

**Proposal Subject** Laboratory Method Approval

**Specific NSSP Guide Reference** NSSP Guide Model Ordinance Chapter III. Laboratory @.02 Methods

**Text of Proposal/ Requested Action** At the request of the Executive Board of the ISSC, in November of 2005 the Method Validation Protocol Workgroup was formed to address the issue of method approval within the NSSP and to develop criteria for method validation. The workgroup developed a complete method validation protocol package that included a comprehensive checklist for method developers, definitions of validation criteria, a detailed protocol for submission of a method for review and SOP's to specifically address *Vibrio* PCR methods. In April of 2006 the Executive Board granted interim approval of these documents for use in the ISSC (submitted as a separate proposal for conference approval). The Laboratory Methods Review Committee (LMR) recognized that the interim approved Single Lab Validation Protocol package required changes to Chapter III. Laboratory @.02 Methods of the NSSP Model Ordinance to conform to the new protocol for method approval.

In addition, in response to the Executive Board's interim approval of non-validated, unapproved methods, the LMR committee recommends the following changes to Chapter III as a mechanism to advise the Executive Board on approval of emerging methods or methods needed for immediate need of the ISSC.

Chapter III. Laboratory

@.02 Methods

- A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods ~~required by~~ **validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.**
- B. Chemical and Physical.
  - (1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:
    - (a) Be the current AOAC or APHA method for all physical and chemical measurements; and
    - (b) Express results of all chemical and physical measurements in standard units, and not instrument readings.
  - (2) When an AOAC or APHA method is not available, EPA methods may be used.
  - (3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.**
- C. Biotxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
  - (1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins: and
  - (2) The current APHA method used in ~~the~~ bioassay for ~~*Karenia brevis*~~ ***Karenia brevis***: toxins; **or**
  - (3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.**

**D. Emerging Methods.**

**When there is an immediate need and no NSSP approved methods exists, and the ISSC considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided. Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol shall be submitted.**

**Public Health Significance**

The proposed changes will help to ensure that only analytical methods found to be fit for purpose will be used for regulatory monitoring in the NSSP.

**Cost Information (if available)**

None

**Action by 2007 Laboratory Methods Review Committee**

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  - (3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.
- C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
- (1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins: and
  - (2) The current APHA method used in the bioassay for *Karenia brevis*; toxins; or
  - (3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.
- D. Emerging Methods.
- When there is an immediate need and no NSSP approved methods exists, and the ISSC considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided **as follows**.
- **Name of Method**
  - **Date of Submission**
  - **Specific purpose or intent of the method for use in the NSSP**
  - **Step by step procedure including equipment, reagents and safety requirements necessary to run the method**

- **Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable**
- **Any peer reviewed articles detailing the method**
- **Name of developer(s)/submitters**
- **Developer/submitter contact information**

Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol shall be submitted. **The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation data submission.**

**Action by 2007  
Task Force I**

Recommended adoption of Proposal 07-101 as amended.

Chapter III. Laboratory

@.02 Methods

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- D. Emerging Methods.
- When there is an immediate **or critical** need and no NSSP approved methods exists, and the ISSC **Executive Board** considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided **to the Executive Board and shall contain the following criteria:** as follows.
- Name of Method
  - Date of Submission
  - Specific purpose or intent of the method for use in the NSSP

- Step by step procedure including equipment, reagents and safety requirements necessary to run the method
- Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable
- Any peer reviewed articles detailing the method
- Name of developer(s)/submitters
- Developer/submitter contact information

Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol ~~shall~~ **should** be submitted. The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation data submission.

**Action by 2007  
General Assembly**

Adopted recommendation of 2007 Task Force I.

**Action by  
USFDA**

December 20, 2007  
Concurred with Conference action.