

Summary of the NELAP Accreditation Council Meeting

December 15, 2014

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EST on Monday, November 15, 2014. The minutes from November 17 and December 1, 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)

3. Webinars for Standards Modules under Development

Aaren noted that the webinars for both the Radiochemistry Modified WDS and the WDS for Detection and Quantitation occurred earlier this month, and that one for the Micro WDS is scheduled for December 22. She requested that an agenda item be added to each AC meeting, following future webinars, as the 2015 standard continues to progress.

Comments on the Detection and Quantitation WDS are noted below:

- The revised language requiring an “initial” LOD verification appears to mean that labs must repeat the initial verification that was previously done. This will likely create a host of objections, and perhaps grandfathering of earlier LOD verifications should be considered, since to do otherwise would establish a “false” start date for beginning to perform those analyses, assuming that more than one analysis/year is done and a new initial demonstration of capability is not required.
- NPDES permits need to follow the method requirements as published in the Federal Register, and it’s possible that labs will not understand they must repeat the verification if the standard does not also require it (a similar situation to the qualified data reporting of the Calibration IS.)
- A new MDL procedure, if required by a permit, would be acceptable for LOD but ought not to be a replacement for the original one.
- The acceptance criteria for LOQ is qualitative rather than quantitative (LOQ \geq 3-times-LOD) – these should be quantitative. Some LOQs may be unable to meet the drinking water program requirements under these conditions.
- Will verification of an annual LOD or quarterly LOQ create a problem with ongoing assessments?

Aaren encouraged individual ABs to comment directly to the Chemistry Committee now. She also noted that formal comments will be developed by LASEC and shared with the AC at the VDS stage.

NOTE: Later in the discussion, Aaren asked that Lynn obtain a definitive answer about what happened to the earlier revisions of the Quality Systems Module of Volume 1, since that it had been revised but no one knew its status. All modules of V1 except for the PT module (V1M1) were revised and completed in 2012, and voted upon by TNI membership. These have been awaiting revision of the PT modules, before being proposed for adoption,

and under the “old scheme” whereby LASEC and the AC review the complete Volume all at once, the QS part would have been added in. With the formation of Chemistry, Radiochemistry and Microbiology Expert Committees, those three modules have been handed off to the appropriate committees for further revision, while modules 2 (QS), 3 (Asbestos) and 7 (Toxicity) await adoption. Module 2 will likely have a TIA to remove the notes in two locations, saying that those sections do not apply to environmental labs, once the Standards Development SOP is revised and approved. Now that the status is clear, LASEC will begin reviewing these modules (2, 3 & 7) along with the PT modules of V1 and V2 which have just undergone voting.

4. Request from EPA, relayed by Donna

As the Council began discussing concepts for needed policies, Donna presented a request from the Agency that all assessors involved with assessing drinking water labs must have successfully completed the EPA training, based on the EPA Drinking Water Certification Manual, or else demonstrate that the state employing those assessors has equivalent training. The Agency represents that this is a requirement for state primacy designations, a determination made by each individual region for the states within that region.

According to Donna, the reason for this request arises because a NELAP AB audited an Agency lab for drinking water methods, using assessors who had not completed the Certification Officer (C.O.) training (the Cert Manual.)

Discussion points included the following:

- A change in the TNI Standard (Volume 2) would be necessary to make this a requirement.
- This is similar to the “must assess every method” requirement, which held to be a condition of state primacy but nowhere documented in regulation.
- If NELAP ABs are to be held to this, then the Agency needs to communicate its position more formally, and communicate it to ALL PRIMACY STATES.
- This is in direct contradiction to the “Dougherty equivalency” letter of April 29, 2009 (attached to email transmitting these draft minutes.) It is a substantial change to current policy, and a modification to that letter may need to be issued.
- The requirement that a NELAP assessor pass the C.O. training is problematic for ABs, since if a newly hired staffer does not pass the course (per the test at the end,) that individual remains on the state payroll but unable to perform the duties of the position for which they were hired.
- The Cert. Manual states that an on-site team needs just one C.O.
- The Cert Manual recommends “refresher” training every five years, but EPA offers no such thing. One AB noted that R5 accepts “annual refresher training” by the AB as meeting this requirement.

No resolution was reached, at the end of the discussion.

5. Development of Policies Needed to Support AC Operations

Several additional suggestions for policies were added to the draft list, which is updated in Attachment 2.

Aaren offered her preferences for items from the attached list of needed policies, as being 18 (timeframes for corrective actions after evaluations,) 12 (how to expand FoT,) 5 (how to assess matrix/method/analyte) and 3 (some form of written agreement about prep methods – how to document what is approved, since ABs vary in procedures.) She then suggested beginning with numbers 3 & 12, and then perhaps numbers 1, 2 & 5 (which are all focused on the on-site assessment issue.)

Another AB recommended that the Council sit down at conference (separately from the public session) to develop a concept for these policies.

6. Possible Use of NIST Document

Paul Bergeron inquired whether other ABs might be supportive of using NIST Special Publication 819, *A Procedure for the Effective Recalibration of Liquid-in-Glass Thermometers*, August 1991, as an exception to the current requirements of the TNI Standard. This relates to the AC's discussion of SIR 206 (see http://nelac-institute.org/load_sir.php?SIR=206). Another AB noted that the procedure itself works fine and would surely save money, but is not in conformance with either standard. This same commenter did note that the standard does not require recalibration of NIST thermometers, but rather leaves that up to the lab's quality system.

7. Lab ID Codes

Lynn mentioned that, during the December Board meeting, there was discussion about an unexpected retirement that left the Agency with no one knowledgeable about assigning LAB ID codes, and inquired whether this was a problem for the NELAP ABs.

At the DMRQA meeting, December 1, and also on the State Assessor Forum, drinking water program staff discussed this and assured states that the Technical Support Center is moving as fast as possible to resolve the issue, since 23 states and three PT Providers use those ID Codes as unique identifiers for labs.

8. Next Meeting

The next meeting of the AC will be Monday, January 5, 2015, 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	Yes
	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	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	No
	Alternate: Sara Hoffman shoffman@kdheks.gov	No
LA DEQ	Paul Bergeron T: 225-219-3185 E: Paul.Bergeron@la.gov	Yes
	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	No
	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	Yes
	Alternate: TBD	
OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	No
	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	Yes
TX	Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov	No
	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	Yes
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

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.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

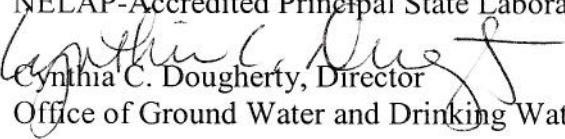
WASHINGTON, D.C. 20460

APR 29 2009

OFFICE OF
WATER

MEMORANDUM

SUBJECT: Clarification of Regional Office Responsibilities Related to Oversight of
NELAP-Recognized State Drinking Water Laboratory Programs and
NELAP-Accredited Principal State Laboratories

FROM: 
Cynthia C. Dougherty, Director
Office of Ground Water and Drinking Water

TO: Regional Science and Technology Directors
Regional Certification Authorities
Regional Drinking Water Branch Chiefs

The Office of Ground Water and Drinking Water (OGWDW) has been asked to clarify roles and responsibilities for EPA's Regional Offices, vis-à-vis those of the National Environmental Laboratory Accreditation Program (NELAP) in oversight and decision-making associated with state Accreditation Bodies (ABs) and NELAP-accredited state laboratories (i.e., "principal state laboratories" [PSLs]). Clarification of roles and responsibilities is particularly important as we work together to ensure that primacy conditions are being met, and as we collectively seek to maximize drinking water laboratory integrity and minimize vulnerabilities, per the recommendations from the Office of Inspector General's 2006 review of drinking water laboratories.

EPA oversight of state drinking water programs and PSLs is fundamentally a primacy responsibility that is carried out by the Regions, as described in Attachment 1. OGWDW anticipates that Regions will typically use the NELAP-led evaluations of the state (AB) programs and the NELAP audits of PSLs to support the Region's determination that the state is meeting its "primacy" requirements. Accordingly, OGWDW values Regional participation in the NELAP evaluations of the state programs and encourages continued participation; OGWDW similarly encourages Regions to participate in NELAP audits of PSLs seeking to attain or renew NELAP accreditation. However, we note that Regions may choose to independently review the drinking water portion of a NELAP state program, or may choose to independently audit the PSL for a NELAP state, just as they would for a non-NELAP state.

Ongoing Regional participation in the NELAP process (evaluation of ABs, audits of PSLs) promotes quality and consistency, and allows for efficient use of limited resources. Such collaboration results in better communication between EPA and NELAP and helps

minimize the potential for disputes. Nonetheless, we recognize that there may be times when a Region and NELAP will have different opinions regarding the acceptability of a state program or PSL. In such cases, we encourage the Region to work directly with the particular AB and, as appropriate, the NELAP Board to resolve the differences. OGWDW is also available to work with you, especially if you need input regarding program requirements or policy matters or you are not able to resolve differences through the other channels. *Ultimately, the primacy decisions regarding the acceptability of the state program and the PSL rest with the Region.*

OGWDW appreciates the input from the Regional Science and Technology (RS&T) Directors, Regional certification programs, and representatives of NELAP and The NELAC Institute (TNI), among others, towards our development of this memo and its attachments. Should you have any further questions regarding the subject, please contact Greg Carroll of OGWDW's Technical Support Center at 513-569-7948 or carroll.gregory@epa.gov.

Attachment 1: *“Respective EPA/NELAP Roles Associated with NELAP-Recognized Accreditation Bodies/Programs and NELAP-Accredited State Drinking Water Laboratories”*

Attachment 2: *“OGWDW Clarification Regarding Principal State Laboratory Definition/Oversight”*

cc (w/ attachments):

Regional Certification Officers
Pamela Barr
Gregory Carroll
OGWDW Laboratory Certification Team
Carrie Wehling, OGC
Lara Autry, ORD
Judy Duncan, TNI
Dan Hickman, NELAP
Jerry Parr, TNI

Attachment 1

Respective EPA/NELAP Roles Associated with NELAP-Recognized Accreditation Bodies/Programs and NELAP-Accredited State Drinking Water Laboratories

Issue: For State¹ Drinking Water accreditation programs and for Principal State DW Labs (PSLs) being recognized/accredited by the National Environmental Laboratory Accreditation Program (NELAP), there are really two sets of decisions being made: one regarding NELAP accreditation status (i.e., Should the State be recognized to serve as a NELAP Accreditation Body [AB]? Should the PSL be NELAP-accredited?) and the other regarding SDWA primacy conditions (i.e., Are the conditions of 142.10(b) being met?). The former is a NELAP decision; the latter is an EPA decision. Respective roles are described further below.

	NELAP/TNI - Drinking Water	NELAP/TNI - Other (non Drinking water)
<u>State Accreditation Program</u>		
On-site (typically triennial) evaluation of State program ²	NELAP (and Region, as appropriate)	NELAP
Off-site, annual review of State DW program	Region	NA
Decision regarding <i>NELAP</i> recognition of State program as an Accreditation Body	NELAP	NELAP
<i>EPA</i> determination that the State program is meeting primacy conditions [142.10(b)(3)]	Region	NA
<u>Principal State Lab³</u>		
Audit/review of Principal State Lab	State ⁴ Accreditation Body [AB] (and Region, as appropriate)	State AB
Decision regarding <i>NELAP/TNI</i> accreditation of Principal State Laboratory	State AB	State AB
<i>EPA</i> determination that Principal State Laboratory is meeting primacy conditions [142.10(b)(4)]	Region	NA
<u>Commercial (non-PSL) Laboratory</u>		
Audit/review of commercial laboratory	State AB	State AB
Decision regarding accreditation of commercial laboratory	State AB ⁵	State AB

¹The term "State" is used for simplicity and refers, for purposes of these discussions, to Primacy Agencies

²Typically includes observation of the State during their review of a non-PSL lab(s)

³Includes commercial labs serving as the PSL under contract to the State

⁴Potential for conflict of interest should be evaluated/addressed if the AB and PSL are with the same State, particularly if the Region is not involved in PSL audit/review

⁵If the commercial laboratory is being accredited by other than its "parent" State/primacy agency, this presumes that the primacy agency has established an agreement whereby it will accept/recognize accreditation by a NELAP AB (e.g., a VT lab being accredited by FL). Commercial laboratories residing in a NELAP state are accredited by that State, per the TNI Standard.

Attachment 2

OGWDW Clarification Regarding Principal State Laboratory Definition/Oversight

What Constitutes A Principal State Laboratory (PSL)?

40 CFR 142.10(b)(4) requires that a primacy agency ensure the availability of certified laboratory facilities capable of performing analytical measurements of all contaminants specified in the State primary drinking water regulations. These laboratory facilities may be made available to the State by the operation of a State laboratory, by contracting with commercial laboratories (within or outside of the State), by making arrangements (e.g., a Memorandum of Understanding (MOU)) with another State, or by some combination of the above. These laboratories, collectively, represent the Principal State Laboratory (PSL) network.

Above and beyond meeting the minimum requirements of 40 CFR 142.10(b)(4) (i.e., having at least one laboratory available to analyze each regulated contaminant), States may have additional laboratory capacity available to them (e.g., multiple State/district laboratories, contracts with multiple commercial laboratories, MOUs with multiple States). Regions are not obligated to treat these additional supplemental/secondary laboratories as PSLs; therefore, these laboratories are not strictly subject to the PSL certification conditions described below. Regions may choose to implement additional measures for the oversight of such laboratories, particularly if the secondary laboratory routinely does work for the State (as opposed to a secondary laboratory that is available to the State for occasional or emergency use), and/or if there are conflict of interest issues associated with certification of those laboratories by the State.

How Does A Principal State Laboratory (PSL) Become Certified/Accredited?

40 CFR 142.10(b)(4) requires certification of PSLs by EPA; this authority has been delegated to Regional Certification Authorities but cannot be further delegated to the States or to other non-EPA parties. Regional certification of the PSL may be achieved by one of the following approaches:

1. A Region may certify the PSL directly, acting either on their own audit of the laboratory or on an audit performed by a third party expert (e.g., a contractor). Certification of a PSL by one Region (presumably their parent Region) may be accepted by other Regions that rely on that laboratory as a PSL.
2. A Region may use NELAP accreditation of a laboratory serving in a PSL capacity to support Regional recognition. If the NELAC AB (i.e. the State) has accredited a laboratory that ultimately serves as a PSL for the same State, the potential for conflict of interest should be considered and, as need be, addressed by the Region to ensure that the AB is independent of the PSL. The Region should document its recognition of the laboratory as a PSL by issuing a letter to the PSL.

3. A Region may use State certification of a laboratory serving in a PSL capacity to support Regional recognition. If a State has certified a laboratory that ultimately serves as a PSL for the same State, the potential for conflict of interest should be considered and, as need be, addressed by the Region to ensure that the State Certification Authority is independent of the PSL. The Region should document its recognition of the laboratory as a PSL by issuing a letter to the PSL.

Regions may apply additional conditions as they see fit (e.g., limiting their reliance on State certification of commercial laboratories to support Regional certification to States within their particular Region).

How Should a Mobile Laboratory Affiliated with a Principal State Laboratory (PSL) be Treated?

At the discretion of the Region, a mobile laboratory can be considered an extension of the “primary”/stationary Principal State Laboratory, particularly when the mobile laboratory is used on an interim, emergency, and/or transient basis. On this basis, the Region may extend their recognition/certification of the stationary PSL to the mobile laboratory if the mobile laboratory only performs analytical techniques for which the stationary laboratory is certified/accredited. If the mobile laboratory is operating as a stand-alone laboratory (such that media preparation, etc. are occurring in the mobile laboratory), particularly on an ongoing basis, OGWDW generally believes that an independent certification of the mobile laboratory is warranted (as opposed to extending the stationary laboratory certification to the mobile laboratory).