Summary of the NELAP Accreditation Council Meeting

November 7, 2016 1:30 pm Eastern

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm on Tuesday, November 7, 2016. Those members and invited guests in attendance are listed in Attachment 1. Minutes of October 3, 2016, were approved.

Final voting results from the October 3, 2016, meeting are as follows:

- For renewal of recognition for Oregon – 13 yes votes, OR abstaining.
- To approve revisions to the NELAP Evaluation SOP 3-102 – 14 yes votes.
- To approve revision to the NELAP Mutual Recognition Policy 3-100 – 14 yes votes.

Aaren asked that AB representatives please review the evaluator assignments as well as the revised application form and revised instructions for the Technical Review checklist, and provide any comments to her and Lynn no later than Thursday, November 10. NOTE: no comments were received by the deadline. The evaluator assignments are considered approved by acclamation, as are the two documents.

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
- Per TNI Board request, Aaren to talk with Val Slaven about AC objections to Chemistry module, and all ABs voting no on that module to meet with Chemistry committee (date TBD) to seek resolution to concerns without re-opening the standard for re-revision.

3. Technical Clarification Edits to the PT Module (V1M1)

Four issues were raised and returned to the PT Expert Committee by LASEC (see minutes of September 6, 2016.) Shawn Kassner, PT Expert Committee Chair, explained how the PT committee addressed these concerns and provided a version of V1M1 with minor edits that addressed the concerns, per the discussion during the meeting. See Attachment 2 for details.

One additional edit was requested, to change "real environmental samples" in the Note copied from V2M2 into sections §5.1 and 5.2 of V1M1 to "routine environmental samples" so that the wording is consistent throughout the module. Since it will not delay adoption of the full Volume 1 (other concerns remain to be addressed), Lynn recommended putting this minor revision back through the Expert Committee and LASEC, just to follow the process as documented. Shawn agreed to do this, and to edit the words for the same note in V2M2 as a technical clarification, as well.

Once the AC is satisfied with all revisions, the Consensus Standards Development Executive Committee will be asked to review and approve these edits as "technical clarifications" to the module, not requiring a re-vote by TNI membership.

4. Revisions to the Chemistry Module (V1M4)

Similarly, four issues that had been the basis for objections to the Chemistry module were returned through LASEC to the Chemistry Expert Committee. Val Slaven, current Chemistry Chair, and Richard Burrows, former Chemistry Chair, were present to discuss the revisions approved by Chemistry committee as well as the one area where editorial revision was deemed to be inadequate. The proposed solutions are detailed in Attachment 3.

Aaren initiated the discussion by explaining that there was an apparent misunderstanding, and that what the Council seeks is for the standard to require that the labs define, for themselves, a quantitative criteria for the ongoing verification of LOQ, and not to have the standard specify quantitative criteria. Further discussion clarified that those limits would need to satisfy both the lab's clients and the regulators (data users) and thus could not be so broad as to be meaningless. Participants discussed a possible process that would involve annual examination of the data from quarterly verifications of the LOQ, running statistics for mean and standard deviation, and comparing the result with the stated requirements in the lab's quality system documentation. There was general agreement that 1) the limits for the ongoing verification would be much wider than those for the initial verification and 2) outliers would occur and that a single outlier (failure) could represent either a statistical failure or an equipment failure. Perhaps a second failure should reasonably trigger a repeat of the initial LOQ verification (presumption of equipment failure) or possibly some other response as a corrective action, and failures might vary by chemical class. A later suggestion was to compare the result of this annual examination of data to the initial verification limits, and adjust the limits if warranted.

The Chemistry committee representatives noted that language to require a process as was being discussed could not be considered an editorial "fix" but would require a re-opening and re-revision of the standard. Further, while Richard stated that the 2009 standard does not require an ongoing (or initial) verification of the LOQ if the lab has performed a LOD verification, the Chemistry committee was able to get the current language approved but they have serious concerns about whether labs will object to the additional effort required in the process discussed here. There were also concerns about the actual benefits of such additional work, and some discussion about whether data users would actually care about the improved data quality from this proposed process.

Judy Morgan noted that these statistical methods are different than for all other types of limits used in methodology, and suggested seeking a more simple solution. There was general agreement that simplicity is desirable, but also that failure of an ongoing verification of the LOQ must have some consequences.

The conclusion was that the Chemistry module will need to be revised, beyond a technical clarification, and process considerations for that were discussed – hopefully, a "fast track" through the current Standards Development SOP 2-100 could produce a final revision in 2017.

The other three issues were not discussed due to time constraints, and there was general agreement that those proposed technical clarifications could easily be addressed during the revision process. AB representatives were asked to provide any additional feedback to Val as well as the AC members.

NOTE: The TNI Board of Directors, at its November 9 meeting, expressed great resistance to re-opening the Chemistry module for revision. The Chair directed Val and Aaren to

discuss the concerns of the Council, and then for the eight ABs that voted “no” on accepting the Chemistry module to meet with the Chemistry committee to seek an alternative resolution, if at all possible. The Board will require an update at its monthly meetings until the problem is resolved.

5. Next Meeting

The next teleconference meeting of the Council will be on Monday, December 5, 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	Yes
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: 225-219-3247 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: Stephanie Drier 651-201-5326 E: stephanie.drier@state.mn.us	Yes
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

	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	Yes
	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	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	No
	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	No
Guests:	Valerie Slaven, Chair, Chemistry Expert Committee, mslaven@teklabinc.com Judy Morgan, Chair, LASEC, Judy.morgan@pacelabs.com Shawn Kassner, Chair, PT Expert Committee, skassner@neptuneinc.com Richard Burrows, former Chair, Chemistry Expert Committee, richard.burrows@testamericainc.com Ken Jackson, Program Administrator for PT and Chemistry Expert Committees, ken.jackson@nelac-institute.org	

Attachment 2

Problems and proposed resolutions for the 2016 final version of PT module

AB definition

The problem called "show-stopper" by at least two Accreditation Bodies is 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. Simply deleting the V1M1 definition would resolve this issue.

The definition of Accreditation Body has been deleted.

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 Standards Interpretation Request (SIR) was raised. LASEC believes that approving standard language when we already recognize the need for clarification through submission of a SIR is not acceptable.

The term "established" is replaced by the phrase "routine" in order to avoid the potential for a SIR in the future.

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. We recognize 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) but needs to be addressed prior to adoption of the revised V1M1.

A "note" was added to point out the risks of running PTs by technology rather than by method.

Successful PT

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

The "note" from V2M2 about this issue has been copied directly into §5.1 and 5.2 of V1M1. That note reads:

> *"Note: "Acceptable" PT study scores from a PT Provider do not automatically result in a successful evaluation of a PT study by an AB. For example, failure to report an analytical method or reporting of an incorrect method, failure to provide the PT Provider with a release of results to the AB before the close of the study, failure to report results to the PT Provider*

before the closing date, failure to handle PT study samples in the same manner as real environmental samples, etc. may be cause for an unsuccessful evaluation by an AB."

Attachment 3

Problems and proposed resolutions for the 2016 final version of the Chemistry module

MDL = 3X LOQ

The biggest problem is the requirement that MDL = 3XLOQ, and this is considered to be a "show-stopper" by several Accreditation Bodies, meaning that it would cause them to veto adoption of the entire standard in its current form. This ratio has historically been a guideline but its use of an absolute requirement rather than an approximate range created concerns with some ABs that labs might be unable to comply in the case of some drinking water methods, particularly for volatiles where an unreasonable and potentially unattainable MDL would be needed to meet the required LOQ. This degree of specificity is not something that could be resolved with a guidance document.

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, and it would be confusing to labs as written. Some wording such as "3X is the default and the LOQ must exceed the limit of detection (LOD)" might be acceptable.

The Chemistry Committee has added the phrase "unless otherwise specified" to this section, as was done earlier to address a similar issue where drinking water methods were involved.

Definition of MDL

There are also consistency issues with the definition of MDL. The one used in V1M4 is the definition expected to be published in the soon-to-be-released Method Update Rule (MUR,) but is not the same as other existing definitions (which vary from one another, too.) One participant noted that the LOD definition has been an issue in the Defense Department's accreditation program. Another participant suggested awaiting the MUR publication so that the TNI standard can just reference that definition. At the present time, the wording in the standard is not identical to the current Agency wording in 40 CFR Part 136. AB representatives 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 considered but deemed undesirable 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).

The language of V1M4 has been revised to use the term "Detection Limit (DL)" exclusively. This avoids the confusion with Defense Department accreditation standards that the problematic change was intended to address, and will also make the TNI standard more general than the highly prescriptive EPA MDL. Chemistry believes that, with this new language, the EPA MDL will always meet the standard's requirements for DL, but will not be the only option for doing so.

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.

The Chemistry Expert Committee believes that inadequate data exist for setting a quantitative range for ongoing verifications, and will participate in the NELAP AC call when this recommendation is presented to explain its position and rationale.

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.

The Chemistry committee agrees that removing the problematic sentence will improve the standard,

and has done so.