Summary of the NELAP Accreditation Council Meeting Monday, August 16, 2021 1:30 pm Eastern

1. Welcome and Introductions

Kristin welcomed everyone to this specially scheduled meeting to address a SIR veto vote. The minutes of July 6 were approved unanimously, and the minutes from the August 9 conference session were not presented for approval, since the status updates for all NELAP ABs were not yet complete. Attendance is noted in Attachment 1.

The last remaining status updates were delivered by the end of the meeting, so that the August 9 minutes will be complete and presented for approval at the September 7 meeting.

2. Veto Vote on SIR 390

The NELAP Voting SOP 3-101 requires that any veto vote, including on the SIR voting site, have justification provided within two weeks of when it is cast, and that the Council consider and vote on whether, based on the justification, the veto is persuasive or non-persuasive. Per SOP 3-101, a veto vote is a special type of negative vote cast when an element of the motion at hand would preclude implementation by a member AB because existing statutory or regulatory requirements could not be appropriately changed before the motion, if passed, would be implemented.

For this SIR, one AB voted "veto" and did provide its justification within the allotted timeframe. Two other ABs had noted their agreement with the veto, but when requested to provide justification, changed their votes to "against response" rather than provide justification.

The submitted rationale along with the current SIR votes were distributed to Council members prior to the meeting. The AB representative offering the veto vote discussed the submitted rationale, using somewhat different language than was in the written version, making the points noted below.

- 1) TNI is interfering with the AB's operations by not following the TNI SIR Management SOP 3-105
- The technical merits of the SIR response contradict technical principles of chemistry.
- 3) The initial interpretation was approved but inexplicably returned to the expert committee, and now the revised interpretation is wrong. (NOTE: the original interpretation had too many "against" votes to pass and was properly returned to the expert committee for revision. Apparently, the AB submitting the veto vote had voted "approve" and thus believed that the SIR itself was approved.)
- 4) An issue about whether linear or regression calibrations, or whether neither should apply in the question submitted.
- 5) The expert committee violated SOP 3-105 by rendering an interpretation that created a new requirement (exemption in this case) and conflicts with the existing requirements of the module.
- 6) The interpretation rendered by the Expert Committee contradicts known analytical chemistry and physical chemistry precepts.

Kristin noted that the points submitted to justify the veto do not mention conflict with state

statutes or regulations and that violations of the SIR Management SOP are not valid grounds for a veto. The AB offering the veto maintains that this SIR was submitted as a result of an assessment finding and thus constitutes a "dispute" and should not be accepted as a valid SIR. However, LASEC has already addressed that issue and determined that while an AB may deal with a corrective action of "I submitted a SIR" however it wishes and that a submitted SIR stating that its question originates with a dispute may be rejected (and has updated the SIR submission page appropriately). In making this decision, LASEC recognized that many important questions arise from different interpretations by different assessors and thus SIRs that emerge from assessments ought not to be invalidated without consideration.

The issue of the revised interpretation has been researched and the outcome noted in number 3 above. There was additional discussion about the technical merits of the expert committee's revised response and the AB voting "veto" declared that if the veto were not upheld, the AB's vote would change to "against" but that the original response (which had too many "against" votes to pass) should be restored.

Kristin called for a motion on the veto. Carl moved that the veto be upheld (i.e., declared persuasive) and Millie seconded. A simple majority vote is adequate for this decision, but an initial voice vote established that the outcome could not be determined, so a roll call vote was taken (but not recorded) in order to count individual votes. The outcome was 2 votes in favor, 2 votes against, and 8 abstentions. The motion did not carry and the veto vote is thus determined to be non-persuasive.

3. Discussion of SIR 402

While this SIR has sufficient votes for approval, the "needs discussion" request remained outstanding. The issue for discussion is that data reported after a failed calibration, in the interim before a new calibration is completed, could violate regulatory limits (if reported with a valid calibration). There are two options – either withhold the report until new calibration is completed or issue the report and follow-up with an amended report upon completion of the new calibration. There was general agreement that this point should be clarified, and SIR 402 will be returned to the expert committee for this specific revision.

Two other SIRs were on the agenda, SIRs 391 and 403, but their issues were administratively resolved with minimal discussion. It turned out that SIR 391 (related to SIR 390) had already been returned, and there was a needs discussion vote on SIR 403 where the AB was absent during the Council meeting where the SIR was discussed, but agreed to remove the request for discussion as the outstanding question(s) was resolved.

4. Next Meeting

The next meeting of the NELAP AC will be on <u>Tuesday</u>, <u>September 7</u>, <u>2021</u>, <u>at 1:30 pm Eastern</u>. This is a rescheduled date due to the Labor Day holiday falling on Monday of that week. The agenda and documents will be provided in advance.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
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Attachment 2



Agenda

- Introductions
- State AB Status Updates
 - > Operational status in re-opening from to pandemic
 - > 2016 Standard implementation status
 - 2021 Method Update Rule implementation plans
- Discussion and Q&A
 - Virtual participants may ask questions or make statements – Use Q&A – not "chat"

