

Summary of the NELAP Accreditation Council Meeting January 7, 2019

1. Introductions

The NELAP Accreditation Council (AC) met at 1:30 pm Eastern on Monday, January 7, 2019. Aaren welcomed Kristin to her first meeting as Vice Chair. Minutes from December 3, 2018, were approved unanimously with one minor edit required. Those present are listed in Attachment 1.

2. Recommendation to Renew Recognition of Virginia

Voting on this recommendation was tabled at the December meeting, so that the materials from the Lead Evaluator could be properly distributed. Celeste moved and Carl seconded that the recommendation be accepted and the recognition of Virginia as a NELAP AB be renewed. In the meeting, there were eleven votes to approve, with Virginia abstaining. Three email votes to approve Virginia were received after the meeting, the last on January 9, 2019, which becomes the date of renewal.

3. Implementation Date for the 2016 TNI Standard

The agenda was adjusted to move this item ahead of the approval of a guidance document because several AB representatives stated that they would need to depart early.

When the Council adopted the new standard in July 2018, the motion included a declaration that the implementation date would be set after the requested guidance documents were approved. It is now apparent that approval of the LOD/LOQ Guidance (GUI 3-109) will be further delayed, but the entire TNI community wants to know the implementation date of the new standard. Aaren asked whether any representative objected to setting an implementation date now, instead of waiting indefinitely for that approval, and there were no objections. She also noted that the PT Program wants to implement its Volume 3 of the standard concurrent with the Council's implementation.

Aaren then initiated a discussion about what might be an appropriate date. Florida noted that its regulation implements the standard on April 1, 2019, and suggested that be the Council's date, but there was general agreement that three months is too soon to prepare. Another AB suggested six months, based on anticipated completion of rulemaking, and still another asked for nine months. Most ABs that adopt "by reference" were clear that one year is needed to have databases updated and all assessors trained. Initially, participants suggested January 1, 2020, but then implementing on a holiday might not be wise, so they settled on January 31, 2020.

Aaren was clear that, as with prior standard changes, this will be a "rolling implementation" where each NELAP AB will continue to recognize the laboratory accreditations granted by other NELAP ABs, regardless of which standard is operative in that state during the transition period, however long that might take. PT Providers will be asked to continue their dual scoring in order to accommodate ABs that are not able to transition to the 2016 Standard on the actual implementation date. NOTE: this part of the conversation led to a brief tangential discussion among several ABs about one particular PT Provider that is not providing timely and useful electronic reports, and a clear sentiment to no longer use that provider. That, however, is within the purview of PTPEC and not the Council. Aaren has already filed written

complaint about this group with PTPEC and offered to share those with Carl, who is a PTPEC member.

At the close of the discussion, Lynn Boysen moved and Michele seconded that January 31, 2020, be set as the implementation date for NELAP ABs to transition to the 2016 TNI Standard. All twelve ABs represented in the meeting voted to approve this date, and the remaining three voted by email to approve the date. The final email vote was cast on January 9, 2019. At the January 9 TNI Board of Directors meeting, the Board was informed of this decision.

4. SIRs From the AC's SIR Voting Site

SIR 297, about demonstrations of competency, had an outstanding "Needs Discussion" vote although there were ten "approve" votes cast. During the discussion, Florida (an "against" vote) offered to change its vote to a "veto" since its current regulations conflict with the interpretation, but as discussion continued, it became obvious that others were going to change from "approve" to "against" as well, so that the somewhat onerous burden of substantiating a veto vote (per SOP 3-101) would not need to be undertaken. NOTE: as of January 13, 2019, there were six "against" votes, meaning that this interpretation cannot be approved. It will be returned to the Chemistry Expert Committee for a revised interpretation.

As of the meeting date, SIR 301 also had too many "against" votes to pass. On January 13, there were eight "against" votes and one "not voting"; several additional votes were cast as a result of the discussion. This SIR will be returned to the Microbiology Expert Committee for review and requested revision.

5. Chemistry Guidance Documents

LASEC provided a recommendation dated December 18, 2018, that the AC accept the Calibration Guidance as revised. The formal name of this document is *TNI Guidance on Instrument Calibration, GUI-3-110-Rev0, December, 2018*. Carl moved and Cathy seconded that the recommendation be accepted and the guidance document approved. There was no discussion, and all ten AB representatives remaining on the call voted in favor. As of January 9, 2019, four of the remaining ABs voted in favor by email, and New Hampshire abstained.

NOTE1: During its review of the PTRL Guidance, Policy Committee requested that the numerous bullets in the document be numbered. The revised document will be shared with LASEC and the Council as FYI, after its final approval by Policy Committee. NOTE2: The LOD/LOQ Guidance was reviewed by several additional people, at Judy Morgan's request, and additional comments were identified. These further comments caused considerable consternation and will be discussed at the Chemistry Expert Committee session in Milwaukee.

6. Miscellaneous Information and Updates

Aaren discussed the draft memo that will be reviewed and eventually sent to the Council by PTPEC, concerning the timing of transition in PTRL scoring. There were no comments from participants.

Lynn asked participants to please let her know of any desired revisions to the NELAP Evaluation SOP 3-102 that might have been noticed during the current evaluation cycle. The NELAP evaluators will scrutinize the document for potential revisions in the next few months.

7. New Business

Ken noted that TX will be holding an assessor training course, taught by Marlene Moore, in April, 2019. This course is now posted in the TNI Training web page.

8. Next Meeting

The next meeting of the Council will Monday, January 28, 2019, at conference in Milwaukee, WI. The NELAP AC session is scheduled for 3:30 pm Central time.

The LASEC meeting, scheduled for 1-3 pm Central, will include an extended discussion of the Lessons Learned document and hopefully will clarify needed changes to the standards review and development processes.

Teleconference information for both of these sessions will be shared prior to the conference.

The next teleconference meeting of the NELAP AC is scheduled for February 4, 2019. If this meeting takes place, an agenda and documents will be shared in advance.

Attachment 1

| STATE | REPRESENTATIVE | PRESENT |
|-----------|---|---------|
| FL | Carl Kircher E: carl.kircher@flhealth.gov | Yes |
| | 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: Becky Hambelton Rebecca.Hambelton@Illinois.gov | No |
| | For information purposes: Kathy Marshall Kathy.Marshall@Illinois.gov | No |
| | For information purposes: John South John.South@illinois.gov | No |
| KS | Paul Harrison paul.harrison@ks.gov | No |
| | Alternate: N. Myron Gunsalus 785-291-3162 E: ngunsalus@ks.gov | No |
| LA DEQ | Kimberly Hamilton-Wims T: 225-219-3247 E: Kimberly.Hamilton-Wims@la.gov | No |
| | Alternate: Elizabeth West elizabeth.west@la.gov | Yes |
| LA DOH | Grant Aucoin Grant.aucoin@la.gov | Yes |
| | Alternate: Scott Miles Scott.Miles@la.gov | No |
| MN | Lynn Boysen E: lynn.boysen@state.mn.us | Yes |
| | Alternate: Stephanie Drier 651-201-5326 E: stephanie.drier@state.mn.us | No |

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| 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 F: (609) 777-1774 E: michele.potter@dep.nj.gov | Yes |
| | Alternate : Rachel Ellis E: rachel.ellis@dep.nj.gov | No |
| 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: David.Caldwell@deq.ok.gov | Yes |
| | Alternate: Chris Armstrong (405) 702-1000 E: chris.armstrong@deq.ok.gov | No |
| OR | Alia Servin 503-693-4122 E: alia.d.servin@dhsosha.state.or.us | No |
| | Alternate: Lizbeth Garcia 971 865 0443 E: LIZBETH.GARCIA@dhsosha.state.or.us | No |
| | Included for information purposes: Ryan Pangelinan E: Ryan.pangelinan@dhsosha.state.or.us | No |
| | Included for information purposes: Scott Hoatson Oregon Department of Environmental Quality (503) 693-5786 E: hoatson.scott@deq.state.or.us | No |
| PA | Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@pa.gov | Yes |
| | Alternate: Dana Marshall E: dmarshall@pa.gov | No |
| TX | Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov | Yes |

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| | 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 |
| NELAP AC PA and EC | 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 | No (furloughed) |
| California | Christine Sotelo Christine.Sotelo@waterboards.ca.gov | No |
| Guests: | | |