Summary of the NELAP Accreditation Council Meeting

June 6, 2016

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm Eastern time on Monday, June 6, 2016. Minutes from May 2 were approved. Those members in attendance are listed in Attachment 1.

2. Action Items Pending

- Continue review of draft revisions to Evaluation SOP 3-102, containing recommended changes
- Email vote on final revision when provided
- Donna to request that EPA/TSC identify items subject to possible non-conformities as "applicable federal regulations" in the definition of Findings in SOP 3-102

3. Final Renewal Recommendation for KS

The recommendation from the KS Evaluation Team for closing out provisional recognition and awarding full recognition as a NELAP AB to KS was distributed to AC members in advance of the meeting. This recommendation letter explained how the provisional conditions were met and also included an additional recommendation that the next evaluation for KS be delayed one year (from December 2016 to December 2017.) Sara confirmed that KS has a plan to distribute the assessment visits conducted in the past six months over a longer period of time in the next assessment cycle, but still remaining within the two year plus/minus six month timeframe. The recommendation to delay the next evaluation was discussed in unfavorable terms.

Paul moved to accept the team's recommendation for full recognition with the proviso that the next evaluation take place an extra year from the originally scheduled date. There was no second to this motion.

Cathy moved and Paul seconded that the AC accept the team's recommendation for full recognition with the exception of not accepting the one-year delay in the next evaluation. Eleven "yes" votes were cast, with KS abstaining, and the remaining two votes await email completion.

4. Recommendations for the Remaining Standards Documents and Modules

The LASEC reviewed all the remaining standards documents and provided recommendations to accept them to the Council. See Attachment 2 for the full text of the recommendations. These documents are:

- V1M1 – PT Requirements for labs
- V1M2 – Quality Systems
- LOD/LOQ standard (sections 1.5.1-1.5.2 of V1M4)
- V1M4 – Chemistry (with both Calibration and LOD/LOQ standards included)

- V1M5 – Microbiology
- V2M2 – PT Requirements for ABs

Aaren asked that all ABs review these documents for acceptability and be prepared to vote on accepting the LASEC recommendations at the next AC meeting (July 5.) Lynn forwarded the six documents and the recommendations to AC members the following day.

5. Revising the NELAP Evaluation SOP 3-102, continued

Since the May meeting, Cathy received comments from EPA (via Donna), Carl and Victoria on the revised draft distributed shortly after the meeting. EPA's comments were not received in time to allow for preparation and distribution of another revision, so the comments were briefly reviewed and will be incorporated into the next and hopefully final revision.

During discussion of the comments, EPA was asked to expand on its recommended revisions to the "non-conformity" type of finding, to provide a more definitive list of what it expects to be evaluated for the "applicable federal regulation" portion.

Cathy noted that the application document and completeness review will likely need to be redone, and that the modifications used to form the NGAB application look like a reasonable way to proceed – a list of items to be submitted, rather than the current "completeness checklist." Also, the color-coding of the "observation" items in the Technical Review checklist will need some additional explanation, since on-site observations will not be routinely performed.

In order to complete all additional reviews and have evaluator training available in time for the January 2017 conference, the revised SOP needs to be approved in July. For this reason, Aaren asked for a motion to conduct an email vote to accomplish this goal. Paul moved and Kristin seconded that the AC vote by email on the "cleaned-up" document, to be provided by Cathy. This motion was carried by unanimous voice vote, as a matter of "general business." The actual vote on the revised document will be tabulated individually, by AB, as required by the NELAP Voting SOP 3-101.

5. Next Meeting

The next meeting of the AC will take place on Tuesday, July 5, 2016, at 1:30 pm Eastern. This is a rescheduled date due to the July 4 holiday. An agenda and teleconference information will be sent out before the meeting.

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: TBD	
KS	N. Myron Gunsalus 785-291-3162 E: ngunsalus@kdheks.gov	No
	Alternate: Sara Hoffman shoffman@kdheks.gov	Yes
LA DEQ	Paul Bergeron T: 225-219-3185 E: Paul.Bergeron@la.gov	Yes
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes
	Alternate: TBD	
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes
	Alternate: TBD	
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	No
	Alternate: Tyler Croteau Tyler.Croteau@des.nh.gov	Yes

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	Mike Ryan T: (518) 473-3424 F: (518) 485-5568 E: michael.ryan@health.ny.gov	No
	Alternate: Victoria Pretti victoria.pretti@health.ny.gov	Yes
	Included for information purposes: Lynn McNaughton lynn.mcnaughton@health.ny.gov	No
OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	No
	Shannon Swantek T: 503-693-5784 E: Shannon.swantek@state.or.us	No
	Included for information purposes: Scott Hoatson T: (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: Yumi Creason E: ycreason@pa.gov	Yes
TX	Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov	Yes
	Julie Eldredge E: Julie.Eldredge@tceq.texas.gov	Yes
UT	Kristin Brown T: (801) 965-2540 F: (801) 965-2544 E: kristinbrown@utah.gov	Yes
	Alternate: Jill Jones T: (801) 965-3899 E: jilljones@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	Yes
California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
Oklahoma	David Caldwell E: David.Caldwell@deq.ok.gov	Yes
Guests:		

Attachment 2

LASEC RECOMMENDATIONS TO NELAP AC ABOUT 2016 STANDARDS

PT Modules V1M1 and V2M2

Explanation:

Vol 1

The 2016 version of V1M1 addresses major concerns of the AB Council. The laboratory reporting for proficiency testing has been restored to the TNI PTRL reporting. Tracking PT results by analysis date has been switched this back to the close date of the study. The waiting time between PTs has been reduced to 7 days from 15 days.

Vol 2

The 2016 version of V2M2 has been expanded the definition of an Accreditation Body to include non-governmental ABs. The AB requirements for suspension and revocation have been expanded to allow the ABs to follow their established rules for these activities. The note addressing clarifications for accreditation has been re-written to be much clearer. To avoid inconsistencies between Vol 1 and 2, all laboratory requirements for PTs now exist only in V1M1. ABs will be assessing the labs to Vol 1.

Recommendation:

TNI Standard V1M1 and V2M2, Proficiency Testing, approved April 2016, Approved by LASEC May 26, 2016

The LASEC has reviewed the Proficiency Testing Modules (V1M1 and V1M2) as revised and approved in 2016, and recommends that the NELAP AC adopt these modules as presented.

QS Module V1M2

Recommendation:

TNI Standard V1M2, Quality Systems, approved March, 2016, Approved by LASEC May 26, 2016

The LASEC has reviewed the Quality Systems Module (V1M2) as revised and approved in 2015, and recommends that the NELAP AC adopt this module as presented.

LOD/LOQ Standard Document

Explanation:

The following has been transmitted to the Chemistry Expert Committee, concerning information to be included in the Guidance Document:

We do recommend developing a flow diagram that will show the process. For example, reading through the document, it is tough to picture exactly how everything is to flow, for example the one path for MDL and another one for LOQ noting where the initial and continuing checks fall and basics about how they are performed and analyzed (per instrument, etc.)

The guidance should explain how the decision about when an MDL is not necessary should be made. Not in examples (which tend to become requirements) but maybe a decision tree about how an MDL is not practical if any of the assumptions or conditions of the procedure are not met. An example, based on the most used process in 40CFR Part 136 Appendix B, follows:

All gravimetric and titrimetric tests – *reason* – there is no variability at zero concentration so the assumption that the variability at a low level concentration mimics that of zero concentration is not met.

All gravimetric tests – *reason* – the measurement device, the balance, is not calibrated using solutions of known concentration of analyte. They are calibrate using standard weights.

All tests using senses (known as organo-leptic tests) – *reason* - the measurement device (nose, eyes, tongue) cannot be calibrated and the variability of one “device” is not mimicked by another.

pH is the unique case here simply because there is no such thing as a zero concentration. Pure water has an H^+ concentration of 10^{-7} or a pH of 7. A pH of zero represents 10^0 or 1 mole concentration something definitely not zero and the log of 0 is infinity.

It would be helpful if the guidance can address the following questions:

1.5.2.1.2 In the event that verification fails, the laboratory shall perform a new MDL study within 30 calendar days.

Or what? Can samples be run within this 30 day window. Should it say 'shall be performed prior to samples being analyzed"?

1.5.2.3 If no analysis was performed in a given year the verification of the MDL/LOQ is not required, but a new initial MDL/LOQ verification shall be performed prior to analysis of client samples

Will there be guidance for the situations in which samples were only run once or twice during the year?

Please note that LASEC did not consider whether technical edits to the standard could resolve the need for guidance on these issues, but if Chemistry Expert Committee considers that approach to be preferable, we would surely consider having these points clarified that way rather than in the guidance itself.

Recommendation:

TNI Standard for Detection and Quantitation, §1.5.1-1.5.2 of V1M4, Chemistry Module, approved by Chemistry Expert Committee January 20, 2015
Approved by LASEC May 26, 2016

The LASEC has reviewed the Detection and Quantitation sections of the Chemistry Module (V1M4) as revised and approved in 2016, and recommends that the NELAP AC adopt this module as presented.

There are several issues noted that should be addressed in the requested guidance document. (see transmittal above)

Chemistry V1M4

Recommendation:

TNI Standard V1M4, Chemistry, approved April 16, 2016, Approved by LASEC May 26, 2016

The LASEC has reviewed the Chemistry Module (V1M4) as revised and approved in 2016, and recommends that the NELAP AC adopt this module as presented.

Microbiology V1M5

Recommendation:

TNI Standard V1M5, Microbiology, approved October 22, 2015, Approved by LASEC May 26, 2016

The LASEC has reviewed the Microbiology Module (V1M5) as revised and approved in 2015, and recommends that the NELAP AC adopt this module as presented.