Laboratory Accreditation System Executive Committee Meeting Minutes
September 27, 2016 12:30 pm

1) Welcome and Roll Call

Judy Morgan welcomed everyone to the meeting. This was a rescheduled time, an hour earlier than normal, due to the Chair's availability. In the absence of a quorum, minutes of July 26 and August 8, 2016, were approved by acclamation. Attendance is recorded in Attachment A.

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2) Standards Review SOP 3-106

The previous revision (May 25, 2016) addressed comments from the Consensus Standards Development Program but had neglected to address several specific points about the definition of "suitability" from Policy Committee, so one more revision was needed. David moved and Kristin seconded to approve the revised version with the voting process to conclude by email after the meeting.

NOTE: Five "yes" votes were cast during the meeting, with four additional "yes" votes cast by email, concluding at the end of the following day. There were no nays and no formal abstentions, but five committee members did not respond to the request to vote by email. The revision of September 27, 2016, is approved.

3) Status of Standards Review

The recommendations to accept the remaining standards documents (PT/V1M1&V2M2, QS/V1M2, LOD/LOQ, Chemistry/V1M4, and Microbiology/V1M5) were delivered to the NELAP AC at its June 6 meeting. Asbestos/V1M3, Rad Chem/V1M6 and WET/V1M7 recommendations were previously accepted by the AC.

The AC's vote to accept those June recommendations from LASEC was initiated at conference but delayed for a week until the Expert Committee sessions could make their presentations and Council members returned home. The vote concluded on August 29, with the recommendation to accept V1M4 being rejected with one AB noting a "show-stopper" (but not a veto vote) and the recommendation to accept V1M1 barely passing but with a "show-stopper" comment. V1M2 and V1M5 passed with only "yes" votes; there were too few votes on the LOD/LOQ document for validity, but that section is considered to be included within the Chemistry module (V1M4).

At its September 6 meeting, the NELAP AC discussed its collective objections to V1M4/Chemistry and V1M1/PT, with Jerry Parr and Judy participating. The summary of that discussion (taken from draft AC minutes) is in Attachment C, below.

<u>V1M4 Chemistry</u>

Judy asked Kristin (as the only AB on the call at that point) to discuss the Council's objections to V1M4, the Chemistry Module. The biggest problem is the requirement that MDL = 3*LOQ. 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.

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.

Judy noted that it's not clear how to proceed, since the solution is not immediately obvious. After some discussion, the best approach seems to be to write up the Council's concerns as clearly as possible, submit that to the Chemistry Expert Committee, and then engage in conversation(s) as they wish to further help with understanding why the issues are critical. It looks like the next Chemistry committee meeting will be Friday afternoon, October 7, so perhaps LASEC members and Judy could join the Chemistry committee then. There is some urgency to resolve this, beyond the AB's adopting the standard, since labs are already beginning to upgrade their quality systems to the new standard.

V1M1 Proficiency Testing

For V1M1, the PT module, the issues are less complex. The "show-stopper" for one AB is the definition of AB that does not exclude non-governmental ABs, but a suitable definition exists in Volume 2, so that the V1 definition can just be deleted with no harm. The other issues can be returned to the PT Expert Committee to determine how best to resolve them. These are the need to clarify the role of ABs and how they score PTs by either method or technology, and the need to relate "successful participation" in a PT with attaining "acceptable score" on the PT, since successful participation is more than just the scoring.

4) Draft Policies

The draft on-site assessment policy was discussed in the session at conference, and will be up for consideration at the October LASEC meeting, for possible revisions.

A first draft of the prep method policy is available and will be distributed for discussion at the October meeting, also. As we realized at conference, these two policies will need to be developed in tandem, since selecting and assessing methods will need to include the prep methods, whether they are reviewed as separate methods or as part of the determinative method package.

Carl moved and David seconded to adjourn the meeting.

5) Next Meeting

The next scheduled teleconference meeting would be Tuesday, October 25, 2016, at 1:30 pm. Teleconference information and an agenda will be sent ahead of time.

Action Items are included in Attachment B.

Attachment A

PARTICIPANTS --TNI LABORATORY ACCREDITATION SYSTEMS EXECUTIVE COMMITTEE

	NAME	EMAIL	TERM, End Date	INTEREST	AFFILIATION	S/H CATEGORY	PRESENT
1	Judy Morgan, Chair	Judy.Morgan@pacelabs.com	3 years, 12/18	Chair (all)	Pace Analytical	Lab/FSMO	Yes
2	JoAnn Boyd	jboyd@swri.org	3 years, 12/16	StdsRev	Southwest Research Inst.	Lab/FSMO	No
3	Kristin Brown, Vice Chair	kristinbrown@utah.gov	2 years, 2/17	SIRs/Assmt Forum/FAQ	UT Bur. of Lab Improvement	NELAP AB	Yes
4	David Caldwell	david.caldwell@deq.ok.gov	2 years, 12/17	Assmt Forum	OK DEQ	Non-NELAP AB	Yes
5	Karen Costa	Costa.Karen@epa.gov	3 years, 12/17		US EPA	Other	No
6	George Detsis	george.detsis@eh.doe.gov	3 years, 12/17	Assmt Forum	US DOE	Other	No
7	Barbara Escobar	Barbara.Escobar@pima.gov	3 years, 12/18	Mentor, AssmtFrm, FAQ	Pima County, AZ	Lab/FSMO	no)
8	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	No
9	Myron Gunsalus	ngunsalus@kdheks.gov	3 years, 12/18	KS DHE	KS Lab Director	NELAP AB	No
10	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	No (Tyler Croteau attended for info purposes)
11	Carl Kircher	carl.kircher@doh.state.fl.us	3 years, 12/18	SIRs, FAQs	FL DOH	NELAP AB	Yes
12	Dorothy Love	dorothylove@eurofinsus.com	3 years, 12/18		Eurofins Env't'l	Lab	Yes
13	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	No
14	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	Yes
Ex Officio							
	Elizabeth Turner	eturner@ntmwd.com		Ex Officio	Small Lab Issues	North TX Mun. Water District	No

Associate Members							
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	no
	Carol Barrick	cabarrick@msn.com, Carol.Barrick@mosaicco.com			FCC Environmental	Lab/FSMO	No
	Kirstin Daigle	Kirstin.daigle@testamericainc.com			TestAmerica	Lab	No
	Carol Haines	bio.haines@gmail.com		Stds Rev, ad hocs	Retired from EPA as of 5/1/15	Other	No
	Harold Longbaugh				Houston Lab	Lab	No
	Christelle Newsome	cnewsome@c2nassociates.com			C2N Associates, Inc.	Other	No
	Carol Schrenkel	CSchrenkel@suburbantestinglabs.com		Mentor, Ass. Forum		Other	No
	Nick Straccione	nicholas.straccione@sgs.com			SGS	Lab	Yes
	Gale Warren	ggw01@health.state.ny.us		SIRs	NY ELAP	NELAP AB	No
Program Admin. Lynn Bradley		Lynn.bradley@nelac-institute.org					Yes
Guests							

Attachment B

Action Items – LAS EC

	Action Item	Who	Expected Completion	Actual Completion / Comments
61	Review final modules of 2016 Standard	Individual committee members per 6/28 minutes	Conclusion of full V1 review on hold pending resolution of AC issues with V1M4 & V1M1	Working to resolve concerns that led to AC rejection of individual module recommendations to accept
62	Request status update on reviews	Judy	open	
63	Distribute draft policies	Judy	After September meeting	On-site assessment policy draft discussed at conference. Prep method policy draft distributed in early October
64	Update SOP 3-106 with "lessons learned" once the 2016 standard is in place	LASEC	"parking lot issue" open	Particularly, add review of committee decisions about non-persuasive comments
65				

Attachment C

Excerpt from DRAFT 9/6/16 NELAP AC Minutes
Discussion of What's Needed to Resolve Outstanding Objections to Final Versions of V1M4 and V1M1

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.

[three paragraphs not relevant to Chemistry Module omitted]

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.

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.)