

**Summary of the NELAP Accreditation Council Meeting**  
**Forum on Laboratory Accreditation, Chicago, Illinois**  
**July 16, 2015**

**1. Roll Call and Approval of Minutes**

The NELAP Accreditation Council (AC) met at 10:30 am Central time on Thursday, July 16, 2015. This meeting was part of the summer conference, in Chicago. Those members in attendance are listed in Attachment 1, but please note that teleconference capability was not planned for this meeting and some AB representatives were not allowed to travel to conference.

**2. Update from Database Administrator**

Dan Hickman, TNI's Database Administrator, told the AC about status and development of the generic application, as he presented to the Information Technology Committee on Monday morning at conference. It presently can provide the lab's demographic data as a pdf file, and the requested scope of accreditation and some other information as \*.csv files. The csv files can be filtered in different ways by the AB user. The TNI webmaster who developed this application has a few more items to add, such as security features, and then it will be complete according to the approved Database Development Plan.

At that point, the IT Committee will deliver the application to the LAB Expert Committee for review and testing, and the LAB will work with the various ABs to identify whether and how the output of the application needs to be adapted for each state's use. LAB will then work with Dan and the webmaster to address those adaptations, as possible.

Dan also noted that filtering for only "approved methods" is possible, with or without Alternative Test Protocols (ATPs), and that nearly all publicly available methods are now in the compendium, which is part of LAMS. Links to each method in LAMs are provided, and if the method is not publicly available, a link to where it can be purchased is provided. This compendium is vastly larger than NEMI and is available to any internet user. Dan did note that, for custom method SOPs, he needs to know the laboratory name, since numbering of such SOPs is not unique.

**3. Status of Evaluations of NELAP ABs**

Aaren asked the AC members present to review the status of their evaluations for this cycle, and then Lynn filled in the missing ones. The status by AB follows:

- FL – has submitted additional information as requested by the team, for its response to the site report
- IL – renewal letter goes out next week
- KS -- has submitted additional information as requested by the team, for its response to the site report
- LA DEQ – technical review underway
- LA DHH – renewed August 2014
- MN – renewal letter goes out in November

- NH – renewed in March 2015
- NJ – awaiting completion and delivery of the site report
- NY – renewed in January 2015
- OR – technical review underway, site visit to be scheduled
- PA – renewed September 2014
- TX – site visit completed, observation scheduled for August
- UT – renewed August 2014
- VA – site visit scheduled for late July, observation in fall

And for anticipated future AB applicants:

- OK – legislative approval complete, finalizing application for submission later this year
- CA – awaiting recommendations from its advisory panel, but once the program revisions are in place, will likely apply to be a NELAP AB (in several years)
- KY – is considering applying to be a NELAP AB

#### **4. Discussion of Possible Revisions to the NELAP Evaluation Process**

Aaren first reviewed the evolution of the evaluation process. Each cycle has had an Evaluation Coordinator, a TNI staff person who facilitates team compositions and interactions with the NELAP AC as well as monitors timelines and correspondence, but does not participate in either the technical review or the site visit.

Initially and under NELAC, each AB was evaluated by a team composed of an EPA regional person and a state AB person, with the NELAC Director (Laura Phelps) accompanying each team in a QA role. Then under TNI, the first cycle was an EPA person serving as Lead Evaluator (LE) with a state AB person completing the team, with the addition of a contract QA officer (2008-2010.) The next cycle was the same, but some EPA regions chose not to participate (2011-2013), but other EPA regions participated more than once so that each team had an EPA member.

For the current cycle (2014-2016,) about half of the EPA regions are participating in evaluations. A contract LE was chosen (with an alternate selected in the event of a conflict of interest), and this individual also fills the QA role. A state AB person is paired with the LE, and the EPA regions are welcome to join the team if they wish.

Earlier this year, a question of competitive advantage for the contract LE arose, and consumed a lot of resources to resolve. In 2014, the AC had planned that the contract LE would not evaluate any ABs for which that individual was also a contract assessor, and the budget would accommodate the alternate for the existing two situations where that was the case. The AC discussed that, for other ABs using contractors, the LE would simply avoid reviewing information about the contract assessors and leave that for the other team members to examine, but in one case, this was not sufficient to satisfy the objections of an AB's contract assessors. The TNI Board as well as the NELAP AC considered possible options for resolving this situation, and eventually, the AC determined to accept Carl Kircher's offer to serve as Lead Evaluator for that AB as well as another AB that has begun using contract assessors (including the contract LE.)

NOTE: The AC is exceedingly grateful to Carl for his willingness to go above and beyond

the routine participation in the NELAP program. His contributions are massive, and gratitude is scarcely enough to acknowledge the impact he has had on the program.

While a solution appeared that does not delay the evaluation cycle this time, a longer term solution must be in place before the next evaluation cycle begins in December 2016. The options that have been identified thus far are to have a TNI staff member serve as lead evaluator or to pay state AB staff to serve in that role (as they are able to do so, outside of normal working hours.) Other aspects of the process may also be altered, such as changing the 3-year cycle to 4 years, or eliminating the observation of an assessor. There is considerable sentiment that the goals of the observation could be accomplished by file review, since the state ABs do not want and cannot use any feedback on assessor competence from the NELAP observation.

Comments made by both AB representatives and participants are listed below.

- ABs are responsible for training and observing their own assessors. The upcoming revision of V2 might include a mandatory observation of each assessor by each AB, every 3 years
- Have the previous evaluator review the current site report
- Some ABs presently observe their assessors annually, but this is difficult to accomplish for the contract assessors
- The current observation is for process only – a lot of time and travel money (especially if a separate trip is needed) for very little return
- To date, no findings have emerged from observations, although they are included in each site report
- The team can affirm that process was followed through file reviews
- Could NELAP states accept contractor observations performed by other NELAP states? This “reciprocal acceptance” might save time and effort for those states using contract assessors (even outside of the evaluation process.) This would require rewriting contracts to include such activity
- Contract managers (for the contract assessor firms) observe their staff on a regular basis – could this sort of assessment be used by the ABs?
- Contractor turnover is problematic for assessor observations by the ABs
- Reliance on returned evaluation forms by labs after assessment is not likely to be helpful, due to low return rates
- EPA requires a 3-year evaluation of the certification body
- EPA also requires observation of an assessor (per the Certification Manual)
- The 3- vs. 4-year cycle of evaluations is a “sticky point” with the Non-governmental ABs that are about to become a TNI program element
- Would a 4-year cycle work if a mid-cycle surveillance visit were included (perhaps without travel, but electronically?)
- A request to space out the ABs better, as part of transition to a 4-year cycle. Presently, the 3-year cycle is heavily front-loaded
- Eliminate communications about the Technical Review until the site visit, and just put all deficiencies into the site report

Ken Lancaster from TX discussed how the site visit worked for them, with the contract LE being shielded from reviewing contract assessor information as well as being absent during interviews with contract assessors. While, in that case, the contract LE deleted all information about contract assessors from the application as it arrived, in the future such information could (and should) simply not be included in the package sent to the contract

LE, or the contract information could be omitted from the application and only reviewed during the site visit.

No conclusions were reached, but the AC will continue its deliberations about the optimal solution to these issues. All agree that we are a small community, and anyone qualified to be a contract LE probably has other business (past or present) that could be used to create a potential conflict of interest.

## **7. Next Meeting**

The next NELAP Assessor call will be Monday, August 3, and the topic will be assessing mobile labs. A "hold the date" notice was sent out and all ABs requested to notify their assessors of the upcoming event.

The next teleconference meeting of the AC will take place on Monday, August 17, 2015, at 1:30 pm Eastern. An agenda and teleconference information will be sent out before the meeting.

**Attachment 1**

STATE	REPRESENTATIVE	PRESENT
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: <a href="mailto:steve.arms@flhealth.gov">steve.arms@flhealth.gov</a>	Yes
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IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: <a href="mailto:scott.siders@illinois.gov">scott.siders@illinois.gov</a>	Yes
	Alternate: Janet Cruse T: 217-785-0601 E: <a href="mailto:Janet.Cruse@illinois.gov">Janet.Cruse@illinois.gov</a>	No
KS	N. Myron Gunsalus <a href="tel:785-291-3162">785-291-3162</a> E: <a href="mailto:ngunsalus@kdheks.gov">ngunsalus@kdheks.gov</a>	No
	Alternate: Sara Hoffman <a href="mailto:shoffman@kdheks.gov">shoffman@kdheks.gov</a>	Yes
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Oklahoma	David Caldwell E: <a href="mailto:David.Caldwell@deq.ok.gov">David.Caldwell@deq.ok.gov</a>	Yes