Summary of the NELAP Accreditation Council Meeting

October 17, 2011

1. Roll call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EDT on October 17, 2011. Minutes of the October 3 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 – requested and received 30-day extension, application to be submitted late October

FL – technical review underway, onsite scheduled for week of November 14

KS – ET awaits revised SOPs to address technical review and findings from site visit, so that it can verify the corrective action is adequate.

LA DHH – onsite completed; observation scheduled for November. Site report will follow.

NH – awaiting onsite report.

NJ – technical review is approaching completion

NY – onsite report delivered September 29; team awaits response

PA – site visit report in preparation

UT – response to onsite report being reviewed by team

3. WET PT Issues

The PT Expert Committee had asked the AC to formulate a recommendation for how to address the conflict that PTs for WET are presently required because there is a WET PT FoPT table but yet there is no appendix in the standard that addresses WET PT. The AC was not able to make progress on this issue at its previous meeting due to lack of sufficient information

Aaren asked that either Eric Smith, PT Executive Committee, or Mitzi Miller, PT Expert Committee, please explain the "problem" and identify the potential solutions. Several labs have inquired whether the intent for WET PT is once or twice per year, bringing this latent issue to the fore. WET PT was historically part of EPA's Discharge Monitoring Report QA study (DMRQA), and preparation and distribution of the samples was handed over during the transition from NELAC to INELA to TNI, and was mostly complete before TNI became the "home" of the NELAP program.

There is no appendix in the TNI Standard to accompany the WET FoPT. All agree, this was an oversight, when the TNI standard was developed. Additionally for consideration, an update review of the WET FoPT table is underway and is not anticipated to be completed for at least another year.

The optimum solution offered by the PT representatives was to eliminate WET PT as NELAP required FoPT table and rely on the DMRQA study only.—Removal of the WET Table from the list of NELAP required FOPTs but keeping the FoPT table available on the TNI website for DMRQA purposes only would clarify the WET PT frequency requirement to one WET PT per year; this is not acceptable to the AC as explained below. Another solution offered would be to make WET PT an "experimental" PT table, even though the AC sought to eliminate experimental tables completely and this action alone would not fully address the frequency issue.

Several AB representatives noted that PTs are available from PTPs, as often as 4x/year, so this is not an "availability" issue. Labs complain that WET PT takes a long time to run, and many believe 2x/year is excessive. Labs and ABs agree that the control charts for WET testing are far better evidence of the quality of test performance than is the PT specimen. There was also discussion that as long as a lab can pass 1 WET PT/year, it will never be out of compliance (must pass 2 out of 3, but there is no "failure", only required corrective actions if the test is not successfully completed.)

The PT representatives asked that the AC adopt and publish a policy that WET PT would only be required once/year, despite the requirement of the TNI standard. ABs were reluctant to take this step, which would be tantamount to overruling a requirement of the TNI standard, and sought an alternative approach. There was more discussion about whether the AC endorsement of such a policy if adopted by the PT Executive Committee would be preferable, but no agreement.

At length, discussion turned to the possibility of proposing a Tentative Interim Amendment (TIA) to the standard, since this issue is, in fact, the result of an oversight or error in developing the standard, one that did not become apparent until after the standard was adopted. Conceptually, the TIA would essentially hold to the NELAC standard, until such time as all steps can be completed to upgrade the TNI standard to accommodate WET PT (i.e., new FoPT table and new appendix for WET PT testing.) This would leave all labs performing one PT/year to support WET PT accreditation, regardless of rolling implementation, until the revised standard could be adopted.

The PT representatives requested firm commitment from the AC that this solution would be acceptable to all. Aaren proposed that each AB should declare whether it believes a TIA to be "a good idea," "an idea worth considering" or "a bad idea." At this point in the call, there were 11 ABs still participating; by a roll call poll, each of those said that it is "good idea." The remaining 4 ABs are being polled by email (and given some background information), and the PT representatives will be notified when that process is complete.

4. Follow-up on the Draft Bill of Rights for Labs

At the TNI Board meeting, Alfredo Sotomayor, Chair of the Consistency Improvement Task Force, indicated that he has forwarded to the workgroup all that he learned from the AC members who contacted him about the draft Bill of Rights, and that he intends to ask the AC to quickly review the revised draft before it is submitted to the Board with the CITF's recommendations.

5. Request from EPA Liaisons to Consider Third Party Evaluators and other ways to Accomplish Evaluations with the Growing Limitations on Staff Time

After the October 3 vote to extend AB certificates of recognition due to delays in accomplishing the evaluations, Art and Marvelyn wrote to the AC, as follows:

We are satisfied that the evaluations are proceeding according to the procedures in the evaluation SOP. However, the EPA recommended in November 2010 that the use of third-party evaluators be pursued, knowing that the Agency was no longer in a position to fully support the evaluations. We believe that the delays that have occurred should prompt TNI and NELAP to find an alternative approach or approaches for carrying out future rounds of evaluations, which will begin in December 2013. The Agency looks forward to working with TNI and NELAP on a solution that works well for all parties involved.

A question was raised about whether this was the "third party evaluator" question or if now this has somehow shifted to being a third party AB for evaluating ABs. Within a few minutes, it was clear that, the original question was strictly about individual evaluators, but a 3rd party AB to perform the evaluations might be one of the alternatives to consider.

Art explained that EPA is participating less in evaluations – regional budgets have shrunk just as state programs have, so both workload and travel funds are making EPA participation more difficult. He noted that there was initial uneasiness about TNI contracting out the Quality Assurance Officer (QAO) position, although the QAO has worked out well.

Everyone is concerned about how the Drinking Water certification and state primacy delegations will be impacted by EPA's diminished participation in evaluations. Some EPA regions have expressed intent to continue participating in evaluations (as equivalent to state primacy determination,) while others have already begun conducting separate site visits to the state ABs to evaluate the NELAP program for compliance with state primacy regulations. No one presently has answers for these questions, but EPA's Drinking Water program will clearly need to be satisfied that, whatever approach is adopted, it will meet the needs for maintaining state primacy delegation.

Lynn had invited the NELAP Evaluators to offer thoughts about this, at their October 12 conference call, with Art and also Paul Ellingson (QAO) present. The evaluators stressed that training requirements needed to be the same, regardless of who comprised the evaluation teams, and expressed a strong preference for a state representative to be the team leader, if a 3rd party evaluator were used. Paul shared with the AC, as he had done with the evaluators, some of his thoughts about streamlining the process; these will be transmitted formally to Jerry as part of his QAO contract, but in brief, his suggestions will be to eliminate the formal technical review report in favor of an all-encompassing site report, and also a suggestion he liked from an evaluator, to have the applicant AB paste the full text instead of the citation for each item in the tech review checklist, so that the evaluators need not hunt down the pertinent paragraph for each checklist item, sometimes within a very long cited document. Paul also expressed willingness to share some tools he is developing, separate from his NELAP contract, that will streamline report writing.

Lynn indicated that she will also ask the Laboratory Accreditation Body Expert Committee and the Laboratory Accreditation Systems Executive Committee to join with the evaluators and the AC to begin conceptualizing what the new evaluation process might be, so that the procedures and checklists can be created and adopted in time for the next cycle of evaluations. This next cycle begins in less than two years, which is quick turnaround for a

consensus-oriented group like TNI. The AC will need to clarify how much change it is willing to accept, so that the details can be fleshed out and documented.

6. Next meeting

The next AC meeting will be Monday November 7, at 1:30 pm EST. Agenda items (thus far) will be:

- Welcome and Roll Call
- Approval of Minutes
- Update on Renewals
- Wrap-up of WET PT issue, as needed
- Follow-up on NELAP Consistency email
- Alternative approaches to evaluation
- Other issues that may appear before the meeting convenes

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>jjensen@cdph.ca.gov</u>	no
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KS	Michelle Wade E: <u>MWade@kdheks.gov</u> Ph: <u>(785) 296-6198</u> Fax: <u>(785) 296-1638</u>	yes
	Alternate: none	no
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: Paul.Bergeron@la.gov Altérnate: TBD	no
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	no

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NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	yes
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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: <u>seo01@health.state.ny.us</u>	yes
	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	no
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: <u>aaalger@state.pa.us</u>	yes
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UT	David Mendenhall T: (801) 584-8470 F: (801) 584-8501 E: davidmendenhall@utah.gov	no
	Alternate: Kristin Brown E: kristinbrown@utah.gov	yes
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: 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	yes
EPA Liaison effective 2012	Marvelyn Humphrey T: (281) 983-2140 E: Humphrey.Marvelyn@epa.gov	yes
	Quality Assurance Officer Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	yes
	Oklahoma: David Caldwell	no
	Guests: Eric Smith, Chair, PT Executive Committee Mitzi Miller, Chair, PT Expert Committee	