ISSC Laboratory Methods Review Committee September 30, 2014 Conference Call Meeting Report

Committee Members Present:

Stacey DeGrasse (Chair), Carol Dorsey, Matthew Forester, Tom Howell, Gregg Langlois, Linda McFarland, Leonora Porter, Alison Sirois, Wade Rourke, Valerie Wunderly, Cheryl Lassiter, Linda Chandler, Melissa Evans, Steve Plakas, Jessica Jones, Quay Dortch, Joey Marchant

Committee Members Absent:

Richard Burrow, Darcie Couture, Brian Hiatt, Jackie Knue, John Schwarz, Arturo Vargas, Dave Wallace, Kathleen Wickman, Joel Hansel

Agenda:

- 1. Roll Call
- 2. Meeting minutes from August
- 3. Report from August
- 4. MSC Summit Report
- 5. Workgroup Reports
 - a. Biotoxins
 - b. Checklist
 - c. Method Validation
- 6. Interim versus Emergency Use Methods
- 7. Priority Biotoxin Methods/Matrices
- 8. Method Validation Guidelines for Research Scientists
- 9. Other Business

Meeting Discussions/Decisions/Action Items:

Internal meeting minutes from the conference call on August 19, 2014 were approved.

The LMRC conference call report from August 19, 2014 was approved.

Tom Howell provided a report from the MSC Summit that took place in August 2014. Tom stated that most of the growing area committee was present and that the success of the summit may serve as a model moving forward for addressing other issues/challenges that the ISSC faces. Tom emphasized the aspects of the Summit that had relevance to the LMRC.

Steve Plakas gave the update from the Biotoxins Workgroup. The Biotoxin Workgroup is working on providing feedback to Neogen on their Reveal for DSP protocol.

Tom Howell gave the Checklist Workgroup update. Tom is organizing the Workgroup's first conference call, and the PCOX PSP Checklist will be the first task the Workgroup will address.

Jessica Jones gave the report on the Method Validation Workgroup. The Workgroup has had 2 conference calls and has agreed upon an approach to evaluate and improve upon existing guidelines for method validation submissions. The goal is to develop a single document with all requirements/guidelines per method type (e.g., quantitative biotoxin method, qualitative biotoxin method, classical micro method). The group will begin with guidelines for quantitative biotoxin methods.

The LMRC discussed the need for Interim Use Methods, in addition to the existing designation of Emergency Use Methods. The minimum criteria needed for both designations however should be the same. The LMRC recommends that an expiration of 2 years be placed on both Emergency and Interim Use Methods, with the intention that full SLV proposals will be submitted within that timeframe. Members of the LMRC noticed that the direct plating colony hybridization method that was previously approved no longer appears in the table of methods. Action item: Stacey will inquire with the ISSC why the direct plating method was removed and if/how it can be added back. Action item: Stacey will work with Ken to draft a proposal for an Interim Use Method designation according to the recommendations from the LMRC.

Quay Dortch led a discussion on priority biotoxin methods/matrices. Developing such a list would be valuable for prioritization of research needs. There was discussion about obvious priority methods (e.g. DSP and AZP, where no approved methods exist) and whether methods solely for shellfish matrices were of interest or if determining cell counts would be of value to the ISSC.

There was a discussion on developing clear method validation guidelines for research scientists who may not be well-versed in the ISSC and the NSSP requirements. Action item: Stacey charged this task to the Method Validation Workgroup.

No other business was discussed.