Summary of the NELAP Accreditation Council Meeting May 2, 2011

1. Roll call

The NELAP Accreditation Council (AC) met at 1:30 PM EDT on May 2, 2011. Those members and guests in attendance are listed in Attachment 1.

2. Update on AB Renewals

Technical reviews are underway for KS, NH, LA DHH, PA and NY. The completeness review for UT is underway and nearing completion. Onsites are scheduled for KS (week of May 23) and NH (week of June 6.)

The recommended teams for future evaluations were presented for AC approval. KS noted that Michelle Wade is slated to lead the FL team, while Carl Kircher of FL is leading the KS team; Steve Arms declared that while it's a potential conflict of interest to declare, that he doesn't see it as a problem and will be comfortable with Michelle leading the FL evaluation team. Cathy Westerman of VA noted that, even though her duty as Lead Evaluator is postponed as long as possible, VA will still be in very busy part of their initial round of lab assessments, and asked that the AC be tolerant of any delays her team might encounter due to workloads at home.

At the close of discussion, there were no objections to the teams presented. Team compositions are listed below. The teams already underway (shaded) are included for completeness' sake. EPA still needs to identify team members, where there are question marks.

AB	Region	Lead Evaluator	Start Date	Projected Completion Date
Kansas	2	C Kircher	12/19/2010	- 9/15/2011
NH	۷ .			
	1	S Wyatt	12/19/2010	- 9/15/2011
LA DHH	6	P Bergeron	12/19/2010	- 9/15/2011
Utah	7	F Choske	1/23/2011	- 10/20/2011
PA	3	S Gibson	1/23/2011	- 10/20/2011
New York	2	S. Hoatson	2/6/2011	- 11/3/2011
New Jersey	2	V Pretti	5/29/2011	- 2/23/2012
Florida	9-Berges	M Wade	6/19/2011	- 3/15/2012
California	9-Kutnink?	B Wilk	8/7/2011	- 5/3/2012
Texas	?	C Kircher	12/12/2011	- 9/7/2012
Louisiana DEQ	6	K Brown	2/19/2012	- 11/15/2012
Virginia	3	B Hall	2/19/2012	- 11/15/2012
Oregon	10	C Westerman	3/14/2012	- 12/9/2012
Illinois	?	A Alger	7/22/2012	- 4/18/2013
Minnesota	?	LA DHH	11/15/2012	- 8/12/2013

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

The LAS EC created and unanimously passed a document recommending two things to the AC. In summary form, these are:

- An acceptable corrective action for any finding associated with the evaluation of an Accreditation Body that is solely attributed to a new requirement in either Volume 1 or Volume 2 of the 2009 TNI standard will be a plan from the Accreditation Body (AB) to implement by rule the new TNI standard. When the 2009 standard is implemented, the AB will provide a report to the NELAP Accreditation Council documenting their conformance to the new standard.
- In light of the concerns over the 2009 standard and the plans underway to revise the standard in the near future, the Laboratory Accreditation System Executive Committee (LAS EC) recommends that the Accreditation Council continue to use the PT requirements contained in Chapter 2 of the 2003 NELAC standard until such time as the revised standard has been adopted for use in NELAP. This recommendation will maintain reciprocity and will alleviate concerns over laboratories, PT providers, and ABs in changing their systems to meet requirements that might be changed again in the near future.

Judy Morgan addressed the recommendation presented to the AC from the LAS EC, concerning implementing the TNI Standard, focusing primarily on the PT recommendation since the differences in the 2009 TNI Standard implementation schedule and the recommended language regarding corrective action is not controversial. She explained that a number of factors led to creation of this recommendation, and that the LAS sought to provide some way to bridge the time period until the PT standards can be revised, approved, and adopted. (This is underway in the PT Expert Committee now.)

To summarize for the record, there are long standing concerns about the use of a non-accredited PT provider, use of analysis date *vs* closing date, experimental PTs, LOQ reporting and PTs for Whole Effluent Toxicity (WET) testing – as well as the letter dated April 20, 2011, sent from NYS' Director of the Wadsworth Center to the TNI Board Chair concerning conflicts between their state regulations and the 2009 TNI standard.

The letter requests that TNI not implement the new PT standard and states how NY would have to resolve those conflicts if implementation of the TNI standard is not delayed, by requiring all labs with NY secondary accreditation to obtain primary accreditation in NY (essentially withdrawing from the NELAP by declining to participate in reciprocal recognition.)

Aaren asked Stephanie if she could clarify the import of that letter. If a lab reports "<LOQ" for a PT where there should be a discrete number reported instead (the "real" value being more than the PT reporting limit and more than the level of detection, but less than the LOQ,) this might be acceptable to the non-NY primary AB but would be a failure according to the NY PT program and the state's regulations.

A number of questions and discussion followed. These are summarized in bullets below, to the extent the Program Administrator can understand and translate the conversation.

- Is the problem LOQ reporting or the evaluation of PT results both are equally problematic
- Is the problem primarily with NY's AB or the PT program -- the NY AB and its PT program are integral parts of state regulations, it's not possible to separate the two.

- Since PTs are to be run as ordinary samples, the reporting requirement is unchanged from the 2003 NELAC standard, so why is it now a problem PT providers (probably all but certainly NY) score to the PT reporting limit, not the LOQ. If a lab is not running "real world" samples in the low concentrations of the PT samples, then they cannot possibly treat the PT samples as "typical environmental samples" but then the lab is required to state that they have run PT as a "typical" sample anyway, when reporting the result. Essentially, some labs are forced to misrepresent their practices in order to report certain PTs. (in the real world, those results would be "qualified" to indicate additional uncertainty) this is presumed to be a small subset of the lab community.
- Did the LAS EC explore how the recommendation to delay implementation of the TNI Standard (and essentially revert to the NELAC standard) would impact PT providers, all of whom are being assessed to the TNI standard prior to July 1, 2011 no, the PT Executive Committee is the governing body for that group, but the LAS recommendation came from the PT Executive committee. The PT Expert Committee is struggling to write the revised standard to address all of the concerns, and it will take at least a year to get the revisions adopted.
- The requirement for LOQ reporting adds burden to the AB, since they will need the "normal LOQ" of each laboratory for comparison this is not information that is ordinarily collected. Trying to fix the problem of not running PTs as typical samples had unintended consequences that we're now encountering
- What is the accreditation status of NY's PT program it was assessed to the 2009 TNI standard in fall of 2010, and renewed but there were "notations" (not considered deficiencies at the time) about items that did not meet the TNI standard but corrective actions were not required at that time (but will be required by July 1 to maintain that accreditation, presumably.) This is the genesis of NY's problem, and they seek to see if the standard can be remedied so that they can remain a NELAP AB
- Lynn stated that the Compliance ("technical review") Checklist for evaluations
 under the 2003 NELAC standard had been sorted by topic (thanks to the QAO)
 and thus the PT items are available as a single document that could be substituted
 into the Compliance Checklist for the TNI standard. This would permit the
 evaluation process to continue with minimal interruption, provided a decision is
 made before the first site visit occurs (beginning May 23.)

The entire AC was polled on the question below, with results tabulated.

"If we were to revert to Chapter 2 of the NELAC Standard for PT (only), is it a problem for your AB as a regulator?"		
Accrediting Body	Answer	
CA	no problem	
FL	no problem. already has NELAC in its rule, although is beginning to develop new rule to adopt new standard, can follow the group's decision	
IL	absent – if response received, will insert in final minutes	
KS	no problem. PT standards are not in the regulations, can conform to group decision	
LA DEQ	absent – if response received, will insert in final minutes	
LA DHH	no problem. PT not in regulation	
MN	no problem. Adopts by reference the standard adopted by NELAP	

	program
NH	no problem. Old rules still in place for at least another year
NJ	no immediate problem, but rulemaking is underway to adopt TNI Standard by reference, so they won't be able to use both NELAC and TNI. A year's delay in changing to TNI standard unlikely to be problematic, since rulemaking will take that time and the revised TNI PT standard would likely be available to adopt by then
NY	since the PT program and the AB program are a "unified front" and by their regulations, inseparable, NY cannot remain a NELAP PT provider under the 2009 PT standard, so any lab accredited by NELAP and NY would need to do two sets of PTs and have two primary accreditations (which could pose other problems)
OR	could comply with Ch. 2, but other parts might create "issues" such as the rigid requirement for 6 months between PTs, OR's rulemaking language needs to be determined by June 1, 2011, in order to move towards implementing the new standard (all or part, must be determined)
PA	no problem. Adopts standard "by reference"
TX	no problem. Adopts standard "by reference"
UT	Regulation is in pipeline to adopt 2009 TNI standard, but will go with the group and anticipates no problem.
VA	will go with the group – unable to adopt TNI standard for at least another year anyhow

As Chair, Aaren declared that it's important that the AC be realistic about the impact of this decision on both labs and ABs, and thus it would not be appropriate to vote on accepting the LAS EC's recommendations at this May 2 meeting. She recommended that AC members talk with their legal counsel and consider further, before the May 16 meeting. A vote will likely occur at that time.

Scott Hoatson had shared some thoughts about having the TNI PT program be an entirely separate entity from NELAP, such that the PT standard would not necessarily be adopted by the AC for AB implementation (similar to ILAC), but that ABs could choose whether to adopt the PT standard or use some other form of PT program. Scott asked for AC members to share any thoughts they might have about such a restructuring of the PT program.

4. Next meeting

The AC agreed to hold its next regular conference call on Monday, May 16, 2011, at 1:30 pm Eastern. The agenda items will include:

- Roll Call and Approval of Minutes
- Update on Renewals
- Continuation of discussion of LAS EC recommendation re PT portion of the standard
- Presentation and discussion of the Report to the Board of Directors from the AB Assistance Task Force (Judy Duncan, presenting)
- Discussion and vote on revised draft Provisional Recognition SOP (time permitting)

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@cdph.ca.gov	yes
	Alternate: Jane Jensen E: <u>jiensen@cdph.ca.gov</u>	no
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: <u>steve_arms@doh.state.fl.us</u>	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	no
	Alternate: TBA	
KS	Dennis L. Dobson 785-291-3162 E: <u>ddobson@kdhe.state.ks.us</u> F: (785) 296-1638	yes
	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>	no
	Altérnate: TBD	
LA DHH	Louis Wales T: (504) 219-4662 F: (504) 219-4661 E: <u>louis.wales@la.gov</u>	yes
	Alternate: Ginger Hutto E: ghutto@dhh.la.gov	no

MN	Susan Wyatt T: 651.201.5323 F:	yes
	E: susan.wyatt@state.mn.us	
	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	yes
	Alternate: TBD	
NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 E: joseph.aiello@dep.state.nj.us	yes
	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>	no
	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: <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	yes
	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 Morgan, TNI Board and Environmental Science Corporation (Tennessee,) representing the Laboratory Accreditation Systems Executive Committee JMorgan@esclabsciences.com	