Summary of the NELAP Accreditation Council Meeting July 8, 2019

1. Introductions

The NELAP Accreditation Council (AC) met at 1:30 pm Eastern on Monday, July 8, 2019. Minutes from June 3, 2019, were approved. Those present are listed in Attachment 1.

2. Discussion of Renewal Recommendation for LDEQ

The recommendation letter wrapping up the LDEQ evaluation and recommending renewal was received by the NELAP AC on April 1, 2019, the day of a regularly scheduled NELAP AC meeting, so that it was not possible to distribute materials in time for review prior to the meeting. The evaluation team offered, and Aaren agreed, to discuss the PT issue that was identified in the later stages of the evaluation, since a similar issue arose once before and the team suspected that it might exist in other NELAP ABs as well. The team noted that Rachel Ellis, the state AB team member, would not be available for discussion of the issue until July, and since NJ had dealt with and resolved its own related issue, Steve Arms, the Lead Evaluator, felt it was essential that Rachel be part of the discussion. Thus, consideration of LDEQ's renewal recommendation was postponed until July.

Steve began the discussion by explaining that the team identified some problems with LA DEQ's PT program, and the AB proposed appropriate corrective actions. However, in reviewing the corrective action plan, the team noted that LDEQ was requiring PT analytes that are not in the TNI FoPT tables (to be submitted as "data packages" for the analysis of PT specimens), and was suspending ABs for failing those non-TNI PTs. To be clear, this issue was not identified in the initial review of LDEQ's PT program, but rather in the review of the proposed corrective action.

Rachel added some detail to the explanation, and noted that, several evaluation cycles previously, New Jersey received a similar finding, that it was requiring non-accredited PTs and suspending labs' accreditations if those PTs were not acceptable. Since the state of NJ requires those PT analytes as a condition of reporting data to NJ, the corrective action was to add a separate column on the lab scopes for those analytes, identifying whether or not the lab is allowed to report those analytes without TNI-approved PTs to the state, while clearly identifying analytes eligible for reciprocal recognition. This system allows the mutual/reciprocal recognition to continue unimpeded while ensuring that NJ-accredited labs meet the NJ-specific requirements.

For LDEQ, the proposed corrective action is to highlight the non-compliant PT on the lab's scope and in a letter to the lab with a note that the "method/analyte combination is suspended for LELAP only", and that LDEQ will not accept data from that lab until the cause of the suspension (i.e., failed PT) is fixed. The evaluation team considered this acceptable, so there is no question and there are no concerns about LDEQ's renewal of its recognition, provided that it completes the corrective action as proposed.

Discussion continued with the following points:

- Both NJ and LDEQ have two-tier programs, which makes addressing this particular issue easy to solve, even as it is the source of the problem.
- An AB must be careful that state-specific requirements do not conflict with other NELAP states' requirements.

- PA also has "extra" PTs that it requires for NELAP accreditation and has been suspending labs based on those PTs. The PTs may be based on CFR requirements.
- Oregon has been suspending the NELAP accreditation for labs that fail the cannabis PTs (which are not TNI-accredited). As OR's evaluation is underway now, ORELAP believes that the solution (for cannabis labs) is to remove labs with non-compliant PTs from the state's "lab list" that authorizes reporting of cannabis data. Since cannabis cannot be a federal program, this field of testing is not eligible for reciprocity. (NOTE: In OR, the cannabis program is under regulatory purview of a different agency, but ORELAP was charged with accrediting the testing labs to the NELAP standards, and is authorized to use the NELAP logo for that purpose.)
- New York noted that it offers accreditation for legionella testing, but as an
 in-state-only program using NY State PTs, and has several other testing areas which
 it accredits in the same fashion. So long as those fields of testing are not eligible for
 mutual recognition, it is a non-issue.
- The NELAP Evaluation SOP 3-102 does not currently address non-conformities identified during the review of corrective actions. Some language will be added during the revision presently underway to address this issue. Cathy offered language from Virginia's program, that it "will not accept language for a corrective action that includes the same or additional non-conformities" related to the initial finding. No one wants a situation where completely new issues can be opened during the corrective action phase, but yet a non-conformance related to the initial finding, identified during the corrective action phase, should not be ignored.

At the close of the discussion, Carl moved and Celeste seconded that the recommendation to renew the recognition of LDEQ as a NELAP AB be accepted. All twelve ABs present voted in favor. The three absent ABs voted by email, all in favor of the motion, and the final vote was received on July 11.

3. Revising the NELAP Evaluation SOP 3-102

A planned teleconference to discuss this document had to be cancelled due to urgent work priorities. The small group plans to meet in Jacksonville to discuss revisions. Cathy offered to participate via speakerphone, and Steve asked if he could participate, as well. Aaren invited any others on the call to join her, Yumi Creason, Cathy and Donna in the revision effort, if they wished.

4. Tentative Evaluation Team Assignments and Evaluation Schedule

Lynn provided a tentative schedule for team assignments and a schedule for renewal letters to go out to NELAP ABs at two-month intervals, based on the most renewal date from this current evaluation cycle. The NELAP evaluators had already been provided with these tentative assignments and a few minor adjustments made, plus the three absent ABs confirmed their acceptance of the proposed assignments and schedule prior to the meeting. There were no objections to the assignments and schedule.

5. Updated Technical Review Checklist, including the 2016 V2M2 (PT) Module

The PT Expert Committee provided the LAB Expert Committee with a first draft of the updated checklist and the LAB committee completed its review and color-coding of the new items in the checklist at its March 2019 meeting. The updated checklist has been sent to the webmaster for posting and was presented to the Council for information purposes.

The V2M1 and V2M3 sections of the checklist will remain unchanged until such time as the revised V2M1 is adopted and implemented by the NELAP AC. Since there are fewer checklist items from the 2016 V2M2 module, roughly twenty numbers of the numbered checklist have been "reserved" (unused) so that the cross-references for duplicate language between M1 and M3 remain accurate.

6. New Business Items

Steve had remained on the call, and asked that the NELAP ABs provide consistent usage for the "yes/no/NA" columns, since it has been difficult to discern which marking means materials are included or omitted or simply overlooked. Participants briefly discussed adding language to the Evaluation SOP to clarify completion of this checklist item.

Several participants requested access to the Quality Systems checklist for the 2016 Standard. It is available at https://nelac-institute.org/content/NELAP/qscheck2016-access.php and Carl noted that he has a Word file of the document (which is in Excel) that he would share on request.

Another participant asked for time during conference in Jacksonville in August to discuss implementation of the updated Volume 2. The AC will have a private meeting on Tuesday afternoon, at conference. A note will be in representatives' registration packets about the location.

7. Next Meeting

The next meeting of the Council will at conference in Jacksonville on Wednesday, August 7, at 3:30 pm Eastern. If we have access to a speakerphone, I will share the information in advance of the 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
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Guests:	Steve Arms, NELAP Lead Evaluator Arms.steve@comcast.net	
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