Laboratory Accreditation System Executive Committee Meeting Minutes
February 4, 2015 – Forum on Lab Accreditation, Arlington, VA

Judy Morgan welcomed everyone to the meeting and shared an introductory presentation about the committee's mission and membership, its accomplishments, and the agenda for the session at conference. She reflected on the history of both the Assessment Forum and the Mentor Session, noted the committee's role in reviewing standards and the successful elimination of the backlog of Standards Interpretation Requests (SIRs.) She also introduced the new Standards Implementation Guidance (SIG) documents that will offer supplemental information about questions submitted as SIRs that do not actually warrant an interpretation but could benefit from clarity about how to implement or apply the standard.

1) Discussion of SIGs

Judy explained that one of the SIGs turned out to have more than one way to read the submission, so that it was reversed and sent back into the SIR process, after all. Two SIRs on the same topic were combined (276 and 281) were discussed at length with participants actively engaged in how the standard's requirement that a lab have a procedure for verifying the concentration of titrants can be used to address titrants where the result is part of the analytical calculation as well as those where the titrant's purpose is solely to remove an interfering ion from the analytical reaction. The points made during discussion are captured below, and the question itself will be submitted to the Chemistry Expert Committee for interpretation as a SIR, with the request for a single answer applying to both SIRs.

- ISO requires that all interpretation requests be answerable with either yes or no.
- ISO participants are presently discussing the definitions of "validation" and "verification."
- In preparing an interpretation, the Expert Committee is asked to only state the meaning of the cited section of the standard. Any discussion of intent of the standard or rationale behind the interpretation should be captured in the committee minutes, and may (or not) be included in the Committee Comment section, but is inappropriate for the Response to the submission.
- The interpretation may not expand the standard in any way.
- A "response to comments" document from the standards development process may be helpful in the "paper trail" of reasoning behind an interpretation.
- Is there any place for assessor discretion? 1) Labs and assessors have widely varying levels of experience; 2) the standard should be clear so that an assessor has no need to use discretion; 3) the tightrope between flexibility and prescriptiveness is difficult when writing a standard.
- Labs want and need consistency. If a new assessor makes a finding about something considered acceptable by previous assessors, does that call all previous data (results) into question?
- Regarding the SIR *vs.* SIG purpose, can we describe a suitable policy for a lab (in this instance, about titrants) that would help with consistency?
- TNI sometimes uses terminology from ISO in ways that have different meanings to the environmental community. A preference to utilize the original ISO meaning would be useful.
- Providing examples in SIGs borders on offering consultancy. Examples are more appropriate in the Assessment Forum.

2) Discussion of Standards Review for Suitability SOP 3-106 – What is "Suitable?"

Judy opened this part of the session with an explanation of LASEC's role in review of developing standards, and a broader description of the evolving consensus standards development process, and the SOPs that describe those processes. The Consensus Standards Development Executive Committee is finalizing its SOP 2-100, to include some changes required from the 2014 ANSI audit of our process. Once that SOP is final, then LASEC can finalize its SOP 3-106.

We expect that the significant changes to both SOPs, from a broad TNI perspective, to be first, early involvement with the standards being revised through webinars and expanded committee participation by AB representatives as associate members on the various expert committees, and second, in-depth review by LASEC of the Voting Draft Standard (VDS) for each module being revised, rather than waiting to review the entire package (all modules at once) as has happened previously. The idea is to be able to submit meaningful comments at the VDS stage, while revisions can still be made to the modules.

Additionally, once the individual modules are finalized by the expert committees, LASEC will perform one last review, and make one of three possible recommendations to the NELAP AC. The choices are 1) to recommend adoption, 2) to recommend adoption once specified policies, SOPs and guidance are prepared, or 3) to recommend adoption after specified changes are made. If early reviews are thoroughly performed, the third option should never be needed. LASEC would take responsibility for drafting any policies, SOPs or guidance that might be needed.

Separately as part of the Consensus Standards Review Executive Committee's process, there will be a Standards Review Council that reviews the individual standards (and the full package) for clarity, formatting and internal consistency but not technical content. This essential role was previously accomplished by LASEC, by default. This review begins once the comment period for the VDS closes, and continues until complete.

Judy led the LASEC and meeting participants in an intense discussion of "what is suitability" – what criteria should actually guide the LASEC in its review – and the converse, what would be "unsuitable." Comments are captured below, followed by a list of terms for applying the "suitable" decisions.

- ISO requires that laboratories review their policies for determination of "suitable for use" – this might be one criteria.
- One commenter offered auditable, consistent with prevailing rules (implementable), enforceable, clear (understandable) and if the standard is not presently implementable, is it reasonable to expect that regulations can be modified to make that possible.
- Is the revision an improvement – easier to understand, better for data quality, affordable – or is it merely different?
- In addition to being clearly written and easily understandable, the revision should be amenable to only one interpretation, and more efficient to use.
- A request was made to eliminate the passive voice, since that leaves unstated which party is responsible for doing the action required. (Consensus was that the revisions are too far along, for the 2015 standard, but this should be adopted for the 2020 revisions.)

- One piece of evidence that the new standard is an improvement will be fewer SIRs submitted.
- Training for both labs and ABs will be needed, to explain the differences in the new standard.
- Several third party assessors expressed concern that the AC might have three standards being implemented all at the same time, since there are presently two and it is not certain that all states will be able to move away from the 2003 NELAC standard in the next 2 years.
- One measure of improvement in the standard would be better quality and defensibility of the analytical data produced by labs. More discussions about what "improved" means should occur, both during the comment periods and within the Accreditation Council.
- Some changes to the standard might impact non-NELAP state certification bodies, since a number of those either recognize NELAP accreditation or incorporate parts of the standard into their programs. It's not clear how to obtain input from those groups, but a negative impact to them would absolutely be counterproductive to our goal of a national program, and only ten states do not mention TNI or NELAP in their regulations. Some consideration of using "TNI ambassadors" as raised in the Advocacy Committee's "Future of National Accreditation" workshops may help with this aspect. Another option offered was to work with the APHL State Assessor Forum.
- Problems with the PT portion of the 2009 standard need to be resolved with this 2015 revision, without any additional costs being passed from PT providers to labs.
- All revised standards still need to be consistent with, or at minimum, not in conflict with, existing federal regulations.
- Several more general comments were about TNI promoting states to utilize lab certification for media other than drinking water, and also to market accreditation to "data users" instead of just to labs.

The list of terms offered for describing "suitability" follows:

- Auditable
- Implementable
- Understandable
- Improvement over previous version
- Clearly written -- only one possible interpretation of the language
- Enforceable
- Clearly defined responsibilities
- Economically advantageous to labs and/or ABs

3) Next Meeting

The next meeting of the LAS EC will be on Tuesday, February 24, 2015, at 1:30 pm Eastern. Teleconference information and an agenda with any other materials will be sent the week before.

Action Items are included in Attachment B.

Attachment A

PARTICIPANTS --TNI LABORATORY ACCREDITATION COMMITTEE

	NAME	EMAIL	TERM, End Date	INTEREST	AFFILIATION	S/H CATEGORY	PRESENT
1	Judy Morgan, Chair	JMorgan@esclabsciences.com	3 years, 12/15	Chair (all)	Environmental Science Corp.	Lab/FSMO	Yes
2	JoAnn Boyd	jboyd@swri.org	3 years, 12/16	StdsRev	Southwest Research Inst.	Lab/FSMO	No
3	Kristin Brown	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	George Detsis	george.detsis@hq.doe.gov	3 years, 12/17	Assmt Forum	US DOE	Other	Yes
6	Barbara Escobar	Barbara.Escobar@pima.gov	3 years, 12/15	Mentor, AssmtFrm, FAQ	Pima County, AZ	Lab/FSMO	Yes
7	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	Yes
8	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	No
9	Betsy Kent	bkent@rcid.org	3 years, 12/15	Mentor Sessions	Reedy Improv. District, FL	Lab/FSMO	No
10	Carl Kircher	carl_kircher@flhealth.gov	3 years, 12/15	SIRs, FAQs	FL DOH	NELAP AB	Yes
11	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	No
12	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	No
13	Kim Sandrock	Kim.Sandrock@state.mn.us	3 years, 12/15	Training	MN ELAP	NELAP AB	Yes
14	Carol Schrenkel	CSchrenkel@suburbantestinglabs.com	3 years, 12/16	Mentor, Ass. Forum		Other	No
	Elizabeth Turner	eturner@ntmwd.com		Ex Officio	Small Lab Issues	North TX Mun. Water District	No

Associate Members							
	Aaren Alger	aaalger@state.pa.us			PA DEP	NELAP AB	No
	Carol Barrick	cabarrick@msn.com, Carol.Barrick@mosaicco.com			FCC Environmental	Lab/FSMO	No
	Myron Gunsalus	ngunsalus@kdheks.gov			KS Lab Accred.	NELAP AB	Yes
	Carol Haines	haines.carol@epa.gov		Stds Rev, ad hocs	EPA Region 10	Other	No
	Christelle Newsome	cnewsome@c2nassociates.com			C2N Associates, Inc.	Other	No
	Gale Warren	ggw01@health.state.ny.us		SIRs	NY ELAP	NELAP AB	No
Program Admin. Lynn Bradley		Lynn.bradley@nelac-institute.org					Yes

Attachment B

Action Items – LAS EC

	Action Item	Who	Expected Completion	Actual Completion / Comments
24	Consolidate "clarifications" for approval and circulate to LAS members	Judy	September 2014	Nine "implementation guidance" documents approved 10/28/14 – awaiting posting to website
26	Formally re-transmit SIR SOP 3-105 and Standards Review SOP 3-106 to Policy Committee for final approval	Lynn	August 2014	Both SIRs plus the NELAP Standards Review and Approval SOP 3-103 are now final
28	Draft language to provide to Chemistry Committee about "remove and replace" for points in a calibration curve, in the Calibration IS.	Judy, with input from committee members	October 1 – draft circulated 10/25/14	Language sent. Awaiting full "response to comments" document from CEC
30	Talk with CSD EC Chair and Program Administrator about process revisions. Specific issues are: 1 -- permit adequate time for LAS EC to review upcoming standards revisions 2 – build in that time at a stage when changes can still be accomplished to address problematic language 3 – consider whether to handle TNI committee reviews of developing standards in some parallel process that may allow either additional time or additional weight for those comments, or both	Judy/Lynn	Prior to October LAS meeting , hopefully at Strategic Planning session	Conversations held. Small workgroup appointed by CSD EC, includes both Judy and Aaren, to address needed revisions to both the CSD and LAS SOPs governing standards development and review. Workgroup to review CSDEC revisions, and approve final draft SOP during February.
32	Review/revise POL 3-100 for recommendation to AC	Workgroup led by Judy	Fall 2014	Approved by LASEC for AC review
36	Ask Christelle if she can review the WETT module (V1M7)	Lynn	December 2014	Christelle agrees to participate in review and awaits further info after January meeting
38	Collect AB reviews of new Implementation Guidance documents and complete former SIR 262 draft	Judy and workgroup	January 2015	2 documents approved for posting, will be sent to webmaster.

				Former SIR 262 to be discussed at conference.
39	Talk with Aaren and Carl about possible NELAP policy concerning third party assessor qualifications	Judy	January 2015	At conference?