Summary of the NELAP Accreditation Council Meeting

November 21, 2011

1. Roll call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EST on November 21, 2011. Minutes of the November 7 meeting were approved. Those members and guests in attendance are listed in Attachment 1.

2. Updates on AB Renewals

Lynn reported on the status of ongoing evaluations:

CA – completeness review underway, scheduling on-site

FL – on-site and observation conducted week of November 14

KS – awaiting revised SOPs to address technical review and findings from site visit; extension granted until December 31

LA DHH – site report in preparation

NH – onsite report sent Nov 15

NJ – technical review sent, scheduling of site visit initiated

NY – recommendation for renewal sent to AC 11/16/11

PA –recommendation sent 11/9/11

UT – team review of response to site report completed, preparing recommendation

3. Voting on Recommendations from Evaluation Teams for PA and NY

Steve Stubbs stepped in to chair the part of the meeting about the PA renewal recommendation. There were no questions, and a roll call vote was taken; with PA recusing itself from voting, there were 14 "yes" votes, and the recommendation to renew the recognition of PA as a NELAP Accreditation Body was approved as of November 21, 2011.

Aaren resumed chairing the meeting for the part about NY's renewal recommendation. There were no questions, and a roll call vote was taken; with NY abstaining from voting, there were 13 "yes" votes, with one AB requesting to vote by email since the representative had not had time to complete reading the recommendation. That outstanding vote was received as of and the recommendation to renew the recognition of NY as a NELAP Accreditation Body was approved, as of November 22, 2011.

4. Alternative Approaches to the Evaluation Process

Paul Ellingson presented an outline of his suggestions for streamlining the cumbersome evaluation process. The TNI Standard does not require some of the cumbersome steps that were mandated by the previous standard, and with the current cycle about half

completed, Paul has discussed with evaluators and now with the AC, possible ways to reduce the time and travel expenses for the process and asked for feedback from the AC about the general concepts. See Attachment 2 for the outline Paul presented.

Essentially, Paul recommends conducting the technical review but finishing it during the site visit, so that only one report and one set of corrective actions is needed, and also to revise the technical review checklist to combine identical items (from M1 and M3), to clearly state the expectation where "when applicable" is in the standard, and to insert the relevant text into the checklist, in addition to the citation. He also expects to provide an online tool for easing the review process and report writing.

Discussion addressed the possibility of using only a single Lead Evaluator for all ABs, and single/dedicated reviewers for the checklist, as well as performing much of the document review remotely. The observation of an assessment was deemed critical to the purpose of the evaluation process, and will continue to be conducted as it stands now.

AB representatives were enthusiastic about these changes, and have directed Lynn, in conjunction with Paul, to proceed with drafting a revised Evaluation SOP, to be completed and adopted prior to the next round of evaluations (beginning December 2013.) An accompanying revised Technical Review (Compliance) checklist will also be prepared, probably by volunteers from the evaluator community. The revisions will accommodate Paul's suggestions as well as third party evaluators, and will be vetted by the evaluators' workgroup, the Laboratory Accreditation Body Expert Committee (LAB,) and the Laboratory Accreditation Systems Executive Committee (LAS EC) before being presented to the AC for adoption.

4. Possible Sharing of State Assessors

Michelle Wade asked whether it might be possible to "borrow" another AB's assessor for some of KS's larger in-state labs (with expenses paid by KS.) KS uses contract assessors for out-of-state labs, but does not have the option of using contractors for in-state labs, and now has only one staff person for the program. There are a few large labs in KS that would need additional assessors, but not a lot. Other ABs were supportive but dubious about workload constraints. MN could likely provide help through their contract mechanism for third party assessors, depending on the timeline, so Susan and Michelle will work on this option.

5. Third Party AB Assessment Reports (DoD and DOE) – update on LAS EC activities

Kristin Brown has been active in LAS EC's efforts on this issue, and provided an update. It appears all Defense Department (DoD) ABs will release assessment reports with the permission of the laboratory, although there "may" be an issue with 3rd party client contracts, with this process. The Energy Department (DOE) maintains that assessment reports contain "For Official Use Only" (FOUO) information and can only be released through the Freedom of Information Act (FOIA) process. In all cases, the laboratory is free to distribute the report to any party, but there are concerns about receiving information directly from the AB versus the accredited lab.

Lynn will continue to monitor the LAS EC's activity in this matter.

6. ACIL Newsletter item about Environmental Sciences Section Activity

The ACIL newsletter (Nov/Dec 2011) contained an item about its Environmental Sciences Section's (ESS's) efforts to expand its "nongovernment accreditation initiative" from NJ into NC, MN, CA, FL, KS and VA, identifying coordinators and approach for promoting a "non-government-based accreditation system."

Since 5 of the 6 identified "target" states (plus NJ) are NELAP ABs, and 3 of the individuals named in the article are TNI Board members, the AC discussed at length how to counter what might be construed as an effort to dismantle the NELAP program.

Participants acknowledge that ACIL (and others) truly desire a "national" accreditation system for labs, and that NELAP has not yet attained that level of success. The Environmental Laboratory Advisory Board (ELAB, an EPA Federal Advisory Committee Act chartered group or FACA committee) is also seeking to address the goal of a national system. A number of interactions have occurred between AB representatives, TNI staff, and individuals involved with the ACIL and ELAB activities, and more will surely occur in the coming weeks. Some of the same individuals are involved with the AB Assistance Task Force's (AB/TF's) subcommittees for Recommendation #8 (to develop/promote third party ABs) as well as groups named to address the other 7 recommendations of the AB/TF.

Participants coalesced around several concepts:

- It appears that the ACIL/ELAB efforts to create a national accreditation system include eliminating state ABs.
- Those seeking to dismantle state ABs need to understand state government responsibilities and authorities, and the value of having state governments require (i.e., non-voluntary) accreditation beyond testing of drinking water, such as for waste water treatment plant labs especially.
- The states are a vital, critical component of any enforcement system for accreditation.
- Labs probably prefer a single accreditation so they don't have to pay state fees for recognition of their accreditation.
- It is easier for outside forces to change state laws, than to change state regulations regarding accreditation.
- NELAP ABs need to strengthen their self-policing and to fix the problematic issues (consistency issues, primarily) with the NELAP program.
- Non-governmental ABs are not necessarily better than state ABs.
- Non-governmental ABs have no official/formal responsibility for protecting public health, whereas state ABs implicitly have responsibility for supporting the protection of public health.
- By not taking a stand against the ACIL position, TNI's Board of Directors may be unintentionally undermining NELAP.

The AC seeks to engage TNI's Board of Directors and TNI's Advocacy Committee to address the apparent conflicts between TNI's (state-based) NELAP program and TNI's Board members' activities in advocating for a national (non-state) accreditation program. Specifically, the AC will ask that the TNI Board consider this threat to NELAP at its December meeting, and decide whether it will actively or passively support the continuation and expansion of the NELAP program. Lynn will ask the Executive Director to put this issue on the Board's agenda for its December 14, 2011, meeting.

Lynn will also collect information about ELAB's activities and provide that to the AC at its next meeting. Michelle Wade is the individual representing state ABs on ELAB; Lara Autry is the EPA staff person responsible for ELAB activities. The AC will also request a public meeting with the ACIL ESS at the upcoming Sarasota conference. The goal of that meeting would be to reach agreement on how to pursue a national accreditation program that does NOT involve dismantling NELAP.

7. Next meeting

The next AC meeting will be Monday December 5, at 1:30 pm EST. Agenda items (thus far) will be:

- Welcome and Roll Call
- Approval of Minutes
- Update on Renewals
- Vote(s) on renewal recommendations for NELAP ABs (if received in time to distribute)
- Update from LAS EC about using assessment reports from federal accreditations (Kristin and/or Lynn)
- Follow-up on ACIL ESS and TNI Board interactions

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@cdph.ca.gov	no
	Alternate: Jane Jensen E: jjensen@cdph.ca.gov	yes
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve_arms@doh.state.fl.us	yes
	Alternate: Carl Kircher E: carl_kircher@doh.state.fl.us	no
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	yes
	Alternate: TBA	
KS	Michelle Wade E: MWade@kdheks.gov Ph: (785) 296-6198 Fax: (785) 296-1638	yes
	Alternate: none	no
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: Paul.Bergeron@la.gov	yes
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	yes
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MN	Susan Wyatt T: 651.201.5323 F: E: susan.wyatt@state.mn.us	yes

	Alternate: Stephanie Drier E: stephanie.drier@state.mn.us	yes
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	yes
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NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	yes
	Alternate: Dan Dickinson E: dmd15@health.state.ny.us	no
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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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UT	David Mendenhall T: (801) 584-8470 F: (801) 584-8501 E: davidmendenhall@utah.gov	yes
	Alternate: Kristin Brown E: kristinbrown@utah.gov	no
VA	Cathy Westerman T: 804-648-4480 ext.391 E: cathy.westerman@dgs.virginia.gov	no
	Alternate: Ed Shaw T: 804-648-4480 ext.152 E: ed.shaw@dgs.virginia.gov	yes
	NELAP AC Program Administrator and Evaluation Coordinator Lynn Bradley T: 540-885-5736 E: lynn.bradley@nelac-institute.org	yes
EPA Liaison	Arthur Clark T: 617-918-8374 F: 617-918-8274 E: clark.arthur@epa.gov	no
EPA Liaison effective 2012	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	yes
	Oklahoma: David Caldwell	no
	Guests:	

Attachment 2

Proposed SOP and Procedural changes to the AB Evaluations

It is well documented that resources are becoming more difficult and expensive to provide for the evaluation of Accreditation Bodies (AB). There are three goals of this proposal. These are:

1. Reduction in time and cost for the evaluations
2. Improved consistency between evaluations
3. Continued participation from the existing parties (e.g. ABs and EPA)

The current SOP is based on the old NELAC 2003 standard and perhaps some of the procedures have become outdated. Some of the proposals described below are already being employed out of necessity in the current evaluations. The outline below contains suggested changes to the SOP and evaluation procedure.

Proposed changes

1. Eliminate all reports except for one final report. The report for Technical Review (TR) would be eliminated as would a report for the laboratory observation (this is not always done anyway). The TR would still be performed prior to the On-site evaluation. Alleged findings/deviations from the TR would be discussed at the On-site evaluation. Findings/deviations not cleared up at the On-site evaluation would then be part of the final report.
2. Modify the checklist to better define what is expected from the AB. Some standards clearly have a requirement to document the ABs policies and procedures whereas implementation of other standards may only need to be verified. The checklist could be modified to clearly state the expectation of the standard and what each evaluation team (ET) should be looking for to fulfill each standard.
3. Modify how the AB fills out the checklist. Instead of just placing a reference to a QAM, SOP or regulation next to the question, the AB would paste the actual wording to their policy in the checklist. The current practice in too many cases is that the AB answers a question by offering a reference to a QAM, SOP, regulation etc. that may or may not meet the requirement. Often the hope is that the vague reference will somehow stick. The problem with this technique is that sometimes there are many wasted hours from the ET are spent on a wild goose chase because the AB has given a bad reference or just hoped that the ET will pass over the question. Yes this will cause the AB more work when filling out the checklist because the AB will have to actually paste the relevant policy into the checklist. However, the time savings will be on the other end of the evaluation when the AB does not have to spend wasted hours searching for answers. This process will also put pressure on the AB to make sure that their policies are sufficient for each requirement. This could also be a useful tool for the internal audit.
4. Create TR specialists. Currently there are 42 sections of the checklist. One person (or possibly team) could specialize in one or more sections and do the evaluation for all ABs in those sections. For example one specialist could review the sections on Internal Audits, Management and document control for all ABs.
5. Use an on-line tool so all ABs, ET members, ET coordinator and the QAO can access the evaluation. Rather than use the old Word checklist, all parties would have access to on-line tools. This tool is a by-product of other tools developed by AQS and could be of much benefit to the evaluation process. This also has tools for the On-site evaluation to

allow for better and more consistent evaluations by the ETs. This tool would also write the report, track dates, allow the AB to respond to evaluations as well as other functions.

6. Give the ABs 1-2 years to fill out the checklist. Make this a one-time effort, and once it is done, it is done and does not have to be done for the next evaluation unless the documents have changed or a new requirement is put into effect.
7. Perform some of the current On-site evaluation off site. For example the ET could select a representative number of labs to perform a PT review prior to the On-site evaluation. The team could inform the AB of the labs they have chosen along with the parameters to review and then give the AB a reasonable amount of time (perhaps 3 days) to provide the PT for those labs electronically. This technique could also be applied to other areas of the evaluation. These would be defined in advance so that all ABs would know what to expect for pre On-site evaluation documents. This would save time and expense in travel.
8. With the pre-evaluation activities described above it would be possible to reduce the time of the On-site evaluation and combine every evaluation with the laboratory shadow. Nearly every AB can facilitate a small to medium size lab the week of the On-site evaluation. Time of the On-site evaluation could be reduced to 1 day before the lab shadow, a 1 to 2 day lab shadow, and no more than ½ a day after the shadow for a closing conference and review of observations. Total time would be 3-4 days for smaller ABs and 4-5 days for the larger ABs. This follows a more traditional ISO 17011 format for evaluations.