Summary of the NELAP Accreditation Council Meeting Forum on Laboratory Accreditation, San Antonio, TX January 19, 2022 1 pm Central

1. Welcome and Introductions

Kristin welcomed everyone to the call and invited Council members to introduce themselves. Attendance is noted in Attachment 1.

2. Updates from NELAP ABs

The primary agenda items (see Attachment 2) were updates from each of the NELAP AB representatives about three items – current implementation status of the 2016 TNI EL Standard, current operational status from pandemic disruptions, and expected implementation plans for the 2021 Method Update Rule (MUR). State responses to these items are displayed in the three separate tables below.

Implementation Plans for 2016 TNI ELS Standard – 1/19/2022		
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	Hope to implement later this year. Allows labs to upgrade now and is assessing to 2016 Standard even though 2003 NELAC standard is still the official version	2022?
LA DEQ	Departmental management now in place and briefings planned, rulemaking will follow.	Unknown
MN	Adopts by statute, and is updating its databases now. Is encouraging labs to implement 2016 standard now, with database updates ready and checklist going into electronic data system now	January 2021
NH	Regulation finalized on November 23, 2021	March 1, 2022
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	Rulemaking in process; several additional steps including approval by state legislature. Anticipate completion by June or July.	September 2022
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.	January 31, 2020

	Implementation has gone well.	
UT	Rulemaking complete, 2016 standard implemented.	June 11, 2021
VA	Regulation signed, awaits publication. Implementation will follow.	Unknown

Next, the ABs provided updates on their operational status during pandemic emergency. Kristin expressed her appreciation to TNI's labs for working with the NELAP ABs through constant changes over the past two years.

State	Current Operational Status for NELAP ABs – 1/19/2022	
FL	Ceased remote assessments after June 2021 and resumed in-person site	
	visits. Has an SOP for remote assessments in place, should it be needed.	
IL	Has returned to doing only remote assessments, as positivity rate in Illinois	
	is >8%. (IL does not accredit out-of-state labs.)	
KS	All assessments are in-person, but remote assessments are being defined, in	
	case it becomes necessary.	
LA DEQ	Performing in-person assessments but with reduced exposure times; document	
	reviews are being done off-site.	
MN	Staff continue working remotely with no travel. All assessments done by third	
	party assessors. After allowing remote assessments from March 2020 through	
	July 2021, in-person assessments are now being done. Delays of up to 6	
	months are allowed in the event of an outbreak at the lab or for illness of the	
	assessor.	
NH	Has a strong preference for in-person assessments but if an outbreak	
	postpones the assessment, they will do partial remote assessment, as needed,	
	for particular methods.	
NJ	Staff were full time in office for a while, after full time remote at outset of	
	pandemic; currently, staff are in office 2 days/week and working remotely 3	
	days/week on a rotating basis (few staff in office daily). In-person assessments	
NIV	are used for in-state labs; out-of-state labs are remote assessments only.	
NY	Implemented an SOP for virtual assessments in June 2020. During summer	
	2021, performed in-person assessments for in-state labs. Continues to	
	perform in-person in-state assessments, but with some virtual due to COVID outbreak at a lab. All out of state assessments are virtual.	
ОК	In-person assessments for all primary labs (OK in-state only), but does have an	
O.K	SOP for remote assessments if needed.	
OR	Most assessments are in-person, but has a permanent rule in place to allow	
	remote assessments under the Governor's emergency declaration. For lab	
	relocations, is using remote facility inspections.	
PA	After creating a remote assessment SOP in April 2020, began performing all	
_	assessments remotely as of May 2020. Presently, 99% of assessments are	
	remote, but 2 in-person assessments have been done. Plans to continue	
	remote assessments for duration of pandemic emergency.	
TX	Performing in-person assessments but with data reviews done off-site to	
	minimize exposure times; will reschedule in outbreak situations.	
UT	In-person assessments for in-state labs; out-of-state labs can be either remote	
	or in person, taking into account any restrictions the lab might be subject to. All	
	international assessments are completely remote.	
VA	All assessments are remote since September 2020. Documentation reviews	
	are followed by assessment by videoconference.	

Kristin asked for ABs having remote assessment SOPs to please share them with the other NELAP ABs.

Several ABs detailed staffing needs. NY has an assessor position open in Albany but no applicants, and plans to hire a QA Officer soon. OR will soon have two assessor positions open with a third one to follow sometime later; this is due to program expansion to cover non-traditional analytes (psilocybins, and also marijuana testing). KS has one new assessor but lost two recently. OK has hired a third assessor who is now training and should be qualified by September 2022. VA has a new director for its environmental lab, within which the accreditation program is located – Shane Wyatt.

And then, lastly, the AB representatives share their state's plans for implementing the most recent Methods Update Rule (published at 86 FR 27226).

State	Implementation Plans for 2021 Method Update Rule	
FL	Accepting applications for labs to update method on a case-by-case basis.	
IL	Once the state legislature and Secretary of State approve the process, they will	
	update each lab's accreditation as it renews.	
KS	Working with permitting authority to determine date. Possibly mid-summer.	
LA DEQ	Will implement as of July 1, 2022.	
MN	MN PCA is responsible for implementation decision. Anticipates a rolling implementation, will work with labs through 2022 with full compliance by 2023.	
NH	No word yet from NH DES but updated methods can be accredited upon request	
NJ	No action yet, but intends to notify labs of July 2022 date for implementation when renewal notices go out in February	
NY	Recently implemented this MUR and is updating its database. Will fully implement by April 1, 2022	
ОК	Implementation requires rulemaking; AB working in cooperation with permitting staff to update simultaneously.	
OR	State regulations reference "current federal regulations". OR DEQ permit writers will implement this as a rolling implementation, and labs will update methods as they renew accreditations. AB will work with labs for NPDES methods and intends to enforce requirements during the coming year.	
PA	Implementation in process. 90% of labs responded with request to update their methods. Will have database and lab scopes updated by June 2022 and has firm deadline for complete implementation by December 2022.	
TX	The Water Quality Division decides on implementation and has not yet done so.	
UT	From UT DEQ, will do a rolling implementation as lab accreditations renew.	
VA	VA DEQ must update its rule. Fast track rulemaking is expected but has not begun, so no timeline estimate is available.	

After all of the AB representatives who were present provided their updates, Kristin noted that the evaluation process for AB recognition renewals is progressing, although more slowly than some cycles. A second Lead Evaluator has been brought in so that the cycle can finish by the end of this calendar year.

3. Discussion: Questions and Answers

Victoria noted that NY now offers accreditation for WET test methods, as the NY DEC is expanding its NPDES permits to include WET testing requirements.

PFAS Method

A participant asked about implementing the "draft" PFAS method, whether there is a draft method for SCM outside of the MUR or are labs just using lab-developed methods for SCM? OR noted that most PFAS testing is SCM – chemical wastes for PFOAs – but the EPA-published method's status is unclear, due to its title as a draft. FL will accredit the draft method if requested; only one lab has accreditation for the 1633 draft method. NH foresees confusion as the draft reference method (1633) lacks QC; they will accredit lab SOPs (and is tracking revision numbers) but do not allow them to be called by the EPA name. NJ accredits in both NPW and SCM, tracking revision numbers, but hopes for consistency with 1633. PA offers accreditation to 1633, and already was accrediting lab SOPS for SCM and NPW; they have implemented an annual review of current SOPs for version number control.

One participant questioned how the AB evaluates method performance for SCM/NPW when there is no QC in the method? Do they use the TNI QC? NY has a method validation SOP that it requires to be used. NJ considers the "draft method" as an Alternate Test Procedure" and requires labs to meet the DQOs from either NJ DEQ or the Defense Department. FL expects that the method QC for lab-developed methods uses the TNI Standard. NH requires that the lab SOPS meet the TNI Standard on the test report, using the SOP name (not the EPA method number).

Another participant asked what will happen if EPA publishes a final Method 1633. NY will ask labs to replace the lab-developed SOPs with the EPA final method. For NJ, the method requirement(s) are program specific, so that it's not up to the AB. FL will expect labs to upgrade to the EPA method. MN has a protocol for QC for lab-developed methods; labs cannot report the "official" EPA method. NH would require the new/final version unless the QAPP needs the older method, in which case that project will be allowed to continue using the specified method. NY noted that since the MUR was published, there is much crossover with NJ and also PA, so that those states will need to work together for secondary accreditations of PFAS methods.

Assorted Program Updates and Issues

Carl noted that the LAB Committee continues going through comments on the Draft Standard, and that those completed were addressed in the morning's session, but that assessor competency issues remain to be addressed. Aaren Alger, as incoming LAB Chair, invited TNI members to join the LAB calls to discuss comments and asked that, if someone identifies a new issue that they missed previously, please submit that comment now, instead of waiting for the Draft Standard Revision 1 publication.

OR stated that they will be increasing fees, probably in mid-March, and will be accrediting for psilocybins.

NY will no longer be accrediting medical marijuana testing, as that is shifting to the new Office of Cannabis Management. Also, its PT program has downsized and no longer offers soil PTs, but that should only affect a few in-state labs.

Multiple ABs noted that method codes for PT reporting that are offered by PT Providers don't always match the FoPT tables or the methods for which labs are actually accredited, and that this has become a bigger problem recently.

LAMS Database

Dan Hickman, TNI Database Administrator, thanked the ABs for their LAMS uploads. He commented that he has been doing some database cleanup, and that if a lab has not been updated in a while, that usually means it is no longer accredited, so he reminded ABs that withdrawals must be manually done. He also stated that he is eliminating obsolete method codes and asking for reviews of the list destined for final removal, but that a few of the ones proposed for deletion are actually still in use and those will be retained. The list is in a notice on the News section of the TNI website.

He also discussed a recent SIR about reporting secondary accreditations into LAMS. While there is no requirement in the Standard itself that secondary accreditations must be reported to LAMS, the database doesn't work properly without them. This requirement got dropped in the transition from the 2003 NELAC standard to the ISO-based standard. He asked that a requirement either be put into the Standard or into a policy or SOP. Carl noted that it has been a conscious decision not to include any accreditation scheme requirements in the Standard, thus making a policy update more likely, so Dan will provide Kristin with language to update the Mutual Recognition Policy POL 3-100 to include reporting of secondary accreditations into LAMS.

Dan also mentioned the idea of opening LAMS to non-NELAP states, explaining that in order to use the generic application, access to the database and the method and analyte codes would be necessary. Some states have expressed interest in the generic application.

Kristin thanked everyone for their participation, and with no further questions, adjourned the meeting a little bit earlier than scheduled.

4. Next Meeting

The next regularly scheduled teleconference meeting will be on **Monday**, **February 7**, **2022**, **at 1:30 pm Eastern**. The agenda and documents will be provided in advance.

Attachment 1

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Attachment 2



Agenda

- Introductions
- Updates from the NELAP ABs
 - > Implementation Status for 2016 TNI EL Standard
 - > Operational Status
 - > 2021 Method Update Rule Implementation Plans
- Discussion and Q&A from Participants
- Adjourn

