Laboratory Accreditation System Executive Committee Meeting Minutes
October 25, 2016 1:30 pm

1) Welcome and Roll Call

Judy Morgan welcomed everyone to the meeting. Discussion began without a quorum but several members arrived in time to participate in the voting and most of the discussion. Minutes of September 27, 2016, were approved. Attendance is recorded in Attachment A.

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2) Technical Clarifications to the PT Module, V1M1

After the September LASEC meeting, the concerns (as identified in Attachment 3 to the September 27 minutes and also in the LASEC Recommendation that is Attachment 3 of these minutes) were conveyed to Shawn Kassner, Chair of PT Expert Committee, and Ken Jackson, the Program Administrator supporting that committee. Judy and Shawn met by teleconference (with Ken and Lynn present) on October 10 to discuss the concerns presented, and explore possible solutions. The PT Expert Committee met on October 21 and approved a few technical clarifications to V1M1, for presentation to the NELAP AC in hopes that its concerns would be fully addressed.

Judy reviewed those edits with meeting participants, and while there was some discussion that perhaps the explanatory notes added were excessive, participants agreed that the AC's expressed concerns were addressed with clarifications that do not change the standard itself. A motion from Carl to approve the recommendation (see Attachment 3) and forward it to the NELAP AC received eight "yes" votes (a unanimous approval.) This recommendation will be presented to the NELAP AC at its November 7 meeting with Judy and Shawn present to discuss any questions the AC might have.

3) Technical Clarifications to the Chemistry Module, V1M4

Similarly, the AC's concerns were conveyed to Margaret "Val" Slavin, the new Chair of the Chemistry Expert Committee, and Ken Jackson, its Program Administrator. These concerns were in Attachment 3 of the LASEC September 27 minutes.) Judy, Val, and Richard Burrows, plus Lynn, met by phone on October 14 to discuss the concerns presented and explore possible solutions. The Chemistry Expert Committee met on October 21 and approved several technical clarifications for V1M4 as well as an explanatory document for the issue that the Chemistry committee feels cannot be addressed without reopening the standard.

The AC's objections were 1) the requirement that LOQ = 3*MDL, 2) consistency issues with the definition of MDL, 3) lack of specificity about whether MDLs must be calculated for each instrument and 4) conflict between initial and ongoing verifications of LOQ.

Judy walked through the proposed changes and moderated discussion about them, as follows:

<u>MDL definition</u>
The Chemistry committee opted to change terminology and use the term "detection limit (DL)" in place of both Method Detection Limit (MDL) and Limit of Detection (LOD), throughout the module. This change does seem to resolve the consistency issues

noted, but participants pointed out that “detection limit” is nowhere defined, and thus a definition should be added to the Quality Systems module (V1M2) which is referenced for all definitions in V1M4.

Initial/Ongoing Verifications of LOQ

The chemistry committee added clarifying language to §1.5.2.1.1.c, that the determination be performed “on each applicable instrument.” Participants understood this edit in different ways – some that it meant running seven replicates across the total number of instruments used for the particular method while others believed it would require running seven replicates on each instrument used for the method on multiple days, and still another possibility would be to run seven replicates on one instrument and simply verify the result on other instruments, unless there would be an outlier instrument with a different detection limit.

Commented [j1]: This section is determination of the MDL. Section 1.5.2.1.2 addresses verification.

The consensus of participants was that the proposed technical clarification does not result in clarifying the section but rather in additional confusion, and would likely result in all labs running seven replicates on each instrument, a significant burden, in order to accurately capture the detection limit variability across the instruments. The only thing that is clear is that some form of detection limit must be established for each instrument but that perhaps it would be up to the lab to define how that should be accomplished.

NOTE: After the meeting, one participant provided language from the 2015 EPA Method Update Rule, that seems to be a possible source for the reworded language of the standard: “MDLs that represent multiple instruments: if a laboratory uses MDL values that represent multiple instruments, then the laboratory would be required to calculate the MDL using spiked samples and blank samples from all of these instruments. Currently, laboratories can run all of their MDL samples on the most sensitive instrument, and then use that MDL for other instruments. This modification will make the MDL more representative of the laboratory’s actual capability.”

LOQ = 3XMDL

The Chemistry committee added a phrase to the third sentence of §1.5.2.2 and also to the final sentence of §1.5.2.2.1.c, “unless otherwise specified by mandated program or method.” The AC’s issue with this requirement in the new standard was that it might put labs in a position where, with a drinking water method, meeting the mandated LOQ would require pushing the MDL impossibly low, or alternatively, the achievable MDL would force the LOQ too high to comply with the regulatory method.

One participant noted that Appendix B of the proposed Method Update Rule (from the February 19, 2015 Federal Register proposing changes to 40 CFR Part 136) includes the 3x as one of the options in the definition of “minimum level” and another noted that EPA Region 6 specifies for its NPDES permits that the LOQ must equal 3x MDL.

Consensus of participants was that adding the phrase “mandated program or method” does not provide an acceptable exception to address the potential problem created by the 3x requirement.

Ongoing Verification of LOQ

The AC objected to having only qualitative criteria for the ongoing LOQ verification, in §1.5.2.2.2, and believes that quantitative criteria should be set, as with the initial verification. Both in the conversation between the committee chairs and then in a

document, “Response to the AC” provided after the Chemistry committee meeting, the Chemistry committee argues that there are insufficient data to allow setting reasonable limits for the ongoing verifications, and thus that qualitative limits are the only viable option. Notably, at this point, setting quantitative limits would require re-opening the standard as an Interim Standard that would require a re-vote. The Chemistry committee declined to make any changes to this portion of the module.

Committee Conclusion
Based on the reasoning described in this section of the minutes, participants declined to forward a recommendation to accept the proposed changes to the NELAP AC. Rather, participants would like Val and Richard, as the Chemistry committee representatives, to meet with the AC at its November 7 meeting to discuss these problematic issues and see whether some acceptable solutions can be found through further conversations. Participants recommend that a summary of the LASEC’s review of the proposed technical clarifications offered by the Chemistry committee be provided to the AC, along with all of the materials reviewed by LASEC – the draft revisions, the response to the AC and multiple data tables illustrating that inadequate information is available to set quantitative limits for the ongoing LOQ verifications.

Additional Item
One participant also noted that the example in §1.5.2.1 of not requiring that a DL be determined when no spiking solution is available, such as for total suspended solids, is inappropriate since there is an LCS available for that analyte that can be used. This information will be forwarded to the Chemistry committee as a “parking lot” issue for the next revision of V1M4.

Carl moved and David seconded to adjourn the meeting.

5) Next Meeting

The next scheduled teleconference meeting would be Tuesday, November 21, 2016, at 1:30 pm. Teleconference information and an agenda will be sent ahead of time.

LASEC may need an additional meeting following the November 7 NELAP AC meeting to further address issues about one or both of the revised modules, but nothing was scheduled at the end of the October 25 meeting.

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	Yes
7	Barbara Escobar	Barbara.Escobar@pima.gov	3 years, 12/18	Mentor, AssmtFrm, FAQ	Pima County, AZ	Lab/FSMO	Yes
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	Yes
10	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	No
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	No
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 October meeting – these will be addressed as time permits, once concerns about standard are resolved	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 and examine timing of multiple reviews in light of SOP 2-100 restrictions
65				

Attachment C

Approved Recommendation to NELAP AC about V1M1

Recommendation of LASEC to NELAP AC
TNI Standard V1M1, Proficiency Testing, technical clarifications to final version approved April 2016
APPROVED BY LASEC October 25, 2016

The LASEC has reviewed the edited Proficiency Testing Module V1M1 as revised and approved by the PT Expert Committee at its October 21, 2016, meeting and recommends that the NELAP AC find the edits in the accompanying redline version to be acceptable for addressing the objections identified during its August 2016 vote on LASEC's earlier recommendation.

The problems with the 2016 final version of this module and the PT Expert Committee's proposed resolutions follow:

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."*