

Laboratory Committee

Meeting Report

February 15th, 2022

In Attendance: Andy Haines, Dana Dvoracek-Driksna, Joseph DeCrescenzo, Matthew Forester, Shelley Lankford, Jill MacLeod, Linda McFarland, Diane Regan, Wade Rourke, Mona Hochman, Leanne Flewelling, Jacob Madden, Joel Hansel, Shannara Lynn, Cheryl Lassitter, Stephanie Haynes, Johnna Fay, Gina Olson, Sara McGrath, Jonathan Deeds

Absent: Jennifer McDonald, Richard Burrow, Drew Sheehan, Steve Archer, Maggie Broadwater, Lizzie Farrell, Jessica Jones

Guests: None

Note Takers: Andy, Cheryl

AGENDA

1. Roll Call
2. Meeting Minutes – January 2022
3. Meeting Report – January 2022
4. Subcommittee Reports
 - a. Biotoxin
 - b. Microbiology
 - c. Checklist
 - d. Method Validation
 - i. Review Matrix Extension Updates/Species Groupings
 - e. Method Portal
 - i. Review Draft Questionnaire
 - f. Engagement
 - g. Lab Evaluation
5. Review of Action Items
6. Other Business
7. Adjourn

Next Meeting – Tuesday, March 15th, 3:00 – 5:00 p.m. ET

MEETING NOTES SUMMARY

Roll Call:

The meeting was called to order, followed by roll call and a review of the agenda. A quorum was present.

Meeting Minutes:

The meeting minutes are designed for internal use, and contain more detail, names, notes on deliberations, action items, etc. The draft meeting minutes from the January 2022 Laboratory Committee Meeting were reviewed and discussed. There was a motion to approve the minutes as written, with a second, and the motion carried.

Action Item: LC Chair will remove the watermark, finalize, and distribute to the LC.

Meeting Report:

The meeting report is designed for public use, including potential posting on ISSC website once approved. Names are removed, and the report is typically less detailed than what is included in the minutes. The draft meeting report from the January 2022 Laboratory Committee Meeting was reviewed and discussed. There was a motion to approve the report as written, with a second, and the motion carried.

Action Item: LC Chair will remove the watermark, finalize, and distribute to the LC along with the Executive Office.

Subcommittee Reports:

Biotoxin Subcommittee

- Updates were provided from the proposal liaison on the status of 17-108.
- Bulk of the meeting focused on review of some questions and comments Neogen sent in response to the subcommittee review of their DSP rapid test kit pre-proposal study design.
 - Highlighted some potential updates to make to the SLV SOPs, particularly as it relates to quantitative versus qualitative methods.

Microbiology Subcommittee

- Rescheduled February meeting planned for Wednesday, February 23rd., with plan to focus on review of 15-114.

Checklist Subcommittee

- Completed review of two proposals at last meeting, and are forwarding the subcommittee recommendations to the full LC for review at the March meeting.
 - 19-141 – subcommittee recommends adoption as amended.
 - Ended up revising five checklist items, including 1.2.5, 1.2.6, 2.3.2, 2.4.5, 2.4.10

- 19-132 – subcommittee recommends adoption as submitted.
 - Proposal focused on updating one line item from the existing micro checklist, item 1.4.24.
- Both subcommittee recommendations will be discussed in more detail at the March LC meeting prior to the full committee review.
- Next subcommittee meeting will likely be rescheduled for March 4th, with a focus on 19-131.

Method Validation Subcommittee

- Reviewed history and background on matrix extension guidelines, including rationale behind the draft proposal being presented to the committee.
- Draft proposal includes an update to the Constitution, Bylaws, and Procedures to eliminate the use of the word “species” and replace it with “matrix”, and also to provide direction on where to look for guidance on the matrix extension process.
- Draft also includes a new Guidance Document, Section .21, which includes details on when a matrix extension is needed, and also includes the new table that defines what constitutes a matrix, and what individual species are considered the same matrix versus what are separate and would require a matrix extension.
- Draft also includes updates to existing Guidance Document, Section .20, indicating when a matrix extension might be needed for a method verification within a lab.
- During review and discussion on this proposal, some questions arose on how different forms of a shellfish product might be considered in the matrix extension concept. Scallop muscle versus roe on scallops and whole geoducks versus geoduck gut balls were included as some examples.
- Some questions also arose on how, if at all, new species could be added to this table.
- These questions/comments will be discussed at the next subcommittee meeting, and an updated document will be circulated back to the LC in time for the March meeting.

Method Portal

- Introduced the draft questionnaire that the subcommittee has prepared for circulation to ISSC membership to generate feedback to help guide subcommittee efforts on updating Table .14. No comments were noted, so the subcommittee will work on finalizing this document at their next meeting tomorrow, and will arrange to have it sent out.

Engagement

- No updates. Subcommittee will not meet until a new meeting date/time is identified.

Lab Evaluation

- FDA interpretation being prepared to address remaining subcommittee questions. Subcommittee meetings will recommence once that interpretation is ready.

Review Action Items:

- LC Chair will finalize the January Meeting Minutes and Meeting Report and will distribute both to the LC and the Executive Office.
- LC Chair will prepare Meeting Minutes and a Meeting Report for the February meeting, and will also update the Tracker and Proposal Status documents to reflect recent activities.
- Full LC will review checklist subcommittee recommendations on 19-141 and 19-132 and come prepared to discuss at the March LC
- Method Validation subcommittee will update Matrix Extension Guidelines proposal document based on comments from LC, and will recirculate in advance of March LC meeting for additional review.
- Portal subcommittee will finalize questionnaire and arrange to have it sent out to membership.
- Full LC will review pre-proposal document discussed in the “Other Business” section of the meeting for consideration at the March LC meeting.

Other Business

- LC has received a preproposal from a company requesting approval of a triplex quantitative microarray method for analysis of ASP, DSP, and PSP. The letter requests feedback on SLV experimental design as well.
 - The full LC will be tasked with reviewing this preproposal as dictated by the ISSC Constitution, Bylaws, and Procedures, and the Biotoxin subcommittee review the proposed experimental design.
- The April LC meeting may need to be rescheduled, and a poll identifying committee availability on a new date will be circulated.

Adjourn

Next Meeting – Tuesday, March 15th, 3:00 – 5:00 p.m. ET