

Laboratory Committee

Meeting Report

March 15th, 2022

In Attendance: Andy Haines, Dana Dvoracek-Driksna, Joseph DeCrescenzo, Matthew Forester, Shelley Lankford, Jill MacLeod, Linda McFarland, Diane Regan, Wade Rourke, Richard Burrow, Steve Archer, Jacob Madden, Joel Hansel, Shannara Lynn, Maggie Broadwater, Stephanie Haynes, Johnna Fay, Jessica Jones, Gina Olson, Sara McGrath, Jonathan Deeds

Absent: Jennifer McDonald, Drew Sheehan, Mona Hochman, Leanne Flewelling, Cheryl Lassitter, Lizzie Farrell

Guests: None

Note Takers: Andy, Gina

AGENDA

1. Roll Call
2. Meeting Minutes – February 2022
3. Meeting Report – February 2022
4. Review Preproposal Submission From LightDeck Diagnostics
5. Subcommittee Reports
 - a. Biotoxin
 - b. Microbiology
 - c. Checklist
 - i. 19-132
 - ii. 19-141
 - d. Method Validation
 - i. Review Matrix Extension Updates/Species Groupings
 - e. Method Portal
 - i. Review Draft Questionnaire Responses
 - f. Engagement
 - g. Lab Evaluation
6. Review of Action Items
7. Other Business
8. Adjourn

Next Meeting – Tuesday, April 26th, 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 February 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 February 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.

Review Preproposal Submission From LightDeck Diagnostics

- Be sure to reference the letter dated February 17th, 2022, as the submitter provided a revised version of the document with significant changes following their initial submission.
- Proposing to introduce a quantitative duplex rapid test for PSP and ASP toxins using microarray wavelength technology.
- The letter is a request to review their study design before they proceed with an SLV, and will also serve as the necessary pre-proposal submission.
 - Need to determine if it meets the requirements of the Constitution, Bylaws, and Procedures (must include a description of the method, a proposed use for the method, and a time table for the SLV). Is there a use for this method within the program?
 - Description of method = yes
 - Proposed Use = mussels only, want to get approval for a variety of uses.
 - Timeline – dependent on the feedback we provide during our review of their study design, but want to try and complete the work within the grant window, which expires in September 2023.
 - Discussions touched upon a variety of questions that can be addressed during the study design review including:

- It would be good for them to include more detail on the working range of the method, as that might help to determine the end uses of the method. Is it actually quantitative, or just semi-quantitative?
- They might need solid guidance on spiking, and if they are going to have to spike separately with all of the individual congeners listed for their specificity testing, which would be a lot of work.
- They should provide cross-reactivity data, even though it isn't specified in the SLV guidelines right now.
- There was a motion and a second to accept this pre-proposal with the additional note that the LC will provide the submitter with feedback on their experimental design before they proceed with their SLV. The motion carried.
- Jon Deeds volunteered to serve as the liaison. There was a motion and a second, and the motion carried.

Subcommittee Reports:

Biotoxin Subcommittee

- Finished review of proposed Neogen study design, and hope to have a completed review document to them soon.
- Briefly discussed LightDeck proposal
- Also began discussing SLV SOPs and potential ideas for improvement based on the subcommittee's experience using them for review purposes recently. Planning to create a process map as a starting point to identify gaps and needs, and then will begin reviewing SOP documents for revisions or creation of new ones.

Microbiology Subcommittee

- Will continue review of 15-114 at next meeting, along with a review of the proposed study design submitted by Washington to address remaining comments on 19-128.

Method Validation Subcommittee

- Reviewed the updates in response to comments received at the last LC meeting
 - Spelling corrections
 - Section on how to add new species to the table
 - An additional reference table summarizing the "nutritional content" of the various shellfish species was added to the proposal package to help with determining where to place new species in the future.
 - Added footnotes to matrix category table to specify the form that Scallops and Geoducks that are typically used in different lab methods.
 - Added further edit to these footnotes that the muscle-only form of scallops is not part of the NSSP.

- It was suggested that the LC double check all common and scientific names in this table versus the Seafood List to ensure consistency.
- There was a motion and a second to forward the proposal to the Executive Board for interim action with the additional instruction to make any editorial changes involving genus, species, or common names no later than 5 days prior to the Executive Board meeting.
 - During discussion of this motion, there was a motion and a second to amend the matrix table to add manila clams in matrix category #2.
 - The common name in the Seafood List is Japanese Littleneck Clam, and the scientific name is *Venerupis philippinarum*, so these two corrections were made.
 - This motion to amend carried.
 - The original motion also carried. The LC will finish these edits and the comparison with the Seafood List before the end of the week.

Checklist Subcommittee

- 19-132 – Hold discussion until April meeting in the interest of time today.
- 19-141 – Checklist for Receptor Binding Assay for PSP
 - Checklist subcommittee recommending that the LC recommend adoption of this proposal as amended:
 - 1.2.5 – “verification of licensing” struck, and replaced with a passage that training on safety, handling, and disposal of radioactive material must be documented. Licensing isn’t necessarily required if you handle less than 50 µCi/year.
 - 1.2.6 – Not all labs maintain licenses from the Nuclear Regulatory Commission, so “or equivalent state license” was added.
 - 2.3.2 – Original passage very prescriptive and not reflective of the original SLV (Van Dolah). Added “At least” five grams of tissue..., and replaced “an equal amount” with “a 1:1 mass to volume ratio” of 0.1 M HCl.
 - 2.4.5 – An inter-assay QC calibration and reference blank are important to run with each plate, instead of daily. A portion of the original passage was struck and replaced with a new sentence reading “An inter-assay QC calibration and reference blank are required for each plate analyzed.”
 - 2.4.10 – There is currently only one source for tritiated STX and quality can vary, so it is important that this item be required. The “ifs” and “should bes” were removed from the original passage.
 - There was a motion and a second to recommend adoption of 19-141 as amended. There was no further discussion, and the motion carried.

Method Portal Subcommittee

- Have received about 26 responses on the Table 14 questionnaire, and will review at next Portal meeting tomorrow.

Engagement Subcommittee

- NOAA is working on a PCM HAB funding opportunity with a focus on biotoxin method development.
- ISSC Biotoxin Committee continuing to work on proposals 19-123 and 19-124, updating the Biotoxins sections of the Public Health Reasons and Guidance Documents portions of the Guide.

Lab Evaluation Subcommittee

- No updates

Review Action Items:

- LC Chair will finalize the February 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 March meeting, and will also update the Tracker and Proposal Status documents to reflect recent activities.
- LC Chair will prepare a letter for LightDeck Diagnostics indicating that the LC will review their study design, that Jon Deeds will be the liaison, and that, once the LC review of their study design is complete, that they are invited to submit a full SLV for consideration.
- Method Validation subcommittee will finalize Matrix Extension Guidelines proposal document based on comments from LC, and will submit to the Executive Office for distribution to the Executive Board.
- LC Chair will present the Matrix Extension Guidelines along with the LC recommendations on 19-140 and 19-141 to the Executive Board for potential interim approval at their spring meeting on 3/29.
- LC should review Checklist Subcommittee recommendation on 19-132 and come prepared to discuss at next meeting.
- LC Chair will work with Executive Office to distribute revised invitation for April LC meeting reflecting the updated April 26th meeting date.

Other Business

Adjourn

Next Meeting – Tuesday, April 26th, 3:00 – 5:00 p.m. ET