Summary of the NELAP Accreditation Council Meeting Forum on Laboratory Accreditation, Jacksonville, FL, August 7, 2019

1. Welcome and Introductions

The NELAP Accreditation Council (AC) met at 3:30 pm Central on Wednesday, August 7, 2019, during the NEMC conference. Those present and on the phone introduced themselves, and attendance is noted in Attachment 1.

2. Evaluations of NELAP ABs

Aaren asked that Steve Arms, the NELAP Lead Evaluator, provide an update on the remaining evaluations. Oregon's site report was delivered and its corrective action report is being prepared; Illinois' application review is underway; and Minnesota's application awaits action. The Minnesota evaluation will begin once Illinois' evaluation is complete, due to unanticipated revisions in state evaluator assignments that left Illinois' program manager as the state evaluator for MN.

Evaluation team and QA Reviewer assignments for the next round of evaluations are in place. The next evaluation cycle begins in October, and renewal letters will go out, one every two months thereafter.

3. Implementation Plans for the 2016 TNI Standard

The official implementation date for the 2016 Standard is January 31, 2020. Each NELAP AB will implement the new standard as it is able to do so. Mutual recognition will continue, regardless of which version of the standard is in use by any of the NELAP states.

Implementation Plans for 2016 TNI ELS Standard			
State	Process for Implementing the New Standard	Anticipated Implementation Date	
FL	FL adopted the TNI 2016 Standards by regulation on September 26, 2018. Laboratories were granted a grace period until April 1, 2019, to implement the new standards	Fully implemented on April 1, 2019	
IL	Rulemaking was finalized in July 2019, with a 6 month integration period and full implementation on January 1, 2020	January 1, 2020	
KS	Discussions with state lawyers about the regulations are underway, but there may be a six month delay in implementation	Mid 2020 (hopefully)	
LA DEQ	Regulation updates are underway and expected to be complete by July 2020	July 1, 2020 (hopefully)	
LA DOH	Rulemaking initiated, hope to complete in time to implement by January 2020, with time for labs to comply	January 31, 2020 (hopefully)	
MN	Incorporated into regulation by reference, expect to fully implement by the end of 2020 but is encouraging labs to move forward with	December 31, 2020	

	implementation sooner	
NH	Requires rulemaking plus time for labs to comply	2020 (hopefully)
NJ	Incorporated into regulation by reference	January 31, 2020
NY	Adopts by reference. Is rewriting regulation to update other aspects on separate timeline	January 31, 2020, with a 6 month grace period while it brings IT systems online
ОК	Requires rulemaking, is currently doing outreach to labs	Earliest will be September 2020
OR	Requires rulemaking plus time for labs to comply; database development is underway	March 30, 2020
PA	Incorporated into regulation by reference	February 2020
TX	Incorporated into regulation by reference	January 31, 2020
UT	Rulemaking underway; will need database updates	February 2020
VA	Rulemaking is beginning now	Unknown

Jerry Parr inquired whether NELAP ABs have a mechanism to require labs to purchase the TNI Standard, noting that sales of the standard represent only about 15% of accredited labs. TX and NJ stated that they have policy requiring ownership and VA is considering adding this to its regulation. Consensus of the discussion is that, going forward, the standard itself should require that an accredited lab possess a legitimate copy of the standard to which it is accredited. For now, Jerry will cross reference the purchasers with the LAMS database and send a letter to all labs that have not purchased the standard, with a copy to the primary AB.

4. Proficiency Testing for PCBs (Aroclors)

The Council has been discussing how to craft a second Analyte Request Application for submission to PTPEC that will solve the problem of labs that repeatedly miss the quantitation or identification of specific Aroclors (one of seven possible PCB congeners in a PT sample), but because it's never the same "miss" twice in a row, their accreditations cannot be suspended. The solution seems to be a combination of a quantitative PT sample with a qualitative one, with both needing to be successful for retaining accreditation for that group of analytes. The most recent draft language is included in Attachment 2, but was not provided to participants during this discussion.

PT providers have declined to score a PT as "failure" when the individual Aroclor is scored as a "pass", so that an unacceptable score on one Aroclor PT would mean failure for the entire group (seven congeners). The best solution looks to be to add a new FoPT for "Aroclor group" where a qualitative identification failure of whichever congener is in the PT would constitute a failure for the entire group, while an incorrect quantitation with correct identification would not fail the entire group. One Council member proposed adding a footnote similar to the one in the Drinking Water FoPT table, to both the Non-potable Water and the Solid and Chemical Materials tables.

The goal is to find some solution that requires correct quantitative <u>and</u> qualitative scores on the Aroclor PT samples. One NELAP AB noted that it does not accredit the identification of Aroclors, only the quantitation, so that it needs some way to connect a qualitative PT with the quantitative one.

ADDITIONAL NOTE FROM AC DISCUSSIONS: in the future, the Council meetings will address PT and PT provider performance on a quarterly basis.

5. Technical Director Qualifications

The Quality Systems Expert Committee sought draft language from each of the expert committees, and spent considerable time discussing the various proposed requirements in its first session of the week. All involved recognize that the eventual language of the standard will need to be acceptable to all of the NELAP ABs.

One major discussion point in the Council's session was whether the title itself (Technical Manager or Technical Director) is the sticking point, rather than the qualifications themselves, and whether just specifying the credentials of an individual performing the oversight function would be adequate, regardless of the title of the person fulfilling that role.

NOTE: Quality Systems is planning an off-agenda meeting among the expert committee chairs and the NELAP AB representatives at conference in Newport Beach to discuss this issue, without an audience.

6. Open Forum Discussion

One commenter asked about a lab that needs accreditation for three analytes not offered by its primary AB, posing the question as these analytes are needed for secondary accreditation in a different state. The discussion suggested that the lab explain to the primary AB why those analytes are needed, even though they are not regulated by the primary AB state, and then to consider whether the analyte is already "in the system" (has method and analyte codes), whether the method is valid, and what the regulatory compliance need is.

Then, the ABs should try to work with the lab to accomplish the accreditation in the primary AB, but this will not always be possible, so that a second primary AB might be needed for those specific analytes. Also, if the initial negative response is from a staff person, the lab should seek an answer from the program manager directly, but again, some states can only accredit analytes that are regulated in that state.

Utah noted that it has a separate (and somewhat lower) fee for adding methods as a second primary AB. If it's a new technology, they may conduct a site visit, but if it's just adding analytes to an existing method, only a document review would be needed. Kansas indicated that it would like to adopt a similar system, while the Lead Evaluator, Steve Arms, noted that clear documentation of that process would be needed in the AB's quality system.

Another question arose about acceptance of Non-governmental AB accreditations (NGABs), but this was deferred to the individual NELAP ABs with the comment that drinking water accreditation can only be granted by a state agency. One NGAB noted that it accredits the EPA regional labs for performing drinking water analyses, but that's under the authority of the program office itself, apparently.

7. Next Meeting

The next teleconference meeting will be Monday, September 9, 2019, at 1:30 pm Eastern. In Aaren's absence, Kristin will lead this meeting. An agenda and documents will be provided in advance.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Carl Kircher E: carl.kircher@flhealth.gov	No
	Alternate: Vanessa Soto E: Vanessa.sotocontreras@flhealth.gov	No
IL	Celeste Crowley T: 217-557-0274 F: 217-524-6169 E: celeste.crowley@illinois.gov	Yes
	Alternate: Dave Reed Dave.Reed@Illinois.gov	No
	For information purposes: John South John.South@illinois.gov	Yes, as designated representative for IL at this conference
KS	Paul Harrison paul.harrison@ks.gov	No
	Alternate: N. Myron Gunsalus 785-291-3162 E: ngunsalus@ks.gov	Yes, with Chuck Tucker, a new KS employee
LA DEQ	Kimberly Hamilton-Wims T: 225-219-3247 E: <u>Kimberly.Hamilton-Wims@la.gov</u>	Yes
	Altérnate: Elizabeth West elizabeth.west@la.gov	Yes (phone)
LA DOH	Grant Aucoin Grant.aucoin@la.gov	No
	Alternate: Scott Miles Scott.Miles@la.gov	No
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes (phone)
	Alternate: Stephanie Drier 651-201-5326 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

NJ	Michele Potter T: (609) 984-3870	Yes (phone)
	F: (609) 777-1774 E: michele.potter@dep.nj.gov	
	Alternate : Rachel Ellis E: rachel.ellis@dep.nj.gov	No
NY	Victoria Pretti 518-485-5570 E: victoria.pretti@health.ny.gov	No
	Alternate: Lynn McNaughton E: lynn.mcnaughton@health.ny.gov	Yes (phone)
OK	David Caldwell (405) 702-1000 E: <u>David.Caldwell@deq.ok.gov</u>	Yes
	Alternate: Chris Armstrong (405) 702-1000 E: chris.armstrong@deq.ok.gov	No
OR	Alia Servin 503-693-4122 E: alia.d.servin@dhsoha.state.or.us	No
	Alternate: Lizbeth Garcia 971 865 0443 E: LIZBETH.GARCIA@dhsoha.state.or.us	No
	Included for information purposes: Ryan Pangelinan E: Ryan.pangelinan@dhsoha.state.or.us	Yes, representing OR for this conference
	Included for information purposes: Sara Krepps Oregon Department of Environmental Quality (503) 693-5704 E: sara.krepps@state.or.us	No
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: <u>aaalger@pa.gov</u>	Yes
	Alternate: Dana Marshall E: dmarshall@pa.gov	No
ТХ	Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov	Yes
	Alternate: Kristy Deaver T: (512) 239-6816 Kristy.deaver@tceq.texas.gov	No

UT	Kristin Brown T: (801) 965-2540 F: (801) 965-2544 E: kristinbrown@utah.gov	Yes
	Alternate: Alia Rauf T: 801-965-2511 E: arauf@utah.gov	No
VA	Cathy Westerman T: 804-648-4480 ext.391 E: cathy.westerman@dgs.virginia.gov	Yes (phone)
	Alternate: Ed Shaw T: 804-648-4480 ext.152 E: ed.shaw@dgs.virginia.gov	No
	Lynn Bradley T: 540-885-5736 E: lynn.bradley@nelac-institute.org	Yes
EPA Liaison	Donna Ringel T: 732-321-4383 E: Ringel.Donna@epa.gov	Yes
California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	Jacob Oaxaca representing CA was in attendance
Guests:	Steve Arms, NELAP Lead Evaluator Arms.steve@comcast.net	

Attachment 2

Current draft language for requesting that a qualitative identification PT for Aroclors be added to the NPW and SCM FoPT tables:

Currently, if the laboratory mis-identifies an Aroclor and quantitates the misidentified Aroclor, the laboratory would pass the five "non-detect" Aroclors and fail the other two Aroclors (the one that was not correctly identified and the one that was quantitated in error). The addition should be made to add the "PCB Aroclor Identification" line in the same way that it currently appears on the DW FoPT. Additionally, we would like to have Footnote 2 on both the NPW and SCM table expanded to include the addition of "Successful participation in a proficiency study for PCBs includes an Acceptable score on the PCB Aroclor Identification. A Not Acceptable evaluation of any one or more Arochlor Identifications constitutes a failure to demonstrate proficiency for all Aroclors (listed above) which comprise the study".