

**Laboratory Accreditation System Executive Committee
SIR Subcommittee Meeting Minutes
April 18, 2024 1:30 pm Eastern**

1) Welcome and Introductions

Maria welcomed everyone to the meeting. The agenda was approved by unanimous consent after adding an additional SIR (475) to be reviewed (see Attachment B), and attendance is recorded in Attachment A. The minutes of the March 22, 2024, meeting were approved by unanimous vote after a motion by Stacie, seconded by Harold.

2) SIR 423

At the March meeting, participants decided to ask that the word “prove” be replaced with “ensure” or “verify”, and this SIR was returned to Microbiology for rephrasing. The requested change was made. There was again discussion about the advisability (as well as the feasibility) of obtaining and using testing performed by the manufacturer – if it is even possible to obtain the level of detail required to determine compliance with the requirements of V1M5 §1.7.3.6.d.i.b and 1.7.3.6.d.ii.b as well as V1M2 requirements. Silky moved and Bill seconded that this revised response be sent to LASEC with a recommendation that it be posted to the NELAP AC SIR voting site.

Voter	Motion to Approve Response and Forward to LASEC for Final Approval
Maria	Yes
Aaren	Absent
Debbie	Yes
Stacie	Yes
Bill	Yes, changed to NO after SIR 425 discussion (see below)
Silky	Yes
Harold	Yes
Super-Majority Approval Met?	5 of 7 in favor – 71% Motion approved

3) SIR 425

This SIR was returned for revision after the March meeting with a request to replace the word “prove” and also to modify the response so that it actually answers the question asked. After lengthy discussion about whether each laboratory location must literally perform their own media checks (sterility, positive and negative checks) or if the lab can rely on documentation from the manufacturer (or some other lab, probably in its same corporation) for some of the testing -- should each location be required to obtain the verification documents mentioned in 423 or if it’s a multi-lab corporation, can one lab can share this documentation with other labs? Essentially, SIRs 423 and 425 provide different and seemingly contradictory responses to a very similar question.

When it became clear that the Subcommittee could not resolve the issue, Maria asked for a motion to send both SIRs (423 and 425) to LASEC for further interpretation and resolution of the issues. Stacie offered such a motion, and Silky seconded it. After the meeting, Bill sent an email describing his concerns as discussed, and that email will be shared with LASEC, along with both SIR responses.

Voter	Motion to Approve Response and Forward to LASEC for Final Approval
Maria	Yes
Aaren	Absent
Debbie	Yes
Stacie	Yes
Bill	Yes
Silky	Yes
Harold	(Departed early, did not vote)
Super-Majority Approval Met?	5 of 7 in favor – 71% Motion approved

Additionally, in the discussion of this SIR, it became clear that the current definition of “laboratory” as found in the Glossary and from two CSDEC SOPs (2-100 and 2-101) is insufficiently clear to distinguish a corporation owning/running multiple labs from a single laboratory facility. This issue will be raised to the full LASEC also, in hopes of generating either a revised definition to recommend or at least a request that the definition be revisited and updated for clarity.

4) SIR 471

This SIR was returned to the expert committee with a request that the response be edited for clarity, and to remove reference to a prior SIR which is difficult to find and pertains to the 2003 NELAC Standard, which is functionally obsolete. A request to note in the response that the second question cannot be addressed because an interpretation does not provide “how to” information. Those concerns were addressed in the current revision. Bill moved and Debbie seconded that this revised response be sent to LASEC with a recommendation that it be posted to the NELAP AC SIR voting site

Voter	Motion to Approve Response and Forward to LASEC for Final Approval
Maria	Yes
Aaren	Absent
Debbie	Yes
Stacie	Yes
Bill	Yes
Silky	Yes
Harold	Absent
Super-Majority Approval Met?	5 of 7 in favor – 71% Motion approved

5) SIR 475

This SIR was returned with a request to revise the response so that it does not state that one section of the standard “supersedes” another – all requirements must be met independently, and to clarify the distinction between an invalid PT and a failed (unacceptable) PT. The revised response addresses both of these concerns. Bill moved and Stacie seconded that this revised response be sent to LASEC with a recommendation that it be posted to the NELAP AC SIR voting site

Voter	Motion to Approve Response and Forward to LASEC for Final Approval
Maria	Yes
Aaren	Absent
Debbie	Yes
Stacie	Yes
Bill	Yes
Silky	Yes
Harold	Absent
Super-Majority Approval Met?	5 of 7 in favor – 71% Motion approved

6) New Business

Stacie again noted her upcoming change in status and provided her new email address. There was no other new business.

8) Next Meeting

The next scheduled SIR Subcommittee meeting will be on **Thursday, May 16, 2024, at 1:30 pm Eastern**. If there are no SIRs to review, members will be notified in advance of the meeting date; otherwise the SIRs will be sent with the agenda.

Attachment A

PARTICIPANTS – SIR SUBCOMMITTEE OF LASEC

	NAME	EMAIL	LASEC Term end date	INTEREST	AFFILIATION	S/H CATEGORY	PRESENT
1	Maria Friedman, Chair	gamfriedman@gmail.com	1/26 (2nd term)	SIRs	CA ELAP	Non-NELAP AB	Yes
2	Aaren Alger	Aaren.s.alger@gmail.com	1/26 (2nd term)	SIRs	Alger Consult- ing & Training	Other	No
3	Debbie Bond, Vice Chair	DBOND@southernco.com	Associate	SIRs	Alabama Power	Lab	Yes
4	Stacie Crandall	scrandall@hrsdc.com	Associate	SIRs	Hampton Roads Sanitary District	Lab	Yes
5	Bill Hall	George.W.Hall@des.nh.gov	1/25 (second term)	SIRs	NH ELAP	NELAP AB	Yes
6	Silky Labie	elcatllc@centurylink.net	1/25 (second term)	SIRs	ELCAT	Other	Yes
7	Harold Longbaugh	harold.longbaugh@houston.tx.gov	1/25 (3rd term)	SIRs	Houston Lab	Lab	Yes
	Program Admin. Lynn Bradley	Lynn.bradley@nelac-institute.org					Yes

Attachment B – Agenda as amended

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (March minutes attached)
- Review of Revised SIR Responses (SIR responses for 423, 425 and 471 attached, SIR 475 added)
- New Business, if any
- Adjourn