ISSC Laboratory Methods Review Committee April 21, 2015 Conference Call Meeting Report

Committee Members Present:

Stacey DeGrasse (Chair), Darcie Couture, Matthew Forester, Tom Howell, Jackie Knue, Linda McFarland, Alison Sirois, Wade Rourke, Valerie Wunderly, Melissa Evans, Quay Dortch

Committee Members Absent:

Richard Burrow, Carol Dorsey, Brian Hiatt, Gregg Langlois, Leonora Porter, John Schwarz, Arturo Vargas, Dave Wallace, Kathleen Wickman, Joel Hansel, Cheryl Lassiter, Linda Chandler, Steve Plakas, Jessica Jones

Agenda:

- 1. Roll Call
- 2. Meeting minutes
- 3. Meeting Reports
- 4. Beacon Analytical Experimental Design Review
- 5. Vibrio Direct Plating Method
- 6. Vp Interim Method Submissions
- 7. Proposals 13-117
- 8. Workgroup Reports
 - a. Biotoxins
 - b. Checklist
 - c. Method Validation
 - d. Engagement
 - e. Proposed Microbiology
- 9. Other Business

Meeting Discussions/Decisions/Action Items:

Meeting minutes from 3 March and 17 March 2015 were approved.

Meeting reports from 3 March and 17 March 2015 were approved.

Beacon Analytical Experimental Design Review: It was decided that the response letter to Beacon should clearly state that the studies conducted should address performance characteristics beyond ruggedness/robustness and that the original letter from ISSC to Beacon outlining the data gaps be included in the response. It was decided that the recommendation would be to add one more experiment to Beacon's design to incorporate evaluation of reagent temperature. **Action item:**Stacey will prepare the response and submit to Ken for the ISSC to respond.

Vibrio Direct Plating Method: Based on the historical use and incorporation of the method in the program, the committee decided to recommend to the Executive

Board grandfather the Direct Plating Method for Vibrio into the NSSP with the stipulation that if APW is used for dilutions that the samples be analyzed immediately. **Action item: Stacey will share the recommendation with the ISSC.**

Vp Interim Method Submissions: The committee discussed the Vp Interim Methods submitted. No concerns were raised about any of the methods. The committee decided to: (1) recommend that the *Vibrio parahaemolyticus* enumeration and detection through MPN and real-time PCR method submitted by the State of Washington Department of Health be approved as an Interim Method; (2) recommend that the MPN-PCR for tdh/trh Vp method submitted by FDA be approved as an Interim Method; (3) recommend that the DNA Probe for trh Vp method submitted by FDA be approved as an Interim Method, and (4) recommend that the MPN-PCR for Total Vp method submitted by FDA be approved as an Interim Method. The committee recommended specific liaisons from the LMRC for each of the methods submitted. **Action Item: Stacey will share these recommendations with the ISSC.**

Proposals 13-117: Given time limitations and lack of representation of key members, discussion of this proposal was tabled until the next call.

There were no new updates from the Biotoxin Workgroup.

There were no new updates from the Checklist Workgroup. The PSP checklist will be up next for full LMRC review.

There were no new updates from the Method Validation Workgroup.

There was an update on the newly formed Engagement Workgroup. The WG had their first call, which was productive and focused on establishing a list of priority needs for marine biotoxin and HAB methods. The WG drafted a survey intended for ISSC members. Action item: LMRC review the draft survey and provide comments to the WG Chair no later than May 5, 2015.

There were no updates on the proposed Microbiology Workgroup.

Other business: The LMRC was reminded of the regional webinars on HABs and hypoxia and encouraged participation in the remaining ones. There was a discussion about whether the LMRC should recommend that the ISSC send a letter to the FDA regarding the outstanding issue of the lack of availability of saxitoxin standards. Action item: Stacey will seek advice from the ISSC about whether to send a letter to FDA regarding the saxitoxin standard situation.