Laboratory Accreditation System Executive Committee Meeting Minutes
November 22, 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 October 25, 2016, were approved. Attendance is recorded in Attachment A.

.

2) Update on SIRs

There has been no SIR activity in LASEC for several months. A few new SIRs have arrived and been evaluated and sent to the appropriate expert committees, but there are no reviews of responses or re-reviews of NELAP AC comments; four SIRs were approved and are now posted to the TNI website (http://nelac-institute.org/content/NELAP/interpret.php).

3) Standards Review

a) The LASEC Standards Review for Suitability SOP 3-106 has been formally endorsed by the TNI Board of Directors.

b) Technical Clarifications to the Chemistry Module, V1M4

During this November 22 meeting, participants reviewed the revisions to the technical clarifications that the Chemistry Expert Committee submitted to the NELAP AC immediately prior to the AC's November 7 meeting. During that NELAP AC meeting, the revised technical clarifications were not discussed, but only the suggested need to re-open the standards revision process to accommodate the AC's objections to having only qualitative criteria for the ongoing verification of the LOQ. The summary of LASEC's review of the revised technical clarifications follows below. The previous conclusions about the technical clarifications are summarized, with a description of the further revision and the LASEC's current conclusions.

- The term MDL brought confusion due to its use in other parts of the environmental testing industry as different meanings. It was changed to DL (detection limit) throughout V1M4, and this technical clarification was deemed adequate on October 25. DL is already defined in the 2016 standard, V1M2, but not in the 2009 standard.

- LOQ = 3XMDL -- Chemistry committee initially 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" as a technical clarification that would avoid situations where labs could not meet the regulatory LOQ requirement since the MDL thus required would be impossibly low. On October 25, 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.

The Chemistry committee revised that technical clarification to read, instead, "If a LOQ is determined in accordance with drinking water method requirements this requirement is waived." This sentence was added to §1.5.2.1.3, §1.5.2.2 and §1.5.2.2.1.c.iii. LASEC participants expressed concerns that calling out one specific program for exception might be problematic, and that some methods only specify reporting limits, and also that reported data may be qualified for any methods except drinking water monitoring for regulatory compliance (where qualified data may not be reported.) Also, the monitoring of drinking water for unregulated contaminants uses an entirely separate methods.

The situation is further complicated by an anticipated requirement in the soon-to-be-published EPA Method Update Rule (MUR), for 40 CFR Parts 136 and 141, which will incorporate the "3x" factor, so that such a waiver would be invalidated by the regulation. Such a regulatory conflict (between the actual analytical reality and the requirement imposed by a new regulation) could not possibly be resolved in the TNI standard. NOTE: Judy did considerable research on this issue, and was able to establish that Part 141 refers to Appendix B of Part 136, which does mention the "3x" requirement but in terms of reporting limits rather than LOQ. She was also able to establish that inclusion of the 3X factor in the upcoming final MUR is uncertain. (The proposed Method Update Rule from February 19, 2015, Federal Register was originally planned for final publication, several months ago, but remains "pending.")

The consensus of the discussion was that LASEC believes that this revised wording does not solve the problem. The final recommendation provided to the NELAP AC and the Chemistry Expert Committee (see Attachment C, below) asks that the Chemistry committee please reconsider, using phrasing that clearly states that method requirements must be followed even when that violates this section of the standard, and that compliance with this portion of the standard may not always be possible. Where federal regulatory limits are very low and qualifiers are not allowed, the standard should allow this flexibility.

- The wording for initial verification of LOQ was unclear, whether the seven replicates were to be performed on each instrument or just seven replicates performed on the total number of instruments available to the lab. The rephrasing to require performing DLs "over multiple days on each applicable instrument" appears to be sufficiently clear.

- A new edit was added to the November 7 version of V1M4, so that §1.5.2.2.1.c.ii now reads "[(c.) The LOQ is verified if the following criteria are met:] (ii.) Average recovery of each analyte is within the laboratory established accuracy acceptance criteria." It is unclear what "average recovery" means or why this change was made, but it requires additional clarification to be meaningful.

  NOTE: It was agreed in the meeting that Lynn would draft language summarizing LASEC's discussions, and Judy would review and clarify it, and that the language would be circulated to committee members for a quick turnaround review. However, as it played out, Judy's research took far longer than anticipated, and there was no time for committee review before the results of LASEC's review needed to be distributed to the NELAP AC. To further complicate matters, once the LASEC

recommendations were distributed to the NELAP AC, the Chemistry committee immediately provided a re-revised version of V1M4, essentially making LASEC's efforts an exercise in playing catch-up. The Chemistry committee has expressed the belief that its negotiation now is exclusively with the NELAP AC, until language agreeable to the AC is agreed upon.

c) Technical Clarifications to the PT Module, V1M1

Time ran out and participants agreed to address the revisions to this module, made to address the AC's concerns as discussed at the AC's November 7 meeting are satisfactory. See material from those minutes in Attachment D, below.

5) Next Meeting

The next scheduled teleconference meeting would be Tuesday, December 20, 2016, at 11:00 am. This rescheduling was agreed upon to avoid meeting during the "holiday week" of December 26-30, when many members are likely to be out of the office. 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	Yes
10	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	Yes
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	No
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		Vanessa Soto, vanessa.sotocontreras@flhealth.gov					

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		ongoing	
63	Distribute draft policies	Judy	these will be addressed as time permits, once concerns about standard are resolved	Possible discussions at conference
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	Review and approve new recommendation to NELAP AC to approve technical clarification revisions to V1M1, provided by PT Expert Committee Chair to LASEC Chair on Nov. 22, 2015	LASEC	By email, ASAP – in time for December 12 NELAP AC meeting?	Revised module and revised draft LASEC recommendation sent December 4, 2016

Attachment C – distributed to NELAP AC for its December 5 meeting

LASEC Consideration of Second-Round Technical Clarifications to the Chemistry Module (V1M4)
December 2, 2016

At its November 7, 2016, meeting, the NELAP Accreditation Council (AC) included the former and current Chemistry Expert Committee Chairs as well as the LASEC Chair, Judy Morgan. Immediately prior to that meeting, the Chemistry committee had provided this "second-round" revisions the technical clarifications to V1M4 to the AC, but the only issue discussed by the AC was the one considered to need a formal revision to the module, specifically the qualitative-only criteria for ongoing verification of the LOQ. LASEC undertook a review of these "second-round" revisions to see whether they addressed the concerns as documented in the minutes of the October 25 LASEC meeting. The previous conclusions about the technical clarifications are summarized below, with a description of the further revision and the LASEC's current conclusions.

1. The term MDL brought confusion due to its use in other parts of the environmental testing industry as different meanings. It was changed to DL (detection limit) throughout V1M4, and this technical clarification was deemed adequate on October 25. DL is already defined in the 2016 standard, V1M2, but not in the 2009 standard.

2. LOQ = 3XMDL -- Chemistry committee initially 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" as a technical clarification that would avoid situations where labs could not meet the regulatory LOQ requirement since the MDL thus required would be impossibly low. On October 25, 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.

   The Chemistry committee revised that technical clarification to read, instead, "If a LOQ is determined in accordance with drinking water method requirements this requirement is waived." This sentence was added to §1.5.2.1.3, §1.5.2.2 and §1.5.2.2.1.c.iii. LASEC participants believe that calling out one specific program for exception is problematic, but after extensive discussion and post-meeting research by the Chair, LASEC is unable to identify a satisfactory way to allow exceptions for those drinking water methods that specify some other conditions for establishing the DL, LOQ or reporting limit. We note also that drinking water compliance results may not be reported as qualified data. 40 CFR Part 141 directly references the use of 136 Appendix B in multiple places but with no requirement for numerical relationship between reporting and detection, laboratories are able to meet the reporting requirements through calibration regardless of how near the value is to the DL. We need language that allows labs to meet the reporting limit without violating the 3X requirement of the standard.

   The situation is further complicated by anticipated requirements in the soon-to-be-published EPA Method Update Rule (MUR), for 40 CFR Parts 136 and 141, which will incorporate the "3x" factor, so that such a waiver would be invalidated by the regulation. Such a regulatory conflict (between the actual analytical reality and the requirement imposed by a new regulation) could not possibly be resolved in the TNI standard.

   LASEC believes that this revised wording does not solve the problem and asks that the Chemistry committee please reconsider, using phrasing that clearly states that method requirements must be followed even when that violates this section of the standard, so that compliance with this portion of the standard may not always be possible. Where federal regulatory limits are very low and qualifiers are not allowed, the standard should allow this flexibility.

3. The wording for initial verification of LOQ was unclear, whether the seven replicates were to be performed on each instrument or just seven replicates performed on the total number of instruments available to the lab. The rephrasing to require performing DLs "over multiple days on each applicable instrument" appears to be sufficiently clear.

4. A new edit was added to the November 7 version of V1M4, so that §1.5.2.2.1.c.ii now reads "[(c.) The LOQ is verified if the following criteria are met:] (ii.) Average recovery of each analyte is within the laboratory established accuracy acceptance criteria." It is unclear what "average recovery" means or why this change was made, but it requires additional clarification to be meaningful.

Attachment D

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

Attachment 2 of draft NELAP AC Minutes for November 7, 2016, meeting

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.”

NOTE additional text from AC minutes:

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.