

Summary of the NELAP Accreditation Council Meeting

June 16, 2014

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EST on Monday, June 16, 2014. The minutes from June 2 were approved. Those members in attendance are listed in Attachment 1.

On June 2, plans were not to hold the June 16 call, but an issue arose that needed the Council's attention, so it was convened after all. Some members had already committed elsewhere for the time.

2. Action Items Pending

- Review and approve Policy Committee-recommended revisions to the NELAP Evaluation SOP 3-102

3. Calibration Interim Standard

Aaren briefly described the events leading to this AC meeting. During the June Board of Directors meeting, the possibility arose that states needing to adopt each standard by rulemaking are considering skipping the 2009 TNI Standard and must wait another year to begin rulemaking to adopt the 2015 version. This discussion led to the fact that rulemaking requires a detailed review of the standard, which led Aaren to mention her objections to the Calibration Interim Standard (IS) as well as the current PT Voting Draft Standards (VDSs) based on parts of the language as written containing phrasing that cannot be enforced, and examples that may lead to confusion rather than clarity. Judy Morgan was invited to join the AC for this call, since the LAS EC has equally important review responsibilities for review of revised standards or portions thereof.

The new process as laid out in SOP 2-100 includes Working Draft Standard (WDS,) VDS, then IS and possibly Modified Interim Standard (MIS,) all prior to formal, final approval of a new module or in the case of the Calibration IS, a document addressing a portion of a module, which is done by the Standards Review Council, as one last cross check of all aspects of the document. Only the WDS and VDS provide an opportunity for member comments on any aspect of the document, and the VDS provides opportunity for members to approve or disapprove the document with comments.

The IS is the VDS with persuasive comments from the voting process addressed and incorporated into the IS. Only items modified in response to persuasive comments from the VDS stage may be commented upon in further reviews -- either by the commenter to indicate that the response to comment is acceptable or inadequate, or by others to indicate that the modified language negatively impacts the standard itself.

If the Expert Committee determines that the Interim Standard needs to be further modified,

based on comments received during the IS review period, the next revision is an MIS. If an MIS is created, then the MIS must undergo another vote by the membership before progressing to the Standards Review Council.

NOTE: This is complicated to present, but differs from information provided during the AC meeting, in that there is a voting step if the MIS is created. For clarity, see section 5.4 of SOP 2-100, Provisional, Procedures Governing Standards Development.

Participants then undertook a discussion of the Calibration IS. Points made during that discussion follow.

§1.7.1 – why does this section focus only on average response factor and linear or quadratic regressions? Those are typically used for organic analyses, but the new language seems to make the standard less clear. Commenter suspects that this section was written to address a very specific but unspecified issue, and that it is likely to confuse most laboratories as well as to generate many Standards Interpretation Requests (SIRs.)

§1.7.1.1.d.i & ii – it's unclear why the term instrument was repeatedly deleted.

- For multi-analyte calibration curves, one cannot just remove one point for one single compound, but rather must remove that same point for all compounds in the calibration run.
- The most frequent comment from bench chemists and QA staff asked to review the Calibration IS was that it would be incomprehensible to the average lab technician.
- The language regarding removal of calibration standards is genuinely needed in the standard document, since previously the AB could only advise about that.
- Yes, the intent is good but as written, the language is not clear and not enforceable, so effectively is still only guidance.
- Labs will like the option to replace a standard, for instance if the calibration run was overnight, they can “adjust” the curve rather than repeating the entire calibration.

A few participants offered the opinion that the Calibration IS is an improvement over the prior language in the standard. Still, given the opinion of several participants that the Calibration IS is too difficult to comprehend, discussion turned to how can the NELAP ABs accomplish revisions that will make the Calibration IS workable.

Only 71 TNI members voted on the Calibration IS. Of those, 47 voted affirmative (only 1 with comment) while 21 negative voters offered 158 comments total. The vast majority of comments, 124, were ruled “persuasive.”

Further comments were:

- It has happened in the past that an Expert Committee chose not to advance the status of a standard, after addressing comments, but to move backwards so as to allow more discussion and feedback (Quality Systems Expert Committee about the Quality System Module of Volume 1.)
- One participant who participates in the Chemistry Expert Committee as an Associate Member noted that there were many discussions but none completely settled the issues, and that the language offered in the current version will be difficult to assess against.

- The vagueness of this document resembles the ISO language, where it becomes the responsibility of the lab to include its process in its quality system documentation, and that, indeed, this is far harder to assess.
- Vagueness is impossible to assess, and if an AB can't assess to the standard, the AB cannot enforce the standard once it's incorporated into the state rules and laws.
- One noted, "I am not opposed to more clarity" but that the Calibration IS passages resemble the complexity and vagueness of SW846.
- Perhaps some form of external review after committee approval might be warranted, prior to voting.
- Because regulation writing receives a much different form of scrutiny than standards development, a second review prior to voting may be what the ABs need to obtain a standard that is suitable for governmental, enforceable use.
- Some determination of readiness for vote beyond the approval of the expert committee would be wise, since the experts already understand what they mean to write.

While LAS EC will review each individual standard or portion thereof, sequentially as they emerge from the development process, the AC needs to review and adopt all the pieces comprising the "whole" standard, all at once, for implementation purposes. The reviews of the two groups will necessarily be different.

Judy noted that LAS EC would be discussing the Calibration IS at its meeting the following day, since two teams of committee members were assigned to review the two sections. She committed to providing separate feedback to appropriate groups in TNI as well as raising the issue of having fewer than 5% of members voting. It was noted that, just from the colors of "track changes," more than half the content of the document was revised – a substantial portion.

Aaren will draft a memo from the AC addressing the concerns discussed, and circulate that for comment among the AC members, while noting that the Calibration IS is an improvement but still needs additional clarity. Those present on the call agreed.

Aaren also urged all AC members to please read and vote on the two PT VDS items that are now available.

4. Next Meeting

The next meeting of the AC will be on Monday, July 7, 2014. As Vice Chair, Paul Bergeron will lead this meeting. An agenda and teleconference information will be sent out before the meeting.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve.arms@flhealth.gov	yes
	Alternate: Carl Kircher E: carl.kircher@flhealth.gov	No
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	No
	Alternate: Janet Cruse T: 217-785-0601 E: Janet.Cruse@illinois.gov	No
KS	N. Myron Gunsalus ngunsalus@kdheks.gov 785-291-3162 Fax: (785) 296-1638	Yes
	Alternate: none	
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 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: Susan Wyatt T: 651.201.5323 F: E: susan.wyatt@state.mn.us	No
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	No
	Alternate: TBD	

NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 E: joseph.aiello@dep.state.nj.us	No
	Alternate : Rachel Ellis E: rachel.ellis@dep.state.nj.us	No
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	Yes
	Alternate: TBD	
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	No
	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 Ken.Lancaster@tceq.texas.gov	No
	Ruthie Wedig Ruth.Wedig@tceq.texas.gov	no
UT	Kristin Brown T: (801) 965-2540 F: (801) 965-2544 E: kristinbrown@utah.gov	Yes
	Alternate: Jill Jones T: (801) 965-3899 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	Marvelyn Humphrey T: (281) 983-2140 E: Humphrey.Marvelyn@epa.gov	no
Oklahoma	David Caldwell David.Caldwell@deq.ok.gov	Yes
Guests:	Judy Morgan, Environmental Lab Sciences, Mt. Juliet, TN, and Chair, TNI Laboratory Accreditation Systems Executive Committee JMorgan@esclabsciences.com	