Summary of the NELAP Accreditation Council Meeting

August 8, 2016 Garden Grove, CA

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 9:00 am PDT on Monday, August 8, 2016, during conference in California. Those members in attendance are listed in Attachment 1.

2. Action Items Pending

- 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. Update on Activities since Tulsa – presented by Aaren Alger, NELAP AC Chair

Evaluations

MN is the final evaluation of the current cycle. The team has completed the site visit and is working with the program to schedule a suitable lab for the observation.

KS now has been approved for full recognition and NJ continues to make progress towards resolving its provisional recognition issues by the end of calendar 2016.

Revisions to Evaluation SOP 3-102

A small working group of AC members sought to revise the evaluation process to improve time usage and reduce travel costs. The group began with a review of all findings from completed evaluations in the current cycle. Specific changes are:

- to use teleconferencing, email and WebEx for document reviews, information management and interviews prior to a one-person, one-day site visit
- the Evaluation Coordinator role will be performed largely by the Lead Evaluator, who will likely be a TNI staff person
- the application form will be amended to require certain document submissions, as the NGAB application does
- a QA reviewer was added and some experience requirements and qualifications for evaluators were revised
- the document was reorganized
- specific numbers of lab files for review are mandated
- the observation is dropped for existing ABs, with the responsibility for observing assessors placed on the Program Manager
- new ABs will have "interim" status until an observation of an assessment can be performed, if needed
- corrective actions will no longer be recommended.

Aaren explained that this revision has already been reviewed by TNI's Policy Committee, and a few edits were requested but no major changes, so that it should soon be "final." The next round of NELAP evaluations starts in November 2016 and evaluator training will

probably be conducted at the winter conference in Houston. EPA personnel are still welcome to participate in the evaluation teams and to accompany the Lead Evaluator on the site visit.

Comments and questions from participants were:
How will the process ensure consistency of the Program Managers' assessor performance reviews? Four commenters addressed this issue and one recommended using a checklist across all ABs for these assessor reviews. OR will share its checklist.
Please put the new requirements into the upcoming revision of Volume 2.
Jordan Adelson offered to provide his DoD SOP about the observation of an assessment (and has done so.)

Aaren asked that Carl consider including the use of technological tools as an option for laboratory assessments, when revising the modules of Volume 2. Carl chairs the Laboratory Accreditation Body Expert Committee.

4. Recommendations for the Remaining Standards Documents and Modules

Aaren noted that the AC has LASEC recommendations to accept the remaining modules of Volume 1, and reminded the AB representatives to attend the presentations about the revised modules, scheduled for Thursday, August 11, during conference. These modules with recommendations 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 -- is also ready for review.

Carl moved and Paul seconded to accept the remaining recommendations for V1 modules, and both then accepted a friendly amendment to their motion that the voting begin on Monday, August 15 (after conference) and continue for two weeks, until August 29. This would allow the AB representatives to return home and take some time to review the documents before the two-week voting time is over (per the NELAP Voting SOP 3-100.)

5. Additional Meetings at Conference Included with these Minutes

AC members were invited to meet with TNI's Information Technology Committee over lunch on Monday, August 8, at conference. A summary of that meeting is included with these minutes as Attachment 2.

Following an informal lunch meeting of the AC, at conference on Thursday, August 11, the Council scheduled a teleconference meeting to discuss the revised modules of Volume 1, to be held on Monday, August 22, at the usual 1:30 pm Eastern time. That meeting was held before these minutes were completed, and Aaren's summary of the discussion points raised about the various modules is attached to these minutes as Attachment 3.

6. Next Meeting

The next teleconference meeting of the Council will be on Tuesday, September 6, 2016, at 1:30 pm Eastern time. An agenda, teleconference information and meeting materials will be distributed with the meeting reminder, prior to the meeting.

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 (phone)
	Alternate: Janet Cruse Janet.cruse@illinois.gov	no
KS	N. Myron Gunsalus 785-291-3162 E: ngunsalus@kdheks.gov	Yes
	Alternate: Sara Hoffman shoffman@kdheks.gov	Yes (phone)
LA DEQ	Paul Bergeron T: 225-219-3247 E: Paul.Bergeron@la.gov	Yes (phone)
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes (phone)
	Alternate: TBD	
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes (phone)
	Alternate: Stephanie Drier 651-201-5326 E: stephanie.drier@state.mn.us	No
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	Yes
	Alternate: Tyler Croteau Tyler.Croteau@des.nh.gov	No

NJ	Michele Potter T: (609) 984-3870 F: (609) 777-1774 E: michele.potter@dep.nj.gov	Yes (phone)
	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	Yes
	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	no
TX	Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov	Yes
	Julie Eldredge E: Julie.Eldredge@tceq.texas.gov	No
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	No
California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
Oklahoma	David Caldwell E: David.Caldwell@deq.ok.gov	Yes
Guests:	Becky Hamilton, IL (phone)	

Attachment 2

Summary of NELAP AC Meeting with TNI IT Committee
August 8, 2016 Garden Grove, CA

Participants:

Jerry Parr, TNI Executive Director
Dan Hickman, TNI Database Administrator
William Daystrom, TNI Webmaster
Maria Friedman, IT Committee
Mei Beth Shepherd, IT Committee

Cindy Story

David Caldwell, OK
Bill Hall, NH
Cathy Westerman, VA
Kristin Brown, UT
Aaren Alger, PA
Myron Gunsalus, KS
Ken Lancaster, TX
Gary Ward, OR
Victoria Pretti, NY

The NELAP AC met with the IT Committee over lunch on Monday, August 8, 2016, at the conference in California to discuss the LAMS database.

Dan noted that LA DHH, MN, NH, TX, UT and VA now have all their labs and FoAs in LAMS, and that OR is working to resolve some issues so they can upload, that IL is beginning to work on their uploads, and that PA is underway. Apparently, LA DEQ is not yet responding to requests. Dan stated that at minimum, sporadic updates are needed, and asked the ABs try, whenever possible, to use the same method codes that the other ABs are using. The ABs agreed to use the specific method revision rather than a general one. This will be a big help and decrease resources for ABs granting secondary accreditation.

Dan indicated that ABs are not required by the standard to use LAMS at present, but he and Jerry asked that reporting to LAMS be added as an eighth responsibility of ABs, in the NELAP Mutual Recognition Policy 3-100. Participants also discussed the struggles with the letter-named versions of SW methods, and acknowledged there is still no satisfactory resolution available since EPA's Office of Resource Conservation and Recovery declines to revise its position that any of the letter-coded method versions is acceptable. EPA Drinking Water and Clean Water Programs have started to use Standard Method approval date instead of hard copy edition now and moving forward but until they drop approval for specific edition LAMS will continue to track those separately.

Participants also briefly discussed the Generic Application. This now-functional software is being used by KS to gather FOAs for LAMS. When used for a lab's renewal application (eventually), it will show the original scope of accreditation plus a separate list of changes. Other states are invited to beta-test the software, and a few labs have indicated willingness to complete their application to KS with this software.

For optimal usefulness, all ABs need to have their demographic and FoA information in LAMS, since those data are used to populate the Generic Application's initial choices. Dan noted that more method selections will appear in the Generic Application as additional ABs add their FoAs to LAMS.

Attachment 3

Summary of August 22 Teleconference Meeting of the NELAP AC
Prepared by Aaren Alger and taken from her August 23 email to all Council members.

Thank you for taking the time to make today's call. For those of you who were unable to make the call, I just wanted to reiterate a few things that came up today.

1. The vote on this standard is for each AB to make their own determination of the acceptability, usability, enforceability, etc. of the PT, QS, Chemistry, and Microbiology modules as it relates to your own preference, interpretation, regulations, laws, etc. You are in no way to consider how your vote will impact the AC, the labs, or TNI.

2. The vote is on Modules 1, 2, 4, and 5 independently, so you need to cast 4 separate votes.

3. You may vote, Yes, No, or Veto.

4. If you choose to vote 'No', please include comments as to why you are voting No. A No vote does not necessarily stop the standard in its tracks, but it will open up the discussion between the AC, LASEC, TNI Expert Committee(s), and Consensus Standards Development. Maybe something needs additional clarification, guidance, or discussion and that will clear it up and another vote can be made.

5. If you choose to vote 'Veto" you must include your state law/rule and include a reference and an explanation of how the 2016 Standard (particular section please) would cause you to violate your own rules and laws. Again, this does not necessarily stop the standard, but it will open up the conversation.

6. Please ensure that you read the whole standard carefully before you vote.

7. You are not being encouraged to vote one way or another. This vote is for you to make based on your own preference, laws, regulations, and expectations for a standard.

8. Here are some questions that you can ask yourself as you evaluate these standards:

    a. Are these standards an improvement from the current standard?

    b. Does this represent a cost savings or cost benefit to the laboratories or ABs without reducing quality?

    c. Does this provide an unreasonable cost or additional work load to the laboratories or ABs without an improvement in quality?

    d. Do I understand these standards and can I explain them to my staff or my laboratories?

    e. Are these standard written in such a way as to improve compliance by laboratories and reduce inconsistency between assessors?

    f. Will the laboratories be able to comply with these standards? Or How difficult will laboratories find it to comply with these standards?

    g. Are these standards enforceable?

Here are some of the comments that came out of today's meeting. Not all of these are show stoppers or even problems. These are items that were brought up as notable changes, interesting differences, or possible show stoppers.

Many of the below comments are from me. During the call, I mentioned that I will probably vote No to the Chemistry module because I have some real problems with some of the LOQ section. I am also not a fan of how the MDL section is written. I have not performed a thorough review of the second half of the chemistry module or most of the microbiology module. I will continue to read these this week and send comments or concerns to all via e-mail. I encourage all of you to also email everyone with you observations or concerns.

V1M1: PT

1. Section 3.1: definition of AB, changed from 2009 and now says that it is an organization…which grants accreditation under this "program". What does "program" mean and should it really be "standard"? V2M2 defines accreditation body as "Authoritative body that performs accreditation." And has a note that says "NOTE: the authority of an accreditation body is generally derived from government." Both statements are ISO language.

2. All other modules reference the definitions within module 2, why are there definitions in V1M1?

3. Section 4.2.2: No longer states that PTs must be analyzed in the same manner as real environmental samples, using the same staff procedures, equipment, facilities, number of replicates, and methods. And it now states that the labs must follow their "established SOPs" using the same QC, acceptance criteria, and staff. But, what if the labs establish SOPs specifically for PTs that are different from those of regular samples?

4. Section 4.3.4 says that the labs can choose to analyze and report a single method to represent a technology. But, what if the lab reports multiple methods by the same technology and passes some and fails others? How are these PTs scored and how will this impact ABs that are using the current standard that says fail one method, fail them all? Is it up to the AB to determine how PTs are evaluated and scored?

5. Sections 5.1.1 and 5.2.1.1 add the term "(acceptable scores)" to define successful PT performance. However, successful performance includes reporting the correct method, a method that the lab actually has accreditation for or is applying for, and other factors. PT performance is based on more than an acceptable score. Will this present an enforcement problem?

6. Section 5.1.2 only requires one WETT PT, instead of 2 for initial accreditation. Will this cause problems with anyone's state laws?

7. Section 5.2.2 does not require the lab to pass a WETT PT. This is not a new requirement, but why are we not making it one?

V1M2: Quality Systems:

1. Definition of Finding states that a finding is a "deviation". This seems to be in conflict with the actual use of the term within the standard, see 4.14.2 and 4.15.2 and V1M3: 1.7.5.1.1

2. Terms are duplicated within V1M1 and V1M2 that don't seem to be duplicated in any other module.

3. There is new language in the definition of "Reference Method". Specifically, the last sentence says "If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another reference method of the same matrix and technology."

4. Section 5.5.13.1.d: While this is not new language, this section states that temperature measuring devices shall be calibrated or verified at least annually. Does this mean that the NIST reference thermometer must be calibrated annually? The standard never says otherwise.

5. Section 5.5.13.1.d - The committee tried very hard to clarify when a thermometer must be verified at bracketing temperatures or when a single point is acceptable. But, there are no criteria for when a correction factor is unacceptable. What happens when a thermometer shows two different correction factors at the bracketing points?

V1M4: Chemistry

1. Section 1.5.2.1 – In general this section is difficult to understand. It provides details of what the laboratory's procedure for MDL or detection limit (the terms are used interchangeably and this makes less sense since the term "MDL" is defined by EPA) but does not instruct the user how to evaluate the data/information or how to actually determine the MDL/DL. Interestingly, Section 1.5.2 is titled "Limit of Detection and Limit of Quantitation (however named)" and then Section 1.5.2.1 is titled "Method Detection Limit (MDL)".

2. Section 1.5.2.1 – states that spikes are not required for analytes for which no spiking solutions are available such as TSS, but spiking solutions are available for TSS, TDS, and TS.

3. Section 1.5.2.1.1.e – There is going to need to be a very good guidance document to explain what this section wants and how to achieve it.

4. Sections 1.5.2.1.1.c and f seem to be in conflict because (c) says to use low level spikes and (f) says to use a matrix of interest where there are neither target analytes or interferences. Should we assume that (f) really means that a "matrix of interest where there are not target analytes" is "spiked with target analytes"?

5. Section 1.5.2.2.a – Why can the LOQ – Limit of Quantitation be verified at or BELOW the selected LOQ? How can you verify you "limit" below that limit?

6. Section 1.5.2.2 – This whole section is confusing. The term "LOQ" is used to mean various things throughout the section. Sometimes it's used as a noun sometimes a verb. The standard uses "LOQ" instead of "LOQ *study*" or "LOQ *verification*" or "LOQ *sample*". For example, in (c), should it say the "*established"* or *"verified"* or *"selected"* LOQ?

7. Section 1.5.2.2.1.c.ii requires that the lab initially verify the recovery of each analyte in the LOQ within the laboratory established accuracy acceptance criteria. But, Section 1.5.2.2.2.a states that the ongoing verification of the LOQ must meet QUALITATIVE identification criteria and the QUANTITATED result shall be greater than zero. Isn't a qualitative identification and a result greater than zero the same thing? Why isn't the ongoing verification of the LOQ required to meet at least the same standards as the initial verification of the LOQ? Isn't this allowing less accuracy at the LOQ instead of improving the quality of the results?

8. Section 1.5.2.2.1.c includes the following note "NOTE: It is not necessary to repeat the LOQ verification at a higher concentration when it is necessary to raise the LOQ to three (3) times the MDL." I assume this means that if the MDL verification fails, and the lab must raise the MDL value, then they can automatically multiply the new MDL (which by the way is not defined in how to perform this at all in the standard) by 3 and have a new LOQ…without verifying that the instrument can actually see the new calculated LOQ.

9. There is a formatting error in 1.5.2.2.2, there is a paragraph (a) with no paragraph (b).

10. Section 1.5.2.4 seems like an exercise in paperwork. The lab is required to tabulate results of ongoing verification sample testing once per year with all results obtained within the last 2 years and there must be 7

samples. The standard doesn't say for what, so I assume it means for MDL and LOQ. What happens if they don't have 7 samples in the last 2 years? What do they do with these results other than "provide to the clients upon request" as stated in the last sentence of (b)?

11. Section 1.7.1- includes a sentence that explains how calibrations can occur. This statement is not a standard and not a requirement. It actually can create a situation where a laboratory believes that it can perform a type of calibration that is not allowed by method or regulation. I feel that the inclusion of this sentence actually weakens a laboratory's ability to comply by implying that they can do something that might not be allowed.

12. Section 1.7.3.1 – This language is not new, but what does it really mean? Why is there a "and" after (b)?

V1M6: Microbiology

1. Section 1.7.3.1 – This section now requires that the laboratory cannot use the sterility checks performed PRIOR to receipt at the laboratory. The laboratory must verify sterility after the material is received at the laboratory.

2. Section 1.7.3.7.b.v.b introduces a new term "under test". Which is basically saying 'any time there is a sample in the incubator'.