

Summary of the NELAP Accreditation Council Meeting

February 4, 2015, Forum on Laboratory Accreditation, Arlington, VA

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 3:30 pm EST on Wednesday, February 4, 2015, during the TNI Forum on Laboratory Accreditation. Those members in attendance are listed in Attachment 1.

2. Action Items Pending

None at present.

3. Recap of Meeting between NELAP AC, EPA OGWDW and Regional Certification Officers

Aaren summarized the discussions from this meeting. The summary provided by EPA is in Attachment 2.

4. Policies Needed to Support AC Operations

In its recent meetings, the AC has been compiling a list of policies needed to document its operations, presently twenty items long. Several copies of this list were available to participants, as well as to the AC members, and Aaren itemized the twenty items identified thus far. The list is provided in Attachment 3, below.

One participant suggested an additional item to add, about what constitutes adequate refresher training for assessors, and suggested that perhaps the Assessment Forum should count for this. This will be added to the list.

Discussion resulted in consensus agreement that the following policy areas need to be addressed:

Secondary accreditation – this is addressed in the Mutual Recognition Policy 3-100 which was approved by LASEC at its January meeting, and will be presented to the AC at its next meeting, for consideration.

On-site assessment – to what extent must all methods be assessed, and what level of detail is required. The AC earlier agreed to honor EPA OGWDW's request that all drinking water methods be assessed individually, but other fields of accreditation need to be addressed with at least minimum requirements. This policy area includes numbers 1, 2, 4 and 7 on the attached list of policies, and the starting resource may be the 2003 NELAC Standard, Chapter 3, Appendix C §4, and possibly information in Modules 1 and 3 of the TNI ELSS Volume 2. This area is considered to be defined enough that it can be referred to LASEC for the drafting of a policy document.

Prep methods – how ABs document the accreditation of these. Some accredit the “prep” separately, others include the prep with the method accreditation; some way for all ABs to be able to verify that prep methods were assessed needs to be agreed upon. This is #3 in

the attached list. Oklahoma noted that this is a critical issue before it begins actually assessing labs. This area is considered to be defined enough that it can be referred to LASEC for the drafting of a policy document.

Interim accreditations – there was general agreement that this is needed for a new AB in its first round of accreditations, but dissatisfaction about its use beyond the initial round. This is #8 in the attached list. A transfer from one NELAP AB to another is not “interim” and the receiving AB may schedule the lab’s site visit to occur two years after the previous AB’s site visit. The AC was not satisfied that sufficient agreement exists to request that a policy be drafted, at the close of the session.

Home state applications – under NELAC, a lab was required to apply to the NELAP AB in the state where it was located, but this is not documented in the TNI standard. This is #10 in the attached list. After some discussion about whether it should be a state regulatory issue or a policy, and possibly in Policy 3-100 (see above), this area was tabled for further discussion by the AC.

Training of assessors – training records are reviewed during evaluations of the NELAP ABs, but there is no requirement for annual refresher training in the TNI standard. This new issue, #21, requires further discussion before a policy draft is initiated.

Mobile labs – this issue needs to be addressed but there is not yet any agreement on how to recognize a mobile lab’s other-state accreditation when that mobile lab is doing business in a NELAP state. This is #14 on the list, and may also require interaction with the NEFAP program to resolve; it requires further discussion prior to action of any sort.

5. Next Meeting

The next meeting of the AC will be Monday, March 2, 2015, at 1:30 pm Eastern. A reminder will be sent in advance. An agenda and teleconference information will be sent out before the meeting. Alfredo Sotomayor noted at the close of the conference session that he would like to address the AC about the use of TNI and NELAP logos, at its next teleconference.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve.arms@flhealth.gov	Yes
	Alternate: Carl Kircher E: carl.kircher@flhealth.gov	No
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	No
	Alternate: Janet Cruse T: 217-785-0601 E: Janet.Cruse@illinois.gov	No
KS	N. Myron Gunsalus 785-291-3162 E: ngunsalus@kdheks.gov	Yes
	Alternate: Sara Hoffman shoffman@kdheks.gov	No
LA DEQ	Paul Bergeron T: 225-219-3185 E: Paul.Bergeron@la.gov	Yes (by telephone)
	Alternate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	No
	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	Tyler Croteau participated in the audience
	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	Yes
NY	Mike Ryan T: (518) 473-3424 F: (518) 485-5568 E: michael.ryan@health.ny.gov	no
	Information Contacts: Victoria Pretti victoria.pretti@health.ny.gov and Lynn McNaughton lynn.mcnaughton@health.ny.gov	No
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	Yes
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	Yes
	Ruthie Wedig E: Ruth.Wedig@tceq.texas.gov	No
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
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	Yes
Guests:	none	

Attachment 2

Notes from NELAP AC and EPA OGWDW Meeting Arlington, VA, February 4, 2015

List of Attendees:

Dan Hautman, USEPA OGWDW-TSC
N. Myron Gunsalus, Kansas Dept. of Health and Env.
David Caldwell, Oklahoma DEQ
Ken Lancaster, Texas CEQ
Judy Brisbin, USEPA OGWDW-TSC
Michella Karapondo, USEPA OGWDW-TSC
Jennifer Best, USEPA OGWDW-TSC
Debra Waller, NJDEP
Lynn Boysen, MNELAP
Kristin Brown, UT DOH
Cathy Westerman, VA DCLS
Aaren Alger, PA-DEP
Lynn Bradley, TNI
Christine Sotelo, California WRCB
Steve Weisberg, California SCCWRP
Martina McGarvey, PADEP
Tyler Croteau, NH ELAP
Stephen Arms, FDOH
Donna Ringel, EPA Region 2
Gary Ward, Oregon-ORELAP
Frank Lagunas, EPA Region 5
Rita Bair, EPA Region 5
Viola Reynolds, EPA Region 4
Scott Siders, Illinois
Donnell Ward, LHHS
Sandra Aker, EPA Region 4
Marcie Tidd, EPA Region 8
Julie Hankison, EPA Region 6

Topics Discussed:

1) DW Certification Officer Training

Dan Hautman stressed the importance of using trained assessors for drinking water assessments. Dan believes that the courses currently being provided by OGWDW-TSC constitute full assessor training and should be used to train all state DW Certification Officers. However, the EPA Regions have been delegated the authority for the oversight of the state laboratory certification programs, so EPA Regions may require state certification officers to attend the EPA course or they may allow use of other training programs after determining their equivalency. If Regions choose not to use the EPA courses they must document their equivalency determinations.

The following concerns regarding the current EPA training were expressed during the meeting:

- States often have restrictions on out-of-state travel and this prevents them from sending staff to the EPA courses
- States have limited resources, and while there is no cost for the training itself, there are significant costs associated with travel to the courses
- Since the training is only offered once per year, states are forced to send new employees who are not fully prepared or have them wait an entire additional year to take the training
- Slots in EPA training courses have been limited

The following suggestions were made to address some of the concerns noted above:

- EPA was asked to consider outsourcing the EPA courses to allow others to present the course materials
- EPA was asked to consider a mechanism to allow re-testing of staff that fail the course, rather than making them wait a full year to re-take the course
- EPA was asked to allow COs needing refresher training be able to participate remotely by telephone
- EPA was encouraged to consider on-line training options similar to what has been done for the *Cryptosporidium* Training Course
- EPA was asked to limit the need to memorize information for the written test and instead to consider an open-book approach.
- Use of on-line pre-testing of course applicants to screen those that are ready to take the full course from those that require more preparation

OGWDW expressed the following regarding some of the suggestions noted above:

- EPA utilizes some of the experienced assessors who come for refresher training to assist with the course
- EPA believes the material COs are expected to have memorized for the written tests is basic and that COs should know this information without having to check reference materials
- EPA committed to making a greater effort to accommodate all individuals requiring their training each year
- EPA outsourced these courses a number of years ago and the feedback from this effort was not favorable.

2) On-Site Assessments

Dan Hautman stated that it was EPA's expectation that every drinking water method (40 CFR 141) that the laboratory is accredited/certified for be assessed during the on-site. Accreditation and assessment by technology is not acceptable to the EPA Drinking Water Program. Dan further clarified EPA's position that PTs must be run for every drinking water method (40 CFR 141) each year. OGWDW has plans to issue a letter clarifying this position.

There was agreement by the meeting participants that this was their understanding and that they would be implementing these requirements within each of their respective programs.

3) Accreditation of Non EPA-Approved Methods

Dan Hautman clarified his concern regarding the accreditation of non EPA-approved methods. He indicated that the concern is only for those methods/parameters regulated by the SDWA. If a state would like to accredit laboratories for additional methods/parameters that is not a concern to EPA OGWDW. However, if the state is accrediting non EPA-approved methods/parameters for SDWA regulated contaminants, this is a concern because it may lead to confusion on the part of the regulated community. Dan would like the states that are accrediting for these non-EPA approved methods/parameters to somehow ensure that labs and clients know that those results cannot be used for SDWA regulatory compliance. Perhaps there can be a way to identify these non EPA-approved method/analyte combinations and place a disclaimer on certificates? Dan sees this as a potential vulnerability for state programs. He also noted that EPA may have reviewed the method and may have had a specific reason for not approving it. He suggested that states check with EPA to see if there are valid reasons for not approving these methods, before adding them to their DW scopes.

4) Data Qualifiers

It is the EPA Drinking Water Program's position that data used for compliance not be qualified. All QC criteria required by the methods must adhere to and the acceptance criteria passed. In many

cases SDWIS databases do not accept data qualifiers.

Aaren Alger from PADEP provided some background regarding this issue in her state. She indicated that several labs asked about reporting data that might be qualified but still valid. In response, PA issued guidance for requesting a usability assessment of qualified laboratory data. PADEPs guidance is available on their website. All such assessments are done by the state program office in conjunction with the laboratory accreditation program. Decisions regarding the acceptability of qualified data are communicated to the EPA Region and the issue is reviewed during the next on-site assessment of the laboratory to ensure it is not a continuing problem.

Dan Hautman indicated that he liked the PADEP approach. His concern is a blanket allowance of flagged data. EPA will leave the decision about acceptance of qualified data to the states. If an individual set of data is reviewed by the state agency and determined to be usable for compliance purposes, the EPA is okay with the data being reported.

Steve Arms noted that he was against telling labs not to report qualified data because it may simply result in the same data being reported with a lack of the qualifiers. Steve also noted that FL uses a data usability assessment document which is available on their website.

Myron Gunsalus noted that the regulator should be deciding whether or not to report qualified data into SDWIS, not the laboratories or the regulated water systems. The laboratories/systems should inform the regulator when their data is qualified. Myron requested that EPA make state drinking water programs aware that their labs and systems may be reporting qualified data. The state drinking water programs, in consultation with their laboratory accreditation programs, should determine how this is to be handled.

Dan Hautman reported that he has talked with AWWA regarding data defensibility. AWWA is planning to send information to their water systems reminding them that they have responsibility to ensure that compliance data is usable. The information will also provide assistance to help systems get usable data from their contract laboratories.

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.
18. Timeframes for ABs to complete corrective actions after evaluation site visit.
19. Policy outlining desirable qualifications/credentials for contract assessors or all assessors (as discussed at Dec. 10 Board meeting.) May be useful for contracting, but might also be useful for getting higher rankings (grade ratings, salaries) for state employee assessors (again, as discussed at Board meeting.)

20. A polling policy, to clarify whether email questions versus a more formal discussion in an AC meeting or possibly a SIR submission will be adequate to resolve an implementation question among the ABs.
21. Documentation of what NELAP ABs find acceptable for refresher training for assessors.