Summary of the NELAP Accreditation Council Meeting Forum on Laboratory Accreditation Virtual Conference 11:45 am – 1 pm Eastern, January 28, 2021

1. Welcome and Introductions

Kristin welcomed everyone to the meeting and invited the AB representatives to introduce themselves.

2. State Adaptations to Pandemic Emergency

State	State Adaptations to Pandemic Emergency – January 2021
FL	Program Manager is working from home; other staff working in office. All third party assessors were required to submit SOPs for remote assessments and have them approved by AB staff, or else continue in-person assessments. Each remote assessment requires approval by the Program Manager.
IL	Staff are mostly working remotely from home, only coming to the office as required to pick up and drop off files and resources. Initially delayed assessments, then began remote assessments in May, while catching up on the schedule. After one on-site assessment in July, the positivity rate climbed so reverted to remote assessments and now plan to continue those at least through April 2021. Will only resume on-site assessments when it is safe.
KS	Performing on-site assessments for in-state labs with rapid tests for COVID-19 in use prior to travel. All out-of-state labs are assessed by third party assessors (not specified whether remote or in-person).
LA DEQ	Staff originally ordered to work from home but now those with cubicles are in office 1 day/week and those with offices, 2 days/week. All travel and all assessments were initially halted, but some are reinstated now. Seeking regulatory change or Executive Order to permit remote assessments, but for now, more off-site reviews are being done where possible and third party assessors are used for out-of-state assessments
MN	Shut down completely from mid-March until state determination that lab personnel are "essential workers", so assessments were delayed. One staff person pulled into COVID-19 response. State Health Commissioner allowed modification to use remote assessments, so staff prepared an SOP for the contract assessors that MN uses. Most assessments are now on time and being performed remotely, but initial applicants or new fields of testing with new technology are not eligible for remote assessment and thus not allowed at present.
NH	Prefer in-person assessments in the Northeast region but are using remote assessments for labs outside of that region. On-site visits are rescheduled if any health concerns exist. Many labs use paper records and those must be visited in person.
NJ	Staff working from home since mid-March and travel ban is in place. Program Manager goes into office 1-2 days/week; other staff only as necessary. Some remote assessments being done and some in-person on-site using safety protocols. Assessments are nearly on schedule.
NY	Performed no audits from mid-March until September, then resumed with entirely virtual audits. Many assessors were already working remotely as normal procedure.
OK	Staff working from home since the end of March. Remote assessments began in October. OK has no out-of-state primary labs, so no out-of-state travel. Maintaining assessment schedule with hybrid assessments (partly remote, partly on-site).

OR	Travel ban since March, but had temporary rules in place since June to allow remote assessments during pandemic emergency. Those rules are now permanent, with rewording to allow remote assessments during any Governor-declared emergency. While remote assessments allow less travel and easy communications with the labs, staff believe they are not as good as in-person because of limited situational awareness. Some site visits occurred from June through November but halted again as COVID-19 case numbers increased. Plan to resume travel when restaurants re-open.
PA	Staff working from home and performing remote assessments since May. An SOP for assessors as well as guidelines for labs to use SKYPE for assessments helped ease the remote assessment process. Occasionally an inperson visit is needed but remote assessments are preferred for safety reasons. Labs offer good feedback, and assessors are "awesome".
TX	Staff are completely teleworking but may visit the office as needed, in compliance with lowered building occupancy limits. Initial travel ban was lifted quickly and staff are now doing modified on-site assessments (minimum time on-site) with safety precautions. Has no plans to do remote assessments and assessments and unsure if EPA R6 would support them for drinking water labs.
UT	Staff are teleworking, with manager in office 2-3 days/week but assessors only "as necessary". Conducting remote assessments for out-of-state labs, but inperson site visits for in-state; considering use of "hybrid assessments" with only 1 assessor on-site and others participating remotely.
VA	All travel halted in mid-March and staff are working from home where possible; some staff were pulled into COVID-19 response. Prepared new SOPs and forms for remote assessments, which began in September. Assessors like using former travel times for document review instead, and feel that the assessments are equally effective although different. Labs are providing positive feedback about the new data packages required and other aspects of remote assessments.

A question was asked about whether staff have been exposed to COVID-19 from the assessment site visits. Multiple states responded that none have been identified to date, and that all CDC, OSHA and state recommended safety precautions are being followed. Also, assessments are rescheduled if any involved personnel (assessors or lab staff) are reporting symptoms or positive tests or even reported exposures requiring self-isolation. While names may not be used (per HIPAA regulations), building occupant notifications are routine when potential exposures may have occurred.

3. Implementation Status of 2016 TNI Environmental Laboratory Sector Standard

Implementation Plans for 2016 TNI ELS Standard – 1/28/2021		
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	Full implementation on January 31, 2020	January 31, 2020
KS	Rulemaking underway, but slowly. Is allowing labs to upgrade now and is assessing to 2016 Standard even though 2003 NELAC standard is still the official version	Unknown
LA DEQ	Regulation updates delayed by pandemic, tropical storms and hurricanes	Unknown
MN	Adopts by statute, and is updating its databases now.	January 2021

	Is encouraging labs to implement 2016 standard now, with database updates ready and checklist going into electronic data system now	
NH	Is encouraging labs to upgrade now, working with counsel about how and when they can proceed with rulemaking	Unknown
NJ	Incorporated into regulation by reference	January 31, 2020
NY	Adopts by reference; unable to obtain permission to complete rulemaking to update other aspects on separate timeline. Implemented PT modules of 2016 Standard immediately but not able to use the updated/2016 checklist yet. Encouraging labs to upgrade now	PT changes implemented; other modules await rulemaking to revise NYS certification manual. Unknown date for completion
ОК	Discussions about rulemaking and implementation have resumed, is allowing labs to upgrade now	Unknown
OR	Implemented 2016 Standard effective January 1, 2021	January 1, 2021
PA	Incorporated into regulation by reference, all labs are required to have the 2016 standard implemented by July 2020.	January 31, 2020
TX	Incorporated into regulation by reference. Implementation has gone well.	January 31, 2020
UT	Rulemaking on hold due to emergency but recently re-started. May be open for comment in February 2021; allowing labs to upgrade to 2016 now	Several more months needed, but during 2021
VA	Regulatory update stalled, awaiting first publication.	Unknown

A follow-up question to implementation asked whether ABs are seeing common findings. While no multi-state compilation has been done, several ABs remarked that the Chemistry module (V1M4) seems to be problematic, with findings about the new MDL procedure and also the relative error calculations.

4. Evaluations

Like everything else, the evaluation process slowed in the spring but the Council approved remote site visits for the evaluations and the processes are moving again. One evaluation with a remote site visit was concluded and the AB's renewal has been approved; another AB had a remote site visit and is working on its corrective actions.

5. Revision to AB Operations Module of TNI Standard V2M1

Not all ABs have completed reviewing this module but there were a few comments. Some of the ISO language may need notes to clarify that governmental procedures and another participant noted that the shift to risk-based and more individualized but less prescriptive requirements is not very adaptable to governmental requirements.

Also, NH issued a request that all NELAP ABs please ensure that accredited methods are in LAMS (with method codes and SOPs if no-standard), especially for PFAS, as monitoring the methods individually to see whether secondary accreditations can be granted is taking excessive amounts of time.

7. Next Meeting

The regularly scheduled February 1, 2021 teleconference meeting will not be held. A special and informal meeting to discuss the Draft Standard V2M1 is planned for <u>Tuesday</u>, <u>February 16 at 11:00 am Eastern</u>.

The next regular teleconference meeting is **Monday, March 1, 2021 at 1:30 pm Eastern**. The 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	Susan Beshaw T: 217-557-0274 F: 217-524-6169 E: susan.beshaw@illinois.gov	no
	Alternate: Dave Reed E: Dave.Reed@Illinois.gov	No
	For information purposes: John South E: john.south@illinois.gov	No
	For information purposes: Shirlene South E: shirlene.south@illinois.gov	No
KS	Jennifer Evans E: jennifer.evans@ks.gov	no
	Alternate: N. Myron Gunsalus T: 785-291-3162 E: ngunsalus@ks.gov	No
LA DEQ	Kimberly Hamilton-Wims T: 225-219-3247 E: Kimberly.Hamilton-Wims@la.gov	Yes
Altérnate: Elizabeth West E: elizabeth.west@la.gov	Elizabeth West	Yes
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes
	Alternate: Stephanie Drier T: 651-201-5326 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:	Yes
	Brian Lamarsh @des.nh.gov	
NJ	Michele Potter T: (609) 984-3870 F: (609) 777-1774 E: michele.potter@dep.nj.gov	Yes
	Alternate : Rachel Ellis E: rachel.ellis@dep.nj.gov	Yes
NY	Victoria Pretti 518-485-5570 E: victoria.pretti@health.ny.gov	Yes
	Alternate: Lynn McNaughton E: lynn.mcnaughton@health.ny.gov	No
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	Travis Bartholomew T: 503-693-4122 E: travis.j.bartholomew@dhsoha.state.or.us	Yes
	Alternate: Lizbeth Garcia 971 865 0443 E: LIZBETH.GARCIA@dhsoha.state.or.us	Yes
	Included for information purposes: Ryan Pangelinan E: Ryan.pangelinan@dhsoha.state.or.us	No
	Included for information purposes: Sara Krepps Oregon Department of Environmental Quality (503) 693-5704 E: sara.krepps@state.or.us	No
PA	Annmarie Beach E: anbeach@pa.gov T: 717-346-8212	Yes
	Alternate: Amber Ross ambross@pa.gov Included for information purposes: Dana Marshall	Yes
	dmarshall@pa.gov	

TX	Ken Lancaster T: (512) 239-1990 E: <u>Ken.Lancaster@tceq.texas.gov</u>	Yes
	Alternate: Kristy Deaver T: (512) 239-6816 Kristy.deaver@tceq.texas.gov	Yes
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
	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	Eric Graybill Graybill.eric@epa.gov	Yes
California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
Guests:		

Attachment 2 - Outline of Slides from Conference

Updates from NELAP Kristin Brown, Chair, NELAP Accreditation Council UT DOH Agenda □ Introductions ☐ Brief Summary of Major Events in NELAP for 2020 Leadership transition Operational adaptations due to pandemic 2016 Standard implementation □ Discussion and Q&A Evaluations underway, delayed by pandemic but ongoing First Draft Standard under improved Standards Development SOP ready for review Participant Q&A (questions typed into Q&A – not "chat") **NELAP AB Representatives** FL - Carl Kircher, FL DOH IL - Susan Besaw, IL EPA KS – Jennifer Evans, KDHE LA - Kimberly Hamilton-Wims, LA DEQ MN - Lynn Boysen, MN DOH NH - Bill Hall. NH DES NJ – Michele Potter, NJ DEP NY - Victoria Pretti, NY DOH OK - David Caldwell, OK DEQ OR - Travis Bartholomew, OR DOH PA - Annmarie Beach, PA DEP TX - Ken Lancaster, TX CEQ UT - Kristin Brown, UT DOH VA - Cathy Westerman, VA DGS **LA DOH withdrew, April 2020 Major NELAP Events, 2020 **Leadership Transition** ☐ New Chair elected January 2020 – Kristin Brown (former Vice Chair) ☐ New Vice Chair elected January 2020 – Michele Potter ☐ Three year terms per new General Operations SOP 3-100 No term limits ☐ Major NELAP Events, 2020, cont'd Operational Adaptations due to pandemic emergency ☐ General changes (not every state) Work from home/remote Remote assessments implemented Staff in health departments tapped to assist with COVID-19 activities

☐ AB representatives discuss individual state

adaptations

Major NELAP Events, 2020, cont'd	
2016 Standard Implementation	
 ☐ 7 states adopt by reference and thus officially implemented as of January 31, 2020 ➢ Actual compliance dates depend on state regulations and necessary database updates 	
□ 7 states in various stages of rulemaking to enable implementation	
Rulemakings delayed by pandemic	
□ AB representatives discuss individual state status	
Discussion	
☐ Evaluations underway, severely delayed by pandemic	
Remote site visits enabled (SOP revised to accommodate)	
□ Review of V2M1 Draft Standard underway	
First module developed in compliance with improved Standards Development Standards	OP
2-100	
Public Meeting on V2M1 – LAB Committee	
Wednesday 1/27, 2 pm Eastern	
☐ Respond to Q&A submitted online	
Thank you for being with us!	
For more information, contact	
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or	
Lynn Bradley, lynn.Bradley@nelac-institute.org	