Laboratory Committee

Meeting Report April 20th, 2021

<u>In Attendance:</u> Andy Haines, Jennifer McDonald, Dana Dvoracek-Driksna, Jill MacLeod, Linda McFarland, Diane Regan, Wade Rourke, Richard Burrow, Joel Hansel, Shannara Lynn, Cheryl Lassitter, Steve Archer, Mona Hochman, Leanne Flewelling, Jacob Madden, Johnna Fay, Maggie Broadwater, Sara McGrath, Jon Deeds, Stephanie Haynes

<u>Absent:</u> Joseph DeCrescenzo, Matthew Forester, Shelley Lankford, Leonora Porter, Gina Olson, Melissa Farrell, Avi Singh, Jessica Jones, Drew Sheehan

Note Takers: Andy, Cheryl, Johnna

AGENDA

- 1. Roll Call
- 2. Meeting Minutes March 2021
- 3. Meeting Report March 2021
- 4. Outcome From 4/15/2021 Executive Board Meeting
- 5. Review Draft Response on 13-114
- 6. Subcommittee Reports
 - a. Biotoxin
 - b. Microbiology
 - i. Platform Extension Progress
 - c. Checklist
 - i. 19-136 Summary of Changes
 - d. Method Validation
 - i. Matrix Extension Species Grouping Update
 - e. Method Portal
 - i. Introduce Updated Page
 - f. Engagement
 - g. Lab Evaluation
- 7. Review of Action Items
- 8. Other Business
- 9. Adjourn

Next Meeting - Tuesday, May 18th, 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 March 16th, 2021 Laboratory Committee Meeting were reviewed and discussed. A motion to approve the minutes as written was made, along with a second, and the motion carried.

During the review of the minutes, a follow up on the question regarding the change in manufacturer for the Scotia Rapid Test was discussed. No progress has been made yet, but the plan is to generate a letter from the ISSC to the new manufacturer requesting validation data comparing performance of the kit between the two manufacturers.

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 March 16th, 2021 Laboratory Committee Meeting was reviewed and discussed. A motion to approve the minutes as written was made, along 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.

Outcome From 4/15/21 Executive Board Meeting:

The LC Chair had the opportunity to update the Executive Board on Laboratory Committee progress at their last meeting on 4/15/21.

- A request was made to prioritize proposal 19-140 (the MSC Method Lab Evaluation Checklist)
- The Executive Board granted interim approval to the LC recommendation to adopt Proposal 17-110 as amended. This means that the Lab Evaluation Checklist for the Alkaline Phosphatase Probe Method for Vv and Vp Detection in Oysters can be used immediately. It will also be presented as a new proposal from the Executive Board at the next biennial meeting for full adoption by the Conference.
- The Executive Board was also provided with a preview of potential upcoming committee votes on updated matrix extension guidelines and a recommendation on proposal 19-136.

• The LC Chair was also asked to present on the Lab Method review process at the PacRim annual conference, and wrapped up that presentation just before this meeting.

Review Draft Response on 13-114:

- The Biotoxin Subcommittee prepared a written summary of their meeting with the proposal submitters, as well as a complete review of their most recent data submission.
- The contents of this review were discussed, and a motion to accept the letter as written was made, along with a second. This motion carried.
- The LC Chair will work with the Executive Office to arrange for this review to be sent to the submitters as soon as possible.

Subcommittee Reports:

Biotoxin Subcommittee

- Neogen Reveal 2.0 for DSP
 - Submitted a study plan for review by the subcommittee in the hopes of avoiding proposal pitfalls.
 - There was discussion on the requirement for the "QC Steps for the Method" in the SLV checklist and whether that line applies to users or developers.
 - Also discussed the benefit of including a lab evaluation checklist in the early stages of review.
 - This method is used widely in the UK and EU, so there was also discussion of potentially requesting that the submitter include feedback/suggestions from existing users to help identify any issues before they arise.
 - There was also some discussion on the SOPs provided as guidance on the ISSC website, and how in certain cases, these general guidelines might not fit (i.e. measurement uncertainty for this one).
- There was also discussion that there is some interest from labs in picking up the pre-proposal on the LCMS for NSP that was submitted several years ago.

Microbiology Subcommittee

• The updated draft of the Platform Extension Guidelines is still under development, but will be circulated for review by the subcommittee in the near future.

Checklist Subcommittee

- The subcommittee met in April to continue review of Proposal 19-136.
- Seven additional line items in the checklist were modified, and a new TEF reference was added.
- There was a lengthy discussion on the intent of some System Suitability requirements in Checklist items 2.5.2 and 2.5.9, and that discussion will continue at the May meeting.
- At the request of the Executive Board, Proposal 19-140 is next on the list for review, followed by Proposal 19-141.

Method Validation Subcommittee

 Work is still ongoing to pull together a draft of the matrix extension species groupings, but the hope is to have a draft ready for subcommittee review in time for the May subcommittee meeting.

Method Portal

 An updated draft of the method portal webpage was presented to the LC, with a request for questions and comments in advance of the May LC Meeting.

Engagement

• The subcommittee met on March 26th to discuss comments/questions received on the Priorities List and on the ISSC Website. A revised priorities list is being developed, and discussion will continue at the next meeting.

Lab Evaluation

• The subcommittee has one last remaining item to discuss at the next meeting, but then hopes to have a recommendation available to the Lab Committee shortly thereafter.

Review Action Items:

- LC Chair will finalize the March 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 April meeting, and will also update the Tracker and Proposal Status documents to reflect recent activities.
- LC Chair will work with the Executive Office to prepare a letter to the new manufacturer of the Scotia Rapid Test to request validation data comparing kits produced at the old manufacturer with kits produced at the new manufacturer.
- LC Chair will work with the Executive Office to finalize and mail the review of Proposal 13-114 that was approved at this meeting.
- All Lab Committee members will review the draft Method Portal webpage and will provide comments/questions in advance of the next LC meeting.
- There is a standing invitation for new members on the Checklist Subcommittee or any of the other LC Subcommittees if you are interested and available to participate.

Other Business

Adjourn

Next Meeting - Tuesday, May 18th, 3:00 - 5:00 p.m. ET