

Summary of the NELAP Accreditation Council Meeting
August 18, 2011, Bellevue, Washington

1. Roll call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 9 am PDT on August 18, 2011, during the 2011 Environmental Measurement Symposium in Bellevue, WA. Steve Stubbs, Vice Chair of the AC, led the meeting. Approval of minutes was postponed until the next teleconference. Those members in attendance are listed in Attachment 1; a call-in number was provided for those not attending the conference.

2. Implementation of the New TNI Standards

Steve reviewed the history of implementing the 2009 TNI standards – the originally agreed-upon date of July 1, 2011, became impossible to meet after the 2010 elections and dismal economy brought many state activities to a slowdown or complete halt. He emphasized that the ABs will sustain mutual recognition among all states, regardless of which standard is in use by individual states. The status of individual states, as stated during the meeting, follows:

STATE	Implementation Status
CA	presently using the 2003 standard, will shift to 2009 standard over the next few months.
FL	uncertainties slowed rulemaking, then the new governor froze rulemaking. The AB is implementing the 2009 standard for its operations, as much as possible, and adapting to circumstances where labs have implemented 2009 standards and 2009 PT requirements. Can only enforce to 2003 standard. Earliest implementation date will be 2012 but no timeline exists at present.
IL	presumed unchanged, no update. (not implementing 2009 at this time.)
KS	remains with 2003 standard for labs. Regulation needs to be developed but in-state circumstances prohibit setting timeline at present.
LA DEQ	draft rules to implement 2009 std have undergone public comment and public workshops are underway. Timeline uncertain.
LA DHH	rulemaking to implement 2009 standard nearly complete
MN	state shutdown and consequent staff departures resulted in delay until probably January 1, 2012 for implementing 2009 standard
NH	presumed unchanged, no update. (not implementing 2009 at this time.)
NJ	presumed unchanged, no update. (not implementing 2009 at this time.)
NY	enforcing 2003 standard, at least 1 year before 2009 can be implemented
OR	implemented 2009 standard on August 9, 2011; changing over checklists, etc.
PA	moving towards September 2011 implementation of 2009 standards
TX	implemented 2009 standard on July 1; rulemaking completed in 2010

UT	implementing 2009 standard in September, after completion of comment period for regulation
VA	will initiate rulemaking for 2009 standard on January 1, 2012

Art stated that EPA believes the states are doing as well as possible, given the political climate.

Scott Hoatson asked how should secondary recognition be handled on certificates – consensus was that the certificates will reflect the standard in use by that AB at the time.

One participant suggested that TNI maintain a record of which standard is in use by which AB, for his reference for legal purposes. The response was that TNI is an “information source” not the “origin of the record” and that for any litigation, the court should refer to the sovereign source (the state AB.) Dan Hickman, TNI database administrator, noted that this is also true for the database of accredited labs – it is not meant to be the legal record, and ought not to be regarded as such. TNI may strive to keep accurate information about implementation on its website (it does not exist there, now, except in AC minutes) but the gathering was reminded that it’s not “TNI accreditation” but rather accreditation by one of the individual ABs, and that the use of accreditation is between the lab and its client.

3. Accreditation Body (AB) Task Force Recommendation 5: Use of Assessments by Other Organizations

Scott Hoatson had earlier agreed to identify issues needing resolution, and he summarized the material he had presented to the August 1 AC meeting, as follows:

1. ABs should have made available, the credentials of the DOD/DOE Assessors to be able to ensure they were qualified for the areas they assessed. In order to consider them either assessors or experts, this is a requirement throughout the standard. Without this, it may be difficult to utilize the assessment report. **ABs will need to be able to consider them either assessors or experts.**
2. The DOD/DOE **Assessment report would need to clearly state the scope of the assessment and the Standard** that the assessment was based upon. (see 4.6.1 below)
3. AB could utilize the DOD/DOE assessment as **part** of the overall assessment **without considering it subcontracting.** (See 7.4 below)
 - a. Trying to utilize the DOD/DOE assessment as the entire laboratory assessment would fall into the subcontracting the assessment category and the ABs and DOD/DOE would have to work out a lot of details to meet the TNI standard.
4. Recommend that AB treat DOD/DOE portion as performed by “experts” rather than assessors. This would minimize the red tape.
5. AB could consider the DOD/DOE assessments as “**Surveillances**” and incorporate into the overall accreditation decision. Identify whether laboratory has completed their corrective actions. If they are not yet completed (very recent assessment) then be sure to receive a copy of their final report to DOD/DOE. Since DOD/DOE assessments are performed approximately annually, they should be relatively current.
6. We may want to check on the possible availability of getting copies of checklists completed by the DOD/DOE assessors as a demonstration of the scope of the assessment.

7. Explore coinciding onsite assessments with the DOD/DOE, it might be beneficial. Recommend the sharing of checklists during an assessment (both ways). We would likely end up with 2 “Lead” assessors – one DOD/DOE lead and one NELAP lead but under the premise of NELAP, there is just one lead assessor. This may cut down on costs for both DOD/DOE and the AB. Potentially, the AB would only need one assessor on-site.
8. A formal arrangement (e.g., Memorandum of Understanding or other mutual agreement) between DOD/DOE and TNI that attests that their assessments are compliant to the current TNI standard and their assessors meet the training requirements in the standard.
 - i. If we want to use the assessments in their entirety, then we would need to be sure that they cover all of the quality systems piece as well as the technical assessment parts that were in the scope of their assessment. If the lab is applying for accreditation beyond the DOD/DOE scope, the AB will still need to assess the other areas.
 - ii. With the understanding agreement, we can stretch the DOD/DOE assessors as subcontractor assessors and with the agreement with TNI, each AB would not have to enter into a subcontractor agreement with DOD/DOE. And TNI could monitor the training status of the assessors.

It is mostly the large laboratories that have these federally recognized accreditations. Perhaps the use of assessment reports or joint assessments could reduce the team size or length of site visit by the AB staff.

Steve Stubbs indicated that, at minimum, the quality system assessment ought to be useful. Steve Arms suggested that these reports are “found” data, and noted that the AC initial reaction was positive towards the willingness of Energy and Defense departments to permit state AB use of their assessment reports.

One participant indicated that the “gray boxes” used by the federal agencies might interfere, and are beyond the NELAP standard. Another participant noted that the “gray box” requirements are clearly identified, and that joint assessments could surely be done. Yet another noted the stringent oversight requirements for the federal contract assessors and the contracted/recognized non-state ABs, and also that it would be difficult for these assessors to meet the NELAP requirement of having completed four NELAC or NELAP assessments as part of their training.

Federal representatives indicated that both departments are seeking to transition to the 2009 TNI standard and to combine their assessment requirements. A participant from the Defense Department noted that they are willing to work with the state ABs and the AC, and also that they do monitor corrective actions and could alert states when those are not satisfactorily completed.

Discussions within the AC and among the AC and the federal representatives and likely the non-state ABs and assessors will surely continue in the coming months.

4. Accreditation Body Renewals

Lynn reported on the status of ongoing evaluations

- CA – renewal letter sent the previous week
- FL – application materials delivered in person at conference, mailed to team members not in attendance

- KS – requested and received an extension until 8/24 to respond to both the onsite report and Technical Review.
- LA DHH -- Onsite occurred the week of July 25; observation is scheduled for November. The Team Leader was encouraged to provide a draft report of the site visit, and not wait for completion of the observation, so the AB could begin work on its corrective actions (if needed.)
- NH – onsite completed, delayed observation now completed. Onsite report is in development, expected completion to be after the Team Lead completes the evaluation site visit for a different AB where she is on the team to fulfill the “NELAC assessor” role. The site report was initially delayed until team leader could catch up with workload from 20-day MN state shutdown.
- NJ – transmission of results of completeness review has awaited identification of team leader; NY will definitely provide an individual for that role, as well as a second individual for the team.
- NY – technical review response received and undergoing team review. Onsite and observation scheduled for August 22-26.
- PA – replacement lead evaluator getting up to speed. Completeness review response submitted and technical review nearing completion. The site visit will hopefully be in early October.
- UT – onsite and observation completed, report in preparation.

Lynn mentioned that coming up with full evaluation teams for this cycle of renewal evaluations has been difficult. Art noted that, for the next cycle (beginning 2014), some EPA regions may choose to participate but that EPA is recommending the use of “third party” evaluators to replace the EPA regional staff, for those regions choosing NOT to participate.

Susan noted that EPA staff are highly valuable contributors to the evaluations.

Discussion about how the altered EPA role might impact the drinking water program and the accreditation of state primacy programs and labs indicated that additional issues will have to be addressed. Michela Karapondo of EPA’s drinking water program stated that the Office of Ground Water and drinking Water has sent a letter to the EPA regions to make certain they address the issue somehow. It seems that some regions will do separate certification of the state primacy program while others will rely on the state AB recognition decisions. It was unclear whether joint visits for separate purposes (EPA doing drinking water only, the evaluation team doing full evaluation) might be possible

Paul Bergeron noted that LDEQ does not include drinking water, so “joint” evaluation would not occur for that AB program. Steve Arms noted that, since in Florida’s case, EPA Region 4 has already informed them that it will send an entirely separate certification team to review the FL AB program, this is duplication of effort and duplicate program resource expenditure for the AB, as well. A TNI Board member present noted that, if the pullback by EPA is truly a resource issue, how could it be that they can still send a separate team to do essentially the same task?

5. PT Issues

All PT providers (PTPs) have now been assessed to the 2009 TNI standard, and transitioned, as planned, on July 1, 2011, but maybe 30% of the ABs have transitioned to the 2009 standard. Because of different wording requiring a different scoring system for PT results -- the new/2009 standard requires reporting “less than” if the quantitated

analyte is beneath the level of quantitation, whereas the old/2003 standard used reporting to the PT Reporting Limit -- some PTs that would have passed the old standard would now fail the new standard. In fact, the PTPs consider the 2003 standard now obsolete, but labs accredited to the 2003 standard by individual ABs still need to report PT results in accordance with that standard.

The AC adopted a motion, with the concurrence of all PTPs, as follows:

As they implement the 2009 TNI standards, the NELAP Accreditation Council requests that PT providers annotate their electronic reports with an asterisk or other demarcation so as to identify any analytes reported with a less than value, i.e., "<," having an assigned concentration greater than zero, and found acceptable according to the 2009 standards.

All believe this will accommodate the dual standards for the transition time, without undue burden on any party, and no objections have been registered. The annotation does NOT apply to paper reports.

Some ABs have pro-actively informed their labs, whether by email, letter, or posting to the website, what their expectations are concerning PT performance. Regardless, each lab should take responsibility for learning the expectations of both its primary and secondary ABs, regarding PT samples and reporting.

One additional issue was noted. In the coming weeks, the PT Expert Committee is expected to ask the AC to affirm removal of chloral hydrate from the list of PT analytes, since it was learned that the Drug Enforcement Administration prohibits shipping chloral hydrate.

6. Opportunity for comment from participants

TNI's Database Administrator, Dan Hickman, gave an update on the LAMS database. This database of accredited labs is nearly completely populated with demographic data for labs (name, contact info, address, primary AB) and will go "live" on the TNI website in a few months. Field of accreditation data are just beginning to be entered, but labs need to be aware this is happening and periodically monitor their individual listings for accuracy, as an additional QC check on the process. Two items are noteworthy – a laboratory's listing can only be removed manually (not by omitting it in the "upload") and per an early requirement for the database, there will be no automatic removal of accreditation. Dan will work with ABs as needed and requested to facilitate populating the full database, and welcomes both suggestions and notice of any errors found.

Also, this database requires that analyte codes be standardized, for the database, and there will be a table of synonyms such that the individual ABs don't actually have to modify all their data systems.

Another participant requested a standardized application for laboratories to complete. The response was, this is one of the items recommended by the AB Assistance Task Force report, and its development has been initiated in the Lab Accreditation Body committee.

7. Next meeting

The AC is scheduled to hold its next meeting on Labor Day, so a rescheduled meeting date will be set. (NOTE: this will be Tuesday, Sept. 6 at 1:30 pm EDT.)

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@cdph.ca.gov	yes
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	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	no
	Alternate: TBA	
KS	Dennis L. Dobson 785-291-3162 E: ddobson@kdhe.state.ks.us F: (785) 296-1638	no
	Alternate: Michelle Wade E: MWade@kdheks.gov	yes
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: Paul.Bergeron@la.gov	yes
	Alternate: TBD	
LA DHH	Donnell Ward E: donnell.ward@la.gov	yes
	Alternate:	

MN	Susan Wyatt T: 651.201.5323 F: E: susan.wyatt@state.mn.us	yes
	Alternate: Stephanie Drier E: stephanie.drier@state.mn.us	no
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 : TBD	
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	Alternate: Raeann Haynes E: haynes.raeann@deq.state.or.us	no
	Scott Hoatson T: (503) 693-5786 hoatson.scott@deq.state.or.us	yes
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@state.pa.us	no
	Alternate: Dwayne Burkholder dburkholde@state.pa.us	yes

TX	Stephen Stubbs T: (512) 239-3343 F: (512) 239-4760 E: sstubbs@tceq.state.tx.us	yes
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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
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EPA Liaison	Arthur Clark T: 617-918-8374 F: 617-918-8274 E: clark.arthur@epa.gov	yes
	Quality Assurance Officer Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	no
	Oklahoma: David Caldwell Judy Duncan	David Caldwell
	Guests: conference attendees present in meeting room, not individually identified	