

**Summary of the NELAP Accreditation Council Meeting
Forum on Laboratory Accreditation
Friday morning, August 9, 2013, San Antonio, TX**

1. Welcome and Roll call

The NELAP Accreditation Council (AC) met at 8:00 am Central time on Friday, August 9, 2013, during the Forum on Laboratory Accreditation in San Antonio, TX. In the absence of the Chair and the Vice Chair, Susan Wyatt moderated the session. Those members in attendance are listed in Attachment 1; members who sought to participate by teleconference are noted but technical difficulties made meaningful participation very difficult and many simply gave up.

2. Status of Implementation of the 2009 TNI Environmental Laboratory Sector Standard

The TNI Board of Directors has requested semi-annual updates on the progress of the NELAP Accreditation Bodies (ABs) in implementing the new standard. This update is generally part of the public session at conference and then missing ABs are filled in and the complete status presented to the Board as part of the monthly Program Report.

AB	Standard in Effect Now	Status/Progress
CA	2003 NELAC	Plans to shift to 2009 TNI standard once evaluation is completed
FL	2003 NELAC	Allows either standard. Expects to use statewide "streamlining" of regulations as vehicle to implement 2009 TNI. Uses 2009 TNI ELSS for PT
IL	2003 NELAC	Officially requires 2003 NELAC but accepts 2009 TNI. Is in early stages of rulemaking to transition to TNI ELSS
KS	2003 NELAC	Regulation still requires 2003 NELAC but accepts 2009 TNI except where 2003 NELAC is more stringent. Uses 2009 TNI ELSS for PT
LA DEQ	2003 NELAC	Transitioned to 2009 TNI effective June 10, 2013
LA DHH	2003 NELAC	Transitioned to 2009 TNI in December 2012
MN	2003 NELAC	Accepts either standard.
NH	2003 NELAC	Plan to update the rules to the 2009 TNI Standards was put off in favor of other

		rule changes deemed more important. If not 2014, the worst case scenario is 2016 when current accreditation rules expire and have to be readopted.
NJ	Assessing to 2009 standard; each non-conformance has a citation for both the TNI and NELAC Standards.	No progress to adopt the TNI Standards by reference. Change of regulations has been shifted to a 2014 activity Senior Management.
NY	2003 NELAC	No plans to transition until PT (V2M2) revisions are adopted. Assessment citations reference deficiencies for both the 2009 and 2003. If a rare citation is only applicable in 2009 - and not to 2003 - it would be cited as a 'comment' - not a true deficiency.
OR	2009 TNI	Transition effective in 2011
PA	2009 TNI	Began assessing labs to new standard in 2011
TX	2009 TNI	Transition effective July 2011
UT	2009 TNI	Completed transition in October 2011
VA	2003 NELAC	Regulations to adopt the 2009 standard were signed by the governor in July 2013 and the required 60-day comment period begins August 26, 2013.

3. Update on AB Evaluations and Renewals of Recognition

Four evaluations remain underway – CA, LA DEQ, MN and IL. Each of these ABs has been granted a temporary extension of its recognition as a NELAP AB, pending completion of the evaluation and the AC’s consideration of the evaluation team’s recommendation once the evaluation process is complete.

Lynn noted that both the NELAP Evaluation SOP and the checklists and application for evaluations have been revised and will shortly be presented to the NELAP AC for its consideration, for use in the upcoming round of evaluations. The wording of the Compliance Checklist (aka, Technical Review Checklist) is unchanged but items have been color-coded to reflect whether the standard requires documentation either in the AB’s quality system or else in some other fashion, or whether observation of practice during the on-site is sufficient.

4. Use of Third Party Evaluators

The AC reached consensus about how it will utilize third party (contract) evaluators for the round of evaluations due to begin in December 2013. One evaluator, with potentially a back-up second person, will be contracted to TNI, and this individual will be the Lead Evaluator for each of the teams. Each team will include at least one state AB representative and may include an EPA representative in instances where the regional offices choose to participate. No regions have formally announced non-participation but about half of them have effectively ceased participation and are conducting their drinking water site visits separately from the NELAP evaluations.

One commenter recommended that there be more than one third party evaluator, and another demanded to know why the deadlines in the Evaluation SOP are not enforced.

5. Progress on the SIR Backlog

Susan noted that considerable progress has been made in reducing the backlog of Standard Interpretation Requests (SIRs,) working with the Laboratory Accreditation Systems Executive Committee (LAS EC,) and that revisions to LAS EC's SIR SOP to ensure more timely future responses are approaching completion. She also noted that a number of SIRs have been discussed within the AC and that a new "batch" of responses was just recently posted to the AC voting site.

6. Meeting with EPA Officials about Crypto Accreditations

On Wednesday, August 7, representatives of the TNI Board and the NELAP AC met with Dan Hautman and Carrie Miller of the Office of Groundwater and Drinking Water's (OGWDW's) Technical Support Center (TSC) in Cincinnati. In recent months, multiple conversations have taken place as NELAP ABs have tried to reconcile EPA's requirements for an AB to be designated "equivalent" to the EPA certification process with the existing NELAP assessment processes. Most of the recognition issues were resolved after a detailed explanation of NELAP assessments was provided to the EPA officials. The summary of this meeting, as revised by Dan Hautman of TSC, is in Attachment 2 of these minutes.

Susan and Carrie are preparing a joint presentation for conference in Louisville, about the implementation plan for Crypto accreditations. Development of this presentation, and the plan, is well underway.

In response to questions, Susan conducted a quick poll of which NELAP ABs are presently accrediting for Crypto, and results are summarized below.

AB	Accrediting for Crypto?
CA	? (absent for poll)
FL	Yes – has 2 trained assessors and several labs already accredited. Will be asking labs if they desire the EPA-style approval, and expects to have TSC and regional representatives observe one of its crypto assessments in September NOTE: laboratories desiring the EPA approval must order the "audit kit"

	from EPA plus perform the required online evaluation of microscope counts, as overseen by EPA/TSC
IL	No, the state's Department of Public Health will handle crypto as a non-NELAP certification, if it occurs.
KS	No plans to accredit for crypto
LA DEQ	Grants secondary accreditations (for crypto in waste or recreational waters) but has not been asked to offer primary accreditations
LA DHH	Does not accredit for crypto
MN	Yes -- has trained assessor and one secondary accreditation now
NH	? (absent for poll)
NJ	Yes, already accrediting for crypto in accordance with EPA requirements
NY	? (absent for poll)
OR	Yes – presently has 2 accredited labs
PA	Is developing a crypto program but will limit the number of accreditations it grants
TX	Has trained assessor, but does not plan to offer accreditation for cryptosporidium in drinking water, including source water
UT	Does not accredit for crypto
VA	Does not accredit for crypto

7. Newly Adopted Policy for AB Notifications to the AC of Changes to AB Operations

Last year, the AC had requested that LAS EC draft either a policy or an SOP to address this issue, and provided the language from the 2003 NELAC standard as a starting point. The LAS completed and approved such a policy and recommended it to the AC, and the AC has approved and adopted the policy. [NOTE: Voting was completed on July 26 with 14 of 15 ABs voting yes and one AB not responding to the request for an email vote.]

8. Developing Revised Standards

Susan presented comments that had earlier been provided by Cathy Westerman (of VA) about the multiple comments given to the PT Expert Committee from NELAP ABs, and appreciating that committee's hard work as well as its rulings that most of the comments were persuasive and need to be addressed before the standard progresses to the next stage. The AC offered a big "thank you" to the PT Expert Committee!

The Calibration Standard being developed by the Chemistry Expert Committee also received many comments from NELAP ABs. Several AB representatives volunteered to serve on the Chemistry Committee – OR and IL, both. Gary (OR) noted that most of his comments were ruled persuasive and that, as a new committee member, he was assigned to draft revisions to address those comments. Gary promised to work with Scott (IL) in doing this.

9. Retirement of Steve Gibson

Susan noted that this would be Steve's last conference as the AB representative from Texas. She thanked him, on behalf of the full Council, for his efforts and contributions to NELAP.

10. Questions and Comments from Conference Participants

With the conclusion of the formal agenda, Susan opened the floor for comments. Those are briefly summarized below.

Understanding that the AC representatives are appointed by their individual states, has the Council considered including the non-governmental ABs (NGABs?) Presently, membership in the AC substitutes for individual mutual recognition agreements with all other NELAP ABs; if NGABs were to be included, the former mutual recognition agreements would need to be entirely re-established. The AC supports the NGABs being endorsed by TNI to accredit to the TNI ELSS, however for drinking water there must be a state role in the accreditations and also there are still two places in the TNI standard where ABs are defined as governmental. (The reference in the PT module, V2M2, will be changed in the revision that's underway presently, and the other reference is merely a non-binding "note.")

Please consider some form of liaison with NGABs for consistency purposes, perhaps with the executive committee of NGABs. The Chair of the NGAB working group responded that it has discussed constituting a different body where the NGABs and NEFAP ABs and NELAP ABs could come together for consistency purposes.

Regarding the Laboratory Accreditation Management System (LAMS) database, Dan Hickman (TNI Database Administrator) noted that 8 ABs have "most" of their Fields of Accreditation (FoAs) entered and a ninth is in process. All ABs have entered demographic data but it seems not to be kept updated. Dan stated that if the FoAs were entered and maintained current in LAMS, the secondary ABs could use LAMS for comparison with the primary accreditation; he asks that this become part of the evaluation process, since maintaining database listings is part of the standard.

Dan also noted that the old NELAP Board wanted method codes used for tracking methods, yet one current AB is not using method codes, and there seems no way to force them. Dan did note that considerable time savings are available to all IF all ABs use method codes in LAMS. Several ABs committed to resuming periodic LAMS updates.

Kudos were offered to the AC as well as the LAS EC and staff for reducing the backlog of SIRs.

With a bit of time remaining, Susan raised the issue of possibly inadequate document control and records management within TNI, since the Chemistry Expert Committee reportedly made edits to an older (not current) version of the Quality System (QS) standard, and also that the Quality Systems Expert Committee was unable to find out where in the review process its developing standard is. She indicated that this needs to be resolved so that ABs and others don't end up performing duplicate reviews of the newly developing standards. Carl explained that when the QS Voting Draft Standard missed its approval date, there was no longer a "working draft" to edit, so that returning to the existing approved document (the latest "official" version) was the only option. There are now four committees working on different parts of what used to be the sole purview of QS Expert Committee – in addition to QS, there are the Chemistry, Microbiology and Radiation Expert Committees. Susan indicated that, even if not a document control issue, this sort of confusion needs to be avoided by improving communications among the affected groups.

Carl moved and Steve Gibson seconded that the meeting be adjourned.

11. Next Meeting

The next AC meeting will be Monday, August 19, 2013. A reminder will be sent the week before the meeting.

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Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	Fred Choske 510-620-31745 F: 510-620-3471 E: fred.choske@cdph.ca.gov	No
	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	No
	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	No
	Alternate: Janet Cruse T: 217-785-0601 E: Janet.Cruse@illinois.gov	Yes/phone Also John South
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/phone
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes/phone
	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	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 : Rachel Ellis E: rachel.ellis@dep.state.nj.us	?
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	No
	Alternate: TBD	
OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	Yes
	Shannon Swantek T: 503-693-5784 E: Shannon.swantek@state.or.us	No
	Included for information purposes: 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: aaalger@state.pa.us	No
	Alternate: Yumi Creason E: ycreason@pa.gov	Yes
TX	Steve Gibson E: sgibson@tceq.state.tx.us	Yes
	Alternate: Alice Colt T: (512) 239-3927 Alice.Colt@tceq.texas.gov	Yes Also Mary Magerkurth and Allison Fischer
	Included for information purposes: Melissa Peters-Kelly E; Melissa.Peters-Kelly@tceq.texas.gov	No

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	No
	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	Yes
NELAP QAO	Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	Yes
Oklahoma	David Caldwell	Yes
Guests:		

Attachment 2

Summary of Crypto Meeting Forum on Laboratory Accreditation, Wednesday morning, August 7, 2013, San Antonio, TX

The TNI Board of Directors requested to meet with Dan Hautman and Carrie Miller of EPA's Office of Ground Water and Drinking Water Technical Support Center (OGWDW TSC) after learning about the ongoing struggle to reach agreement over specifics of EPA's expectations concerning how the NELAP Accreditation Bodies (ABs) might implement accreditations for two specific methods (1623 or 1623.1) for the analysis of *Cryptosporidium* spp. (crypto) and attain the required "equivalent State laboratory certification program" to EPA's Laboratory Quality Assurance Evaluation Program 40 CFR 141.705(a). Attending were Brenda Bettencourt, Susan Wyatt, Sharon Mertens, Marvelyn Humphrey, Patsy Root, Dan Hautman, Jerry Parr, Alfredo Sotomayor and Lynn Bradley. Attempts to teleconference with Carrie Miller and Aaren Alger were less than fully successful due to technical difficulties with the hotel's phone system.

The meeting opened with a frank summary of the ongoing and frustrating efforts of the NELAP Accreditation Council (AC) and the EPA TSC representatives to reach agreement on what a NELAP AB's assessment procedure would need to include, to be designated as "equivalent" to the EPA's Laboratory Quality Assurance Evaluation Program (which has discontinued performing laboratory audits.) Since the most recent discussion between the AC and TSC, Susan Wyatt and Carrie Miller held a conversation with EPA Region 5's Certification Officer, Al Alwan, where Susan was able to explain fully the NELAP assessment process and how NELAP requires a laboratory to abide by the specifics of any and every regulatory method, including the crypto methods. This conversation led to better understanding by the EPA representatives of NELAP requirements and also that the existing NELAP process and procedures already accomplish the TSC's goal, just in different ways than TSC understood from previous meetings.

Points discussed and agreed upon follow.

- ✓ The TNI Microbiology Expert Committee believes that the Microbiology Module of Volume 1 of the TNI Environmental Laboratory Sector Standard will apply adequately to ANY method including the crypto methods with detailed procedural requirements. [NOTE from EPA: TSC supports this determination but EXCLUSIVELY for Crypto by Methods 1623 or 1623.1 because these methods include detailed quality control requirements. NELAP auditors must audit to these requirements per the TNI standard. TSC does NOT support this approach for ANY method unless those methods include comparable detailed QC.] That committee has looked at ISO 17025 crypto accreditations around the world (European Union, China, Australia) and finds that no other nation sees a need for exceptional processes for accrediting crypto methods, and thus concludes that there is no need to modify the Microbiology module or create a new module for crypto or any other parasite or virus. [NOTE from EPA: Only if the method is written to include QC, comparable to 1623 or 1623.1.] The TNI "micro" checklist might need to be expanded for additional microbiological analytes than those presently addressed.
- ✓ EPA's plan is for their regional offices to manage or oversee state certifications or accreditations for labs performing crypto analyses, but with ample support from the TSC. Dan envisions that the regions will support states in meeting the "substantial equivalency" test, and that it is EPA's intent that assessors use the checklist, which are specifically based on defined QC requirements in the crypto methods, found in the new Chapter 7 of "Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water"
<http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#two>
- ✓ Some EPA regional offices have expressed discomfort with the expectation that they "shadow" the state assessors, with the Regional Science and Technology Directors indicating that resources are unavailable for that activity. Carrie responded that shadowing is not crucial since the microscopy training and auditing training is quickly becoming available online, but that Region 4, NJ and NH have been shadowed (by TSC.)

- ✓ Regarding secondary approvals or accreditations, if the EPA provides certification for free then most states would be unable to charge a fee for the same recognition. Carrie responded that it's up to the states whether or not to include crypto in their certification/accreditation programs, but that she estimates perhaps 20 of the 50 states will do so. There likely remains confusion in the industry about the previous (LT2ESWTR) monitoring where only EPA approved labs and the next round of monitoring where the LT2 rule requires "equivalent" state programs and EPA will not be certifying labs. [NOTE: this reference is to the Long Term 2 Enhanced Surface Water Treatment Rule.]EPA has published a document to assist in the development of state programs: [Frequently Asked Questions: State Approval/Oversight of *Cryptosporidium* Laboratories Supporting LT2ESWTR Monitoring \(PDF\)](http://water.epa.gov/lawsregs/rulesregs/sdwa/lt2/upload/epa815F13001.pdf) (3 pp, 218K)
- ✓ "Equivalence" is now being referred to as use of the checklist in Chapter 7 of the C.O. Manual (along with the assessor or a technical expert on the assessment team having completed the training course.) For the non-NELAP states, EPA will recognize laboratories certified by any of the states to perform analyses anywhere, for data being submitted directly to EPA. Aaren inquired about dual program states, and Dan indicated that approval in either program (assuming that program is designated as "equivalent") would be acceptable to EPA.
- ✓ While EPA is no longer approving labs for crypto analyses, TSC will maintain a website listing laboratories with state approvals, and would do quarterly updates to that listing, and that the TSC intends to remain aware of which labs are accredited for crypto, for its own information purposes. After some discussion, it was agreed that, for states which update their listing of accredited labs daily, the EPA listing will instead point to the state listing (which will be more timely and accurate.) Something similar is presently done with radon. EPA will need to provide some list of crypto-accredited labs in time for utilities to have adequate lead time to put their contracts in place, yet the initial listing cannot be done too soon, so as to limit opportunities for the later-accredited labs. Based on phone calls Susan has received, she estimated probably 45 to 60 labs nationwide will want Crypto certification/accreditation, and that these labs will likely also receive work from the recent push by the Centers for Disease Control and Prevention (CDC) to analyze swimming pools for crypto.
- ✓ A substantial issue yet to be addressed is Proficiency Testing, and this falls to TNI to address since virtually all states utilize the TNI PT providers and TNI Field of Proficiency Testing tables. (NOTE: a parasite table has been developed.) For other analytes, the drinking water certification program requires one PT/year, while two/year are required for crypto. Although NELAP requires two presently, it will be difficult for non-NELAP states to require 2/year.
- ✓ There is only one PT provider (WI State Laboratory of Hygiene [WSLH]) and it is not NELAP accredited, but does hold ISO-accredited (ISO/IEC 17043) as a PT Provider (PTP.) Carrie noted that EPA cannot resolve this issue and force WSLH to seek NELAP accreditation, and acknowledged that WI is a state-subsidized program that has not expressed interest in NELAP accreditation previously. Alfredo noted that, with WSLH being ISO accredited, then the NELAP PTP recognition shouldn't be a problem, but there still remains the issue of having one sole PTP for this analyte. The PT Expert Committee should be asked to modify its currently-in-process standard to address this issue, perhaps with language like "unless an appropriate PT provider that meets state or federal government requirements is defined as authorized to support their monitoring program." There apparently is a PTP in the U.K., but shipments to the US can be problematic.

The next step will be a proposal for NELAP accreditation of crypto labs, to be presented at the Forum on Laboratory Accreditation in Louisville in January 2014. Susan and Carrie are jointly working on this already, so it should be in final shape in plenty of time. Carrie estimates that utilities will need to begin putting their contracts in place by January 2014 for monitoring that begins in April 2015, but there are few commercial labs accredited for crypto at present.

A request was made that more accessible training – preferably online – be made available, and that third party assessors have ready access to the training, since several NELAP ABs are shifting to use of third

parties for assessments. Lynn noted that the CDC-APHL National Laboratory Training Network (<http://www.aphl.org/training/nltn/pages/default.aspx>) does have access to well-equipped training labs across the nation, in state public health labs, so that if not available online, the crypto module of the C.O. course could be presented in locations other than Cincinnati by partnering with that group.