

Laboratory Committee

Meeting Report

July 19th, 2022

In Attendance: Andy Haines, Jennifer McDonald, Dana Dvoracek-Driksna, Joseph DeCrescenzo, Matthew Forester, Shelley Lankford, Jill MacLeod, Linda McFarland, Wade Rourke, Richard Burrow, Steve Archer, Leanne Flewelling, Joel Hansel, Shannara Lynn, Jessica Jones, Gina Olson, Sara McGrath
Greg Feister, Stephanie Haynes, Johnna Fay, Jonathan Deeds

Absent: Diane Regan, Jacob Madden, Drew Sheehan, Mona Hochman, Lizzie Farrell, Maggie Broadwater

Note Takers: Andy, Gina

AGENDA

1. Roll Call
2. Meeting Minutes – May 2022
3. Meeting Report – May 2022
4. Brief Update on Status of New Scotia Rapid Test Kits
5. Subcommittee Reports
 - a. Biotoxin
 - i. Summary of SLV SOP Update Project
 - b. Microbiology
 - i. 15-114 Update
 - c. Method Validation
 - d. Checklist
 - i. 19-138 Recommendation
 - e. Method Portal
 - f. Engagement
 - g. Lab Evaluation
6. Review of Action Items
7. Other Business
8. Adjourn

Next Meeting – Tuesday, August 16th, 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 May 2022 Laboratory Committee Meeting were reviewed and discussed. A motion to approve the minutes was made, 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 May 2022 Laboratory Committee Meeting was reviewed and discussed. A motion to approve the report as written was made, 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.

Brief Update on Status of New Scotia Rapid Test Kits:

- New manufacturer of test kits indicated that the original manufacturer of the scanners that can be used to read results has gone out of business, and that they are working on identifying a new scanner to use with the kits.
 - The LC will review whether this change will impact the method as is has been approved for use within the program, and if additional comparison data is needed.

Subcommittee Reports:**Biotoxin Subcommittee**

- Summary of SLV SOP Update Project
 - As the Biotoxin Subcommittee has been reviewing recent proposals/pre-proposals, and particularly qualitative tests, it has become apparent that there are some items that don't fit into our existing validation protocols, which makes review difficult and subjective.
 - The subcommittee discussion has grown to identify not only gaps in the SOPs, but also questions on method categories, limitations, website flow, etc.
 - Would like to suggest that the whole LC get involved with this project, as it will necessitate a diversity of expertise and is too big of a project for any one group to achieve.

- Suggest “Choose Your Own Adventure” style redesign of website to help guide applicants through the process, potential new SOPs and modifications to existing ones, and a redesign of Table .14.
- Also suggest building off of existing Method Validation Subcommittee efforts in some circumstances where drafts of new or updated SOPs already exist.
- Would also like to suggest potentially pulling together a workgroup with reps from all of the different fields of expertise within the LC to help guide this project.
- Another suggestion was to look at ways to make it easier to adopt methods with AOAC or ISO (or other equivalent) approvals into the NSSP.
- **Action Item: Each subcommittee should discuss and think about 1 or 2 concrete things related to this overall project that they can commit to trying to complete.**

Microbiology Subcommittee

- The subcommittee has continued to review proposal 15-114, and has maintained some back and forth with the submitter on questions/comments that have come up during discussion.
- The proposed checklist, with Micro Subcommittee comments, was sent to the Checklist Subcommittee for review.

Method Validation Subcommittee

- Hoping to reconvene next month to discuss next priorities for the subcommittee. Options include projects to contribute towards the SLV/SOP update project mentioned above, or the development of guidance on how to handle method validation or verification when SLV data for the original method does not exist.

Checklist Subcommittee

- Checklist Subcommittee last met on Friday, July 8th and began discussion of the checklist associated with proposal 15-114 (MSC in wastewater).
- Checklist SC also met on June 10th to continue discussion of 19-138 from March. Proposal 19-138 sought to improve checklist consistency by updating several NSSP requirements in Part I of the Microbiology checklist to incorporate what is actually being performed in NSSP labs, while maintaining the requirement intent. The proposed changes are as follows:
 - Checklist changes to 1.4.5 were proposed to incorporate following manufacturer instructions, which is something that FDA LEOs always default to when conducting evaluations.
 - Checklist changes to 1.4.21 were proposed to eliminate the reference to a mercury-in-glass thermometer. The intent of checklist item 1.4.21 was to stipulate the calibration points, and 1.4.23 already allows for non-mercury-in-glass thermometers.
 - The proposed changes to 1.6.10 and 1.6.11 were submitted to allow for NSSP labs to use dry heat sterilization ovens without being penalized for exceeding 180°C because there are no unintended consequences when extending the 160 - 180°C range.

- The checklist subcommittee recommends that the LC recommend adoption of this proposal as submitted.
- There was a motion to recommend adoption of proposal 19-138 as submitted, with a second, and the motion carried.

Method Portal Subcommittee

- No updates

Engagement Subcommittee

- The ISSC Biotoxins Committee has been asked to provide a recommendation to the ISSC Executive Board whether cyanobacterial toxins including microcystins, cylindrospermopsin and anatoxin-a should be considered under the NSSP. The FDA has a forthcoming position paper that will inform the recommendation and identify related data gaps and the Committee has formed a small workgroup tasked with compiling information/data that can inform the Committee recommendation.
- NOAA's National Centers for Coastal Ocean Science is planning to release a Fiscal Year 2023 funding opportunity for the National Competitive HAB Programs. Projects that involve biotoxin detection method development, validation, and transfer to end-users will be encouraged.

Lab Evaluation Subcommittee

- No updates

Review Action Items:

- LC Chair will finalize the May Meeting Minutes and Meeting Report and will distribute both to the LC and the Executive Office.
- Committee members will research the old proposals associated with the Scotia Rapid Test to identify if a scanner was involved in any of the original proposals, and to determine if the introduction of a new scanner to the process will necessitate any additional comparison data.
- All subcommittees (and individuals or small groups, if interested) will identify one or two concrete tasks they can commit to that will help towards achieving the SLV process and SOP revisions project that was discussed at the meeting. These goals will be summarized at our August meeting.

Other Business

Adjourn

Next Meeting – Tuesday, August 16th, 3:00 – 5:00 p.m. ET