

Summary of the NELAP Accreditation Council Meeting

October 15, 2014

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EST on Monday, October 15, 2014. This was a called “special meeting” to discuss with the LAS EC Chair the interactions with Chemistry Expert Committee (CEC) about comments on the Calibration Interim Standard (IS.) Those members and guests in attendance are listed in Attachment 1.

2. Background

Since there are several new participants in the Council, this information is provided for perspective on the process. This “background” was not explicitly part of the discussion on the teleconference. The SOPs referred to as “provisional” may be most easily found on the relevant committee web pages.

The currently adopted 2009 TNI Standard has at least one item in it that several ABs are unable to implement due to internal state program conflicts with the language. This problem did not become evident until the anticipated “implementation date” (July 1, 2011) came and went, but as a result, a Corrective Action Task Force was created by the TNI Board of Directors, and many changes were recommended (and made) to the Standards Development process. TNI is just now, for the first time, trying out these changes, and the LAS EC is trying valiantly to fulfill its assigned role in reviewing standards for the AC. Another part of discussions with the AC is for LAS EC to learn the AC’s needs and expectations for this review – more specifically than something the labs can follow and the ABs can implement. This learning process will continue with interactions over review of upcoming modules of the standard, in the coming months.

The CEC developed the Calibration IS over the past several years. It represents a significant expansion and clarification of V1M4 sections 1.7.1 and 1.7.2. After the revised version was voted upon by TNI membership (with 71 votes, but an adequate number of committee member votes to pass the standard), there were many comments submitted, and these were addressed through the process of developing the “interim standard” as outlined in the Standards Development SOP 2-100 Rev 2 (Provisional) adopted by the Consensus Standards Development Executive Committee (CSD EC) roughly a year ago.

While this SOP 2-100 has been reviewed and approved by Policy Committee, it became clear that additional revisions would be needed after the ANSI audit of TNI’s consensus standards development program to maintain our certification for that. Those changes will result in another revision cycle once the audit is closed out.

This Calibration IS is the first of the entire series of module revisions for the TNI Environmental Laboratory Sector Standard (ELSS), and LAS EC did not become involved in reviewing this standard until the IS version was released. Shortly after its release, the CEC held a webinar to discuss the further changes. This was the first webinar to be held about a standard revision, although TNI envisions that all future stages of all revisions will be the subject of webinars as a highly effective outreach technique, to engage the TNI membership.

3. Discussion of LAS Executive Committee interactions with CEC

The LAS EC has traditionally been charged with reviewing new standards for the purpose of recommending to the AC whether or not they should be adopted for implementation. Presently, the Standards Review for Suitability SOP 3-106 (Provisional) describes the process, and indicates that the LAS's review will occur either after the Voting Draft Standard (VDS) is approved or at the IS stage.

LAS was in process of reviewing the Calibration IS when the CEC webinar was held, and was firmly advised at that time that only material revised as a result of comments submitted during the voting process was subject to comment, even though a few items were found problematic by the LAS EC that had not been commented upon at the VDS stage. Judy later submitted all of LAS's comments (including those from pre-VDS language) as Committee comments, formally approved by LAS EC. The LAS EC looked for language that was either unclear, difficult to implement and vague enough to be not "auditable" (e.g., words like "reasonable" that require professional judgment are not considered enforceable by state ABs.)

As CEC worked forward to address all comments on the IS, a conference call was scheduled between certain CEC members and available members of the LAS EC. While CEC agreed to provide written response to the LAS's comments, it firmly maintained the position that pre-VDS language could not be addressed.

One of the pre-VDS issues is a statement about data usability, indicating that "qualified data" can be submitted. This appears to be in direct conflict with the US EPA Drinking Water Certification Manual, which states that qualified data is not acceptable to the drinking water program. Despite a phrase elsewhere in the module indicating that programmatic requirements supersede the standard, both LAS EC and some ABs are concerned that the wording in the Calibration IS will be used "as is."

Interactions between CEC and LAS EC have not been smooth, with the LAS EC pointing out that this qualified data issue would be a "show-stopper" and might well prevent adoption of the standard, while CEC maintained that it was not able to change that wording, but would put the issue aside for the next revision of the standard. This stand-off became the genesis for the current teleconference meeting, with Judy Morgan, and we note that two AB representatives are also CEC members – Scott Siders and Gary Ward.

To make the point about how labs will not connect the two separate phrases regarding submitting qualified data and that program requirements override the standard, Aaren explained a recent experience:

I only recently became aware of a serious problem that the PA-DEP is having with NELAP laboratories believing that this clause allows them to report qualified DW data. The PA-DEP met with the PA Association of Accredited Environmental Laboratories' Board of Directors last week to discuss the problem we have with qualified DW data. During that meeting, of which included several NELAP laboratories, the Department was informed that they were all interpreting this section of the standard, along with other parts that talk about data usability, to assume that they did not need to consider any method, program or client requirement and that this section superseded these others.

Aaren also noted that it's quite likely other ABs have labs with similar misunderstandings of the language, that are not yet known, and acknowledged the need to educate the labs, but that clarity in the standard itself is also important. She noted that voting to adopt the language presently in the Calibration IS is indeed problematic, and at least one other AB noted that once a standard gets adopted into regulation, its implementation is more than a philosophical issue, it becomes a legal issue. Another participant noted that, it IS acceptable for a lab to report qualified data to its client (based on contractual agreement) but that neither the lab nor the client may report qualified data to the regulatory agency for drinking water.

4. Negotiating Some Resolution to the Problem as Outlined

With the full explanation above, and an understanding that the source of refusal to revisit pre-VDS language is an SOP 2-100 rather than an actual certification requirement for the CSD program, participants undertook to craft a compromise that would pull the two distant phrases together, in the standard language. The compromise language is as follows, and has already been recommended to the CED by Scott and Gary:

For V1M4, section 1.7.2 f) iii of the IS, add the italicized red-text words and delete the struck-out words – “if samples are analyzed using a system on which the calibration has not been verified, the results shall be qualified. Data associated with an unacceptable calibration verification may be ~~fully useable~~ *reported* under the following special conditions, *unless prohibited by the client, a regulatory program or regulation.*”

NOTE: This request was made to the CEC with an explanation of the gravity of the situation and a plea not to let the revision of the standard be derailed by an unforeseeable glitch in our first time using the new SOP. We await a decision about whether this change will be made, but it is clearly being considered.

5. Additional Discussion

Some further discussion occurred about the additional requirement to calculate and use “relative error/relative standard error” and that allowing labs to set their own criteria for these may be problematic going forward, but this does not seem to reach the level of a vote not to adopt the standard.

Judy asked explicitly what else the AC would like from LAS EC, going forward. Aaren noted that having the full stakeholder perspective is valuable, and that several AB representatives are also on the LAS EC (Bill Hall, Kristin Brown, and David Caldwell.) All agreed that continued interaction around review of future module revisions will help clarify review criteria. A few items that might be requested from the Expert Committees were also raised but nothing was decided.

8. Next Meeting

The next meeting of the AC will be on Monday, October 20, 2014.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve.arms@flhealth.gov	No
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	Alternate: Sara Hoffman shoffman@kdheks.gov	Yes
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	Alternate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes
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NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 E: joseph.aiello@dep.nj.gov	No
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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	Yes
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	Included for information purposes: Scott Hoatson T: (503) 693-5786 E: hoatson.scott@deq.state.or.us	No
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Oklahoma	David Caldwell E: David.Caldwell@deq.ok.gov	No
California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
Guests:	Judy Morgan, Chair, Laboratory Accreditation Systems Executive Committee jmorgan@esclabsciences.com	Yes