

Summary of the NELAP Accreditation Council Meeting

February 1, 2012

1. Roll call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 8:30 am EST on February 1, 2012, at the Forum on Laboratory Accreditation in Sarasota, Florida. Those members in attendance are listed in Attachment 1.

2. Updates on AC activities

Aaren noted that the AC is beginning to make progress with backlogged Standards Interpretation Requests. She also noted that the Laboratory Accreditation Management System (LAMS) is online with all lab demographic data entered and good progress being made on the scopes of accreditation.

There have been 6 AB evaluations completed; five have renewals approved and one awaits a vote. Certificates were handed out to three Accreditation Bodies (ABs) present – UT, NH and NY. The LA DHH certificate will be mailed, and the PA certificate awaits signing by the Vice Chair of the AC. Aaren noted that, in reading the evaluation documents supporting the Evaluation Team recommendations, she sees definite improvement since the previous round of evaluations, and expressed her thanks to all the ABs for their efforts, and encouraged them to continue along the improvement path.

She then summarized the previous day's meetings with ACIL's Environmental Sciences Section as well as the TNI Board of Directors, the Environmental Laboratory Advisory Board (an EPA Federal Advisory Committee), APHL and all non-NELAP state ABs. It was helpful to hear from the non-NELAP states about the reasons for their non-participation, and noted that having some states use NELAP accreditations that don't participate as ABs definitely contributes to the workload of the 15 NELAP ABs. The AC will consider holding "open" teleconference meetings periodically, to include these non-NELAP states and others, in the future.

The NELAP ABs have taken ACIL's position paper and the newsletter item from last fall very seriously, and sought to meet with ACIL both to clarify understanding of its position and to help resolve those issues that the AC can improve. AC members were unaware that ACIL and its member labs believed that the AC had been informed of their complaints, but now that they have been expressed to the AC, Aaren commits to addressing them.

The complaints identified in the previous day's meeting were:

- Labs do not complain to ABs, even on evaluation forms, because they fear retribution.
- Labs want wider fields of accreditation in all ABs, to reduce the need for multiple primary accreditations
- Labs want a uniform application among the ABs.

3. AB Assistance Task Force Recommendation to use assessment reports from DoD/DOE

The AC began to address this item in Bellevue, and then learned that the Laboratory Accreditation Systems Executive Committee (LAS EC) was addressing availability and

access to the reports from Department of Defense and Energy (DoD/DOE) accreditations, so waited for the LAS EC outcome, which was transmitted in December. Both departments presently use the 2003 NELAC standard with “gray box” additions, and both have indicated intent to move towards the 2009 TNI standard in the future. DOE performs its own assessments, and reports are considered to contain “For Official Use Only” (proprietary business) information and not release-able; DoD recognizes some or all of the US non-governmental ABS, and depending on the AB’s contract with the lab, the report may or not be obtainable from the AB. Labs may provide the reports (which are the labs’ property) voluntarily but some have expressed reluctance to do so.

AC member ABs agree that the assessment reports, while available only from the labs and not from the non-NELAP ABs involved, have promise as “tools” but have concerns about using the reports in lieu of onsite visits. The AC hopes to receive an “example” report from a DoD assessment from one of the large labs participating in many TNI activities, so they may know what is included.

NH has 4 DoD labs, and has obtained the AB assessment reports from them. NH seeks ways not to duplicate the DoD assessment but have identified some technical issues not noted by the DoD assessment. A TNI Board member suggested going to the DoD AB to discuss such differences in assessment, and NH agreed that might be a good idea. NH noted the necessity of looking at drinking water methods, since DoD assessors typically do not cover drinking water and it’s expected that few DoD assessors will have drinking water certification training.

LA DEQ noted that it permits its third party (contract) assessors to “piggy-back” NELAP assessments on DoD assessments, with apportioned costs, but that it will defer to the AC for its decision about whether it’s acceptable to substitute a DoD assessment report for a site visit.

FL noted that a DoD report would be “found data” but they have not actually seen one yet; FL has 5-6 DoD labs. IL uses the findings and corrective actions as a tool to guide its assessments, similar to how they might use an internal audit. IL noted that the DoD assessors seem no better or worse than NELAP assessors, and that labs complain about DoD also. NJ also noted that it has participated in “joint” assessment with DoD assessors where each AB wrote its own report.

KS noted that it has one in-state lab with DoD accreditation, and that the DoD AB is willing to do its audit in combination with KS, for the drinking water focus, but that the laboratory itself is hesitant to cooperate, for unknown reasons.

MN noted its plans to use a drinking water certification report from a non-NELAP sister agency, in the lab’s state, where the laboratory is already NELAP-accredited, but seeks recognition for drinking water parameters as well.

The DoD program lead, Jordan Adelson (a TNI ex-officio Board Member), noted that the DoD assessments are not regulatory, but that the Department’s relationships with its (non-governmental) ABs is “close” with extensive oversight. DoD reviews all reports and observes all assessors, and holds monthly teleconferences with its ABs, in an effort to attain consistent assessments. Later in the meeting, Mr. Adelson offered to send the DoD conditions and requirements to the AC for consideration, and noted that no DoD money changes hands with this program, that labs contract directly with the approved non-governmental ABs.

The focus of DoD’s 90 lab accreditations is on environmental restoration work, mostly SW-846 methods, and that DoD requires additional quality control steps for SW-846

methods. DoD's accreditation program began in response to problems with lab results, initially using in-house accreditations (as DOE) and then transitioning to use non-governmental ABs. If a lab asked for accreditation to compliance methods, that would be acceptable but surprising. Mr. Adelson invited NELAP ABs to contact him for information exchange if desired, and noted that DoD cannot accept NELAP assessments due to the standard used at DoD having additional "gray box" items in it. He did emphasize that all DoD ABs are signatories of the International Laboratory Accreditation Cooperation (ILAC).

Another TNI Board member noted that the DoD reports focus on findings, not positive aspects of the lab. That individual and several others spoke up to say they would welcome "shared assessments" of their respective labs.

A different Board member stated that their lab requested that its DoD audit examine ALL methods, and noted that with multiple assessors on-site, the differing agendas sometimes create friction, to the detriment of the audit. This commenter also noted that some DoD assessments list all methods examined, but that others do not, so for a NELAP AB to determine what was actually audited may be problematic.

Aaren again noted that the issue is not using assessment reports as a tool to refine an AB's audit plan, but rather the problematic aspect is whether to use a non-NELAP assessment report in lieu of an actual site visit. Using the reports as a tool might strengthen the program, but accepting another AB's report in lieu of a site visit may be perceived as weakening the NELAP program and threatening "mutual recognition" unless all NELAP ABs agree to do so. Obtaining that agreement looks to be a complex issue due to the laws and regulations that govern the various NELAP state ABs.

Pete Unger, A2LA President and current Chair of ILAC, responded that it's only necessary to look at the scope of accreditation requested, and to obtain the technical checklist in addition to the assessment report and the scope. Mr. Unger also invited NELAP into ILAC and inquired whether NELAP ABs were subject to de-certification, and emphasized the peer review of ABs that ILAC utilizes. It was noted that NELAP also uses a strong peer review process in its AB evaluations.

A lab representative noted that DoD ABs arrive on-site every year, performing surveillance audits that cover methods not observed during the 5-year "full assessment", and that DoD offers a strong "systems" audit with technical aspects as well.

A representative of a different non-governmental AB noted that trust is the underlying issue, but wondered why, when some states have issued Requests for Proposals to use third party assessors (TPAs) and/or third party ABs (TPABs), it seems difficult to "trust" an outsider? Aaren re-emphasized that it's not so much "trust" as it is needing all NELAP ABs to be able to sustain mutual recognition.

A TNI Board member noted several points. First, if surveillance audits become a NELAP option (with 5-year assessment cycle), it might be possible to substitute a non-NELAP assessment for surveillance even if not for an initial or "full" reassessment. Second, if TNI pre-qualifies TPAs, then the DoD assessors might be pre-credentialed and that could be a condition of accepting DoD reports? Another Board member asked, if the NELAP ABs "trust" one another, why are the ILAC signatory ABs outside of that "trust"? This individual noted that, if NELAP ABs were to shadow TPAB assessments, that might increase the trust level; an invitation from the lab would be necessary, however.

IL noted that there is some agreement and commonality among the governmental and non-governmental ABs, and requested a firm agreement to work together, and specifically

asked the DoD and non-NELAP states to work with the AC to address some of the issues raised.

Aaren reminded all that Judy Morgan (Chair, ACIL ESS) and herself have committed both the AC and ACIL ESS to work together, as well as with joint stakeholders like the non-NELAP states and the DoD ABs. Aaren also indicated her intent to open 1-2 AC teleconferences each year to all parties working together.

APHL raised the possibility of NELAP accepting recognitions from non-NELAP states. Several commenters asked whether, if non-NELAP ABs visit a lab and find problems, do they notify the AC, regardless of whether they are states or non-governmental ABs? If so, the AC would have an obligation to notify all others in the program. A commenter also noted for this meeting the point raised elsewhere, that while V2 of the Environmental Lab Sector Standard (the TNI Standard) does not restrict ABs to being governmental, V1 does, in the definition of AB in Module 1. A final commenter asked whether non-governmental ABs can apply to become NELAP ABs under the 2009 TNI standard. This question remains to be addressed elsewhere.

4. Implementation Status of the 2009 TNI Standard

Aaren reviewed the agreement to honor “rolling implementation” and noted that ABs are being evaluated to the 2009 standard (Volume 2), regardless of which standard it uses for accrediting labs, and reminded participants that each time the standard has been revised, there has been a similar transition period, with continuing mutual recognition among ABs. A Board member requested state-by-state status, which was reviewed, and this same information will be presented for the mandated semi-annual report to the Board, prior to the next Board meeting. Another Board member noted that there is 85% congruence between the two standards, and that the 2009 TNI standard is generally less stringent than the 2003 NELAC standard, so that this transition time ought not be viewed as problematic. [Note: this table is slightly modified from the version in the 1/17/12 minutes, to reflect anecdotal comments by AC members during this session.]

STATE	Implementation Status as of January 2012
CA	presently using the 2003 standard, will shift to 2009 standard as staff can be trained and the checklist approved
FL	rulemaking timeframe for official transition remains uncertain, but intends to complete the necessary rule revisions by July 2013. Uncertainties about program status make transition problematic. The AB is accommodating circumstances where labs have implemented 2009 standards and 2009 PT requirements.. Can only enforce to 2003 standard.
IL	Intends to implement TNI Standard within 2 years. Should a revised Standard be adopted during that timeframe, IL will implement the newer standard instead. Accommodating labs that choose to change to the 2009 TNI Standard.
KS	Remains with 2003 standard for labs. Allowing laboratories to report PTs under 2009 Standard as a majority of the PT portion for the 2003 standard was not adopted. Allowing laboratories to move forward with changes to 2009 Standard when they are more stringent or new requirements, otherwise labs must still meet 2003 Requirements. Draft Regulation has been developed, but in-state circumstances prohibit setting timeline at present.
LA DEQ	rulemaking still in progress, with 6 of 7 public meetings accomplished for in-state labs; publication and acceptance of out-of-state public comments expected later in 2012. Likely implementation before 2013. Encouraging labs to implement 2009 Standard.
LA DHH	intends to publish rule in January, then await legislative approval; likely implementation

	within 3 months Labs are using 2009 Standard now.
MN	delays in modifying database create delay until probably March, 2012, for implementing 2009 standard
NH	not implementing 2009 at this time; rulemaking expected to begin in mid-2013
NJ	not implementing 2009 at this time, but assessing labs against the TNI standard. Draft regulation written, publication timeline uncertain, possibly mid-2012.
NY	enforcing 2003 standard, at least 1 year before 2009 can be implemented due to regulatory conflicts with the PT portion of the 2009 TNI standard; regulatory development likely to begin once the revised PT portions of the TNI standard are final. Checklists include 2009 standard so that labs become aware of changes needing made.
OR	fully implemented 2009 standard on August 9, 2011
PA	full implementation as of September 2011
TX	implemented 2009 standard as of July 1, 2011
UT	full implementation as of October 2011
VA	Program fully effective as of January 2012. DCLS has initiated the rulemaking process, but no regulatory timeline estimate is available at this time. Continuing to use the 2003 NELAC Standard.

5. APHL Policy Regarding State Environmental Laboratory Accreditation

Mike Wichman from the State Hygienic Laboratory at The University of Iowa, representing the Association of Public Health Laboratories, was invited to discuss this policy, but since it remains under development, he could not provide specifics. The policy is being formulated in response to ACIL’s white paper about National Laboratory Accreditation, and Mike did note that APHL supports the need for quality data from environmental labs, the need to maintain expertise in state programs for accrediting laboratories, and noted that state enforcement powers are closely connected with the licensing privilege exercised by state environmental accrediting programs.

A Board member initiated discussion about why states need to maintain expertise – both for compliance assistance as well as oversight of TPAs. This prompted a question about availability of technically qualified state personnel if TPAs or non-governmental ABs were used, and only administrative staff remained in the state office, and whether other AC members could share in the compliance assistance tasks. Several NELAP ABs were quick to note that they don’t have surplus time or staff to share. FL clarified that at least EP{A Region 4 has stated that the state person making the “final decision” about accreditation or certification must be a qualified drinking water Certification Officer, at least for drinking water certifications, if TPAs are used. The Board member suggested that TNI could broker technical assistance resources, but did not address costs for such a service.

6. Comments from Participants

One participant inquired who pays the fee if a state sends a third party assessor (TPA) to the lab. The response was that it depends on the state and how its contract is written. NY noted that this is not a rulemaking issue, and may not be transparent to labs. TX noted that its use of TPAs IS addressed in regulation, the charges are passed to the lab but paid to the state, and the state pays the TPA. OR uses TPAs for “rad” methods, and while it must have a direct contract with the assessor, the lab pays the costs. NJ assesses labs a fee to cover the cost of TPAs but there is a current rulemaking addressing that issue. MN has a “no cost to state” contract, so that TPAs bill the lab directly. KS has the same as MN for out-of-state labs where TPAs are used. LA DEQ obtains quotes from both of its TPAs;

the lab may choose its assessor subject to approval by the AB.

A follow-on question from a different party concerned controls on TPA fees. This too varies by state. MN selects and assigns the TPA, but the contractor notifies the lab and the AB of the estimated charges and if it seems excessive, the AB may ask for a second quote from a different assessor. For TX, as with LA DEQ, 2 contractors submit quotes for each lab to be assessed; approximate costs are \$5K for a small micro lab up to \$15K for a large lab doing complex testing (including travel.) The questioner expressed concern that fees may be arbitrary, and that they may be excessive for small labs, in particular. Currently, Florida costs are fixed but if TPAs become used there, as may happen for both in state and out of state labs, it could become problematic for the many small labs there. PA noted that it charges out of state labs for assessments, but not in state labs. MN requires an itemized invoice and, if it's a shared assessment, that "attributable cost" be specified. NH noted that, if it uses a contract TPA, the lab may choose from among the bids. One TPA noted that the state contracts specify daily and hourly rates as well as state travel rates, but the length of time for each assessment varies according to the scope of assessment and the size of the laboratory plus travel as well as travel time.

A Board member inquired about pending AB applications and was told that OK's application is "imminent." Consistent with prior practice, once a state informs the AC of its intent to apply, it is invited to join in AC meetings as a non-voting member. In this case, due to a shortage of evaluators, OK contributed an evaluator to the current round even though it had not yet submitted its application.

Another participant asked about conflict resolution, particularly about assessors and interpreting method requirements. The AC and other participants were clear that neither ABs or the AC or the Standards Interpretation Request process are suitable places for resolving interpretation questions, but that the ultimate decision must be made by the EPA region, the method author, or by referral to Standard Methods itself (AWWA, usually.) If an assessor's judgment while observing the method being performed is questioned by the lab, it is the lab's responsibility to 1) identify the disputed finding in the closing meeting and 2) seek resolution (in writing) of the issue and provide it to the assessor and the AB, before the final report is issued.

For interpretations of drinking water methods, Dan Hautman, EPA Technical Support Center (TSC), Office of Ground Water and Drinking Water or the Office of Research and Development (OGWDW,) stated that analytical methods do occasionally have "ambiguities" and that the AB can contact the regional authority (however designated) who can contact Headquarters OGWDW, if necessary. There still remained the unanswered question of whether the regional response can be relied upon, or if it needs to be validated through the TSC.

7. Next meeting

The next AC meeting will be Tuesday, February 21, 2012, at 1:30 pm, since the regularly scheduled 3rd Monday meeting falls on a holiday. Agenda items may include the following

- Approval of Minutes from January 17 and February 1, 2012
- Update on Evaluations
- Vote on Florida renewal recommendation (materials sent Jan 30 or 31)

- Discussion and decision about options for KS evaluation recommendation (or delay until March 5?)
- Discussion of SIRs (numbers????)
- Updates from Conference, including action items to carry forward -- develop a uniform complaint process, make scopes of accreditation consistent across ABs, create a consistent and simpler process for adding new methods or analytes to a lab's scope of accreditation, periodic open meetings of the AC (in addition to meetings at conference) to include one in May 2012 with specific invitations to non-NELAP AB representatives for discussion of ways to work together for more effective program across the nation

And a couple of additions since the conference:

- Change evaluation SOP to add 6.4.3 about reviewing documents offsite – a request from the NELAP evaluators group
- Mock-up of uniform application circulated for input, at request of the LAB committee

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	Jane Jensen 510-620-3174 F: 510-620-3471 E: jjensen@cdph.ca.gov	no
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KS	Michelle Wade E: MWade@kdheks.gov Ph: (785) 296-6198 Fax: (785) 296-1638	phone
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LA DHH	Donnell Ward T: E: donnell.ward@la.gov	phone
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NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 E: joseph.aiello@dep.state.nj.us	yes
	Alternate : TBD	
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PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@state.pa.us	yes
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	Alternate: Ed Shaw T: 804-648-4480 ext.152 E: ed.shaw@dgs.virginia.gov	no
	NELAP AC Program Administrator and Evaluation Coordinator Lynn Bradley T: 540-885-5736 E: lynn.bradley@nelac-institute.org	yes
EPA Liaison	Marvelyn Humphrey T: (281) 983-2140 E: Humphrey.Marvelyn@epa.gov	no
	Quality Assurance Officer Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	no
	Oklahoma: David Caldwell	yes
	Guests: open meeting at conference	many