Summary of the NELAP Accreditation Council Meeting May 16, 2011

1. Roll call

The NELAP Accreditation Council (AC) met at 1:30 PM EDT on May 16, 2011. Those members and guests in attendance are listed in Attachment 1.

2. Update on AB Renewals

KS – technical review is complete, onsite is scheduled for May 23-25, with observation following the end of that week

LA DHH – technical review is underway

NH – technical review is underway, onside scheduled for week of June 6 with observations June 2-3 and early July

NY – technical review received 2-week extension

PA – on hold awaiting identification of replacement Lead Evaluator. Stephanie Drier offered to discuss it with her manager. [NOTE: we also have a non-AB volunteer, but that will be a last resort.]

UT – technical review approaching completion

Lynn noted that several additional "example" checklists offered by the EPA Region 3 evaluators have been posted on the AC webpage, under "Documents and Presentations."

3. Resolution of Recommendation from Laboratory Accreditation Systems Executive Committee (LAS EC)

Aaren summarized responses to an email she sent AC members on May 10, requesting they clarify status as one of three categories:

- 1. They reference the "AC Adopted version of the Standard" (or other equivalent language) and could thus accommodate any decision by the Council (PA, MN, and TX.)
- 2. They have rulemaking underway to adopt the TNI standard, in its entirety. OR has rules very near completion, reversing adoption will be very difficult in the short term. OK's rule is scheduled for the Governor's signature with effective date of January 2013, and CA's rule is nearing completion. UT, FL, and IL have halted rulemaking, pending the AC's decision on this matter.
- 3. They have not begun rulemaking and thus rely on the NELAC standard a handful of states have identified previously that they will be unable to pursue adoption of the TNI standard for their labs until some significantly later date.

Aaren reported that she had sought feedback from the TNI Board of Directors about the

LAS EC's recommendation. The TNI Board voted favorably on a recommendation that the AD not adopt the standard(s) piecemeal, but that it move forward with rolling implementation of the TNI standard as planned, beginning July 1, 2011.

Aaren asked that the AC consider what is in the best interest of NELAP, not their individual states, but for the labs, the group of ABs and the overall program. She noted that the new PT standard "should" be ready in 6-9 months, and expressed her personal opinion that relying on a fragmented standard will not be do-able.

Stephanie (NY) reported that she has sent a proposal to Aaren and Jerry concerning a "near term compromise" that would mean any labs accredited by NY as primary or secondary would need to use NY PTs; that way the secondary accreditations would have PT results already meeting the NY requirements. A possible drawback would be if there were conflicting results between the NY and any other commercial PT samples, but individual ABs could determine how to handle the case where perhaps a lab failed the NY PT but passed the commercial PT (or vice versa.)

This proposal grew from feedback received from the 94 labs that were copied on NY's April 20, 2011, letter to Steve Arms, Chair of the TNI Board of Directors. Those comments were:

- parts of the TNI standard are objectionable
- labs would prefer to do additional PTs to maintain their secondary accreditation instead of seeking primary accreditation with NY, and
- the labs would not like to undergo multiple on-site visits.

Stephanie also discussed possibilities about NY's status as a PT provider (PTP.) If the NELAC portion of the standard were to remain in force for PTs, there will be no problem. If the TNI standard takes effect, then NY will need to investigate its status as PTP, since it's uncertain what its A2LA Accrediting Body might choose to do – delaying the repeat onsite until the new PT standard is adopted would be the ideal response, but there were uncorrected (uncorrectable?) findings in its 2010 assessment.

It was noted that if NY loses its recognition as an approved PTP, then the NY NELAP AB could not accept results from the PTP that all NY primary accredited labs are required to use. NY could in theory acknowledge another "equivalent" PTP, which would mean one accredited by A2LA.

All agreed that a decision is needed as soon as possible, and that the options are

- 1) to delay implementation of the TNI standard until the new PT standards (the ones in development now) are adopted:
- 2) to partially implement the TNI standard, but not implementing the PT modules; or
- 3) to move forward as planned.

The key issues are what can each AB legally do, what can each AB enforce, and what is best for the NELAP. Many AB representatives stated their preference of the above options, and what they considered "best" but no clear consensus emerged. There did seem to be two ends with the full spectrum in-between – NY's position, desiring to retain the NELAC PT standard, and OR's position where the AC member is retiring and its rule adopting the (entire) TNI standard will be final June 1, and it will be very difficult to change, since OR's transition process is nearly complete.

Our EPA liaison noted that the Agency has some concerns about TNI and NELAP being

seen as a credible program, nationally, depending on the outcome of this issue; TNI's Board was also sensitive to the credibility issue, and its recommendation was based in part on its perception that proceeding as planned is the most credible course

At length, a motion was presented by Stephanie Ostrowski and seconded by Irene Ronning that the AC move forward with implementing the 2009 TNI standard except for the PT modules and Volume 3, where the 2003 NELAC standard would remain in effect.

The only formal discussion on this motion concerned whether the prior motion (from August 2009 adopting the TNI Standard and agreeing on implementation date of July 1, 2011, supported by the February, 2011, agreement to rolling implementation of the TNI Standard) needed to be rescinded. It was agreed that the vote on this current May 16 motion would supersede the prior motion, if it passes.

This being an "accreditation issue," a roll call vote was taken, with a quorum certified as being present. Six (6) of the ABs represented voted during the roll call; the remaining 6 requested to vote by email after further consideration, and the 3 ABs not present were asked to vote by email.

A last minute question was asked and unanswered -- if the 5/16 motion fails, is another motion and vote needed in order to proceed? This was not answered as the call ended immediately thereafter.

NOTE from the Program Administrator: As of Friday, May 20, 2011, there were 6 "yes" and 6 "no" votes, with 3 votes still outstanding, and the voting ABs having expressed difficulty in casting a thoroughly considered vote due to the many aspects of the issue not yet addressed, such as comparison of assessment checklists and impact on their labs. Since a two-thirds majority is required for a motion to pass (per the Voting SOP,) with 6 "no" votes, this May 16 motion has failed, regardless of future votes. (12 members have already voted, that constitutes a quorum, 2/3 of voting members, 10 of 15 AC members) The remaining 3 members have until May 30 to cast their votes.

4. AB Assistance Task Force Report Submitting Options for the TNI Board of Directors to Consider

Judy Duncan was invited to discuss the report in the time remaining. This item had been delayed due to other urgent business, but the TNI Board had specifically asked that the Task Force Chair discuss the options with the AC.

Judy noted that the report had been distributed to the AC, and that it had been rearranged and slightly edited from the earlier draft discussed with us. Most of the options presented are non-controversial, but Judy specifically asked for feedback on several questions, presented here:

What would prevent you from accepting an accreditation issued by a non-government AB? Is this the result of statute or regulation? Could you grant mutual recognition to a lab that had been accredited by a non-government AB in another state? Why not?

ABs were asked please to answer on the assumption that any non-government ABs acceptable to NELAP will be going through the same evaluation process as the current

state ABs. The essence of the questions is to determine whether a "third party" AB could be deemed "equivalent" to a state government NELAP AB.

Initial responses were:

- KS state regulations define AB as a governmental body
- TX can grant secondary accreditation to any lab accredited by a "NELAP-approved" AB.
- PA the intent of its statute was to restrict recognition to governmental, but could seek legal interpretation
- OR looking to accept Defense Dept recognized accreditations (using third party)
- LA DEQ could recognize third party
- FL regulatory intent was governmental due to the language in NELAC 1.4 but the specific wording does not specify governmental
- NY regulation specifies "state accrediting body"
- UT can recognize "TNI accredited" lab, per administrative rule. (added to minutes after the meeting ended.)

There are some non-NELAP states that use third party ABs as equivalent to NELAP (e.g., GA/WA/UT) but they perform a state review before granting recognition. It is EPA's position, per letter from EPA Region 4 to the Georgia Environmental Protection Division (as spoken in this meeting, specifics such as date and sender not available) that state primacy will not be given in the instance where a state uses a privatized accreditation or certification process for laboratories.

Judy also asked that AC members email her a response concerning whether, given the current "atmosphere" and economic considerations (but irrelevant to constraints of law and regulation, for this question), are there any other philosophic reasons that would prevent NELAP ABs from agreeing to recognize third parties as part of the NELAP process? Judy's email is at the end of Attachment 1 of these minutes.

This last question is very important, since TNI needs not to pursue a course that is not supported by the Accreditation Council. Please respond directly to Judy, sharing your thoughts.

Next meeting

The AC will hold its next regular conference call on Monday, June 6, 2011, at 1:30 pm Eastern. The agenda items will likely include:

- Roll Call and Approval of Minutes
- Update on Renewals
- Outcome of the vote on the LAS EC recommendation
- Further thoughts on the AB Assistance Task Force options any show stoppers?
- Discussion of request from CSDB to remove Wet PT FoPT completely (since TIA won't work)
- Discussion and vote on revised draft Provisional Recognition SOP (time permitting, most recent version sent with draft minutes from April 4, email of Thu, Apr 7, 2011 at 12:25 PM; if the Chair approves, I will resend with meeting announcement)

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: <u>gkulasin@cdph.ca.gov</u>	yes
	Alternate: Jane Jensen E: <u>jiensen@cdph.ca.gov</u>	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
	Alternate: TBA	
KS	Dennis L. Dobson 785-291-3162 E: <u>ddobson@kdhe.state.ks.us</u> 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: <u>Paul.Bergeron@la.gov</u>	yes
	Altérnate: TBD	
LA DHH	Louis Wales T: (504) 219-4662 F: (504) 219-4661 E: <u>louis.wales@la.gov</u>	yes
	Alternate: Donnell Ward E: donnell.ward@la.gov	no

MN	Susan Wyatt T: 651.201.5323 F:	no
	E: susan.wyatt@state.mn.us	
	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	no
	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
	Alternate: Dan Dickinson E: dmd15@health.state.ny.us	no
OR	Irene Ronning T: 503-693-4122 F: 503-693-5602 E: <u>irene.e.ronning@state.or.us</u>	yes
	Alternate: Raeann Haynes E: haynes.raeann@deq.state.or.us	no
	Scott Hoatson T: (503) 693-5786 hoatson.scott@deq.state.or.us	no
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: <u>aaalger@state.pa.us</u>	yes
	Alternate: Dana Marshall E: dmarshall@state.pa.us	no

TX	Stephen Stubbs T: (512) 239-3343 F: (512) 239-4760 E: <u>sstubbs@tceq.state.tx.us</u>	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	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	no
	NELAP AC Program Administrator and Evaluation Coordinator Lynn Bradley T: 703-867-5966 E: lynn.bradley@nelac-institute.org	yes
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	yes
	Oklahoma: David Caldwell Judy Duncan	David Caldwell
	Guests: Judy Duncan, OK, for the AB Assistance Task Force, judy.duncan@deq.ok.gov Carol Batterton, TNI, for the AB Assistance Task Force, carbat@beecreek.net	