

Laboratory Committee

Meeting Report

September 15th, 2020

In Attendance: Andy Haines, Jennifer McDonald, Dana Dvoracek-Driksna, Matthew Forester, Shelley Lankford, Jill MacLeod, Linda McFarland, Diane Regan, Leonora Porter, Wade Rourke, Richard Burrow, Gina Olson, Joel Hansel, Shannara Lynn, Cheryl Lassitter, Linda Chandler, Mona Hochman, Leanne Flewelling, Johnna Fay, Maggie Broadwater

Absent: Joseph DeCrescenzo, Melissa Farrell, Steve Archer, Avi Singh, Jacob Madden, Jessica Jones, Drew Sheehan

Guests: Sara McGrath

Note Takers: Johnna, Andy

AGENDA

1. Roll Call
2. Meeting Minutes – August 2020
3. Meeting Report – August 2020
4. Committee Structure and Operations
 - a. Voting Members versus Advisors
 - b. Subcommittee Rosters
 - c. Pre-Proposals
 - d. Proposal Liaisons
5. Review Pre-Proposal From FDA
6. Review Draft Letters for 13-111, 15-114, 17-108
7. Data Submission For Proposal 15-109
8. Review of Action Items
9. Other Business
10. Adjourn

Next Meeting – Tuesday, October 20th, 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 August 18, 2020 Laboratory Committee Meeting were reviewed, discussed, and a motion to approve as written carried.

Action Item: The 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 August 18, 2020 Laboratory Committee was reviewed, discussed, and a motion to approve as written carried.

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

Committee Structure and Operations:

- Voting Members vs. Advisors
 - The Laboratory Committee is made up of both voting members and advisors. State and industry representatives are all voting members, and each federal agency (FDA, EPA, NOAA) has one voting member as well. All other LC members from federal agencies serve as advisors, which means that they can participate in committee discussions and provide expertise, but cannot vote on motions before the committee. On a subcommittee level, however, all members and advisors can fully participate.
- Subcommittee Rosters
 - Subcommittee rosters are being developed, and should be distributed to membership shortly.
 - **Action Item: As soon as rosters are available, subcommittee chairs should begin working with membership to set up standing meeting times and begin work on charges.**
- Pre-Proposals
 - Per ISSC Constitution, Bylaws, and Procedures – Procedure XV, Section 1, anyone interested in submitting a method for inclusion in the program must submit a pre-proposal first.

- Each pre-proposal must include a description of the method, a proposed use of the method, and a time table for submission of a full SLV, and are reviewed by the LC to ensure fit for purpose, as well as to identify any major questions or concerns before the developer goes through the work of generating the data necessary for a full SLV.
- If approved, LC will work with Executive Office to send a letter to the submitter inviting them to prepare a full SLV.
- Proposal Liaisons
 - Per ISSC Constitution, Bylaws, and Procedures, Procedure XV, Section 3, upon approval of a pre-proposal, a member of the LC will be assigned as a proposal liaison.
 - Proposal liaisons act as an informal point of contact between the method developer and the LC to help relay questions and information that does not necessitate formal communication via the Executive Office.

Review Pre-Proposal From FDA:

- A new pre-proposal was submitted by the FDA for a matrix extension of the MPN Real-Time PCR Methods for Vv, total Vp, and pathogenic Vp detection in hard clams.
- The pre-proposal was reviewed by the LC, and was found to meet the requirements of Procedure XV, Section 1.
- The LC voted on a motion to recommend approval of the pre-proposal.
- **ACTION ITEM: The LC Chair will notify the Executive Office of the vote to recommend approval, and will work with them to prepare a letter inviting the submitter to submit a full SLV.**
- The LC also voted to assign a liaison, and directed that liaison to work with the submitter to clarify which species are included in the term “hard clams”.

Review Draft Letters For 13-111, 15-114, and 17-108:

- Per ISSC Constitution, Bylaws, and Procedures, Procedure XV, Section 7, a method submitter has 18 months from the date of a written request from the ISSC to provide the information/data necessary to complete an evaluation of a method. If there is no response from the submitter within this timeframe, the LC can vote to recommend no action on the proposal.
- Proposals 13-111, 15-114, and 17-108 reached 18 months of inactivity as of April 2020.
- The LC is drafting letters to these proposal submitters to inquire on their intent to continue pursuing approval of these methods before voting.
- Letters to the submitters of proposals 13-111 and 17-108 were reviewed, edited, and approved by the LC. The letter for proposal 15-114 has not yet been drafted.
- **ACTION ITEM: The LC Chair will work with the Executive Office to finalize these letters and to have them mailed.**

Data Submission For Proposal 15-109:

- The LC recently received a new data submission from the State of Alaska in support of Proposal 15-109.

- The new matrix extension guidelines that were approved at the 2019 biennial meeting were reviewed, and a summary of the method and proposal history was presented.
- This proposal is assigned to the Biotoxin Subcommittee, so they will be responsible for initial review of this new data.

Review Action Items:

- The LC Chair will finalize the Meeting Minutes and Meeting Report and will distribute both to the LC and the Executive Office.
- Once rosters have been sent out, subcommittees will work to set standing meeting times and will begin work on charges.
- The LC Chair will work with the Executive Office to prepare a letter to the FDA notifying them of the approval of their pre-proposal and inviting them to submit a full SLV.
- The LC Chair will work with the Executive Office to finalize and mail the approved letters to the submitters of proposals 13-111 and 17-108.

Other Business

Adjourn

Next Meeting – Tuesday, October 20th, 3:00 – 5:00 p.m. ET