

**Laboratory Accreditation System Executive Committee Meeting Minutes
Thursday, April 25, 2024 1:30 pm Eastern**

1) Welcome and Roll Call

Maria called the meeting to order and attendance is recorded in Attachment A. With no modifications requested, the agenda was declared approved, and is included in Attachment B. The minutes of March 28, 2024, were approved by unanimous vote after a motion by Silky, seconded by Patty.

2) SIR Subcommittee Recommendations

The order in which the Subcommittee’s recommendations were considered was modified on-the-spot to address the non-controversial ones first.

SIR 471

At its rescheduled April 18 meeting, the SIR Subcommittee approved a recommendation to LASEC that this SIR be posted for approval by the NELAP AC for its implementation. There were no questions and no discussion. Patty moved and Aaren seconded that the recommended action be approved. The roll call vote is tallied below.

| Name | Vote | Name | Vote |
|---|-------------|----------------|-------------|
| Maria Friedman | Yes | Brian Hulme | Yes |
| Harold Longbaugh | Yes | Silky Labie | Yes |
| Aaren Alger | Yes | Bill Hall | Absent |
| Patty Carvajal | Yes | Shari Pfallmer | Yes |
| Mike Delaney | Yes | Michele Potter | Absent |
| SIR 471 Vote – Supermajority approval met? | | | |
| Yes (8 of 10 in favor, 80%) | | | |

SIR 475

At its rescheduled April 18 meeting, the SIR Subcommittee approved a recommendation to LASEC that this SIR be posted for approval by the NELAP AC for its implementation. There were no questions and no discussion. Aaren moved and Mike seconded that the recommended action be approved. The roll call vote is tallied below.

| Name | Vote | Name | Vote |
|---|-------------|----------------|-------------|
| Maria Friedman | Yes | Brian Hulme | Yes |
| Harold Longbaugh | Yes | Silky Labie | Yes |
| Aaren Alger | Yes | Bill Hall | Absent |
| Patty Carvajal | Yes | Shari Pfallmer | Yes |
| Mike Delaney | Yes | Michele Potter | Absent |
| SIR 475 Vote – Supermajority approval met? | | | |
| Yes (8 of 10 in favor, 80%) | | | |

SIRs 423 and 425

At its rescheduled April 18 meeting, the SIR Subcommittee initially approved a recommendation to LASEC that SIR 423 be posted for approval by the NELAP AC for its implementation, but then when SIR 425 was considered, the Subcommittee members realized that there was a conflict between the responses for these two similar but distinct SIRs. While it seems that the intent of the Standard is that the lab facility where the media are used should be the place where sterility checks and media performance testing are performed, but the actual word (“demonstrate”) is ambiguous about who/where the testing be performed, and the SIR 425 response indicates that testing performed by the manufacturer is acceptable if the lab can verify that the requirements of the standard are met.

The issues are further complicated by the fact that the definition of a laboratory exists only in two TNI SOPs, the Standards Development SOP 2-100 and the Expert Committee SOP 2-101, and identifies a laboratory as “an organization that collects or analyzes samples in a fixed-base, mobile, or field-testing facility for chemical, and/or physical, and/or bacteriological properties or parameters” but is not clear about whether one or many labs constitute the “organization”.

At one point, participants gave serious consideration to returning both SIRs 423 and 425 to the submitter, saying that the questions cannot be answered without revising the standard, and requesting that the Microbiology committee clarify the language in its module, with the alternative being to let the Accreditation Council review the response and await its decision. Finally, Aaren moved and Silky seconded that SIR 423 be posted for AC approval. The roll call vote is tallied below.

| Name | Vote | Name | Vote |
|---|-------------|----------------|-------------|
| Maria Friedman | Yes | Brian Hulme | Yes |
| Harold Longbaugh | Yes | Silky Labie | Yes |
| Aaren Alger | Yes | Bill Hall | Absent |
| Patty Carvajal | Yes | Shari Pfallmer | Yes |
| Mike Delaney | Yes | Michele Potter | Absent |
| SIR 423 Vote – Supermajority approval met? | | | |
| Yes (8 of 10 in favor, 80%) | | | |

With that resolution, and knowing that the SIR 425 response conflicts with SIR 423’s response, Maria ordered that SIR 425 be tabled until SIR 423 is resolved.

Additionally, Maria will discuss the need for a clarified definition of “laboratory” with Paul Junio, Chair of the Consensus Standards Development Program’s Executive Committee, and the possibility that the current definition is inconsistent with the language of V1M2 §1.1.

3) Quarterly Review of LASEC Charter

Maria inquired about the status of the revised Charter that LASEC approved and sent to Policy Committee back in February. As that document review has not been completed, and may be awaiting the parallel action by the Training Committee to address the transfer of the Mentor Session and Assessment Forum to Training, Maria asked that quarterly reviews of LASEC’s Charter not begin until the latest revision is approved by TNI’s Board.

4) Five-Year Review of NELAP Provisional Recognition SOP 3-108

Silky did return her promised revisions, which are a tremendous improvement to the document, but as time was nearly expired, Maria proposed to table its consideration until the May meeting. Silky noted that her revisions were primarily edits for consistency with other TNI documents and wordsmithing for clarity, but that there are several items where she was uncertain what the NELAP AC actually meant. This item will be the priority for LASEC's May meeting.

5) New Business

Lynn noted that the Conflict of Interest SOP 3-113 has been returned from Policy Committee with multiple recommended revisions, but that it arrived only a few hours before this meeting and will be held until the May meeting.

6) Next Meeting

The next scheduled LASEC teleconference will be on **Thursday, May 23, 2024, at 1:30 pm Eastern.** An agenda and any needed documents will be provided in advance.

The next **SIR Subcommittee teleconference will be on Thursday, May 16, 2024, at 1:30 pm Eastern.**

Attachment A TNI LABORATORY ACCREDITATION SYSTEMS EXECUTIVE COMMITTEE ROSTER

| | NAME | EMAIL | Term End Date | INTEREST | AFFILIATION | S/H CATEGORY | PRESENT |
|----|---------------------------------|--|----------------------|---------------------------|-----------------------------|---------------------|----------------|
| 1 | Maria Friedman, Chair | gamfriedman@gmail.com | 1/26 (first term) | SIRs | CA ELAP | AB | Yes |
| 2 | Harold Longbaugh, Vice Chair | harold.longbaugh@houstontx.gov | 1/25 (3rd term) | SIRs | Houston Lab | Lab | Yes |
| 3 | Aaren Alger | Aaren.s.alger@gmail.com | 1/26 (first term) | SIRs, Assessment Forum | Alger Consulting & Training | Other | Yes |
| 4 | Patty Carvajal | pmcarvajal@sara-tx.org | 1/25 (first term) | | San Antonio River Authority | Lab | Yes |
| 5 | Mike Delaney | mike@mikedelaney.org | 1/26 (first term) | | Retired (MWRA) | Other | Yes |
| 6 | Brian Hulme | Hulme.brian@epa.gov | 1/26 (first term) | | EPA R2 | Other | No |
| 7 | Silky Labie | elcatllc@centurylink.net | 1/25 (second term) | SIRs | ELCAT | Other | Yes |
| 8 | Bill Hall | George.W.Hall@des.nh.gov | 1/25 (second term) | SIRs | NH ELAP | NELAP AB | No |
| 9 | Shari Pfalmer | Shari.pfalmer@pacelabs.com | 1/25 (first term) | | Pace Analytical | Lab/FSMO | Yes |
| 10 | Michele Potter | Michele.potter@dep.nj.gov | 1/27 (third term) | | NJ DEP | NELAP AB | No |

Associate Members

| | | | | | | | |
|--|--------------------------------|--|--|----------------|-----------------------|-------|-----|
| | Debbie Bond | DBOND@southernco.com | | SIRs | Alabama Power | Lab | Yes |
| | Stacie Crandall | crandallstacie@gmail.com | | SIRs | TNI | Other | No |
| | Jack Farrell | aex@ix.netcom.com | | Mentor Session | Analytical Excellence | Other | No |
| | Nick Straccione | nstraccione@emsl.com | | Mentor Session | EMSL | Lab | No |
| | Katie Strothman | katie@sanderslabs.net | | | Sanders Labs | Lab | No |
| | Program Admin. Lynn Bradley | Lynn.bradley@nelac-institute.org | | | | | Yes |

Attachment B Agenda

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (March minutes attached)
- SIR Recommendations from April 18 SIR Subcommittee Meeting (SIR responses for 423, 425, 471 and 475 attached, plus pdf of email explaining the seeming contradiction between 423 and 425 responses and draft minutes of Subcommittee meeting)
 - SIR 471 – recommendation to post to AC voting site
 - SIR 475 – recommendation to post to AC voting site
 - SIR 423 – initial vote to recommend posting to AC voting site being withheld from consideration until possible contradiction resolved
 - SIR 425 – discussion of this SIR response showed apparent conflict with response to SIR 423, see also email pdf
 - Consider Definition of Laboratory – does it need to distinguish between multi-lab corporation and single lab facility, in light of SIR 423/425 responses?
 - Laboratory: An organization that collects or analyzes samples in a fixed-base, mobile, or field-testing facility for chemical, and/or physical, and/or bacteriological properties or parameters
- Quarterly Review of Charter for Possible Updated (current Charter attached, pending Policy review)
- Review and Possible Vote on Revision of Provisional Recognition SOP 3-108 (see Silky's draft revision, attached)
- New Business, if any
- Adjourn