Summary of the NELAP Accreditation Council Meeting

September 6, 2016 1:30 pm Eastern

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm on Tuesday, September 6, 2016. This meeting date was rescheduled due to the Labor Day holiday on Monday. Those members in attendance are listed in Attachment 1. Minutes of July 5 and August 8, 2016, were approved with the exception of the attachment to the August 8 minutes documenting the meeting at conference with the IT Committee about LAMS. Once the IT committee approves the revised summary of that meeting, it will be distributed to the AC and substituted for the version initially attached to the August 8 minutes, with the complete document then posted to the website.

Both email votes from the July 5 meeting passed, with final votes as follows:
Approval of Renewal of Recognition for Illinois – 11 yes votes with Illinois abstaining, 2 ABs not voting.
Approval of Temporary Extension for Minnesota -- 11 yes votes with Minnesota abstaining, 2 ABs not voting.

Jerry Parr, TNI Executive Director, and Judy Morgan, Chair of the Laboratory Accreditation Systems Executive Committee, were invited to participate in discussions about the "no" votes for acceptance of LASEC's recommendations to approve the revised standard modules for Chemistry and Proficiency Testing. The outcome of that vote and the various rationales are documented in an attachment to the minutes of the August 8, 2016 meeting.

2. Action Items Pending

- Judy and Jerry to follow up with expert committees about how best to address the serious objections to certain items in the PT and Chemistry modules as approved by TNI membership, since these objections will interfere with adoption and implementation of the 2016 standard.
- 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. Discussion of Objections to the Chemistry Module

Aaren opened the discussion with an invitation for participants to explain their objections and to offer suggestions for what would be acceptable instead – a change to the standard, some clarifying language or any "out of the box" idea they might have – and to please identify the absolute "show-stoppers" clearly.

In response to a question, Jerry explained that if the AC decides that something must be revised, he will take down the version of Volume 1 that is currently for sale on the website, and when the revision is available, send the new version to all who purchased V1 previously.

Aaren specifically asked Oklahoma (David Caldwell) how he would have voted, since OK is not yet officially a member of the AC. David has reviewed the modules, and indicated that the Chemistry module may be problematic in some respects, especially about the Method Detection Limit (MDL) language and required relationship to the Level of Quantitation (LOQ.)

A question was raised about California's announced decision to use the 2016 standard as the basis for its state certification program. Jerry indicated that CA's actual implementation is far off, yet, and that they have indicated intent to modify the standard to address concerns of the CA laboratory community, so that whatever happens with this AC discussion is highly unlikely to have a negative impact on CA.

Aaren then asked whether the additional documents provided by Jerry (the preamble to the V1M4 Interim Standard and a PowerPoint explaining the 3x relationship between MDL and LOQ) had changed anyone's views about their concerns, but no one responded positively. This opened the more general discussion of specific problems with the Chemistry module (V1M4.)

MDL = 3X LOQ – the rigid requirement that the LOQ be set at three times the MDL may not always be correct or appropriate, particularly for drinking water methods, and may not always meet the needs of the data user.

Jerry explained that the 3X and 10X factors these waypoints have been generally accepted for decades, but acknowledged that the few tenths potentially lost to "rounding" might be significant, and that the Chemistry Expert Committee might be convinced to relax that requirement somehow. "Guidance" would not be an acceptable solution, however.

The problem arises with mandatory reporting limits of drinking water methods, and in at least some ABs, the requirements of the specific state's program in the same or different department/agency than the accreditation program, with the AB needing to follow the state-specific mandates. This could lead to a situation where labs literally cannot meet the federal reporting requirements while adhering to the TNI standard. Yes, the state regulations or laws would supersede the standard, but the standard does not clearly state that. Some wording such as "3X is the default and the LOQ must exceed the limit of detection (LOD)" might be acceptable. Jerry recommended that the AC just state its concern and let the expert committee determine how to address that.

Definition of MDL – the wording in the standard is not identical to EPA's wording in 40 CFR Part 136. Jerry explained that the expert committee decided not to drop the use of LOD, but to keep both MDL and LOD, and that the MDL definition in the standard meets the "new" definition which EPA is expected to publish in the coming months. Participants noted that the EPA MDL process is the only procedure that meets the requirements of the TNI MDL.

Alternatives discussed were to either remove reference to LOD or remove references to MDL from the standard. Strong preference for having the precise wording for MDL in the standard itself, rather than referencing the CFR definition was clear. If the language cannot be repeated verbatim, then references to MDL should be removed and LOD retained; if the EPA language changes, then that EPA program would become an exception.

Another option was to make the AC's adoption and implementation of this module contingent upon actual publication of the EPA's final regulation with the expected language in it. The goal is to remove the mandated relationship between LOQ and LOD, and the requirement to "qualify" any analytical result that falls between the two – apparently language in the "calibration" portion of the Chemistry module helps to address this, explicitly calling out that program requirements override the standard (V1M4§1.7.1.1.g).

Conflict between initial and ongoing verifications of LOQ – the language as currently written is inconsistent and unacceptable, and must be addressed and clarified by the expert

committee.

MDL per instrument – the initial language mentions "per instrument" but the ongoing MDL does not address instruments. The EPA MDL definition (as proposed and expected) would specify "each instrument every quarter" for ongoing MDLs, and thus would solve this omission, or it could be clarified, perhaps in the footnote to §1.7.1.1.f.

Additionally, the last sentence of §1.7.1, about calibrations "may" be performed at the instrument or method level is problematic, since those are the only two choices. Deleting that sentence would improve the standard.

4. Discussion of Objections to the PT Module

AB definition -- The problem called "show-stopper" by one AB was the definition of an Accreditation Body (AB) in the PT module of Volume 1. At least two modules of Volume 2 use a different definition, which would seem to override the V1 definition, since V2 is the module that applies to ABs. Jerry proposed simply deleting the V1M1 definition. Unfortunately, the AB objecting to this definition was not participating in the teleconference.

SOPs relating to performing PTs – from §4.2.2, it seems that a lab could prepare and use an SOP that directs "different" treatment of PT samples, that would qualify as acceptable under this new language. For instance, a corporate QA/QC SOP might qualify as an "established" SOP rather than an SOP that actually meets the TNI standard requirements. Apparently, this change was made in an effort to condense the wording, and when later language was pointed out ("as used for analysis of routine samples"), concerns were eased, but the possible need for a SIR was raised.

Reporting PTs by technology instead of method – this is an area where ABs are not consistent, and the PT module of Volume 2 is silent about scoring of PTs. Judy noted that the expert committee could not address this because the current scoring by PT providers does not allow distinctions between method and technology. For instance, if there are 3 methods for one analyte, but only one technology (used in all three), there is no requirement to perform the PT analysis by all 3 methods, but if all 3 methods are run and one fails, the entire technology fails. The lab has to choose, currently, and balance the risks of failure by running only 1 analysis per technology.

Consensus is that the language is clear for what labs may do (run PTs by method or by technology) and is silent about how ABs must score the PTs. However, §4.3.4 requires clarification about what happens if a lab chooses to report PTs by method – this clarification could instead be made in the PT module of Volume 2 (V2M2.)

PTs no more than 7 months apart – this was raised as a possible issue but the AB that expressed concerns has determined that the language is acceptable and not problematic.

Successful PT – in §5.1.1(a), the expert committee needs to clarify what constitutes a "successful (acceptable scores) PT."

Additional concern – a request arose to add "analyte group" and "multi-component analyte" terms to the definitions of both FoAs and FoPTs. This request will be forwarded to the Consensus Standards Development Executive Committee for its consideration as it creates a glossary for the TNI environmental sector standard. (NOTE: sent on September 7, 2016.)

Aaren asked that any AB representatives having other comments please send them to the Council and to Lynn.

5. Next Meeting

The next teleconference meeting of the Council will be on Monday, October 3, 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. Hopefully, there will be time to address the SIRs needing discussion, as well as the minor revisions to the Evaluation SOP 3-102 and the Mutual Recognition Policy 3-100.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Carl Kircher E: carl.kircher@flhealth.gov	Yes (departing early)
	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: Janet Cruse Janet.cruse@illinois.gov	Yes
KS	N. Myron Gunsalus 785-291-3162 E: ngunsalus@kdheks.gov	Yes (departing early, likely will return)
	Alternate: Sara Hoffman shoffman@kdheks.gov	Yes
LA DEQ	Paul Bergeron T: 225-219-3247 E: Paul.Bergeron@la.gov	Yes
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	No
	Alternate: TBD	
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes
	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	No
	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
	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	No
	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	no
TX	Ken Lancaster T: (512) 239-1990 E: Ken.Lancaster@tceq.texas.gov	No
	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:	Judy Morgan, LASEC Chair, Pace Analytical Jerry Parr, TNI Executive Director	