submit additional topics to Lynn and Aaren. These topics and the process for fleshing out their content will be discussed at the December 15 AC meeting.

6. SIR Discussions

SIR #270 remained to be discussed. Two issues were that the wording of the response, "that the proposed procedure is "acceptable," is problematic for an interpretation and also the concern raised about whether quarterly checks would be needed if a package of disposable volumetric equipment is in use for more than three months.

This SIR is related to SIR #132, discussed at the November 3 meeting. Aaren asked that all ABs vote on this and the remaining SIRs on the voting site. Once voting is complete, then the Council will revisit those that fail to pass.

7. Next Meeting

The next meeting of the AC will be an Assessor Call on Monday, December 1, 2014, at 1:30 pm Eastern. New York will lead this call. A reminder and a draft document have been circulated to the AC and all identified contract assessors, but each AB using contractors should ensure that all of the contractors receive a copy of the meeting invitation.

The next business meeting of the AC will be on Monday December 15, 2014, at 1:30 pm Eastern. An agenda and teleconference information will be sent out before the meeting.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve.arms@flhealth.gov	No
	Alternate: Carl Kircher E: carl.kircher@flhealth.gov	Yes
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	Yes
	Alternate: Janet Cruse T: 217-785-0601 E: Janet.Cruse@illinois.gov	Yes
KS	N. Myron Gunsalus 785-291-3162 E: ngunsalus@kdheks.gov	No
	Alternate: Sara Hoffman shoffman@kdheks.gov	Yes
LA DEQ	Paul Bergeron T: 225-219-3247 E: Paul.Bergeron@la.gov	Yes
	Alternate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes
	Alternate: TBD	
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes
	Alternate: TBD	
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	Yes
	Alternate: TBD	

NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 E: joseph.aiello@dep.state.nj.us	No
	Alternate : Rachel Ellis E: rachel.ellis@dep.state.nj.us	No
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	No
	Alternate: TBD	
OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	Yes
	Shannon Swantek T: 503-693-5784 E: Shannon.swantek@state.or.us	No
	Included for information purposes: Scott Hoatson T: (503) 693-5786 E: hoatson.scott@deq.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	No
TX	Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov	No
	Ruthie Wedig E: Ruth.Wedig@tceq.texas.gov	Yes
UT	Kristin Brown T: (801) 965-2540 F: (801) 965-2544 E: kristinbrown@utah.gov	No
	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
EPA Liaison	Donna Ringel T: 732-321-4383 E: Ringel.Donna@epa.gov	Yes
California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
Oklahoma	David Caldwell E: David.Caldwell@deq.ok.gov	No
Guests:	none	

Attachment 2

Statement from EPA about Assessing Drinking Water Methods Provided to the NELAP AC by Donna Ringel, EPA Liaison to the AC, November 14, 2014

Issue: What is the citation or requirement for reviewing every drinking water method within a lab's scope during the on-site NELAP assessment or to evaluate State Drinking Water Laboratory Certification Programs based on the extent to which they do detailed method-by-method laboratory audits/reviews and not the broader brush review based upon technology which is otherwise a NELAP-acceptable assessment approach outside the drinking water matrix.

EPA Response: EPA recognizes that the TNI standard allows for a sampling of methods for accreditation (V2M3, Section 6.3.5). While, EPA guidance is not specific regarding this issue, it is the EPA Drinking Water Program's position that the CFR references to certification/accreditation requirements are specific to method and analyte and therefore, naturally and logically infer that ABs would be conducting method-specific assessments for each method for which certification/accreditation is granted. The EPA's expectation is that this is done during assessments of drinking water laboratories at a minimum of once every 3 years. ABs need to confirm via an on-site assessment that the laboratory is correctly running the drinking water methods as well as performing and generating data that passes criteria for all method QC requirements. If this is not done, vulnerabilities will exist and there may be implications that could affect public health.

There is a larger issue about what constitutes a complete and adequate assessment of the methods, especially in light of limited resources. EPA is in the process of developing a guidance document for Regional Laboratory Certification Program Reviews and will be attempting to define minimum criteria. At a minimum EPA contends that "due diligence" requires a representative selection of batch data be pulled and reviewed as part of each assessment to ensure that labs are complying with method QC requirements. Minimum method criteria currently being discussed for review during the method assessment includes: 1) Method SOP, 2) PT, DOC and MDL documentation, and 3) analyst interview and/or observation. Asking for data packages in advance can minimize the time commitment on-site. An assessor may have some basis to trust that the lab is doing the required QC based on documentation (QAPPs, SOPs), but the verification must come from looking closely at a randomly pulled data from their files.

To summarize, it is the EPA Drinking Water Program's expectation that every method be assessed and that not doing so is a public health concern that must be immediately addressed and rectified. In instances where resource limitations are a concern, the AB should reach out to their EPA Region so that issues can be discussed and a plan of action implemented to insure public health is adequately protected.

Attachment 3

Draft List of Potential Policies Needed by the AC

1. Assessing all methods versus selected methods for drinking water and other fields, at initial and subsequent site visits (SIR 254)
2. How to assess different FoAs
3. Accreditation of “prep methods” and accommodating the varied approaches of ABs
4. Using technologies as the basis for PT samples and FoPT tables
5. Assessing scopes by matrix/method/analyte (and how do the non-governmental ABs address this?)
6. What to do about PT requirements for scopes where there are no approved PT providers (such as biological tissue)?
7. NELAP Policy on Accreditation Body Conformance to EL-V2M3-ISO-2009, On-Site Assessment, Section 6.3.5 (ISO/IEC 17011:2004 E, Clause 7.5.6).
8. NELAC 4.5 allowed accreditation bodies to grant interim accreditation. This is not addressed in the 2009 TNI standard.
9. NELAC 6.2.i and 6.2.j authorized the NELAP Director to extend deadlines. This authorization appears to be assumed by the NELAP Chair.
10. NELAC 6.2.2.a, 6.2.2.c, and 6.2.2.d required applicants for accreditation to apply first to the recognized home state accreditation body. This requirement does not exist in the 2009 TNI standard.
11. NELAC 6.3.2.1.4 allowed recognized accreditation bodies to perform accreditation functions for each other. This is not addressed in the 2009 TNI standard.
12. Sometimes an accreditation body needs to amend its Fields of Testing list at times other than prior to evaluation, the same way a laboratory needs to amend its scope of accreditation at times other than prior to assessment. A policy or process for expanding the Fields of Testing for an accreditation body in these circumstances would be helpful.
13. Since California left and third party evaluators have been contracted, the cost for participation in NELAP has increased. It would be helpful if there was a communication policy to allow NELAP accreditation bodies advanced notice of cost increases and even better if the budget items were presented in advance.
14. At some time in the future, policy on secondary accreditation for mobile laboratories.
15. The generic application
16. Use of LAMS recognized as useful but cannot be absolutely “current”
17. Secondary accreditations