Summary of the NELAP Accreditation Council Meeting December 7, 2020

1. Welcome and Introductions

Kristin welcomed everyone to the call. Attendance is noted in Attachment 1. The minutes of November 2 were approved unanimously.

2. V2M1 Draft Standard

The LAB Expert Committee completed and approved its revision of the AB Operations module, V2M1, of the TNI Environmental Lab Sector Standard. This module includes the TNI additional language from both V2M1 and V2M3 of the 2016 TNI Standard, and upgrades the foundational ISO 17011 language from the 2004 to the 2017 version of that ISO/IEC document.

This Draft Standard was published for comment on December 1, 2020, and will remain open for comment for ninety days, with the option of an additional thirty days if requested by the NELAP AC. As Carl chairs the LAB committee, this module is referred to as "Carl's Standard" and represents nearly four years of committee work. The response-to-comments file is also published, documenting how all comments received over that time were addressed during the module's development, and additionally, a document describing the major changes to the module accompanies the publication. The formal public meeting on the Draft Standard will be held during the LAB Committee session of the virtual winter conference, on Wednesday afternoon, January 27, 2021, 2 to 5 pm Eastern

One participant asked that the Council discuss its comments during the January meeting and other participants asked that all requirements included in NELAP policies and SOPs be incorporated into the module itself. This request for incorporation of policy and SOP requirements has been captured as a comment from the NELAP AC, in the current, ongoing response-to-comments file for the V2M1 Draft Standard.

3. Recommendation to Restore Florida to Full Recognition

The Florida Evaluation Team provided a recommendation to remove the provisional status from Florida's recognition as a NELAP AB, restoring it to full recognition. The recommendation documents that both corrective actions were successfully completed and are incorporated into the ongoing practices of the AB. Celeste moved and Cathy seconded that the provisional status be removed and full recognition be restored since all corrective actions are completed. All eleven ABs present voted in favor, and the three remaining ABs voted by email, all in favor of the motion, with the final vote arriving on December 9, 2020.

The TNI website has been updated to remove the note about provisional recognition from Florida's listing as a NELAP AB.

4. Agenda for Conference Session

Lynn explained the logistics of the virtual conference and provided a proposed agenda for the session, as follows:

- Introductions
- Brief Summary of Major Events in NELAP for 2020
 - Leadership transition
 - o Operational adaptations due to pandemic
 - o 2016 Standard implementation
- Q&A/Discussion (could include Draft Standard V2M1?)

There were no requested additions, so this item will be sent to the conference organizers. Lynn will prepare a draft presentation for Kristin's review. In the past, the Council's conference sessions were more informal, with no actual presentation, but for a virtual session, an on-screen presentation seems necessary.

- 5. SIR 387 for Discussion
 - This SIR had multiple discussion requests. The question is about V1M4 §1.7.1.1 and asks "Some instrumentation, such as turbidimeters, spectrophotometers, etc. are purchased and received with an internal calibration performed by the manufacturer. Can these internal calibration be used to calculate test results?"

The Chemistry Committee's response was

"It is recognized that the calibration capabilities and sample analysis applications for this type of equipment varies. Yes, the manufacturer established initial calibration may be used for an accredited analysis if the requirements of V1M4 1.7, the method, and any applicable regulations can be met and documented by the laboratory. If the manufacturer established initial calibration is used to calculate test results the manufacturer shall meet all of the requirements for initial calibration as listed in V1M4 1.7.1.1 and shall provide the accredited laboratory applicable data and records for the calibration in order to meet the requirements of V1M4 1.7.1.1. The laboratory must maintain these records per V1M4 1.7.1.1 b)."

There was also a committee comment that

"The committee believes that a user calibration should always be performed when the instrument has this capability. This was not included in the below response so that additional requirements were not added to the standard. This will be considered in a future revision.

Equipment with manufacturer established initial calibration not meeting these requirements may be used for simplified non-quantitative, non-accredited measurements (e.g. "pocket" instruments, screening, threshold tests) and test results reported with an appropriate qualifier."

Discussion points included the following:

- One AB does not permit pre-programmed calibrations. This was later determined not to warrant a veto vote as an AB may require more stringent requirements than the standard.
- One participant would prefer that the response simply state that record-keeping must meet all requirements of the standard.
- Another participant suggested involving the Quality Systems committee to determine if the V1M2 language about traceability is relevant.
- A participant expressed distress that a lab might be required to create a calibration when an instrument arrives from the manufacturer with calibration data already, and

questioned whether some inst4ruments would even have the capability to perform a manual calibration, while noting that obtaining the detailed information from manufacturers is a daunting challenge, at best.

- One participant would want all information that would be required if an analyst had performed the calibration (including lot numbers of standards, etc.) while another is content to examine the manufacturer's certificate of calibration.
- One participant noted that the section assumes that any instrument requires calibration, and makes no allowance for an instrument that is pre-calibrated.
- Yet another participant asked whether the discussion makes voters inclined to change their votes to "approve".
- Several participants agreed that even if an instrument is pre-calibrated, the lab can perform a calibration and certify the instrument.

Consensus was that voters requesting discussion would change their votes to "approve" and that the Council should encourage the Chemistry committee to revise V1M4 to address this issue. The Committee's comment indicates that is Chemistry's intent. NOTE: Three voters have changed their vote to approve, three more have not and the fourth was awaiting this summary of the discussion.

There was no new business. Kristin wished everyone a happy holiday, and adjourned the meeting

6. Next Meeting

The regularly scheduled date of the next teleconference meeting is Monday, January 4, 2021. The agenda and documents will be provided in advance.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Carl Kircher E: <u>carl.kircher@flhealth.gov</u>	Yes
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	For information purposes: Shirlene South E: shirlene.south@illinois.gov	Yes
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California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
Guests:	none	