Summary of the NELAP Accreditation Council Meeting

Forum on Laboratory Accreditation, Denver, CO, January 16, 2013

1. Roll call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 8:00 am Mountain time on Wednesday, January 16, 2013. Those members in attendance are listed in Attachment 1 with members participating by teleconference identified.

In addition to the pre-meeting time changes, Aaren announced that the AC meeting would conclude at 10 am, and the second half of the scheduled session would be used for additional time for the Proficiency Testing Expert Committee, which was already scheduled in the same room for the afternoon session.

2. Election of Vice Chair for the AC

At the January 7, 2013 meeting, Susan Wyatt had nominated Paul Bergeron for Vice Chair, and Scott Siders seconded Paul's nomination. Paul was not on the call but the AC agreed to vote at its next meeting, if Paul were willing to accept the nomination, and he did. There were 12 "yes" votes with Paul abstaining, and the remaining 2 votes will be cast by email (2 AC members had not yet joined the meeting by teleconference.)

3. Updates for Conference Participants

<u>Standards Interpretation Requests (SIRs)</u>

Aaren explained that a 4-person workgroup of AC members has been working on the backlogged SIRs and that its task is nearly complete. Beginning with the oldest and working up to SIR #151, this group sorted the outstanding SIRs into three categories: genuine interpretation requests, never-should-have-been SIRs, and obsolete items (where the timeline for response was long passed or the 2009 TNI Standard resolved the interpretation.) For the genuine interpretation requests, the workgroup also added the relevant citation from the other standard. Only a few more hours work is needed and these long-delayed SIRs will be ready to send back to the Laboratory Accreditation Systems Executive Committee as either accepted or with identification of what makes them not accepted (poor wording or grammar, extraneous information, or similar problematic issues.)

Aaren also noted that if a lab feels the need for an immediate interpretation, then its Accreditation Body (AB) should be asked. The AB will respond, in consultation with the AC as needed, and assuming a SIR is made, the immediate answer will stand until and unless the SIR answer is different.

The AC will dedicate its second call each month to addressing outstanding SIRs. Paul Junio, chair of the Quality Systems (QS) Expert Committee, offered to join those calls, if the AC desires.

Joe Konschnik of Restek inquired about SIR #191, and was told that its interpretation is in the approval process.

Accreditation Body Evaluations

Aaren explained that 11 AB evaluations are completed with the remaining four underway. She noted that EPA regions are no longer committed to participating in all of the AB evaluations, but certain regions may continue to participate. The AC will need to address how the Evaluation Teams will be formed, in the absence of an EPA representative. To date, all teams have had at least one state AB representative and one EPA representative. Options for replacing the EPA representative seem to be 1) having the Quality Assurance Officer participate in the evaluation; 2) having a second state AB representative, or 3) having just a single evaluator.

Non-NELAP State Accreditation Bodies

Realizing that many non-NELAP states use the NELAC or TNI standards, the AC (and TNI's Advocacy Committee) sought to involve them more in the NELAP program. In May 2012, the AC held an "open" call with all state ABs, to explain the changes as EPA has withdrawn from active participation in the lab accreditation program. From the questions posed by some participants, it was clear that many states have misconceptions about NELAP accreditations and the NELAP program in general.

AC Calls involving NELAP Assessors

The AC has initiated quarterly teleconferences involving state and third party NELAP assessors, as a way to involve assessors with the larger organization. The first of these, on December 3, 2012, addressed aspects of traceability and was led by Virginia. Future calls will address similar types of issues – different than training provided by other TNI venues – and focus on information exchange and best practices.

Aaren acknowledged that the AC needs to decide whether and how to address the different practices that come to light in these discussions. The goal is obviously consensus, but there will be some variability. One suggestion was to have a summary of findings produced, as "minutes" from the calls.

Changes to *Cryptosporidium* Lab Certification

Aaren noted that EPA's Office of Ground Water and Drinking Water's Technical Support Center has announced that it seeks to partner with states to certify labs for the next round of monitoring for "crypto" as required by the LT2 regulation (Long Term 2 Enhanced Surface Water Treatment Rule) and that a lunchtime meeting was held with EPA TSC staff the previous day to discuss the hand-off further. Certifying labs for *Cryptosporidium* analyses will not be a condition of primacy for states, but the Agency seeks to ensure that sufficient capacity does exist to accredit the labs that will participate in the next round of monitoring. There may be an additional Certification Officer course to address this in spring of 2013. [NOTE: a summary of the meeting with EPA is included as Attachment 2 with these minutes.]

Status of Implementation of the 2009 TNI Standard

All NELAP ABs were polled about their current status, and results are tabulated below.

Implementation Status of 2009 TNI Standard for NELAP ABs

AB	Standard in Effect Now	Status/Progress	
CA	2003 NELAC	Will change to 2009 TNI Standard once AB evaluation is completed	
FL	2003 NELAC	Laboratories may implement the 2009 TNI if desired. Accepting PT reports per 2009 TNI Standard	
IL	2003 NELAC	Regulations cite 2003 NELAC standard, but are encouraging labs to move to the 2009 TNI Standard. Had intended to skip 2009 TNI standard and adopt its first revision as 2012 TNI Standard; delays in revising the standard mean that rulemaking to adopt 2009 TNI Standard will be undertaken instead	
KS	2003 NELAC	Will publish regulations to adopt 2009 TNI Standard. Currently allows 2009 Standard where it is more stringent than 2003 NELAC	
LA DEQ	2003 NELAC	Regulations to adopt 2009 TNI Standard should be completed by August 2013. Currently allows 2009 TNI Standard without penalty	
LA DHH	2009 TNI Standard	Changed in December 2012	
MN	2003 NELAC	MN statute allows either standard, but certificates show 2003 NELAC. Unable to change completely until database modifications can be completed, but allows 2009 TNI Standard where more stringent	
NH	2003 NELAC	Moving towards 2009 TNI Standard and encouraging labs to implement 2009 TNI	
NJ	2003 NELAC	Regulation cites 2003 NELAC. Assessing to both 2003 NELAC and 2009 TNI Standards and providing findings to both	
NY	2003 NELAC	Implementing and enforcing 2003 NELAC. Accepting secondary accreditations from labs with primary accreditations to 2009 TNI Standard and encouraging labs to move to 2009 TNI Standard	
OR	2009 TNI	Assessing labs to 2009 TNI Standard	
PA	2009 TNI	Assessing and enforcing to 2009 TNI Standard	
TX	2009 TNI	2009 TNI Standard in place	
UT	2009 TNI	2009 TNI Standard in place	
VA	2003 NELAC	Regulation development underway, completion date uncertain	

A commenter insisted that he needed to be able to check this status routinely for activities involving “legal processes” and asked that the implementation status be posted on the TNI website. While this will be added to the listing of ABs on the NELAP webpages as soon as the above information is verified, it is important to note that a laboratory’s certificate of accreditation is the only valid legal source for the standard to which a lab is accredited, and further, that even if an AB changes over to the newer standard, the lab certificates won’t change until the lab’s next site visit is successfully completed.

Non-Governmental Accreditation Bodies (NGABs)

Over the past year, TNI has sought to find a way to recognize NGABs as being accepted to accredit to the 2009 TNI Environmental Laboratory Sector Standard. It is now certain that the program for NGABs must be entirely separate from the AC, since some NELAP ABs can only recognize governmental accreditations for environmental labs. The TNI Board is working to establish the NGAB program. Some NELAP ABs may be able to grant secondary recognition to labs accredited by an NGAB, and all agree on the importance of educating the environmental lab community about the differences and lack of reciprocity outside of the 15-state NELAP community.

4. Other Business Raised During Open Comment Period

LAMS Database

Dan Hickman, TNI Database Administrator, addressed the AC about the Laboratory Accreditation Management System (LAMS) database. He noted that UT, TX, VA, NH, OR, MN and LA DEQ now have their full information in LAMS, and also the status of all other NELAP ABs as they are making progress towards adding their full fields of accreditation. All demographic data for labs has been in LAMS for over a year already.

Dan also noted that he has completed all of the notations on methods in the federal Code of Federal Regulations (CFR) to be compliant with the wastewater program's Method Update Rule (MUR.) This was a huge undertaking.

NGABs

Doug Leonard of Laboratory Accreditation Bureau noted that these organizations are willing to work with the NELAP ABs that are able to utilize non-governmental accreditations to the TNI standard, and invited those representatives to come to the Thursday morning session addressing how the NGAB program might be structured.

Doug also asked for assistance from the NELAP ABs in moving states to require using only accredited Field Sampling and Measurement Organizations (FSMOs) per the National Environmental Field Activities Program (NEFAP.) Aaren noted that it would probably take legislative mandates for state environmental programs to require that, except possibly in states where the ABs presently cover mobile labs and field sampling already. Several NELAP ABs agree on the need for this to happen, and recommended that Doug begin with contacts listed in the Accreditation Body Database (www.nelac-institute.org/abdb). Lynn agreed to provide the spreadsheet version of this database, which is more user-friendly for obtaining contact information.

Other items

One commenter recommended working with the Association of Boards of Certification to accomplish an operator certification credential for analysts.

Another commenter noted that providers of reference materials should be accredited. Discussion suggested that such credentialing should obviate the need for a second source of a standard, and asked whether that issue is in the "parking lot" category for a

future change to the standard. The chair of QS Expert Committee indicated that, with the AC approval, it can be so placed. Another commenter noted that, once a primary standard has been in use, there is value in using a secondary standard as verification of the primary (to detect contamination or unintended change in concentration, for instance.)

Since not all ABs will be implementing the 2009 Standard due to the Proficiency Testing (PT) modules, how will it play out? All PT providers (PTPs) are reporting to the 2009 standard. Discussion indicates that some ABs are just muddling through, about the shipment and analysis dates versus the closing date, although the Level of Quantitation (LOQ) versus PT Reporting Limit (PTRL) seems to have been resolved

5. Next Meeting

The next regular teleconference will be on Monday, February 4, 2013. An agenda and teleconference information will be sent in advance of that date. Agenda items will include

- Non-potable water Field of Proficiency Testing tables (NPW FoPT)
- Composition of ETs without EPA regional evaluators
- Whether and how to address different practices among ABs that came to light during the assessor calls
- Strategy for addressing foundational documents – AC charter, revised voting SOP (including SIR voting changes and discussion of veto votes, need for SOP for reviewing standards during development process
- Other items that may arise

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	Fred Choske 510-620-31745 F: 510-620-3471 E: fred.choske@cdph.ca.gov	Yes/telecon
	Alternate: Dave Mazzera T: 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/telecon
	Alternate: Carl Kircher E: carl_kircher@doh.state.fl.us	Yes
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	Yes/telecon
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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	Yes
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: Paul.Bergeron@la.gov	Yes/telecom
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes/telecom
	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	Yes/telecon
	Alternate : Rachel Ellis E: rachel.ellis@dep.state.nj.us	no
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	Yes/telecom
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OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	Yes/telecom
	Shannon Swantek T: 503-693-5784 E: Shannon.swantek@state.or.us	Yes
	Included for information purposes: Scott Hoatson T: (503) 693-5786 E: hoatson.scott@deq.state.or.us	Yes
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TX	Steve Gibson E: jgibson@tceq.state.tx.us	Yes/telecon
	Alternate: (temporary) Melissa Peters-Kelly E; Melissa.Peters-Kelly@tceq.texas.gov	
UT	Kristin Brown T: (801) 965-2540 F: (801) 965-2544 E: kristinbrown@utah.gov	Yes

	Alternate: Robert Aullman T: 801-965-2541 F: 801-965-2544 E: raullman@utah.gov	No
VA	Cathy Westerman T: 804-648-4480 ext.391 E: cathy.westerman@dgs.virginia.gov	Yes/telecon
	Alternate: Ed Shaw T: 804-648-4480 ext.152 E: ed.shaw@dgs.virginia.gov	No
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	no
NELAP QAO	Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	Yes/telecon
	Oklahoma: David Caldwell	yes
Guests	John South, IL EPA	Yes/telecon

Attachment 2

Summary of January 15, 2013 Meeting with EPA OGWDW TSC about Crypto Certification

On Tuesday, January 15, the AC met with EPA's Technical Services Center (TSC, in the Drinking Water program) representatives to discuss changes to certification processes for laboratories monitoring for *Cryptosporidium.* This meeting was held during the lunch break, noon Mountain time, with a conference line set up for those unable to be present. Carrie Miller of EPA led the meeting, and Dan Hautman (now TNI's primary contact in TSC) was also present. A document of "Frequently Asked Questions" was distributed prior to the meeting, and much of the discussion repeated material in that document. What follows is best effort at a summary based on notes from the meeting.

Having a crypto certification program is not a condition of primacy for state drinking water programs. A number of state assessors have taken the crypto certification course, for which the chemistry and microbiology courses are prerequisite.

Labs that were certified by EPA for the first round of monitoring under the (Long Term 2 Enhanced Surface Water Treatment Rule (LT2 rule) are not grandfathered in. The second round (for which this certification issue is applicable) begins in 2015 and ends in 2021. There is an updated version of Method 1623, known as Method 1623.1, as well as molecular methodologies available now that were not available for the first round. The molecular methodologies are not considered suitable at the 1-2 oocyst level. For methods 1623 and 1623.1, the QA/QC are the same except for validation of results in the revision (1623.1)

Initially, for the Information Collection Request (pre-LT2), EPA approved individual analysts for method 1623. Now, the LT2 rule specifies certification by laboratory, per the new Chapter 7 of the Drinking Water Certification Manual that has requirements for technicians performing the analyses.

EPA's intent to partner with states to approve labs for crypto testing is not limited to NELAP states. The EPA regions will judge state equivalence based on Chapter 7 of the Certification Manual, and then the certification body will have to utilize an approved Certification Officer (CO, one who passed the course for crypto.)

The TSC intends to maintain a list of approved labs. When asked how it will obtain this information, Carrie indicated that it will primarily be from personal communication with the states that are performing certifications. If a lab is needed in a particular region, that region will refer to a state performing certifications, to identify a suitable lab or labs.

Carrie Miller has posted several videos on YouTube.com about "How to Interpret a Crypto Report", and has a pending request for videos on concentrating the elution step of analysis as well as performing immunomagnetic separations. She says there is also an "Adobe Connect" course in how an analyst identifies crypto.

Regions 2 and 4 have COs trained in crypto. Carrie says that about 50 labs nationally will be seeking certification, and there may be other labs seeking certification to Method 1693 for wastewater, as well.

There was some discussion about the feasibility of producing a TNI standard for crypto accreditation (not likely in the timeframe needed to implement by 2015) and there were many

concerns about why a separate standard would even be needed. Because a lab is NELAP accredited to the standard, not the Certification Manual, at most a new appendix might be needed, but not all states have regulations about crypto.

The PT Executive Committee has a subcommittee that has completed a FoPT table for crypto.

The Certification Manual requires observation of a PT sample being analyzed (as a specimen, not for PT purposes). Concerns were expressed that this would take more than one person and more than one full day just to witness the analysis, and that this is excessive for just a single method.

Other concerns expressed were the need to train Third Party Assessors that could be used by NELAP ABs, and also that the current PT provider, Wisconsin Department of Health, is not a TNI-approved provider. It may be that one of the approved PTPs does offer crypto PT samples; I had to leave the meeting at this point, about 10 minutes before it concluded.