

Summary of the NELAP Accreditation Council Meeting

August 9, 2012, at The Forum on Laboratory Accreditation, Washington, DC

1. Roll call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 9:00 am EDT on August 9, 2012. Those members in attendance are listed in Attachment 1.

2. Action Items Pending

- Send memo to TNI Board regarding Use of DoD-DOE reports (AB/TF Option 5)
- Semi-annual report to Board on status of implementing the 2009 TNI standard
- Follow-up to commitments made in Sarasota – staff actions to add state AB complaint processes of states to listing of ABs awaiting webmaster action, implement consensus of AC representatives to devote 1 meeting/quarter to discussion of how ABs handle assessment topics (with assessors invited into the meeting) as a way to improve consistency of assessor practices
- Notify AC and LAS EC about results of small group review of outstanding SIRs, to either improve the interpretations or withdraw items that are really “how-to” questions
- Address MN evaluation team composition, since there will now be no EPA evaluator on that team. Possibly begin to address team compositions for next round as well as for evaluation of NGABs
- Follow ABTFII addressing NGAB option
- Final Response to Complaint from ACIL – pending completion of evaluation process for the AB
- Policy Committee Review and request for revisions to Voting SOP (3-XXX)

3. Updates from the AC

Lynn stated that 5 evaluations are underway, with 7 ABs renewed already and 2 team recommendations for renewal awaiting vote. Only MN remains to be evaluated; EPA will not participate in that evaluation.

Aaren polled the ABs in attendance about their status of implementing the 2009 TNI standard for accrediting labs. Unfortunately, due to technical difficulties, the phone line was not open for this part of the meeting. Results from AB representatives follow, additional ABs will be polled and the full results reported to the Board for its September meeting.

AB	Standard in Effect Now	Status/Progress	
CA		No report	
FL	2003 NELAC	Not penalizing labs that choose to implement 2009 TNI. May have rule in place by July 2013, or wait for next version of standard. Accepting PT reports per 2009 TNI standard.	
IL		No report	

KS	2003 NELAC	Moving forward slowly	
LA DEQ		No report	
LA DHH		No report	
MN	2003 NELAC	Not penalizing labs that choose to implement 2009 TNI. May skip 2009 TNI standard if standards development continues expected pace	
NH	2003 NELAC	Not penalizing labs that choose to implement 2009 TNI. Rulemaking expected to begin mid-2013	
NJ		No report	
NY		No report	
OR	2009 TNI	Transition effective October 1, 2011	
PA	2009 TNI	Began assessing labs to new standard in October 2011; official transition date was July 2011, but needed to get checklists in place, etc.	
TX	2009 TNI	Transition effective July 2011	
UT		No report	
VA	2003 NELAC	Regulation development begun. Where the standards differ, gives lab "benefit of doubt."	

Comments on implementation included the following:

- If the proposed corrective actions for standards development include a 5-year revision cycle, that would help ABs tremendously, since they could plan systematically for regulatory revisions to adopt the modified standard(s).
- When a legislative change is needed to adopt a new standard, that opens the possibility of undesired changes to the AB program or even its existence.

The TIA for WETT PT was adopted, effective August 1, 2012.

4. Follow-up items from Sarasota

An "open" AC call was held on May 7, and representatives from all non-NELAP ABs (from the AB database at www.nelac-institute.org/abdb.php) were invited to participate. There were about 25 ABs on the call, including NELAP ABs. More than the 14 NELAP states actually use the standard in some way, or accept NELAP accreditations, but there remains some confusion in a few states about the mix of management and technical systems review utilized by NELAP. Complaints about unannounced changes to PT programs were also mentioned – PT providers seemingly neglected to update the non-NELAP ABs and drinking water certification programs receiving PT results that they had changed to a new standard last year. It's not likely that more "open" AC calls will be held but rather, the existing APHL-led State Assessor Forum will be used to keep state ABs current on TNI and NELAP activities.

From conversations with ACIL representatives in Sarasota, the two big issues were that specific complaints do not get made due to fear of retribution from ABs on the part of the labs, and the unspecified "inconsistencies" occur among NELAP ABs. In response, the AC has initiated a change to the webpage listing NELAP ABs so that it will include specific links or contacts for filing complaints, state-by-state, and also, the AC will initiate a

quarterly call that includes NELAP assessors, focused on discussing specific assessment practices. Preliminary thinking is that individual ABs will take turns leading discussion of particular parts of items being assessed.

5. PT Issues

The conversation opened with a general statement wishing for the upcoming revised PT standard to be un-ambiguous. Mitzi Miller, Chair of PT Expert Committee, requested more information about what the problematic items were. AC responses follow

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- PT testing every 5-7 months sometimes leads to the 2nd sample being done 14 months after the first, which does not meet the 2/year expectation. Timing of make-up PTs as well as the option of changing PT providers or QA officers makes the minimum of 5 months unenforceable; general agreement on “not more than 7 months” was obvious. The ABs would also like to have “twice per calendar year” back in the standard
- One commenter indicated that such issues should be formalized through SIRs. This was not well received by the ABs since the SIR process is problematic and lengthy, but also, not a suitable mechanism for altering the clear intent of the standard
- The use of “analysis date” for tracking routine PTs is problematic for ABs, although it works for make-up PTs. All prefer the use of “closing date” and the use of “study ID” as an identifier is not viable since that number may repeat with different vendors.

After the break, phone lines were reconnected, and discussion of PTs continued.

Mitzi had several questions for the AC. First, she asked for a discussion of adding PTs for prep methods, since some ABs do accredit prep methods. Consensus response was not to add them, and discussion included the following points:

- Some labs rotate PT thru their different prep methods. All labs ought to do this, per the standard
- From Sarasota conference, there was request for all ABs to accredit prep methods. This is not viable, since some ABs would need legislative change or even changes to their database that could not be accomplished for several years. Plus, this would cause a geometric increase in the number of PTs, burdensome to labs and ABs alike
- One commenter noted that sample prep creates far more errors than the actual analysis and requested that prep method accreditation be mandatory. This brought response from all ABs that the prep methods are ALWAYS assessed during the site visits, and the lab’s quality system is evaluated for its ability to ensure that the sample preps are monitored
- Adding accreditation by prep method would add a 4th tier to the method-matrix-analyte structure now in place. Scoring of PTs by technology and analyte does not alter this paradigm
- If the prep method were not intrinsically linked to an analyte, scoring and enforcing PTs would be highly problematic.

Mitzi’s second question was whether secondary ABs wish to evaluate all PT results for their labs. No AB objected to receiving all PT results for secondary labs; the AB has the

option of which results to evaluate. While not all ABs are able to enforce on PTs, labs were reminded that they are required to notify secondary ABs as well as their clients when all or part of their accreditation is withdrawn for any reason. Questions of fairness to the labs arose, that ABs enforce differently, but no solution is in sight.

6. Other Updates

SIRS For background, Aaren explained the relatively new electronic voting process for SIRs, where the AB representatives can vote online to accept, decline, request discussion or veto for the recommended interpretations by the Expert Committees. AC approval of the interpretations is necessary to avoid the circumstance where a new interpretation would violate a states law or rules, but also to ensure that the new interpretation(s) can be readily understood. The AC has been working continuously on SIRS over the past year, but after wading through some of the backlog, realized that most of the existing recommended interpretations are unsatisfactory – either the answer is excessive or the question sometimes isn't even an interpretation request but rather a “how do I” question.

A small workgroup of AB representatives has gone through the backlogged SIRs, all either with fewer than 10 “yes” votes (minimum for passage) or “needs discussion” votes. This group sorted the SIRs into 4 categories:

- Good answer, ready for vote
- Obsolete
- Not an interpretation request
- Unclear answer provided by Expert Committee

The results of the workgroup's effort will be presented to the AC for review and agreement – hopefully this will be faster than discussing them one at a time – and then forwarded to Ilona and the LAS EC for disposition, whether that be returning the interpretation to an Expert Committee or withdrawal and return to submitter. The “how do I” questions might be passed to the Technical Assistance Committee for consideration in its training development activity.

Assessment Reports from Other ABs The AC considered use of reports from DoD and DOE, and peripherally, reports from other non-NELAP ABs as well. The utility of these reports may vary somewhat across the NELAP ABs but consensus was that they are information useful for assessment planning although not able to be used in lieu of independent assessment of a laboratory.

MUR & Method Codes in LAMS The AC met with the Information Technology Committee, and Dan Hickman, TNI Database Administrator, to exchange perspectives and answer questions about the changes to method codes required by EPA's latest Method Update Rule. This was a productive meeting. Dan asks that any AB seeking a new or corrected method code PLEASE USE THE ONLINE FORM IN LAMS, not earlier standalone versions, since those earlier templates don't request all details now sought, and their use will just extend the time needed to address the request.

Third Party or Non-Governmental ABs The follow-on or second Accreditation Body Task Force (ABTFII) meeting on Tuesday afternoon of conference provided some draft recommendations for expanding national accreditation to include use of NGABs for

accrediting labs not intending to do business in a NELAP state. The ABTFII held a small Wednesday morning panel discussion with NGABs, to which the AC was invited, where the NGABs answered questions from the ABTFII about issues relevant to their receiving TNI sanction to accredit to the NELAP standard. This session was remarkably informative.

Aaren explained the genesis of ABTFII and this panel discussion, acknowledging that having NGABs accredit to the NELAP standard is inevitable, while at the same time, because some states can utilize only governmental ABs, acknowledging there are likely to be ongoing issues about reciprocal recognition outside of the state NELAP ABs for some time to come. Oregon's AB representative, Gary Ward, declared that OR will be unable to approve an NGAB or include them in the NELAP AC for the foreseeable future, and that OR would need to veto any attempts to accomplish that. He also explained the reasoning, both in state law and rules and that the senior manager is firmly opposed to non-governmental involvement in accreditation. This bold statement helped force recognition that some alternative mechanism (beyond the AC) will be needed in order for TNI to sanction NGABs using the NELAP standard.

Roughly half of the state NELAP ABs could include NGABs in the AC, but the remainder cannot due to state law or regulation. For now, the NELAP AC is built upon agreement that the state ABs will follow the standard, accredit to the standard, recognize the accreditations of other state NELAP ABs (mutual recognition and use of the NELAP logo), and deal with one another to work towards consistency in applying the standard and in exchanging information about the accredited labs as needed.

Per the ABTFII, TNI cannot direct what state law or regulations must say, but will continue to seek ways to bring NGABs into a national accreditation program using the NELAP standard. It was learned during the panel discussion that NGABs will not be able to recognize state NELAP accreditations due to ILAC constraints, just as most states won't be able to recognize NGAB NELAP accreditations, so that full mutual recognition is apparently not an option ever. One NGAB representative noted that his company does not seek to become a regulator (as a state is) and also noted that state NELAP ABs do accept and use a PT program administered by NGABs, wondering why one is acceptable and the other not.

Concerns about having a "two tier" system were expressed, as threatening the stability of the current NELAP program, and also about confusion among labs that is likely to result when a NGAB accreditation is not accepted for secondary recognition by a NELAP state AB. Still, some states have two tier programs now and labs seem to manage satisfactorily.

Judy Duncan, chair of ABTFII, spoke up to say that this issue has undergone a transition over the life of the ABTF, and that they are trying to explore possibilities but the Task Force has no intent to force acceptance of NGABs onto the AC but rather to seek ways to use all possible components in a national accreditation system.

In response, several states explained their positions. OR has been told (unclear by whom) that "it's gonna' happen" and clearly will leave the AC if NGABs become included in it; OR does use third party assessors presently. TX noted its inability to accept NGAB NELAP accreditation for secondary accreditation due to being authorized reciprocity with NELAP states (governmental) only, but that it could possibly grant (for in-state purposes) primary accreditation based on an NGAB NELAP accreditation. PA could not use NGAB

accreditations in any way; it doesn't use contract assessors and has union rules as well as regulations. NH noted that it gets asked, routinely, about using NGABs, and noted that the Wednesday morning panel discussion did clarify some concerns about information sharing among states and NGABs, specifically that it may be possible to share assessment reports if the NGAB sanctioning by TNI requires it, and thus a mandate for information sharing gets written into the NGAB-lab contracts. IL noted that some role for NGABs is inevitable but there remain conflicts for now, and expressed hope for eventually consensus and compromise.

7. Next Meeting

Following the AC session at conference (Thursday, August 9, 9 am-noon EDT), the next AC meeting will be Monday, August 20, 2012, at 1:30 pm EDT. Teleconference information and an agenda will be sent the week before. The agenda will include:

- Votes on the Virginia and NJ renewal recommendations
- Progress on SIRs
- Follow-up items from conference
- Plan for quarterly AC meetings w/ NELAP assessors

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	Fred Choske 510-620-31745 F: 510-620-3471 E: fred.choske@cdph.ca.gov	no
	Alternate: Dave Mazzera : 510-449-5600 E: david.mazzera@cdph.ca.gov .	no
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/phone
	Alternate: Janet Cruse T: 217-785-0601 E: Janet.Cruse@illinois.gov	Yes/phone
KS	Michelle Wade E: MWade@kdheks.gov Ph: (785) 296-6198 Fax: (785) 296-1638	yes
	Alternate: N. Myron Gunsalus ngunsalus@kdheks.gov 785-291-3162	No
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: Paul.Bergeron@la.gov	Yes/phone
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes/phone
	Alternate: TBD	
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	no
	Alternate : TBD	
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	Yes/phone
	Alternate: Dan Dickinson E: dmd15@health.state.ny.us	No
OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	Yes
	Alternate: 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@state.pa.us	Yes
	Alternate: Dwayne Burkholder E: dburkholde@state.pa.us	No
TX	Stephen Stubbs T: (512) 239-3343 F: (512) 239-4760 E: sstubbs@tceq.state.tx.us	Yes
	Alternate: Steve Gibson E: jgibson@tceq.state.tx.us	Yes
UT	David Mendenhall T: (801) 584-8470 F: (801) 584-8501 E: davidmendenhall@utah.gov	no
	Alternate: Kristin Brown E: kristinbrown@utah.gov	Yes/phone

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	Yes
NELAP AC PA and EC	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	yes
NELAP QAO	Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	no
	Oklahoma: David Caldwell	yes
	Guests: Meeting participants, not identified by name	