**Proposal Subject:** NSSP Method Approval Review Process

**Specific NSSP Guide Reference:** ISSC Constitution, Bylaws, and Procedures
Procedure XVI. Procedure for the Approval of Analytical Methods for the NSSP

**Text of Proposal/ Requested Action**

Section 1. Prior to NSSP adoption, all laboratory methods shall be evaluated by the ISSC. ~~using the validation criteria developed as detailed in the Single Laboratory Validation Protocol;~~ Persons interested in submitting a method for inclusion in the NSSP must submit a pre-proposal outlining the following:

a. Description of Method;
b. Proposed Use of Method;
c. Time Table for SLV.

~~Section 2. All methods shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP~~

~~Subdivision a.~~ ~~Proposals shall include a completed Single Laboratory Validation Method Application and Checklist.~~

~~Subdivision b.~~ ~~The ISSC Executive Director shall submit the proposal to the Laboratory Methods Review Committee for review and development of recommendations to Task Force I.~~

Section 2. The submitter of the proposal will be notified by the ISSC Executive Office of the action taken on the pre-proposal by the ISSC.

Section 3. Submitters of pre-proposals receiving approval will be requested to submit a full proposal to the ISSC and a liaison from the Laboratory Methods Review Committee will be assigned.

Section 4. The full proposal shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP.

Subdivision a. All proposals shall include a completed Single Laboratory Validation Method Application and Checklist. AOAC approved methods that have undergone the AOAC Official Methods of Analysis (OMA) or FDA Office of Foods Level 3 or 4 validations may be accepted as an NSSP method without Single Lab Validation providing the AOAC or FDA multi-laboratory validation was performed in the raw molluscan shellfish matrix for which the Conference intends it to be used, and is deemed by ISSC as fit for purpose. Submitters of AOAC and FDA validated methods will provide a Single Laboratory Validation Method Application and Checklist along with the AOAC OMA or FDA Office of Foods Level 3 or 4 validation.

Subdivision b. The ISSC Executive Director shall submit the proposal to the Laboratory Methods Review and Quality Assurance Committee for review and development of recommendations to Task Force I.

Section 5. Within six (6) months of receipt the Laboratory Method Review and Quality Assurance Committee will review the proposal package for completeness and recommend to the Executive Board the suitability of the method for a full review for possible inclusion into the NSSP. The recommendation of the Executive Board will be presented to the ISSC Voting Delegates for approval.

Section ~~3~~6. Review by Laboratory Methods Review Committee;

Subdivision a. Within six (6) months of receipt of a complete application proposal, ~~T~~the Laboratory Methods Review Committee shall conduct an evaluation of the data which describes the performance characteristics of the ~~method~~ new proposal, the AOAC approved method or FDA Office of Foods Level 3 or 4 method;

Subdivision i. These performance characteristics include:

Subdivision (a) Accuracy (Trueness);
Subdivision (b) Measurement uncertainty;
Subdivision (c) Precision;
Subdivision (d) Recovery;
Subdivision (e) Specificity;
Subdivision (f) Linear range;
Subdivision (g) Limit of detection;
Subdivision (h) Limit of quantitation (sensitivity);
Subdivision (i) Ruggedness;
Subdivision (j) Comparability if applicable (comparison of the performance of the new/modified method to the accepted method.

Subdivision ii. Method documentation including:

Subdivision (a) Method title,

scope and references;

Subdivision (b) Equipment and reagents required;

Subdivision (c) Sample collection, preservation and storage requirements;

Subdivision (d) Safety requirements;

Subdivision (e) Step by step procedure;

Subdivision (f) Specific quality control measures associated with the method;

Subdivision (g) Cost of the method;

Subdivision (h) Sample turnaround time.

Subdivision iii. Specific application(s);

Subdivision b. Review of need for the method;

Subdivision i. Method meets an immediate or continuing need;

Subdivision ii. Improves analytical capability under the NSSP as an alternative to an accepted method(s);

. Subdivision iii Replaces other approved or accepted method(s).

Section ~~4~~7. The Laboratory Methods Review Committee shall submit one of the following recommendations to Task Force I within six (6) months of receiving a complete proposal application for a method:

Subdivision a. Non-acceptance pending further information as defined by the Committee;

Subdivision b. Accept as an Approved NSSP Method;

Subdivision c. Accept as an Approved Limited Use NSSP Method;

Subdivision d. Accept as an Emergency Use NSSP Method.

Section ~~5~~8. Requests for ISSC recantation of an approved method shall be submitted using the ISSC proposal form. The request for recantation must include reason for the request, i.e. the need no longer exists, poor performance, equipment or reagents no longer available, etc.

Section ~~6~~9. Types of NSSP Analytical Methods.

Subdivision a. Approved NSSP Methods.

Approved NSSP methods are those accepted for use as permanent methods and cited in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. These methods have been long used in the NSSP or have completed the Single Laboratory Validation Method Protocol to show that the method is fit for purpose in the NSSP. Approved NSSP Methods have been:

Subdivision i Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully to detect or quantify;

Subdivision iii. Evaluated and the performance characteristics for specific applications have been determined and found fit for purpose;

Subdivision iv. Collaboratively studied and/ or collaboratively tested.

Subdivision b. Approved Limited Use Methods.

Approved Limited Use Methods are methods accepted for use in NSSP and listed in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. These methods are alternative methods within the NSSP that can meet an immediate need of the NSSP, improve turnaround time, cost effectiveness, and/or increase analytical capacity. Approved Limited Use Methods can include screening, provisional, or methods with limitations as defined by the LMRC evaluation of the method.

Subdivision c. Emergency Use Methods.

Emergency Use Methods are methods used to meet an immediate or ongoing critical need for a method of analysis and no NSSP approved method exists. Emergency Use Methods may be given interim approval by the ISSC Executive Board provided the following criteria are provided:

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| Subdivision i. | Name of Method; |
| Subdivision ii. | Date of Submission; |
| Subdivision iii. | Specific purpose or intent of the method for use in the NSSP; |
| Subdivision iv. | Step by step procedure including equipment, re-agents and safety requirements necessary to run the method; |
| Subdivision v. | Data generated in support of the efficacy of the method if available; |
| Subdivision vi. | Any peer reviewed articles detailing the method and its efficacy; |
| Subdivision vii. | Name of the developer or SSCA submitter; |
| Subdivision viii. | Developer or submitter contact information. |

**Public Health Significance:**
**Cost Information (if available):**

**Action by 2013 Task Force III** Recommended adoption of Proposal 13-309 as submitted.

**Action by 2013 General Assembly** Adopted recommendation of 2013 Task Force III on Proposal 13-309.

**Action by FDA May 5, 2014** Concurred with Conference action on Proposal 13-309.